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MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Progress

DATE: March 27, 2018

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 3-26-18

| **To April Licensure Committee** | 4778-1 (Entire chapter)  
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| **Approved to file with CSI** | 4730-1-05  
| 4730-2-05 |
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| **Rules at CSI** | 4731-1-07 |

**Comment Deadline 2/6/18**

| 4731-28-02  
| 4731-28-04 |
| 4731-28-03  
| 4731-28-05 |

**Comment deadline 3/9/18**

| 4731-01-08 |

**Initial Circulation to Interested Parties – 4/6/18 Deadline**

| 4731-16-17  
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| 4731-16-18  
| 4731-16-21 |
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| **Circulated to Interested Parties – 3/8/18 Deadline** | 4730-4-01  
| 4731-33-01 |
| 4730-4-03  
| 4731-33-03 |

| **Circulated to Interested Parties – 3/16/18 Deadline** | 4731-6 (Entire chapter) |

| **Rule Assignments for 2018** |

| **Estimated Dates** |

Pharmacy Consult Rules – Nate - Jun
Dietetics/Respiratory Care Review – Nate - Mar
4731-27 Rules – Termination – Sallie - May
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4731‐13‐35
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4731‐14‐01

4731‐16‐07

4731‐16‐06

Supervision of Hearing Examiners
Prehearing Conference
Transcripts of Prior Testimony
Prior Statements of the
Respondent
Physician's Desk Physician
Ex Parte Communication
Severability
Disciplinary Actions
Pronouncement of Death
Licensee Reporting Requirement;
Exceptions
Healthcare Facility Reporting
Requirement
Malpractice Reporting
Requirement
Professional Society Reporting
Liability; Reporting Forms;
Confidentially and Disclosure
Rules governing impaired
physicians and approval of
treatments programs ‐
Definitions
General Procedures in
Impairment Cases
Other Violations
Examinations
Consent Agreements and Orders
for Reinstatement of Impaired
Practitioners
Treatment Provider Program
Obligations
06/08/16

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Broadcasting and Photographing
Administrative Hearings
Sexual Misconduct Evidence

4731‐13‐26
4731‐13‐27

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Comm
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Conviction of a Crime
Evidence

Rule Description

4731‐13‐24
4731‐13‐25

Rule

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Rules
Hearing

Board
Review

Board
Adoption

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New
Effective
Date

11/17/22

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Current
Review
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**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: Amol Soin, M.D., Chair, Policy Committee
    Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: FSMB Resolutions and Board Reports

DATE: March, 2018

Attached for your review are six (6) resolutions that will be presented to the 2018 House of Delegates for action on April 28:

Resolution 18-1: Acute Opioid Prescribing Workgroup and Guidelines (OH)
Resolution 18-2: Testing Under Time Constraints of the Necessary and Explicit Component of the USMLE (MN)
Resolution 18-3: Supporting the Practice of Physician Assistants (WA-M)
Resolution 18-4: Permitting Out-of-State Practitioners to Provide Continuity of Care in Limited Situations (WA-M)
Resolution 18-5: Interprofessional Continuing Education (FSMB BOD)
Resolution 18-6: Workgroup on AI and Its Potential Impact on Patient Safety and Quality of Care in Medical Practice (PA-M)

Also attached are five (5) Board Reports:

BRD RPT 18-1: Report of the Workgroup to Study Regenerative and Stem Cell Therapy Practices
BRD RPT 18-2: Report of the Workgroup on Prescription Drug Monitoring Programs
BRD RPT 18-3: Report of the FSMB Workgroup on Physician Wellness and Burnout
BRD RPT 18-4: Guidelines for the Structure and Function of a State Medical and Osteopathic Board
BRD RPT 18-5: Report on Resolution 17-2: Advocacy for Professional Licensure of EMS Providers

Finally, the Report of the Bylaws Committee and a REVISED Report of the Nominating Committee are also attached.

Proposed Action: Review and provide any feedback to Mr. Giacalone, Board President
Federation of State Medical Boards  
House of Delegates Meeting  
April 28, 2018

Subject: Acute Opioid Prescribing Workgroup and Guidelines

Introduced by: State Medical Board of Ohio

Approved: January 2018

Whereas, long-term use of opioids frequently begins with the treatment of acute pain; and

Whereas, millions of Americans undergo surgical procedures and sustain painful injuries every year; and

Whereas, many, if not most, people have their first exposure to opioids in the acute medical and postoperative settings; and

Whereas, acute medical and postoperative prescribing varies widely by prescriber; and

Whereas, the duration, dosage, and formulation of opioids can have a dramatic impact on the likelihood of risk of acute medical and postoperative persistent opioid use; and

Whereas, prescriber awareness of risk factors for persistent opioid use could deter overprescribing of opioids, which could lead to a decreased incidence of long-term opioid use. This would lead to a decreased incidence of addiction, comorbidity, and diversion; and

Whereas, a number of states may be considering – or have already implemented – rules or laws limiting the permissible number of days, morphine equivalency and type of opioid to prescribe for acute conditions; and

Whereas, prescribers frequently practice in multiple states in which acute opioid prescribing laws and rules may vary significantly;

Therefore, be it hereby

Resolved, that the Federation of State Medical Boards (FSMB) perform a comprehensive review of acute opioid prescribing patterns, practices, federal laws and guidance (including Centers for Disease Control and Prevention guidelines), and state rules and laws across the United States; and

Resolved, that the FSMB perform a comprehensive review of data related to patient outcomes, comparing states with and without limitations on opioid prescribing for acute conditions; and
Resolved, that the FSMB establish a workgroup tasked to formulate acute opioid prescribing guidelines and best practices, and to present these guidelines and best practices to the House of Delegates at the FSMB annual meeting in 2019.
Subject: Testing Under Time Constraints of the Necessary and Explicit Component of the United States Medical Licensure Examination (USMLE)

Introduced by: Minnesota Board of Medical Practice

Approved: November 2017

Whereas, the USMLE is an exam used for licensure by states; and

Whereas, the USMLE is used to determine the safety of physicians in the independent practice of medicine; and

Whereas, the practice of medicine is constrained by time; and

Whereas, the USMLE has been publicized as a test of knowledge; and

Whereas, testing under time constraint is not considered a component of the USMLE;

Therefore, be it hereby

Resolved, that the Federation of State Medical Boards study and consider the addition of testing time constraint as an explicit component of the USMLE examination.
Whereas, a recent study estimates that by 2025, the US will face a shortfall of between 61,000 and 94,000 physicians, a third of them in primary care; and

Whereas, many US citizens live in medically underserved areas and lack access to primary care; and

Whereas, the profession of physician assistant is rooted with physicians in the medical team-based model, with physician assistant choice, flexibility of practice area, and degree of practice independence considered a benefit of the profession; and

Whereas, numerous outcome studies show physician assistants provide affordable, high quality primary care to patients; and

Whereas, physician assistants play a vital role in easing the health care shortage and expanding access to primary care in underserved areas, but are limited by state laws; and

Whereas, permitting qualified physician assistants to conduct Optimal Team Practice up to the full scope of their education and training, subject to approval by their state medical board, is a natural and logical evolution of the profession and will help ease the physician shortage and improve access to primary care; and

Whereas, medical boards are better able to meet their mandate to ensure licensees are qualified, to discipline unethical or incompetent practitioners, and to set professional standards, when the boards include physician assistants as full members;

Therefore, be it hereby

Resolved, that the Federation of State Medical Boards (FSMB) shall adopt an advocacy position for the voluntary full Optimal Team Practice of physician assistants up to the full scope of their education and training; and be it further

Resolved, that the FSMB will revise the “Elements of a State Medical and Osteopathic Board” and the “Essentials of a State Medical and Osteopathic Practice Act,” to recommend that all medical boards integrate physician assistants as full members with proportional representation or other method deemed acceptable; and be it further
Resolved, that the FSMB will collaborate with national hospital, clinic, and credentialing employer groups to establish guidelines and best practices for on the job training programs for physician assistants that promote best clinical outcomes and the highest standards of practice; and be it further

Resolved, that the FSMB will provide support to fully integrate physician assistant regulatory bodies and their representatives into all relevant aspects of FSMB operations and offerings as full members; and be it further

Resolved, that the FSMB will create a dedicated physician assistant position on the Board of Directors, but shall not limit the physician assistant representation on the Board to that single position; and be it further

Resolved, that the FSMB will provide support, upon request, to state medical boards to amend their laws to permit the voluntary full and independent practice of physician assistants up to their education and training; and be it further

Resolved, that the FSMB will collaborate with the USMLE and its stakeholders to allow physician assistants to take the appropriate levels of the exam and satisfy requirements for licensing bodies in lieu of or in addition to other national exams; and be it further

Resolved, that the FSMB will advocate on the federal level to identify and address regulatory barriers which impede recognition of the voluntary full Optimal Team Practice of physician assistants in all federal institutions.
References

1. ARNPs and PAs as Usual Source of Care: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2794129/
2. PAs and ARNPs in Team Based Settings of Chronic Care Patients: http://www.med.wisc.edu/news-events/study-supports-team-role-for-physician-assistants-and-nurse-practitioners-for-chronic-illness/42167
5. Kaiser Family Literature Review comparing NPs and PAs: https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8167.pdf
Resolution 18-4

Federation of State Medical Boards
House of Delegates Meeting
April 28, 2018

Subject: Permitting Out-of-State Practitioners to Provide Continuity of Care in Limited Situations

Introduced by: Washington State Medical Commission

Approved: January 2018

Whereas, state medical boards are responsible for protecting the citizens of their states by ensuring that physicians are qualified and competent; and

Whereas, state medical boards determine, within the context of their enabling statutes, under what circumstances a license is required for a physician to treat a patient in their states; and

Whereas, many states have license reciprocity and/or the Interstate Medical License Compact which establishes reliance on sister state licensing processes; and

Whereas, due to rapid changes in telemedicine technology, the practice of medicine is occurring more frequently across state lines; and

Whereas, telemedicine is a tool that has the potential to increase access, lower costs, and improve the quality of healthcare; and

Whereas, the historic practice of medicine has prioritized the continuity of care delivery to established patients over recognition of jurisdictional boundaries; and

Whereas, continuity of care is an essential element in consistently delivering high quality health care; and

Whereas, physicians can promote continuity of care by using telemedicine to provide follow-up care to established patients who travel outside the physician’s state of licensure. For example, a physician at a major academic medical center who treats a patient who then returns home, can maintain a connection with the patient by providing follow-up care, including having access to timely and accurate data from the patient; and

Whereas, permitting physicians who are duly licensed in another jurisdiction to provide follow-up care to established patients, and to engage in peer-to-peer consultations, will result in better outcomes and lower costs;

Therefore, be it hereby

Resolved, that the Federation of State Medical Boards (FSMB) will encourage state medical boards to interpret their licensing laws, or work to change their licensing laws if
necessary, to permit physicians duly licensed in another jurisdiction to provide infrequent and episodic continuity of care by providing follow-up care to established patients or a peer-to-peer consultation without the need to obtain a license in the state in which the patient is located at the time of the interaction.
Subject: Interprofessional Continuing Education (IPCE)

Introduced by: FSMB Board of Directors

Approved: February 2018

Whereas, a commitment to lifelong learning and continuing professional development is critical to a physician’s ability to keep up with advances in medicine and with changes in the delivery of care; and

Whereas, state medical and osteopathic boards require continuing medical education for license renewal as a means of assuring the public that licensed physicians are maintaining their competence; and

Whereas, insufficient communication and coordination of care between physicians and other health care professionals in team-based care settings is a patient safety issue; and

Whereas, interprofessional education and team-based care among physicians, nurses and pharmacists is a critical component of health care delivery and improvement; and

Whereas, the Federation of State Medical Boards (FSMB) works with the National Council of State Boards of Nursing (NCSBN) and the National Association of Boards of Pharmacy (NABP) to support collaborative educational opportunities, including regularly hosting Tri-Regulator Meetings for state and territorial licensing boards for medicine, nursing and pharmacy; and

Whereas, Interprofessional Continuing Education (IPCE) is defined as a process by which individuals from two or more professions learn with, from, and about each other to enable effective collaboration and improve health outcomes; and

Whereas, a Joint Accreditation system for Interprofessional Continuing Education was launched in 2009 that is a collaboration of the Accreditation Council for Continuing Medical Education (ACCMER®), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC); and

Whereas, the Joint Accreditors have adopted a shared credit (IPCE credit) that designates an educational activity as having been planned by and for an interprofessional team;

Therefore, be it hereby

Resolved, that the Federation of State Medical Boards supports and recognizes Interprofessional Continuing Education for physicians that is identified by IPCE credit and is accredited by the Joint Accreditation system launched by the Accreditation Council for Continuing Medical Education, the Accreditation
Council for Pharmacy Education and the American Nurses Credentialing Center, as an additional means of satisfying continuing medical education requirements for medical license renewal.
Whereas, The Internet can gather large amounts of data from diverse sources that include but are not limited to electronic health records, digital images, and mobile apps; and

Whereas, Technology enables the compilation, storage, and processing of vast amounts of data to help identify clinically significant patterns and provide predictions; and

Whereas, Recent developments propel interest in healthcare AI, whether defined as “artificial intelligence,” the ability of a computer to complete tasks in a manner typically associated with a rational human being, or “augmented intelligence,” design that enhances human intelligence rather than replaces it; and

Whereas, Healthcare AI has been developed and applied to clinical decision support, treatment protocols, diagnostic recommendations, clinical prognostication, drug development, personalized medicine, patient monitoring, chronic care, and patient flow analytics; and

Whereas, Healthcare AI operates with variable levels of transparency, vetting, and oversight by experts and regulators; and

Whereas, Technology industry leaders and academic institutions have developed and implemented healthcare AI for radiology, pathology, oncology, ophthalmology, cardiology, and dermatology, and further applications are anticipated; and

Whereas, Modern machine learning technology in healthcare AI can readily re-identify data sources posing a challenge to confidentiality of protected health information; and

Whereas, Investment in healthcare AI is robust and a recent report from Markets and Markets pins the healthcare AI sector at nearly $8 billion in 2022, accelerating at a compound annual growth rate of 52.68 percent over the forecast period; and

Whereas, State medical boards should have an understanding of AI and its impact on medical practice;
Therefore, be it hereby

Resolved, That the Federation of State Medical Boards will convene a workgroup comprised of relevant stakeholders and subject matter experts including the American Medical Association to provide state medical boards with an understanding of AI and its potential impact on patient safety and quality of care in medical practice.


REPORT OF THE BOARD OF DIRECTORS

Subject: Report of the FSMB Workgroup to Study Regenerative and Stem Cell Therapy Practices

Referred to: Reference Committee B

The Federation of State Medical Boards (FSMB) Workgroup to Study Regenerative and Stem Cell Therapy Practices was convened in May of 2017 by FSMB Chair Gregory B. Snyder, M.D., DABR, in response to a letter from U.S. Senator Lamar Alexander (R-TN), Chairman of the U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee, urging the FSMB to develop best practices for state medical and osteopathic boards (hereinafter referred to as “state medical boards”) in regulating the promotion, communication, and practices of treatments received at stem cell clinics in the United States.

Members of the Workgroup are: Scott A. Steingard, DO, Chair (FSMB Director-at-Large, Past President, Arizona Board of Osteopathic Examiners in Medicine and Surgery); Debbie J. Boe (Former Public Member, Minnesota Board of Medical Practice); Sandra L. Coletta (Public Member, Rhode Island Board of Medical Licensure and Discipline); Sarah L. Evenson, JD, MBA (Former Public Member, Minnesota Board of Medical Practice); H. Joseph Falgout, MD (Chair, Alabama Board of Medical Examiners); Joseph E. Fojtik, MD, FACP (Deputy Medical Coordinator, Illinois Department of Financial & Professional Regulation); Gary R. Hill, DO (Member, Alabama Medical Licensure Commission); Howard R. Krauss, MD (Member, Medical Board of California). Subject matter experts included: Ronald E. Domen, MD, FACP, FCAP (Penn State College of Medicine); Zubin Master, PhD (Mayo Clinic); Douglas Oliver, MSW; and Bruce D. White, DO, JD (Alden March Bioethics Institute). Participating ex officio were Gregory B. Snyder, MD, DABR, FSMB Chair; Patricia A. King, MD, PhD, FACP, FSMB Chair-elect; and Humayun J. Chaudhry, DO, MS, MACP, MACOI, FSMB President and CEO.

The Workgroup was charged with: 1) evaluating the prevalence, promotional practices, and incidences of patient harm related to regenerative medicine and adult stem cell therapies in the U.S.; 2) evaluating current regulatory approaches that will protect the public, recognizing the potential for improved patient outcomes through health innovation and technology; 3) identifying best practices for state medical and osteopathic boards in investigating complaints of patient harm, fraud, and compliance with licensure requirements; and 4) issuing a report on the Workgroup’s findings from prevailing research and recommending best regulatory practices and guidelines related to physicians’ use of regenerative medicine and adult stem cell therapies in a manner consistent with safe and responsible medicine.

In completing its charge, the Workgroup drafted its report in the form of a guidance document, with recommendations that address the regulation of the provision of stem cell and regenerative therapies, as well as their promotion and communication to patients, and documentation of treatments provided. The recommendations do not address which uses are appropriate or for specific conditions or symptoms, as this area of medicine continues to be dynamic and subject to change. Rather, the recommendations focus on sensible and necessary principles of patient safety, autonomy, and non-exploitation.

A draft of the report was distributed to FSMB member boards and other key stakeholder organizations in December 2017 with comments due January 26, 2018. The draft report was distributed to the American Medical Association (AMA), American Osteopathic Association (AOA), Council of Medical Specialty Societies (CMSS), U.S. Food and Drug Administration (FDA), Office of U.S. Senator Lamar Alexander (R-TN), Association of Clinical Research Organizations (ACRO), and others for comment. Minimal comments were received, and all were generally positive.

The FSMB Board of Directors considered the draft Report of the FSMB Workgroup to Study Regenerative and Stem Cell Therapy Practices at its meeting on February 8, 2018 in Washington D.C. and discussed clarifications to the document.

ITEM FOR ACTION:

The Board of Directors recommends that:

Section One. Introduction and Charge:

The Federation of State Medical Boards (FSMB) Workgroup to Study Regenerative and Stem Cell Therapy Practices was convened in May of 2017 by FSMB Chair Gregory B. Snyder, M.D., DABR, in response to a letter (Attachment 1) from U.S. Senator Lamar Alexander (R-TN), Chairman of the U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee, urging the FSMB to develop best practices for state medical and osteopathic boards (hereinafter referred to as “state medical boards”) in regulating the promotion, communication, and practices of treatments received at stem cell clinics in the United States.

In order to address Senator Alexander’s request, Dr. Snyder charged the Workgroup with:

1) Evaluating the prevalence, promotional practices, and incidences of patient harm related to regenerative medicine and adult stem cell therapies in the U.S.;

2) Evaluating current regulatory approaches that will protect the public, recognizing the potential for improved patient outcomes through health innovation and technology;

3) Identifying best practices for state medical and osteopathic boards in investigating complaints of patient harm, fraud, and compliance with licensure requirements; and

4) Issuing a report on the Workgroup’s findings from prevailing research and recommending best regulatory practices and guidelines related to physicians’ use of regenerative medicine and adult stem cell therapies in a manner consistent with safe and responsible medicine.

Stem cell and regenerative therapies offer opportunities for advancement in the practice of medicine and the possibility of an array of new treatment options for patients experiencing a variety of symptoms and conditions. Despite significant momentum in research and development, and the potential for such medical advancements, there is reasonable concern about a growing number of providers and clinics in the United States that are undermining the field. Such providers and clinics have been known to apply, prescribe or recommend therapies inappropriately, over-promise without sufficient data to support claims, and exploit patients who are often in desperate circumstances and willing to try any proposed therapy as a last resort, even if there is excessive cost or scant evidence of efficacy.

The following report aims to raise awareness about regenerative and stem cell therapy practices generally, outline their potential benefits and risks, and provide basic guidance for state medical boards and licensed physicians and physician assistants. Central to all of the
recommendations provided herein is a range of imperatives, including the importance of
protecting the public, respecting patient autonomy, preventing patient exploitation, obtaining
informed consent, and appropriately documenting care that is recommended and provided.

The Workgroup’s deliberations were aided by participants and subject matter experts who
brought varying perspectives. For example, Dr. Ronald Domen has expertise in stem cell
therapies, bioethics and humanities, and has served on numerous ethics committees at
institutional, state, and national levels. Dr. Zubin Master of the Mayo Clinic has extensive
training and education in cellular and molecular biology, bioethics and genetics, as well as
research and publications on stem cell therapies. Mr. Douglas Oliver became known to the
Workgroup through a recommendation by Senator Lamar Alexander of Tennessee, was a
recipient of stem cell therapies himself, and has a foundation that advocates for stem cell
therapies based on his own experiences and those of others like him. Dr. Bruce White has
educational backgrounds in medicine, law, pharmacy and ethics and currently serves as
Director of the Alden March Bioethics Institute at Albany Medical College and is Chair of
Medical Ethics at the College. The Workgroup also received written comments from several
external organizations. The sum of these perspectives aided the Workgroup in producing a
balanced report on this emerging issue of national importance.

Section Two. Definitions:

Homologous (Allogeneic) Use: the repair, reconstruction, replacement, or supplementation of a
recipient’s cells or tissues with a HCT/P (human cells, tissues, and cellular and tissue-based
product) that performs the same basic function or functions in the recipient as in the donor,
including when such cells or tissues are for autologous use.¹

According to the Food and Drug Administration’s (FDA) Regulatory Considerations for
Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and
Homologous Use / Guidance for Industry and Food and Drug Administration Staff
(November 2017), the FDA “generally considers an HCT/P to be for homologous use
when it is used to repair, reconstruct, replace, or supplement:

• Recipient cells or tissues that are identical (e.g., skin for skin) to the donor cells
  or tissues, and perform one or more of the same basic functions in the recipient
  as the cells or tissues performed in the donor; or

• Recipient cells or tissues that may not be identical to the donor’s cells or
  tissues, but that perform one or more of the same basic functions in the
  recipient as the cells or tissues performed in the donor.”²

¹ 21 CFR 1271.3(c)
² U.S. Food and Drug Administration (November 2017). Regulatory Considerations for Human
Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous
Use Guidance for Industry and Food and Drug Administration Staff.
**Autologous Use:** the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.³

**Informed and Shared Decision Making:** The process by which a physician discusses, in the context of the use of regenerative and stem cell therapies, the risks and benefits of such treatment with the patient.⁴ The patient is given an opportunity to express preferences and values before collaboratively evaluating and arriving at treatment decisions.⁵

**Informed Consent:**⁶ Evidence documenting appropriate patient informed consent typically includes the following elements:

- Identification of the patient, the physician, and the physician’s credentials;
- Types of transmissions permitted using regenerative and stem cell therapies (e.g. prescription refills, appointment scheduling, patient education, etc.);
- Agreement from the patient with the physician’s determination about whether or not the condition being diagnosed and/or treated is appropriate for regenerative and stem cell therapy;⁷ and
- Express patient consent to forward patient-identifiable information to a third party
- An accurate description of the benefits and risks of treatment or intervention, based on scientific evidence, as well as an explanation of alternatives to treatment or an intervention, and the right to withdraw from treatment or an intervention without denial of standard of care to patients.

**Minimal Manipulation: (minor processing including purification, centrifugation, washing, preservation, storage)** – the Food and Drug Administration (FDA) argues that it has the authority to regulate anything beyond minimal manipulation and homologous use:

“(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement; and
(2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.”⁸

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³ 21 CFR 1271.3(a)
⁶ With respect to informed consent for the purposes of research studies involving human subjects, researchers should be aware of the basic elements of informed consent outlined in 21 CFR Part 50.25 “Protection of Human Subjects.”
⁷ Federation of State Medical Boards (2014). Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.
⁸ 21 CFR 1271.3(f)
Unproven Stem Cell Intervention: Stem cell therapy that lacks compelling evidence, based upon scientific studies, to validate its treatment efficacy.  

Section Three. Background, Prevalence and Marketing of Regenerative and Stem Cell Therapies:

Historically, many of the clinics providing unproven stem cell interventions fell under the definition of “stem cell tourism” because most patients seeking such interventions had to travel outside of North American jurisdictions to receive them. The landscape in the United States has evolved considerably over the last few years with hundreds of new clinics opening across the country and many more physicians willing to provide stem cell and regenerative therapies. A study identified 351 U.S. businesses with over 570 clinics engaged in direct-to-consumer (DTC) marketing of stem cell interventions. It has also been suggested that growth in this area of medicine, especially in terms of adult, amniotic, fat-derived and bone marrow stem cell therapies to treat a host of conditions and injuries, is accelerating, both in the U.S. and internationally, and, perhaps counterintuitively, such growth is noted to be most significant in jurisdictions with more stringent regulatory frameworks.

Stem cell clinics typically reach their patients through online DTC marketing, primarily through information provided on company websites. Data purportedly supporting unproven stem cell interventions commonly undermine information about risks and overemphasize information about benefits. Treatment options are described on such websites and are often accompanied by supporting information in the form of journal articles, patient testimonials, and accolades related either to the clinic itself or its affiliated physicians and researchers. Supporting information that accompanies marketing materials can appear to be legitimate, but can also overemphasize, exaggerate, inflate, or misrepresent information derived from legitimate (or even questionable) sources. A physician engaging in such practices of deceptive or false advertising can be in violation of a state’s Medical Practice Act. Information provided on clinic websites should be represented accurately and come from reputable peer-reviewed publications or respected external organizations.

Some clinics, however, that are engaged in the provision of treatment modalities that lack evidence – or an appropriate rationale for application of that modality to particular medical conditions – often use what have been described as “tokens of scientific legitimacy” to lend credence to treatments offered or the quality of a clinic and its associated professionals. Examples of such tokens of legitimacy include patient or celebrity testimonials and

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endorsements, clinician affiliations or memberships in academic or professional societies, registrations in clinical trials, claims of various types of certifications or awards, and others. Further detail and explanations are provided in Table 1.

Physicians are ordinarily permitted to advertise themselves, their practice and services offered, provided that such advertisements do not contain claims that may be deceptive or are intentionally false or misleading. Further, physicians should be mindful of ways in which patient testimonials, quality ratings, or other evaluative data is presented to prospective patients through advertisements. In advertising stem cell treatments to potential patients, physicians are responsible for ensuring that all information, especially in terms of risks, benefits and efficacy, is presented in an objective manner. Physicians must not deliberately misrepresent the expected outcomes or results of treatments offered. Physicians should be prepared to support any claims made about benefits of treatment(s) with documented evidence, for example with studies published in peer-reviewed publications.

Physicians must be accurate and not intentionally misleading in providing descriptions of their training, skills, or treatments they are able to competently offer to patients. This includes descriptions of one’s specialization and any specialty board certifications.

A recent study on the prevalence and marketing practices of businesses offering stem cell treatments internationally noted the presence of the following elements in their marketing practices:

- Mention of affiliations with a professional society or network
- Claims of partnerships with academic institutions
- Statements of receipt of FDA approval, or explicit mention of exemption from FDA oversight
- Mention of official endorsement from a local or other authority, or professional accreditation
- Listing of patents granted
- Statement that clinical trials of investigational stem cell-based interventions are being conducted

The marketing practices and information found on a business’ website can be important sources of data for state medical boards as they investigate complaints made against physicians.

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14 Ibid.
affiliated with businesses providing regenerative and stem cell treatments. Even where an appropriate informed consent process seems to be in place, deceptive or fraudulent information on clinic websites and other marketing materials could mislead patients into consenting to treatment, thereby invalidating the informed consent process.

Physicians must make accurate claims about the enrollment process of subjects, treatments, and products in clinical trials and are responsible for ensuring that any research conducted and described in marketing materials is carried out according to accepted research protocols and recognized standards. Physicians should consider consulting with Institutional Review Boards (IRBs) to clarify processes and must seek IRB approval, where necessary. The National Institutes of Health (NIH) provides helpful guidance on clinical trials and research methods. Physicians are also encouraged to consult the guidance contained in the *International Conference on Harmonisation’s Harmonised Tripartite Guideline for Good Clinical Practice* to support acceptability of clinical data by patients, state medical boards, and other regulatory authorities.

### Table 1: Co-opted Tokens of Scientific Legitimacy

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<tr>
<td>Boards and advisers</td>
<td>Convening scientific or medical advisory boards featuring prominent business leaders and academic faculty members</td>
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<tr>
<td>Clinical study registration</td>
<td>Registering trials whose apparent purpose is solely to attract patients willing to pay to participate in them</td>
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<tr>
<td>Ethics review</td>
<td>Using the imprimatur of “ethics review” to convey a sense of legitimacy to their products or procedures</td>
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<tr>
<td>Location</td>
<td>Renting of laboratory or business space within a legitimate scientific or government institution</td>
</tr>
<tr>
<td>Membership</td>
<td>Joining established academic or professional societies to suggest legitimacy by association</td>
</tr>
<tr>
<td>Outcome registries</td>
<td>Publication of open-ended voluntary monitoring data sets rather than undertaking controlled clinical trials</td>
</tr>
<tr>
<td>Patenting</td>
<td>Suggesting that patent applications or grants indicate clinical utility rather than initiation of an application process or recognition of novelty and inventiveness</td>
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<table>
<thead>
<tr>
<th>Publication</th>
<th>Publishing research and commentary in journals with limited anonymous peer review</th>
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</thead>
<tbody>
<tr>
<td>Rationales</td>
<td>Citing preclinical and other research findings to justify clinical application without sufficient efficacy testing in humans</td>
</tr>
<tr>
<td>Self-regulation</td>
<td>Forming organizations to self-regulate in ways that support premature commercialization</td>
</tr>
<tr>
<td>Technical Language</td>
<td>Using scientific-sounding words that imply academic rigor</td>
</tr>
<tr>
<td>Testimonials and Endorsements</td>
<td>Providing expert opinions or celebrity comments on unsupported clinical uses or standing of the provider</td>
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**Section Four. Patient Perceptions:**

In seeking treatment for any condition, patients desire safety and efficacy, but may overlook risks to their own safety or a lack of evidence of efficacy in favor of access to treatment, particularly in circumstances where traditional treatment options seem limited or have been exhausted. The power of hope also is known to play a significant role in how patients attempt to gain control over their illness and its potential treatments, thereby putting them in a position of increased vulnerability. This is especially the case when patients and their families have overcome various obstacles on the path to a treatment, including raising large sums of money to pay for it. This can lead to a psychological predisposition to anticipate and assume a positive outcome, regardless of the treatment in question or the availability of compelling evidence.

Given the vulnerable state of some patients who seek regenerative and stem cell therapies, perhaps without the requisite knowledge for making informed decisions, there is increased potential for patient exploitation. Physicians must therefore be mindful of the ways in which at-risk or susceptible patients may process information and arrive at decisions about their treatment options, expectations, and ultimately, the potential for success. A promising way of navigating such difficult circumstances, where treatment options are uncertain or complex, is through the use of shared decision making. This process, whereby the physician describes the risks and benefits of potential treatment options and the patient is given an opportunity to express preferences and values before collaboratively arriving at and evaluating treatment decisions, may help mitigate the risk of patient exploitation and ensure that consent to any treatment option has been provided in an informed manner.

The process of obtaining informed consent and engaging in shared decision making with patients involves conveying information about the reasonable effectiveness of a proposed treatment, as well as its risks and benefits. This can be particularly difficult with respect to regenerative and stem cell therapies, as this is an area of medicine that currently lacks

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substantive data on efficacy. Generation of relevant data and evidence has not occurred to a sufficient enough degree and this is often blamed on the difficulty involved in organizing large-scale, randomized controlled trials as part of the approval process for novel therapies. However, the FDA has recently argued that a statistically significant 100% improvement in an outcome measure (α = 0.05, β = 0.1) may be detected with a randomized trial involving as few as 42 participants.\(^\text{21}\)

The lack of a formal mechanism for reporting outcomes of unproven stem cell interventions, both positive and negative, adds to the difficulty involved in generating data on the effectiveness of such interventions, as does the fact that there is neither a requirement, nor a mechanism, for reporting adverse events related to interventions administered outside of clinical trials and investigations. In the current environment, this increases the importance of appropriate documentation of treatment(s) and ongoing care in patients’ medical records. A centralized cell therapy registry for reporting treatment and outcomes may improve the current information available about the effectiveness of such therapies and interventions. It may also dissuade unscrupulous practitioners from engaging in the provision of unproven interventions without an adequate or appropriate basis in theory or peer-acknowledged practice, a prerequisite for the provision of any intervention, whether proven or not.\(^\text{22}\)

Section Five. Regulatory Landscape:

The current state of affairs for regulatory oversight on regenerative and stem cell therapies (including human cells and tissues), at both the federal and state level, is evolving and will continue to change in the coming years. In November 2017, the FDA released two guidance documents to explain the Agency’s current thinking on stem cell policy. However, this thinking, as well as the agency’s jurisdiction and authority, may evolve in the future.

Until recently, the regulatory landscape for stem cell and regenerative therapies has been at times restrictive, allowing patients to access stem cell interventions only under the Expanded Access to Investigational Drugs for Treatment Use program. Treatments are eligible under this program if they are undergoing testing in a clinical trial and are subject to approval by the FDA. Three-quarters of the states in the nation have passed “Right to Try” legislation, however, which allows terminally ill patients to receive experimental therapies that have passed phase 1 trials without seeking FDA approval.\(^\text{23}\) The U.S. Congress is also considering similarly proposed


\(^{23}\) *Lancet* Commission: Stem Cells and Regenerative Medicine. Published Online October 4, 2017 [http://dx.doi.org/10.1016/S0140-6736(17)31366-1](http://dx.doi.org/10.1016/S0140-6736(17)31366-1)
legislation and in August of 2017, the U.S. Senate passed S. 204, *Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017*.

The 21st Century Cures Act (Public Law 114–255), signed into law in December of 2016, represents legislative efforts at the federal level to expand and accelerate patient access to treatment, in addition to promoting innovation in medical products and treatments. With respect to regenerative medicine, the Act amends Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) by requiring expedited review for regenerative medicine therapies, including human cells and tissues, intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, where there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs. There are also ongoing efforts at the federal level to ensure even greater access to treatments that are not subject to FDA approval prior to administration to patients.

Regulation in the regenerative and stem cell therapy arena is continuing to evolve. Human cells, tissues, and cellular or tissue-based products (HCT/Ps) are currently regulated under Sections 351 and 361 of the Public Health Service Act. However, a HCT/P can be regulated solely under Section 361 of the PHS Act if it is:

1. Minimally manipulated,
2. Intended for homologous use only,
3. Not combined with another article, and
4. Either:
   a. Does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
   b. Has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and is for autologous use, use in a first or second-degree blood relative, or reproductive use.

The difference between an HCT/P that is regulated under both sections of the Public Health Service Act, as opposed to solely under Section 361, is significant for providers of stem cell treatments since the requirements for pre-market authorization of a product are much more stringent under Section 351 and require conducting clinical investigations under an investigational new drug (IND) application and obtaining a biologics license through the FDA, whereas requirements under Section 361 focus only on the prevention of communicable diseases. This represents a lower regulatory threshold for HCT/Ps; their use and transplantation can be considered to fall under the practice of medicine and would, therefore, be regulated by state medical boards.

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24 The Public Health Service Act of 1944 outlines a policy framework for federal and state cooperation in health services and provides for the licensing of biological products.

25 21 CFR 1271.10(a)

26 United States Food and Drug Administration: Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use
In regulating this evolving area of medical practice, state medical boards will need to strive to achieve an appropriate balance between respecting the autonomy of patients as they seek viable and reasonable treatment options, and adequately safeguarding them against the risks presented by novel, but often unproven and potentially dangerous, interventions. Results from a 2017 survey of its member boards conducted by the FSMB indicate that a third \((n = 17)\) of the 51 responding boards have investigated complaints against physicians related to regenerative medicine or stem cell therapy, and that eight of those boards have taken disciplinary action against physicians for issues relating to regenerative medicine or stem cell therapy.

In ensuring that physicians offer regenerative and stem cell therapies in a manner that is consistent with safe and responsible practices, state medical boards should ensure that any treatment offered to patients is informed by an appropriate history and physical examination; such informed consent is obtained after an explanation has been provided describing risks, benefits, alternative treatment options, expected convalescence, and expected treatment outcomes; that relevant information about the clinical encounter and ongoing care plans has been documented in the patient’s medical record; that the physician is appropriately trained in, and knowledgeable about the proposed treatment; and that the patient has not been coerced in any way into receiving treatment(s) or exploited through the charging of excessive fees.

In order to implement best practices for regenerative and stem cell therapies, physicians must understand the relevant clinical issues and should obtain sufficient targeted continuing education and training.\(^{27}\)

The recommendations in the final section of this report provide further detail on various requirements that apply to the provision of regenerative and stem cell therapies that state medical boards may wish to consider.

**Section Six. Recommendations:**

The recommendations that follow address the regulation of the provision of stem cell and regenerative therapies, as well as their promotion and communication to patients, and documentation of treatments provided. The recommendations do not address which uses are appropriate or not for specific conditions or symptoms, as this area of medicine continues to be dynamic and subject to change. Rather, they focus on sensible and necessary principles of patient safety, autonomy, and non-exploitation.

\(^{27}\) Federation of State Medical Boards (2017). *Guidelines for the Chronic Use of Opioid Analgesics.*
The FSMB recommends that:

1. Where evidence is unavailable for a particular treatment in the form of clinical trials or case studies, physicians must only proceed with an appropriate rationale for the proposed treatment, and justification of its use, in relation to the patient’s symptoms or condition. Novel, experimental, and unproven interventions should only be proposed when traditional or accepted proven treatment modalities have been exhausted. In such instances, there must still be a basis in theory or peer-acknowledged practice.\textsuperscript{28}

2. State medical boards raise awareness among licensees of applicable federal and state legislation and guidelines regarding regenerative and stem cell therapies, including “right to try” legislation existing or pending at the state and federal levels. State medical boards should also keep their licensees and the public apprised of new developments and regulations in the field of regenerative and stem cell therapies. This may include educational resources, guidance documents, and appropriate industry and stakeholder information on a state medical board’s website. State medical boards should further provide information as to reporting procedures of adverse actions related to stem cell interventions.

3. State medical boards should examine their policies and rules addressing informed consent and consider expanding these to include a shared decision making framework that includes the following general elements at a minimum:
   \begin{itemize}
   \item An explanation, discussion, and comparison of treatment options with the patient
   \item An assessment of the patient’s values and preferences
   \item Arrival at a decision in partnership with the patient
   \item An evaluation of the patient’s decision in partnership with the patient
   \end{itemize}

4. State medical boards should review professional marketing materials and claims, including any office/clinic and/or doctor websites, and information publicly available about an office/clinic or licensee on online blogs or social media, as information sources in the investigation of complaints made against physicians.

5. State medical boards should pro-actively monitor warning letters sent to licensees that are made publicly available on the FDA website in order to ascertain information, and consider opening an investigation, about licensees who may be engaged in other unscrupulous or unprofessional practices related to the provision of regenerative and stem cell therapy. State medical boards should investigate such practices, when appropriate, in conjunction with applicable state laws, policies, and procedures.\textsuperscript{29}


\textsuperscript{29} The FDA’s warning letters are available at the following address: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
6. Physicians must only offer treatments to patients for which they have a bona fide physician-patient relationship. Physicians must have received adequate and appropriate training, and be able to perform any proposed intervention safely and competently.\(^{30}\)

7. Physicians should employ a “shared decision making” process when discussing treatment options with patients. Physicians must avoid any claims that may be deceptive or are intentionally or knowingly false or misleading, especially in terms of making promises about uncertain or unrealistic outcomes.

8. Physicians should not use gag orders (rulings that a case must not be discussed publicly) or disclaimers as a way to circumvent liability.

9. Physicians should be prepared to support any claims made about benefits of treatments or devices with documented evidence, for example with studies published in peer-reviewed publications.

10. Physicians should refrain from charging excessive fees for treatments provided. Further, physicians should not recommend, provide, or charge for unnecessary medical services, nor should they make intentional misrepresentations to increase the level of payment they receive.\(^{31}\)

11. Physicians should consult and educate patients about stem cell interventions and alert them to important resources available to the community. A list of selected resources is provided in Appendix A.

\(^{30}\) Federation of State Medical Boards (2014). *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.*

\(^{31}\) American Medical Association, *Code of Medical Ethics*, Opinion 11.3.1.
APPENDIX A: SAMPLE LIST OF EDUCATIONAL RESOURCES ON REGENERATIVE AND STEM CELL THERAPY PRACTICES

- The Australian Stem Cell Handbook 2015
- Stem Cell Basics (National Institutes of Health)
- Stem Cell Patient booklet (Albany Medical College)
- A closer look at Stem Cells (International Society for Stem Cell Research)
- Patient Handbook on Stem Cell Therapies (International Society for Stem Cell Research)
- Stem Cell Tourism (California Institute for Regenerative Medicine)
- The Power of Stem Cells (California Institute for Regenerative Medicine)
- SCOPE: Learn About Stem Cells in Your Native Language (The Niche)
WORKGROUP TO STUDY REGENERATIVE AND STEM CELL THERAPY PRACTICES

Scott A. Steingard, DO, Chair
FSMB Director-at-Large
Past President, Arizona Board of Osteopathic Examiners in Medicine and Surgery

Debbie J. Boe
Former Public Member, Minnesota Board of Medical Practice

Sandra L. Coletta
Public Member, Rhode Island Board of Medical Licensure and Discipline

Sarah L. Evenson, JD, MBA
Former Public Member, Minnesota Board of Medical Practice

H. Joseph Falgout, MD
Chair, Alabama Board of Medical Examiners

Joseph E. Fojtik, MD, FACP
Deputy Medical Coordinator, Illinois Department of Financial & Professional Regulation

Gary R. Hill, DO
Member, Alabama Medical Licensure Commission

Howard R. Krauss, MD
Member, Medical Board of California

SUBJECT MATTER EXPERTS

Ronald E. Domen, MD, FACP, FCAP
Penn State College of Medicine

Zubin Master, PhD
Mayo Clinic

Douglas Oliver, MSW
Patient Appointee
Founder and Executive Director, Regenerative Outcomes Foundation

Bruce D. White, DO, JD
Alden March Bioethics Institute

EX OFFICIOS

Gregory B. Snyder, MD, DABR
Chair, FSMB

Patricia A. King, MD, PhD, FACP
Chair-elect, FSMB

Humayun J. Chaudhry, DO, MS, MACP, MACOI
President and CEO, FSMB

STAFF SUPPORT

Jonathan Jagoda, MPP
Director, Federal Government Relations, FSMB

Mark Staz, MA
Director, Continuing Professional Development
In April 2017, the FSMB House of Delegates adopted Resolution 17-1, Mandatory Use of Prescription Drug Monitoring Programs which directed FSMB to –

- Establish a task force to study PDMP use in the U.S. and its territories;
- Evaluate whether mandatory PDMP use positively impacts patient outcomes and prescribing practices;
- Evaluate the feasibility of incorporating the PDMP into an electronic medical record system; and
- Develop recommendations regarding mandatory use of PDMP data by licensed prescribers and dispensers.

Accordingly, FSMB Chair Gregory B. Snyder, MD, DABR, appointed the Workgroup on Prescription Drug Monitoring Programs (PDMP) which was comprised of a diverse group of medical and policy stakeholders. Members of the Workgroup are: Anna Z. Hayden, DO, Chairman; J. Mark Bailey, DO, PhD (University of Alabama at Birmingham); Daniel Blaney-Koen, JD (American Medical Association); Mark E. Bowden, MPA, CMBE (IA); Shawn Brooks (U.S. Food and Drug Administration); Danna E. Droz, JD, RPh (National Association of Boards of Pharmacy); Robert P. Giacalone, JD, RPh (OH); Patrice A. Harris, MD, MA (American Medical Association); Robin N. Hunter Buskey, DHSc, PA-C (NC); William K. Hoser, MS, PA-C (VT-Medical); Christina A. Mikosz, MD, MPH (Centers for Disease Control); Rebecca Poston, MHL (Electronic-Florida Online Reporting of Controlled Substance Evaluation (E-FORCSE) Program); Louis J. Prues, DMin, MDiv, MBA (MI-Medical); Jean L. Rexford (CT); Thomas H. Ryan, JD, MPA (WI); Judy Staffa, PhD, RPh (U.S. Food and Drug Administration); and Joseph R. Willett, DO (MN). Participating ex officio were Gregory B. Snyder, MD, DABR; Patricia A. King, MD, PhD, FACP; and Humayun J. Chaudhry, DO, MACP, FSMB President/CEO.

The Workgroup was charged with evaluating the impact of mandatory PDMP query on patient outcomes and the prescribing of controlled substances; evaluating challenges to increasing PDMP utilization, including, but not limited to: a) authority to access; b) currency of data; c) Electronic Medical Record (EMR) integration; and d) interoperability; and developing recommendations to state medical and osteopathic boards (hereafter referred to as “state medical boards”) regarding physician utilization of PDMPs, including a recommendation regarding mandatory query.

To accomplish its charge, the Workgroup conducted a review of PDMP statutes, rules, and state medical board policies currently enacted across the United States, research reports and peer-reviewed articles in the medical literature and policy statements regarding the use of PDMP. The
The report is provided as a guidance document for state medical boards and other state agencies to maximize the effective use of PDMPs.

The Workgroup met in person and via web conference to develop its report, *Prescription Drug Monitoring Programs* (Attachment 1). A draft of the report was distributed to FSMB member boards and other key stakeholder organizations for comment in December 2017 with comments due January 26, 2018. Comments were generally supportive and have been incorporated to the extent that they did not substantively conflict with the Workgroup’s recommendations. The FSMB Board of Directors considered the draft report at its meeting on February 8, 2018 in Washington D.C. and discussed clarifications to the document.

ITEM FOR ACTION:

The Board of Directors recommends that:

The House of Delegates ADOPT the recommendations in the report, *Prescription Drug Monitoring Programs*, and the remainder of the report be filed.
INTRODUCTION

In April 2017, the Federation of State Medical Boards (FSMB) Chair, Gregory B. Snyder, MD, DABR, appointed a Workgroup on Prescription Drug Monitoring Programs (PDMP) in accordance with FSMB Resolution 17-1: Mandatory Use of Prescription Drug Monitoring Programs, which was adopted by the FSMB’s House of Delegates and which directed the FSMB to establish a task force to study PDMP use in the United States and its territories. The Workgroup was charged with evaluating the impact of mandatory PDMP query on patient outcomes and the prescribing of controlled substances; evaluating challenges to increasing PDMP utilization, including, but not limited to: a) authority to access; b) currency of data; c) Electronic Medical Record (EMR) integration; and d) interoperability; and developing recommendations to state medical and osteopathic boards (hereafter referred to as “state medical boards”) regarding physician utilization of PDMPs, including a recommendation regarding mandatory query.

This document provides recommendations for state medical boards and other state agencies to maximize the effective use of PDMPs.

In developing the recommendations that follow, the Workgroup conducted a review of PDMP statutes, rules, and state medical board policies currently enacted across the United States, research reports and peer-reviewed articles in the medical literature and policy statements regarding the use of PDMP.
Section 1. Background

Overdose deaths from prescription opioids in the United States quintupled between 1999-2016, totaling more than 200,000 deaths during that time. In 2016, more than 46 people died every day from overdoses involving prescription opioids. This escalating public health epidemic has led to a wave of implementations and upgrades to states’ prescription drug monitoring programs over the past decade in an effort to curb substance use disorder.

State regulatory, administrative, and law enforcement agencies have long seen the need to establish systems to track and monitor the prescribing and dispensing of certain controlled substances, a recognition that dates to 1918. California has the oldest continuous program, created in 1939. Early PDMPs were paper-based and collected data on Schedule II prescribing and dispensing only. Collected data was typically reported into such systems within 30 days of the time from dispensing.

In 1990, a new era of electronic PDMPs broke ground when Oklahoma became the first state to require electronic transmission of such data, which helped reduce operational costs and increase accuracy and timely submissions. By 1992, 10 states had operational PDMPs and many other states were considering establishing their own. In 1995, Nevada became the first state to expand the type of drugs reported to the PDMP, expanding from Schedule II only to Schedules II-IV. At the same time, Nevada also became the first state to provide unsolicited reports back to prescribers. By 2000, 15 states had established PDMPs. Between 2000-2012, 34 additional states established such a program, bringing the total number to states with PDMPs to 49. In 2014, the District of Columbia established a PDMP, bringing the total of operational PDMPs to 49 states, plus D.C. and Guam. Puerto Rico has also enacted legislation creating a PDMP but it is not yet operational.

As of September 2017, Missouri remains the only state without a statewide, operational PDMP. To work around this obstacle, St. Louis County established its own PDMP in March 2016 and, since then, this PDMP has gone live (as of April 2017) and more than 50 counties in the state and several individual cities have joined as participants, representing more than 70 percent of Missouri’s population and 91 percent of its prescribers. Separately, in July 2017, the Missouri governor issued an executive order to create a statewide PDMP that allows the Missouri Department of Health and Senior Services to analyze and identify inappropriate prescribing, dispensing, and obtaining of controlled substances, and to address these actions by making

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1 Centers for Disease Control, Opioid Data Analysis. [https://www.cdc.gov/drugoverdose/data/analysis.html](https://www.cdc.gov/drugoverdose/data/analysis.html)
referrals to appropriate government officials, including law enforcement and professional licensing boards.\(^5\)

While the common goal of PDMPs is to provide prescribers and other health care professionals with accurate information about the prescriptions that patients have obtained, a state’s decision to apply comprehensive mandates varies widely. The differences between states relate to the types of drugs monitored and the types of prescribers who are mandated to query, as well as to the circumstances which necessitate querying the PDMP, among other differences.\(^6\) For instance, some PDMPs monitor Schedules II-IV controlled substances, while others monitor Schedules II-V or certain non-controlled substances.\(^8\) Thirty-six states and the District of Columbia mandate PDMP query under certain circumstances. Of those, 27 states require querying the PDMP during the initial prescribing of a designated substance, while nine states require querying the PDMP before each prescription of a designated substance. Twelve states mandate querying the PDMP when prescribing for the treatment of pain and 14 states require it when prescribing for drug addiction. Among those states requiring a prescriber to query the PDMP prior to the initial prescription of a designated substance, some only require it if it is a Schedule II or III opioid, while others require it only if the initial opioid prescription surpasses a seven-day supply.\(^9\)

This report aims to provide guidance to state medical boards about effective PDMP use, one of many strategies being recommended to address the growing prescription opioid epidemic.

Section 2. Definitions

Mandatory Registration – A state’s requirement that prescribers of controlled substances must register with the state’s PDMP.

Prescription Drug Monitoring Program – A patient safety tool designed to facilitate the collection, analysis, and reporting of information about the prescribing and dispensing of controlled substances.\(^10\)

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\(^9\) “Mandated Use of State Prescription Drug Monitoring Programs: Highlights of Key State Requirements.” National Alliance for Model State Drug Laws, June 2017. [http://www.namsdl.org/library/6735895A-CA6C-1D6B-B8064211764D65D0](http://www.namsdl.org/library/6735895A-CA6C-1D6B-B8064211764D65D0/).

Universal Use – A state’s requirement that prescribers must query the patient’s PDMP history before initially prescribing opioid pain relievers and benzodiazepines, and at certain intervals thereafter.\textsuperscript{11}\n
Unsolicited Reports – Proactive communications from the PDMP to prescribers, dispensers, law enforcement, and/or regulators to provide information about patient prescriptions and/or the prescribing activity of a health care professional based upon PDMP data.\textsuperscript{12}\n
3. Mandatory Registration

Studies show that between 2010-2012, states with operational PDMPs saw an average registration rate of 35 percent among licensed prescribers who prescribed at least one controlled substance during that period.\textsuperscript{13} In 2014, a national survey found that 53 percent of primary care physicians used their state’s PDMP at least once, but many were not using the PDMP on a routine basis.\textsuperscript{14} Although there have been extensive educational campaigns to recruit prescribers to participate in their state’s PDMP, results have not always been successful.\textsuperscript{15} At the same time, however, PDMP registration has increased significantly, increasing from approximately 471,000 to more than 1.3 million from 2014 to 2016. During the same time period, queries by physicians and other health care professionals increased from approximately 61 million to more than 136 million.\textsuperscript{16}

States are seeing success in increasing prescriber PDMP registration rates through other methods, such as mandatory registration. Massachusetts took a staggered, low resource-intensive approach by linking PDMP enrollment to the renewal of state controlled substance registration, where renewals are required every three years for practitioners. The process established by Massachusetts allowed for a continuous workflow for PDMP staff, rather than a surge in applications immediately after the enactment of mandatory PDMP registration legislation. As a result, the state first saw a gradual increase in registration, followed by a more dramatic increase, between 2011-2016. In 2011 and 2012, only 1 percent and 2 percent of prescribers were registered with the PDMP, respectively. By the end of 2014, however, nearly 66 percent of prescribers were enrolled. By September 2015, that percentage increased to 83 percent, and by January 2016, more than 90 percent had enrolled.\textsuperscript{17}

4. Universal Use

\textsuperscript{11} CDC Prevention Status Report, https://wwwn.cdc.gov/psr/NationalSummary/NSPDO.aspx
\textsuperscript{14} Ibid.
\textsuperscript{15} Ibid.
Research shows that between 2011-2014, 85 percent of states that implemented some form of a PDMP universal use mandate were based upon legislation that was of limited scope and strength. Due to the weakness of the mandates in these cases, it is unlikely that they will prove effective in improving opioid prescribing practices. Efforts to strengthen universal use mandates are supported by President Donald Trump’s Commission on Combating Drug Addiction and the Opioid Crisis, which recommends that federal agencies mandate PDMP querying.

States that have established an effective PDMP, in part or in whole, employ certain evidence-based practices. These practices include delegated authority, unsolicited reports, data timeliness, streamlined enrollment, educational initiatives, integration and data sharing, enhanced user interfaces, and proper funding, with delegated authority, data timeliness, and integration and data sharing being critical elements.

**Delegated Authority**

Prescription Drug Monitoring Programs can serve as valuable tools to help inform prescribers’ decision making and identify potential substance use disorder, but a significant barrier to increasing prescriber use of them is the time typically needed to query the system. To decrease the time spent by prescribers reviewing patient records, many states authorize registered users to delegate non-prescriber employees the ability to access the system using sub-accounts. States vary, however, in whether a delegate has to be a licensed individual or not, as well as in the number of prescriber delegates permissible. Currently, 47 states and the District of Columbia authorize prescribers to delegate such authority, with 36 states actively doing so. Some states only permit two delegates per prescriber, while others impose no limits.

In Kentucky, the state’s PDMP, known as the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER), does not restrict the number of subaccounts to licensed staff. Prescribers also have no limit on the number of designated delegates, who are also permitted to serve as a delegate for multiple prescribers. For prescribers sharing multiple delegates, delegates are able to select the prescriber from a dropdown list to accurately record for which prescriber a

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report is being queried. The prescriber is responsible for deactivating accounts of delegates who leave the practice or otherwise warrant discontinuance of PDMP access. Delegates are permitted to conduct queries and provide reports for prescriber review, but are prohibited from conducting the clinical review of data that the state’s mandate requires. As a result of allowing such delegated authority, during the fourth quarter of 2015 delegates requested nearly 64 percent of in-state prescriber reports, despite accounting for 42 percent of combined delegate and prescriber master accounts by the end of that year.  

**Unsolicited Reports**

PDMPs provide prescription history reports to authorized users upon request (these are also known as “solicited” reports), but when these reports are not requested useful information can go unseen or unused by prescribers. In an effort to increase utilization, many PDMPs proactively send “unsolicited” (and, therefore, unrequested) reports to specific prescribers, dispensers, state licensing boards, and law enforcement agencies that contain data suggestive, or indicative, of multiple provider episodes or inappropriate prescribing and dispensing.25

In 2005, Maine began sending prescribers quarterly threshold notification reports via U.S. mail, but in 2013 moved to monthly emailed alerts. Originally, these alerts were sent to registered PDMP users only when one of three criteria was met by a patient: 1) exceeds a certain number of prescribers and pharmacies in a three-month period; 2) exceeds a specified average daily dose of acetaminophen coming from prescriptions of opioid-acetaminophen combination drugs; or 3) is prescribed buprenorphine and another opioid in a 30-day period. In 2015, however, the state’s legislature added two new criteria to initiate alerts: 1) multiple overlapping prescriptions for medications containing opioids; and 2) prescriptions for more than 300 morphine milligram equivalents daily for more than 45 consecutive days within a 90 day period. Alert recipients must log into their PDMP account to review the patient’s prescription history, which includes the other providers who prescribed to the patient, the pharmacies that dispensed to the patient, drugs and quantities and other details of prescriptions dispensed for the past three months. Additionally, the state recently enabled prescribers to request reports based on their own set thresholds. It is believed that unsolicited reports may have affected prescriber behavior from 2010 to 2014 when the state saw a steady decline in the rate of multiple provider episodes.26

Additionally, in Indiana, a prescriber who believes a patient’s PDMP data suggests questionable activity has the option to send email alerts to other prescribers and dispensers of the patient. These “user-led unsolicited report” email alerts do not contain a patient’s name or any conclusions, but rather contains a hyperlink to a patient’s prescription history report that registered users can review after logging into the PDMP, thus ensuring Health Insurance Portability and Accountability Act (HIPAA) compliance. These alerts serve to notify prescribers and dispensers that a patient may be using unnecessary prescription drugs, may be receiving controlled substances from multiple providers, or may be involved in controlled substance

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24 Ibid.
26 Ibid.
diversion. Indiana first launched its user-led unsolicited reports in March 2012. After the first three months of the program, 140 practitioners had sent 2,284 alerts on 214 unique patients, at virtually no cost to the program.\(^\text{27}\)

**Data timeliness**

A prescriber’s ability to effectively use PDMP data to assess a patient’s prescription history can only be as complete as the data that is transmitted into the system by a dispenser. If a PDMP report does not contain information about the most recently dispensed controlled substances, a prescriber may lack valuable data to determine the best course of treatment. Because of this, it is imperative to minimize the pharmacy reporting interval. States are increasingly moving away from weekly reporting towards daily PDMP data reporting. In 2015, 24 states required daily data submissions. As of July 2017, 40 states and the District of Columbia required data to be reported within 24 hours or one business day. Oklahoma is the only state currently requiring real-time reporting,\(^\text{28}\) but the transition from daily reporting to real-time required two years and involved intensive effort and overtime for the PDMP, as well as redesign for pharmacy data systems and workflow procedures.\(^\text{29}\)

**Streamlined Enrollment**

In order to access PDMP data, prescribers must typically establish online accounts with a state’s PDMP system. This process requires the prescriber to submit, and the PDMP to verify, identifying information, such as name, date of birth, state controlled substance prescribing or medical practice license number, DEA registration number, driver’s license number, place of employment, medical specialty, and contact information. Once the prescriber’s state controlled substance prescribing or medical practice license number and a DEA registration number is verified, the prescriber may create an account and begin to query patients’ controlled substance prescription history. Unfortunately for many prescribers, the process can be time consuming to complete registration applications as some states require paper applications and notarization.\(^\text{30}\)

To expedite PDMP registration, and to transition away from paper applications, some states began migrating to an online registration system, in addition to automatic prescriber enrollment, during initial medical licensure and licensure renewal.

In 2012, the Tennessee Legislature enacted legislation mandating that prescribers use the state’s PDMP and dispensers register. The comprehensive mandate required DEA-registered prescribers and dispensers to register with the PDMP within the first eight months after the law’s enactment. New licensees are required to register with the PDMP within 30 days. The universal use mandate went into effect four months after prescribers and dispensers were required to register. In an


\(^{28}\) National Alliance for Model State Drug Laws, “Frequency of Prescription Drug Monitoring Program Data,” 30 June 2017. [http://www.namsdl.org/library/03B95893-0EE2-3766-EABAD212B5C8E8D3/](http://www.namsdl.org/library/03B95893-0EE2-3766-EABAD212B5C8E8D3/)


effort to handle the influx of registrations, Tennessee adopted an online registration system. This system automatically attempts to validate a prescriber’s information using electronic databases for the state’s professional health care licenses, driver’s licenses, and DEA prescriber registration. For prescribers who do not have health care licenses or DEA numbers, such as medical residents in hospitals in some states, PDMP registration is still processed manually. As a result of the streamlined online registration system for licensed prescribers and dispensers, the number of registered prescribers has increased 127 percent between 2011 (a year before the mandate went into effect) and 2014. Additionally, average queries per month have increased 203 percent during that same time period.\(^{31}\)

**Educational Initiatives**

Many state medical boards require physicians to complete continuing medical education (CME) in specific content areas, such as pain management and controlled substance prescribing practices. Thirty-two of the 50 states, and the District of Columbia, mandate at least one content-specific CME course. Of those 32 states, 29 states require CME focused on either pain management or controlled substance prescribing practices, or in some circumstances both. In 26 out of those 29 states, the CME requirements are for both allopathic and osteopathic physicians. In two states, Oklahoma and Nevada, only osteopathic physicians are required to complete CME on pain management/controlled substance prescribing practices, while in Vermont only allopathic physicians are required to complete such CME. Additionally, 12 of the 29 states require CME on pain management/controlled substance prescribing practices for all physicians, while the other 17 states only require a subset of physicians to complete such requirements, such as controlled substance providers or certain providers who work in pain clinics.\(^{32}\)

In order to assist prescribers in completing CME requirements, as well as educate prescribers who are not required to complete content-specific CME, the federal government promotes certain educational initiatives. The U.S. Department of Health and Human Service’s (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) jointly developed the “Substance Use Trainings” webpage as an online educational resource that provides one-time and ongoing training activities dedicated to pain management and controlled substance prescribing practices. HHS’s Office of Disease Prevention and Health Promotion also developed an online education resource, *Pathways to Safer Opioid Use*, while the U.S. Food and Drug Administration’s (FDA) Risk Evaluation and Mitigation Strategy (REMS) for extended release/long-acting opioids requires CME to be offered by opioid manufacturers.\(^{33}\) As part of REMS, the FDA released the *FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics*, which contains core educational messages for the development of continuing

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\(^{33}\) Ibid.
education activities focused on safe prescribing. The Centers for Disease Control (CDC) also provides educational materials, such as Applying CDC’s Guideline for Prescribing Opioids: An Online Training Series for Providers and What Healthcare Providers Need to Know About PDMPs.

While a majority of states require physicians to complete certain content-specific CME, FSMB policy states that, “the FSMB believes mandatory continuing medical education is a matter reserved for the individual state jurisdictions.”

Integration and Data Sharing

The value of PDMP data is based in part on whether such data is readily available and accessible. Although PDMPs collect controlled substance prescription information in a central repository, the adoption and utilization of a PDMP by prescribers is slowed when such data is not integrated into health information technology (HIT) systems, specifically electronic health records (EHR).

There have been several efforts and initiatives to spur the pace at which PDMP data is integrated, such as SAMHSA’s PDMP Electronic Health Records Integration and Interoperability Expansion (PEHRIIE) program, which funded projects in nine states from 2012-2016. The goal of this program was to increase prescriber utilization by integrating PDMP data into HITs. The program also sought to increase the comprehensiveness of PDMP data by increasing interstate PDMP data sharing.

Programs such as PEHRIIE demonstrate the effectiveness of integrating PDMP data into HITs. During the fourth quarter of 2014, the state of Washington became interoperable with OneHealthPort, a statewide HIE, enabling integration with the Emergency Department Information Exchange (EDIE), a hub connecting hospital emergency departments. In 2015, the first full calendar year after integration, the PDMP provided 2,222,446 solicited reports to prescribers, compared to 2014, when 26,546 solicited reports were provided to prescribers. Significant increases in solicited reports were also experienced in Kansas after PDMP data was integrated with the Via Christi Health Network, the largest healthcare provider in Kansas, in late 2013. After integration, solicited reports provided to Via Christi prescribers increased from 31,156 reports in 2013 to 223,000 reports in 2015. Compared to other prescribers in Kansas, the number of solicited reports increased significantly less, from 23,171 in 2013 to 65,242 in 2015.

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36 Centers for Disease Control, What Healthcare Providers Need to Know About PDMPs. https://www.cdc.gov/drugoverdose/pdmp/providers.html
37 Federation of State Medical Boards (FSMB), FSMB Policy 100.2, Mandating Continuing Medical Education, Washington, DC: The Federation, 1980.
39 Ibid.
Several states also announced efforts to integrate prescription drug information into EHRs and other HITs. In August 2017, Indiana announced that it would integrate PDMP data into EHRs at hospitals and physician practices across the state at no cost to the facility or individual practitioner. The phased-in integration is scheduled to be completed by 2020. Michigan also announced in June 2017 that state and federal funds will be invested over a two year period to integrate the state’s PDMP, Michigan Automated Prescription System, into EHRs and pharmacy dispensation systems. Additionally, Arizona, Kansas, Massachusetts, Ohio, Pennsylvania, and Virginia are supporting integration into EHRs, HITs, and pharmacy dispensing systems at no cost.

These recent state trends to integrate PDMP data are in line with recommendations being conveyed at the federal level, including the President’s Commission on Combating Drug Addiction and the Opioid Crisis, which recommended in November 2017 that “PDMP data integration with electronic health records, overdose episodes, and substance use disorder-related decision support tools for providers is necessary to increase effectiveness.”

The ability for prescribers to view prescription drug history information across state lines can assist in identifying a potential substance use disorder. To facilitate interstate PDMP data sharing and integration, states have opted to connect to a data sharing hub. Forty-five states and the District of Columbia are currently engaged in some form of interstate data sharing, while three other states are in the process of implementing data sharing. Not all states, however, allow universal data sharing among states. Some states allow prescribers in any state to access PDMP data, while other states allow prescribers from specific states within a region. These are usually in-state policy decisions that often change to expand toward a goal of universal access.

The President’s Commission on Combating Drug Addiction and the Opioid Crisis also recommended supporting federal legislation mandating states that receive grant funds to comply with PDMP requirements, including data sharing, and establishing and maintaining a data-sharing hub.

In an effort to reduce barriers to data sharing across state lines, there have been various data sharing hubs launched to facilitate data sharing in compliance with each state’s data access regulations. At the request of several PDMPs, the National Association of Boards of Pharmacy (NABP) created Prescription Monitoring Program (PMP) InterConnect in 2011. PMP InterConnect provides for encrypted data to be transmitted across state lines. To date, 45 states have executed a memorandum of understanding (MOU) with NABP to participate and 42 of

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those states are now live. Each month, PMP InterConnect processes more than 15 million requests.  
Separately, RxCheck is another data sharing hub that was created with support from the U.S. Bureau of Justice Assistance (BJA) and using the Prescription Monitoring Information Exchange (PMIX) National Architecture specifications. As of July 2017, there are four states that are engaged in interstate data sharing with RxCheck, while two states are currently implementing interstate data sharing and eight states have plans to connect to RxCheck.

Enhanced User Interfaces

While having access to PDMP data is integral for prescribers, it is equally important that prescribers are able to quickly analyze and use that data. As the amount of controlled substance prescription information available to prescribers has increased in recent years, prescribers have sought ways to quickly analyze the most important information for clinical decision making. To address this, states began exploring ways to better interpret the data. Some of these methods included adding an enhanced user interface to the PDMP system that includes, but is not limited to, a total morphine milligram equivalent (MME) calculation for each opioid prescription, a daily MME dose level, and flags or alerts if a patient’s MME surpasses a certain threshold.

In 2016, the California PDMP, Controlled Substance Utilization Review and Evaluation System (CURES) underwent a redesign to help prescribers improve their clinical decision-making when evaluating whether to prescribe a controlled substance. The new updated program contains a dashboard that provides users patient alerts, including a list of patients who are prescribed more than 100 MME per day; have obtained prescriptions from six or more prescribers or pharmacies during the past 12 months; are prescribed more than 40 milligrams of methadone daily; have been prescribed opioids for more than 90 consecutive days; or are concurrently prescribed benzodiazepines and opioids.

Enhanced user interfaces are a recent development and, as such, there is a paucity of evidence on its effectiveness in identifying a potential substance use disorder or coordinating care in the case of a multiple provider event.

Data Security/Patient Protections

As the use of PDMP increases nationwide and controlled substances prescription history is increasingly used by prescribers, patients are increasingly concerned about the security of their data and the possibility of law-enforcement scrutiny. Prescribers are also increasingly concerned

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that medical consultations are no longer a private affair and that staff access pose the potential for unscrupulous use and data leaking.\(^{48}\)

Substance use disorder is a multifaceted problem and often requires collaboration among various agencies and stakeholders. PDMPs are primarily used as a public health tool, but law enforcement agencies see PDMPs as a potential law enforcement tool. An increase in law enforcement scrutiny of PDMP data may significantly affect a prescriber’s clinical decision making and cause a prescriber to under prescribe.\(^{49}\)

A balanced approach between patient safety and data protection has been encouraged by various stakeholders. Both the American Medical Association (AMA) and the American Society of Addiction Medicine (ASAM) believe that PDMP data should be considered protected health information, and should not be released outside of the health care system unless there is authorization for release from the individual patient. The AMA also supports access to PDMP data via a warrant, as well as when the public safety demands in certain situations.\(^{50}\)

The United States District Court for the District of Oregon, Portland Division affirmed the limits of law enforcement access in February 2014 in *Oregon Prescription Drug Monitoring Program v. United States Drug Enforcement Administration*. The Court found that federal drug investigators cannot access patients’ prescription information without proving probable cause and obtaining a warrant. The Court also found that administrative subpoenas are insufficient to demand information relevant to investigations into potential drug violations, such as a doctor who improperly prescribes drugs.\(^{51}\) In June 2017, the United States Court of Appeals for the Ninth Circuit reversed the ruling as it found that requiring a court order to enforce the subpoena on the DEA interfered with Congress’ intent to strengthen law enforcement tools against the traffic of illicit drugs. It recognized, however, that medical records require strong legal safeguards.\(^{52}\)

In Georgia, in addition to authorizing prescribers and dispensers, and their designated delegates, the Georgia Drugs and Narcotics Agency is authorized to provide requested prescription information collected to a patient, or the patient’s attorney; local or state law enforcement or

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\(^{49}\) Ibid.


prosecutorial officials pursuant to the issuance of a search warrant from an appropriate court or
official in the county in which the office of such law enforcement or prosecutorial officials are
located or to federal law enforcement or prosecutorial officials pursuant to the issuance of a
search warrant or a grand jury subpoena; to the Georgia Drugs and Narcotics Agency, the
Georgia Composite Medical Board or any other state regulatory board governing prescribers or
dispensers in this state, or the Department of Community Health for purposes of the state
Medicaid program upon the issuance of a subpoena by such agency, board, or department
pursuant to their existing subpoena power or to the federal Centers for Medicare and Medicaid
Services upon the issuance of a subpoena by the federal government pursuant to its existing
subpoena powers.\textsuperscript{54}

\textbf{Proper Funding}

To continually maintain and update a state’s PDMP system often comes with a certain level of
financial need. It is often difficult, however, for states to properly fund such operations and
projects. In order to meet these demands, states use a wide variety of funding mechanisms,
whether in whole or in part, including state appropriations, registration and licensing fees, and
federal grants.

One source of funding for states has been legislative appropriations and state government
funding. In October 2015, Ohio Governor John Kasich announced that the state would invest up
to $1.5 million a year to integrate the Ohio Automated Rx Reporting System (OARRS) directly
into electronic medical records and pharmacy dispensing systems across the state, allowing
instant access for prescribers and pharmacists.\textsuperscript{55}

In addition to licenses to practice medicine, several states require a controlled substance
prescribing license that is separate from DEA registration. The registration fees from these state
prescribing licenses frequently go to support the PDMP, whether in full or in part. This funding
mechanism assesses a fee on a subset of providers while the more current thinking is that all
licensed providers should have access to their patients’ PDMP data.\textsuperscript{56}

Instead of allocating funds from a specific controlled substance prescribing license, some states
allocate a certain percentage from all professional licensing fees to go towards the state’s PDMP.
Although this avenue provides consistent funding, it is limited in dollar amount and increasing
the allocated percentage may affect other operations of the Board.\textsuperscript{57,58}

States often leverage federal grants to fund and maintain PDMP projects, as well. Since 2003, the
U.S. Department of Justice’s Bureau of Justice Assistance has administered the Harold Rogers
PDMP Grant Program to reduce opioid misuse and the number of overdose fatalities by

\textsuperscript{54} Ga. Code § 16-13-30
\textsuperscript{55} Ohio Automated Rx Reporting System, \url{https://wholesale.ohiopmp.gov/Portal/Integration.aspx}
\textsuperscript{56} PDMP TTAC, “Funding Options for Prescription Drug Monitoring Programs,” 3 July 2013.
\url{http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf}
\textsuperscript{57} Brandeis University PDMP Training and Technical Assistance Center, “Funding Options for Prescription Drug
Monitoring Programs,” 3 July 2013. \url{http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf}
\textsuperscript{58} National Alliance for Model State Drug Laws, “Funding Provisions of PDMPs,” May 2016.
\url{http://www.namsdl.org/library/57555C8D-B77F-0F68-987334839CA29924/}
supporting the implementation, enhancement, and proactive use of state PDMPs. For Fiscal Year 2017, two-year grants were awarded to 10 states and Puerto Rico totaling $3,966,932.59 The CDC also provides funding opportunities to support states’ efforts to enhance and maximize PDMPs, including the Data Driven Prevention Initiative (DDPI) and Prevention for States (PfS) Funding Opportunity Announcements.6061 Additionally, SAMHSA also provides a variety of funding opportunities for states to enhance their PDMPs.62

5. Recommendations

1. Mandatory Registration –
States should require PDMP registration for prescribers of controlled substances. This registration should take place at the time of the prescriber’s initial medical licensure application or next renewal. In an effort to expedite the process, state PDMPs should facilitate online registration to meet the expected increase in applications.

2. Universal Use of PDMPs–
States should require universal use of PDMPs if the state’s PDMP contains certain characteristics. Ideally, all the characteristics listed below would be present within a state’s PDMP system but some are more critical than others to the functionality of the PDMP.

a. Group 1: Critical Characteristics Needed for an Effective PDMP
i. Delegation –
Each prescriber should be permitted to delegate authority to access the PDMP to any member of their health care team by creating subaccounts without limitations. Delegates should be able to be shared by multiple providers, such as a physician group or emergency department or similar setting. The prescriber must have the authority to deactivate a delegate’s subaccount for any reason, including, but not limited to, leaving the practice or no longer serving in that capacity.

In order to ensure delegate accountability, prescribers must be allowed to audit their delegates’ activity and use of the PDMP.

ii. Data timeliness/accuracy –
State PDMPs should require daily reporting of controlled substance prescription. Although it may be ideal to have real-time reporting, there is a paucity of data at this time to support it.\(^6\)

In order to ensure data accuracy, prescribers should be able to review their prescribing history and provide corrections to it, if necessary.

iii. Integration and Data Sharing –
In order to minimize any workflow disruption, states should integrate their PDMP system with electronic health records and pharmacy systems. Ideally, this integration will provide near-instant and seamless access to critical prescription history information to both prescribers and pharmacists.

States should engage in interstate PDMP data sharing.

b. Group 2: Other Characteristics Needed for an Effective PDMP

i. Unsolicited reports –
In an effort to notify prescribers of a patient’s prescribing information, as well as the prescriber’s own prescribing history, PDMP systems should provide unsolicited reports. Examples of information in such reports may include multiple provider episodes, combinations of commonly misused drugs, or exceeding a designated threshold for an average daily dose of an opioid in morphine milligram equivalents.

To protect patients, prescribers should generate user-led unsolicited reports to send to other prescribers treating the same patient. These user-led unsolicited reports are sent at the discretion of the prescriber and serve as a judgment that the patient may be receiving a potentially harmful controlled substance or has experienced a situation, such as an overdose, that may increase the patient’s future risk of overdose or abuse.

When possible, these reports should be sent electronically and should not contain identifying patient information, but rather alert and direct the prescriber to query the PDMP to view the information.

ii. Educational initiatives –
A state medical board may choose to encourage or require prescribers to complete content-specific continuing medical education related to prescribing practices including, but not limited to, PDMP utilization.

iii. Enhanced user interface –

PDMP system tools to increase usability for prescribers should be considered. These components, as part of a PDMP’s interface, may include, but are not limited to, a summary of morphine milligram equivalent (MME) for each opioid prescription and a daily MME dose level, as well as any other “red” flags or alerts for a specific patient.

iv. Data Security/Patient Privacy –
States should grant PDMP data access to local, state, and federal law enforcement only when there is an issuance of warrant/judicial finding of probable cause.

States should grant PDMP data access to state medical boards when a licensee is under investigation by the board for inappropriate prescribing.

In order to protect the privacy of patient information and to ensure proper patient treatment, Medicare, Medicaid, state health insurance programs and/or health care payment benefit providers and insurers should not have access to a patient’s PDMP record unless a subpoena has been issued in accordance with existing subpoena powers.

v. Proper funding –
To meet the demands of updating and maintaining a PDMP, states should implement a sustainable funding mechanism, whether through state funding or federal grant programs.
WORKGROUP MEMBERS
Anna Z. Hayden, DO, Chairman
FSMB Director-at-Large
Member, Florida Board of Osteopathic Medicine

Mark E. Bowden, MPA, CMBE
Executive Director, Iowa Board of Medicine

Robert P. Giacalone, JD, RPh
Vice President, Ohio Medical Board

Robin N. Hunter Buskey, DHSc, PA-C
Past Member, North Carolina Medical Board

William K. Hoser, MS, PA-C
Chairman, Vermont Board of Medical Practice

Louis J. Prues, DMin, MDiv, MBA
Public Member, Michigan Board of Medicine

Jean L. Rexford
FSMB Director-at-Large
Public Member, Connecticut Medical Examining Board

Thomas H. Ryan, JD, MPA
Executive Director, Wisconsin Medical Examining Board

Joseph R. Willett, DO
Member, Minnesota Board of Medical Practice

SUBJECT MATTER EXPERTS
J. Mark Bailey, DO, PhD
Professor, University of Alabama at Birmingham

Daniel Blaney-Koen, JD
Senior Legislative Attorney, American Medical Association

Shawn Brooks
Health Communication Specialist, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Danna E. Droz, JD, RPh
Prescription Monitoring Program (PMP) Liaison, National Association of Boards of Pharmacy

Patrice A. Harris, MD, MA
President, American Medical Association

Christina A. Mikosz, MD, MPH
Medical Officer, National Center for Injury Prevention and Control, Centers for Disease Control

Rebecca Poston, MHL
Program Manager, Electronic-Florida Online Reporting of Controlled Substance Evaluation (E-FORCSE) Program

Judy Staffa, PhD, RPh
Associate Director for Public Health Initiatives, Office of Surveillance and Epidemiology, U.S. Food and Drug Administration

EX-OFFICIOS
Gregory B. Snyder, MD, DABR
Chair, FSMB

Patricia A. King, MD, PhD, FACP
Chair-elect, FSMB

Humayun J. Chaudhry, DO, MACP, President and CEO, FSMB

STAFF SUPPORT
Lisa A. Robin
Chief Advocacy Officer, FSMB

John P. Bremer
Manager, State Legislation and Policy, FSMB
REPORT OF THE BOARD OF DIRECTORS

Subject: Report of the FSMB Workgroup on Physician Wellness and Burnout

Referred to: Reference Committee B

The Federation of State Medical Boards (FSMB) Workgroup on Physician Wellness and Burnout, chaired by Dr. Arthur S. Hengerer, M.D., has been tasked with examining the issues of physician wellness and burnout from a regulatory perspective, identifying key patient safety issues, and determining ways in which member boards can be supported.

The Workgroup’s charge includes identifying resources and strategies to address physician burnout. In accomplishing its charge, the Workgroup focused on: 1) educating state medical boards and physicians through the creation of a compendium of research and resources on identifying, managing and preventing physician burnout; 2) raising awareness about the prevalence of burnout among physicians and other health care professionals and thereby reducing stigma associated with seeking help for burnout symptoms; 3) evaluating current research on the impact of physician burnout on patient care; and 4) convening stakeholder organizations and experts to discuss physician wellness and recommend best practices for identifying, managing and preventing physician burnout throughout the career continuum.

Over the course of two years, the Workgroup examined the issue of physician burnout from a broad perspective, reviewing existing research, resources, and strategies for addressing it. The Workgroup has drafted a report that includes recommendations, most of which pertain to the licensing and license renewal processes of state medical boards, as well as suggestions for external organizations that aim to address physician burnout. Workgroup members include Mohammed A. Arsiwala, MD; Amy Feitelson, MD; Doris C. Gundersen, MD; Kathleen Haley, JD; Brian J. Miller, MD; Roger M. Oskvig, MD; Michael R. Privitera Jr., MD; Jean L. Rexford; Dana C. Shaffer, DO; Scott A. Steingard, DO; and Barbara E. Walker, DO.

A draft of the report was distributed to FSMB member boards in December 2017, as well as to several external organizations and individuals with a nexus to physician wellness and burnout. Comments received were generally positive and the Workgroup has revised its Report to address them, where appropriate. The FSMB Board of Directors considered the draft Report of the FSMB Workgroup on Physician Wellness and Burnout at its meeting on February 7, 2018 in Washington D.C. and discussed clarifications to the document.

ITEM FOR ACTION:

The Board of Directors recommends that:

The House of Delegates ADOPT the recommendations contained in the Report of the FSMB Workgroup on Physician Wellness and Burnout, and the remainder of the Report be filed.
Executive Summary:

The Federation of State Medical Boards (FSMB) Workgroup on Physician Wellness and Burnout was convened in April of 2016 by FSMB Chair Arthur S. Hengerer, M.D. to identify resources and strategies to address physician burnout. While the Workgroup examined the issue of physician burnout from a broad perspective, reviewing as many facets of this complex issue as possible, including existing research, resources, and strategies for addressing it, the recommendations for state medical and osteopathic boards (hereinafter referred to collectively as “state medical boards”) found in this report focus first and foremost on the licensing process. The Workgroup also saw fit to include commentary and recommendations on several other aspects of physician wellness and burnout, though some of these areas may not be under the direct purview of the FSMB or its member boards. The FSMB recognizes the importance of collaboration for effectively supporting physicians and protecting patients in the face of circumstances that lead to burnout, which is ultimately a patient safety issue. A shared accountability model that includes responsibilities to be carried out by providers from all the health professions, including physicians and physician assistants, and with organizations from across the health care community is therefore recommended as the most promising course of action to address this important issue.

Recommendations for state medical boards related to the licensing process include considering whether it is necessary to include probing questions about a physician applicant’s mental health, addiction, or substance use on applications for medical licensure or their renewal, and whether the information these questions are designed to elicit, ostensibly in the interests of patient safety, may be better obtained through means less likely to discourage treatment-seeking among physician applicants.

Where member boards strongly feel that questions addressing the mental health of physician applicants must be included on medical licensing applications, several recommendations are included in this report for the appropriate phrasing of such questions, including focusing only on current impairment, which may be more meaningful in the context of a physician’s ability to provide safe care to patients in the immediate future.

State medical boards are also encouraged to approach physician wellness and burnout from a non-punitive perspective, avoiding public disclosure of any information about a physician’s diagnosis during licensing processes and offering “safe haven” non-reporting options (mentioned later in this report) to physicians.
who are under treatment and in good standing with a recognized physician health
program (PHP) or other appropriate care provider.

It is also recommended that boards take advantage of all opportunities available to
them to discuss physician wellness, communicate regularly with licensees about
relevant board policies and available resources, and make meaningful contributions
to the ongoing national dialogue about burnout in order to advance a positive
cultural change that reduces the stigma among and about physicians seeking
treatment for mental, behavioral, physical or other medical needs of their own.

The Workgroup’s recommendations to external organizations and stakeholders
focus on increasing the awareness and availability of information and resources for
addressing physician burnout and improving wellness. The value of noting and
listing the availability of accessible, private, confidential counselling resources is a
particular point of emphasis in this report, as is dedicating efforts to ensuring that
any new regulation, technology, or initiative is implemented with due consideration
to any potential for negative impact on physician wellness.

This report, which follows two years of careful study, evaluation and discussion by
Workgroup members, FSMB staff, and various stakeholders, is intended to support
initial steps by the medical regulatory community to begin to address the issues
associated with promotion of physician wellness and mitigation of burnout, to the
extent that is possible. The information and recommendations contained herein are
based on principles of fairness and transparency, and grounded in the primacy of
patient safety. They emphasize a responsibility among state medical boards to work
to ensure physician wellness as a component of their statutory right and duty to
protect patients.

Background and Charge:

In 2014, the Ethics and Professionalism Committee of the Federation of State
Medical Boards (FSMB) engaged in several discussions about the risks to patient
safety that may result from disruptive physician behavior. As these discussions
proceeded, it became apparent from a review of the literature and discussions with
state medical boards that a link exists between many instances of disruptive
behavior and symptoms of professional burnout experienced by so-called
“disruptive physicians.” The Committee, chaired by Dr. Janelle A. Rhyne, M.D., MACP,
determined that further research into physician health, self-care, and burnout
should be conducted to identify resources that may be of value for state medical
boards and physicians alike, and to outline possible roles for the FSMB and its
partners to better promote patient safety and quality health care.

Given the complexity of the issue and the many factors contributing to physician
burnout, in 2016, Dr. Arthur S. Hengerer, MD, (while serving as Chair of the FSMB),
established the FSMB Workgroup on Physician Wellness and Burnout to study the
issue further. The Workgroup was specifically charged with identifying resources and strategies to address physician burnout. To accomplish its charge, the Workgroup reported that it would engage in a multi-part work program that would likely involve: 1) educating state medical boards and physicians through the creation of a compendium of research and resources on identifying, managing and preventing physician burnout; 2) raising awareness about the prevalence of burnout among physicians and other health care professionals, helping reduce the stigma sometimes associated with physicians seeking help for burnout symptoms; 3) evaluating current research on the impact of physician burnout on patient care; and 4) convening stakeholder organizations and experts to discuss physician wellness and to recommend best practices for promoting physician wellness and helping physicians identify, manage and prevent burnout throughout their career continuum (i.e. from medical school through residency training and throughout their years of licensed, unsupervised practice.)

The purpose of this report is to summarize the steps taken by the Workgroup in fulfilment of their charge, to share information gathered as part of this process, and to provide a series of recommendations for state medical boards and others to consider for addressing burnout and its symptoms. It should be noted that the Workgroup’s charge does not include tasks related to defining the phenomenon of burnout or performing further analysis into the concept itself, as it was felt there is a significant amount of valuable research that has already been done in these areas and is ongoing. Much of this research, including some that is inchoate, was reviewed by the Workgroup in fulfilment of the third component of its charge. This body of research is referenced herein and informs many of the recommendations contained in this report. While burnout is a phenomenon that may impact physicians at all stages of their career, it should be noted that the recommendations specific to state medical boards in this report focus primarily on the licensing process. The Workgroup feels it is also important, however, to share information in this report related to issues beyond the licensing process. Such additional information and guidance is provided for the benefit of relevant partner organizations and stakeholders responsible for undergraduate, graduate and continuing medical education; medical school, residency training and health facility accreditation; governance, information technology, health insurance, and other activities and functions that support the provision of health care to the nation’s citizens.

In developing the content and recommendations of this report, the Workgroup understands and endorses the importance of the “quadruple aim,” which added a call for improvements in the quality of work lives of physicians and other health care providers to the existing three aims of improving the health of populations, enhancing the patient experience of care, and reducing the per capita cost of health

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As argued by proponents of the fourth aim, improved population health cannot be achieved without ensuring the health and well-being of health care providers.

Several definitions have been applied to the phenomenon of physician burnout and, for the purposes of this report, it is considered a psychological response that may be experienced by doctors exposed to chronic situational stressors in the health care practice environment. This is characterized by overwhelming exhaustion, feelings of cynicism and detachment from work, and a sense of ineffectiveness and lack of accomplishment. While burnout’s manifestations and consequences vary widely, they could result in significant harm to patients.

It has been widely reported for more than a decade that nearly 100,000 preventable medical errors occur in the United States each year. More recent findings suggest that between 210,000 and 400,000 deaths each year are associated with preventable harm. Many of these errors may be attributed to physician burnout and its drivers, such as excessive caseloads, negative workplace culture, poor work-life balance, or perceived lack of autonomy in one’s work. Burnout affects a significant proportion of the U.S. physician workforce. A 2012 study conducted by Shanafelt and colleagues showed that 45.5% of surveyed physicians demonstrated at least one symptom of burnout. When this study was repeated three years later with a different sample, the authors demonstrated that burnout and work-life dissatisfaction had increased by 9% over the three year period. In addition to obvious risks to patient safety, an alarming and extreme result of physician burnout has been the disproportionate (relative to the general population) levels of suicide.

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in recent years by physicians, medical residents and even medical students.\textsuperscript{9,10} One is hard-pressed to find a phenomenon that negatively affects a broader array of stakeholders in health care than burnout. It impacts providers from all health professions. State medical boards’ duty to protect the public, in this regard, also includes a responsibility to ensure the wellness of its licensees.

Features and Consequences of Burnout:

Physicians experiencing burnout, according to the medical literature, exhibit a wide array of signs, symptoms and related conditions, including fatigue, loss of empathy, detachment, depression, and suicidal ideation. The three principal components of burnout are widely described in the medical literature as emotional exhaustion, depersonalization, and diminished feelings of personal accomplishment.\textsuperscript{11} Many of these symptoms are also said to be linked to low levels of career satisfaction.

Career satisfaction may be diminished by even a single influencing factor. Unreasonable increases in workload, for example, may quickly lead to dissatisfaction with one’s career. Loss of job satisfaction has been noted as both a primary contributor to burnout as well as a contributor to its further progression.\textsuperscript{12} Burnout has specifically been found to be the single greatest predictor of surgeons’ satisfaction with career and choice of specialty.\textsuperscript{13} It may also be a significant contributor to increased rates of suicidal ideation among both physicians\textsuperscript{14} and medical students.\textsuperscript{15}

\textsuperscript{9} Rubin R. (2014). Recent Suicides Highlight Need to Address Depression in Medical Students and Residents. \textit{JAMA}, 312(17):1725-1727.
Physicians experiencing manifestations of burnout are also reported to be more prone to engage in unprofessional behavior,\textsuperscript{16} commit surgical or diagnostic medical errors,\textsuperscript{17,18,19} and lose the trust\textsuperscript{20} of their patients, while also decreasing their satisfaction.\textsuperscript{21} At a time when there is compelling evidence of a shortage of qualified practicing physicians in many parts of the United States, losing additional physicians to early or unnecessary retirement would have a detrimental impact on patient access to care across the country. As the American Medical Association's Policy on Physician Health and Wellness states, "When health or wellness is compromised, so may be the safety and effectiveness of the medical care provided."\textsuperscript{22}

**Factors Contributing to Burnout:**

While a large proportion of physicians are said to experience burnout and its correlates, they do not always experience it in the same way or for the same reasons. Physicians may be predisposed to burnout because of personality traits that led them to pursue a medical career in the first place, such as perfectionism, self-denial, and compulsiveness. These are traits that are said to be common among practicing physicians. Predisposition to burnout may be stronger in instances where personal factors such as denial of personal vulnerability, tendencies to delay gratification, or excess feelings of guilt are layered onto these aforementioned personality traits. While burnout is a distinct phenomenon from mental illness and substance use disorders, the latter two issues can play a compounding role in a


physician’s struggle with burnout, making the identification and effective treatment of its symptoms or causes even more difficult.\textsuperscript{23}

It is a common misconception that physicians are more susceptible to suffering from burnout at later stages in their career, presumably from fatigue and aging. In fact, research has demonstrated that physicians in the middle of their careers are at the highest risk for burnout.\textsuperscript{24} Education and training also appear to be critical peak times for physicians, physicians-in-training or medical students to suffer from burnout.\textsuperscript{25,26}

The environment in which physicians work, including their choice of specialty, also plays a significant role in contributing to burnout. Shanafelt and colleagues have shown substantial differences in burnout rates by specialty, although changes in the highest and lowest rates were noted between 2011\textsuperscript{27} and 2014.\textsuperscript{28} The control, or lack thereof, that physicians have over their work environment plays a significant role in predisposition to burnout. This may explain why emergency medicine is frequently found at or near the top of the list of medical and surgical specialties with the highest proportion of physicians experiencing burnout. Emergency physicians often work in environments that are high-demand and low-control.\textsuperscript{29} While finding meaning in one’s work has long been claimed to be the antidote to burnout,\textsuperscript{30} it may be difficult to find such meaning absent an adequate degree of control over one’s work environment.

The movement towards maximal standardization of processes, often labeled a phenomenon of “deprofessionalization,” is also claimed to be a contributor to burnout among physicians. There is worry among some professionals, in medicine and other health care fields, that an expectation for rigid adherence to guidelines

\begin{itemize}
  \item \textsuperscript{24} Dyrbye LN, et al. (2013). Physician satisfaction and burnout at different career stages. \textit{Mayo Clinic Proceedings}, 88(12):1358-1367.
  \item \textsuperscript{26} Dyrbye LN, et al. (2014). Burnout among U.S. medical students, residents, and early career physicians relative to the general U.S. population. \textit{Academic Medicine}, 89(3):443-451.
  \item \textsuperscript{27} Shanafelt TD, et al. (2012). Burnout and satisfaction with work-life balance among US physicians relative to the general US population. \textit{Archives of Internal Medicine}, 172(18):1377-1385.
  \item \textsuperscript{29} https://www.medpagetoday.com/emergencymedicine/emergencymedicine/54916
  \item \textsuperscript{30} Sotile W. (2002). \textit{The Resilient Physician}. 
\end{itemize}
will replace what were formerly considered the more elegant, artistic and satisfying aspects of medical practice. These movements need not be perceived as threats to physician autonomy or to the exercise of professional judgment. Rather, embracing evidence-based medicine, focusing on the value of care that is provided, and celebrating increasingly positive outcomes can contribute to great improvements in patient and population health. Professional judgment will continue to play an important role in realizing these improvements.

Frustrations have also been voiced in relation to the move in health care delivery away from paper-based records to electronic health records (EHRs). Many physicians have expressed dissatisfaction with the intrusiveness and complexity of EHR use and the limits this sometimes places on the ways in which they are able and capable of effectively documenting treatment decisions and provision of care. These frustrations exist in addition to those related to the often complex, redundant, or non-intuitive methods of data entry and other elements of medical record keeping associated with EHRs, as well as the fact that most systems are not yet fully interoperable. However, complaints made about particular aspects of an evolving or disruptive technology should not be interpreted as calls to abandon the important gains in patient safety, professional communication, and even efficiency that have been brought about by the introduction and implementation of EHR systems. Rather, they should be interpreted as important user feedback that may contribute to ongoing improvement of such technology.

The constantly changing and evolving nature of medicine, as well as the challenges faced by the American health care system itself, also appear to be affecting the way many physicians feel within their professional roles. A recent study reported that 65% of physicians who were surveyed predicted an ongoing deterioration in the quality of health care that they deliver, which in turn has been attributed, in part, to the erosion of physician autonomy. When evolving requirements are layered onto

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new expectations with regard to technology, quality reporting, increased clinical
volume, and numerous other initiatives required by payers, employers, and even
state medical boards, it may not be surprising that physicians are experiencing
burnout at alarming rates. While many of the initiatives that place additional
burdens on physicians are grounded in strong rationales related to patient safety
and quality care, the burnout resulting from their combined effect may actually
inhibit the success of the initiatives themselves.\textsuperscript{37} This should certainly bring pause
to those charged with implementing initiatives and requirements to carefully
evaluate their effectiveness, unintended consequences, and potential burden, but
also to communicate their goals and perceived value. The reaction of the profession
to the ongoing changes that are occurring may also indicate particular attitudes
within the culture of medicine that would benefit from further discussion, as would
support to integrate positive change into practice.

Burnout is not always related to stressors arising in a physician’s work environment
or to a physician’s character traits. Family issues, personal and professional
relationships, financial pressures, insufficient work-life balance, or other external
stressors may also contribute to burnout. Efforts aimed at the identification,
treatment, or prevention of burnout must, therefore, approach the issue from a
broad enough perspective to take all of these factors into account.

\textbf{Challenges and Barriers to Addressing Burnout:}

While there has been a promising rise in the number of peer-reviewed research
publications addressing the topic of physician burnout, in the academic medical
literature, popular media and so-called gray literature (e.g., white papers, position
statements, organizational reports), there seems to be a perceived lack of resources
available to identify and address the issue. This perception may be misguided,
however, since several academic institutions, health systems, medical specialty
societies, independent physicians, physician health programs, and state medical
boards make many useful, high-quality resources available (See Appendix A.). While
more resources would be beneficial to physicians, and ultimately their patients,
their development should be complemented with efforts aimed at highlighting best
practices. Research is also needed to identify how sources of burnout might differ
for male and female physicians in order that resources may be appropriately
tailored. A more coordinated effort to raise awareness not only about the issue of
physician burnout but also about resources for ameliorating related circumstances
may also serve to reduce stigma and facilitate identification and treatment. It may
also help improve systems issues that impact burnout by improving communication,
team building, and collaboration within and among health care professions. Broader

awareness may also better equip physicians in their capacity as leaders to improve circumstances for those with whom they work.\textsuperscript{38}

Many physicians are reluctant to seek help for burnout or any of its many underlying causes for fear that they will be perceived as weak or unfit to practice medicine by their colleagues or employers, or because they assume that seeking such care may have a detrimental effect on their ability to renew or retain their state medical license, arguably the most important credential a physician receives during their professional career.\textsuperscript{39,40,41,42,43} This stigma may be felt as early as medical school,\textsuperscript{44} a particularly dangerous cultural feature in a population where symptoms of anxiety and depression have been found to be more prevalent than in the general population.\textsuperscript{45} In a study by Dyrbye and colleagues, it was found that only a third of the medical students experiencing features of burnout sought help and that stigma was seen as a barrier for those who chose not to seek help.\textsuperscript{46} The same reluctance is seen with respect to help-seeking for other types of stigmatized suffering such as depression, substance use disorders, or suicidal ideation.\textsuperscript{47} Without adequate modeling of appropriate self-care behaviors among faculty mentors, progress at stigma reduction will likely be slow. Further, while there are laudable examples of programs at academic medical centers across the country which responsibly offer

\begin{footnotesize}
\begin{enumerate}
\item Chew-Graham CA, et al. (2003). 'I wouldn’t want it on my CV or their records': medical students’ experiences of help-seeking for mental health problems. \textit{Medical Education}, 37(10):873–880.
\end{enumerate}
\end{footnotesize}
accessible, complementary, private, and confidential counselling to medical students, these programs are by no means widely available. Privacy and confidentiality of a physician’s health and treatment history is important to allow those in need of help to come forward without fear of punishment, disciplinary action, embarrassment or professional isolation. The use of confidential services whenever possible in lieu of regulatory awareness is preferred in order to mitigate fear of negative impacts on licensure, employment, or collegial relationships. When confidential services are not utilized, it is less likely licensees will receive early intervention and appropriate treatment, thereby foregoing opportunities for early detection of potentially impairing illness or recovery.

Funding for important programs and initiatives such as those identified above is often difficult to obtain. However, there is a growing body of research that identifies the cost savings for hospitals and employers associated with providing them, particularly when costs associated with medical errors and lower quality of care attributed to burnout are mitigated, as are high turnover rates, absenteeism, and loss of productivity.

Another challenge to identifying and addressing burnout is the fact that the associated stigma may reduce the degree to which the phenomenon itself is discussed. This impacts not only a physician’s own willingness to discuss or seek help for burnout, but also the willingness of fellow physicians to address or report instances of impairment among their colleagues, especially that which unduly risks the safety of patients. While the duty to report impairment or incompetence and the duty to encourage help-seeking may seem to conflict, in that a fear of being reported could cause a physician to conceal problems and avoid help, the duty to report is actually based on principles of patient safety and ethics. The duty to report also aims to assist physicians in seeking the help they need in order to continue practicing safely.

In addition to the cultural stigma associated with admitting experiences of burnout, recent research has shed light on the potential impact of licensure and license renewal processes of state medical boards that may discourage treatment-seeking

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48 Examples include the HEAR Program at UC San Diego (available to everyone at the UCSD Health System, not only medical students), the Henderson Student Counseling Center at Nova Southeastern University, the Wellness Resources offered at Oregon Health and Science University, and the Medical Student Counseling and Wellness Center at the Herbert Wertheim College of Medicine, Florida International University.

among physicians.\textsuperscript{50,51} State medical boards may inadvertently discriminate unfairly against physicians suffering from mental illness or substance use disorders, or against those who choose to take a leave of absence from practice to prevent or recover from burnout. The very presence of application questions for medical licensure or licensure renewal may stigmatize those suffering from mental and behavioral illnesses for which physicians might otherwise seek care. In fact, questions about substance abuse and mental illness on state medical licensure renewal applications have nearly doubled between 1996 and 2006.\textsuperscript{52} While information about a physician's health status (both mental and physical) may be essential to a state medical board's solemn duty to protect the public, the FSMB has previously noted that a history of mental illness or substance use does not reliably predict future risk to the public.\textsuperscript{53} It is also very important to recognize that court interpretations of the Americans with Disabilities Act (ADA) have suggested that state medical boards should focus on current functional impairment rather than a history of diagnoses or treatment of such illness.\textsuperscript{54}

In carrying out their duty to protect the public and ensure that only individuals who are fully qualified to practice medicine are granted licenses, state medical boards usually, and for good reasons, insist that they must have sufficient information with which to make medical licensure decisions. During the licensure granting process, state boards also work diligently to ensure that candidates for licensure (or renewal) provide a thorough assessment of their fitness to practice, balanced by protecting their rights as contained in ADA legislation. Fear among prospective and current licensees about potential limitations placed on their ability to practice medicine independently, however, or of their previous diagnoses or treatments somehow being made public despite HIPAA and other federal privacy and confidentiality laws, may cause some physicians to misrepresent personal information that is requested or not respond accurately at all to licensing application questions.\textsuperscript{55} In such instances, paradoxically, the efforts of state medical boards to get comprehensive information may not yield the accurate information


they seek about a physician’s practice risks to patients. They may also discourage treatment-seeking among physicians, thereby increasing the degree of risk to patients presented by physicians experiencing conditions that remain undiagnosed or untreated.

**Recommendations:**

The majority of the recommendations that follow are designed for state medical boards to consider and pertain mainly to the inclusion and phrasing of questions on state medical licensing applications. Appropriately addressing the issue of physician burnout provides a unique opportunity for state medical boards to declare, directly or indirectly, that it is not only normal but anticipated and acceptable for a physician to feel overwhelmed from time to time and to seek help when appropriate. This is also an important opportunity for state medical boards to highlight and promote the benefits of physician health, both mental and physical, to help reduce stigma, to clarify related regulatory and reporting issues, promote patient safety and assure the delivery of quality health care. Physicians should feel safe about reporting burnout and be able to take appropriate measures to address it without fear of having their licensure status placed in jeopardy.

Safeguarding physician wellness and mitigating damage caused by burnout cannot be accomplished through isolated actions and initiatives by individual organizations alone. Coordinated efforts and ongoing collaboration will be essential not only for addressing the many systemic issues that contribute to burnout but also for ensuring that appropriate tools, resources, and programs are continuously in place and readily available to help physicians avoid and address burnout. As such, the FSMB also offers suggestions and recommendations to its partner organizations, many of which have been instrumental in furthering the FSMB’s current understanding of burnout, its related features, and the role of the regulatory community in addressing and safeguarding physician health.

Ultimately, the Workgroup and the FSMB believe that a shared accountability model that includes several related responsibilities among regulatory, educational, systemic, organizational, and administrative stakeholders provides a promising way forward. The specific recommendations outlined below begin to address what such responsibilities should entail.

The FSMB recognizes its responsibility to help address physician burnout, not only through following its own recommendations and promoting the resources provided in this report, but also by continuing its collaborative efforts with partner organizations from across the wider health care community.
For State Medical Boards:

1. The FSMB recommends that state medical boards review their medical licensure (and renewal) applications and evaluate whether it is necessary to include probing questions about a physician applicant’s mental health, addiction, or substance use, and whether the information these questions are designed to elicit in the interests of patient safety may be obtained through means that are less likely to discourage treatment-seeking among physician applicants. For example, some boards subscribe to notification services such as the National Practitioner Data Bank’s “Continuous Query” service or other data services that provide information about arrests or convictions, including for driving under the influence, within their states which can serve as a proxy finding for physician impairment. The FSMB also recommends in its Essentials of a State Medical and Osteopathic Practice Act that boards require applicants to satisfactorily pass a criminal background check as a condition of licensure.56

2. Where state medical boards strongly feel that questions addressing the mental health of physician applicants must be included on medical licensing applications, they should carefully review their applications to ensure that appropriate differentiation is made between the illness with which a physician has been diagnosed and the impairments that may result. Application questions must focus only on current impairment and not on illness, diagnosis, or previous treatment in order to be compliant with the Americans with Disabilities Act (ADA).

3. The ADA requires licensure application questions to focus on the presence or absence of current impairments that are meaningful in the context of the physician’s practice, competence, and ability to provide safe medical treatment to patients. Applications must not seek information about impairment that may have occurred in the distant past and state medical boards should limit the time window for such historical questions to two years or less, though a focus on the presence or absence of current impairment is preferred.

Questions that address the mental health of the applicant should be posed in the same manner as questions about physical health, as there is no distinction between impairment that might result from physical and mental illness that would be meaningful in the context of the provision of safe treatment to patients.

Where boards wish to retain questions about the health of applicants on licensing applications, the FSMB recommends that they use the language

recommended by the American Psychiatric Association:

“Are you currently suffering from any condition that impairs your judgment or that would otherwise adversely affect your ability to practice medicine in a competent, ethical and professional manner? (Yes/No)”\textsuperscript{57,58}

4. The FSMB recommends that state medical boards consider offering the option of “safe haven non-reporting” to applicants for licensure who are receiving appropriate treatment for mental health or addiction. While it is up to boards to determine what constitutes appropriate treatment, the FSMB recommends that physicians who are monitored by, and in good standing with, the recommendations of a state or territorial Physician Health Program (PHP) be permitted to apply for medical licensure or license renewal without having to disclose their diagnosis or treatment to the board. The option of safe haven non-reporting should only be offered when treatment received is commensurate with the illness being treated and has a reasonable chance of avoiding any resultant impairment.

5. State medical boards should work with their state legislatures to ensure that the personal health information of licensees related to an illness or diagnosis is not publicly disclosed as part of a board’s processes. Information disclosed must relate only to impairment of professional abilities, medical malpractice, and professional misconduct.\textsuperscript{59}

6. State medical boards should emphasize the importance of physician health, self-care, and treatment-seeking for all health conditions by including a statement to this effect on medical licensing applications, state board websites, and other official board communications. Where appropriate, options for treatment and other resources should be made available, such as information about a state Physician Health Program (PHP), services offered through a county, state, or national medical society, and any other relevant programs. These means of communicating the importance of physician health and self-care are aimed at helping physicians with relevant information and resources but could also help raise awareness among patients of the importance of physician wellness and the threat of burnout to their doctors and their own care.


\textsuperscript{58} The American Psychiatric Association (APA) passed an Action Paper in November 2017, resolving to query state medical boards and notify them about their compliance with APA policy and the ADA.

7. **State medical boards should clarify through communications, in print and online, that an investigation is not the same as a disciplinary undertaking.** Achieving an understanding of this distinction among licensees may help begin to dispel the stigma associated with reporting burnout and remove a barrier to physicians seeking help in times of need.

8. **State medical boards are encouraged to maintain or establish relationships with a PHP in their state and to support the use of data from these programs in a board’s decision-making.**

9. **State medical boards should examine the policies and procedures currently in place for working with physicians who have been identified as impaired in a context that is meaningful for the provision of safe care to patients to ensure that these are fair, reasonable, and fit for the purpose of protecting patients. All such processes should be clearly explained and publicly available.**

10. **State medical boards should be aware of potential burdens placed on licensees by new or redundant regulatory requirements.** They should seek ways of facilitating compliance with existing requirements to support licensees and ensure that they are able to spend time with patients and in those areas of medicine which they find most meaningful. “Reducing the cumulative burden of rules and regulations may improve professional satisfaction and enhance physicians’ ability to focus on patient care.”

Upon implementing some or all of the above changes to state medical board policy or processes that are meant to reduce the stigma associated with mental health issues and encourage treatment-seeking, the board should communicate these, and their rationale, to current and prospective licensees, as well as patients and the public. State medical boards should also raise the issue of physician burnout more often, emphasizing the importance of physician wellness, help-seeking, and the availability of accessible, confidential, and private counselling programs for physicians and all health professionals.

**For External Stakeholders and Partner Organizations:**

**Professional Medical Organizations and Societies:**

11. Professional medical societies at local, state, and national levels have a key role to play in encouraging physicians to seek treatment, both preventive

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and curative, for the physical and mental health issues they face, as well as for features of burnout. The FSMB recognizes the many exemplary programs and initiatives of professional medical societies and encourages their continued advocacy for physician wellness and the availability of support and treatment services.

12. The FSMB recommends a sustained focus in the medical profession on the importance of self-care with an aim to reduce the stigma attached with seeking treatment for health issues, particularly ones related to mental health.

13. The FSMB recommends that attempts be made to expand the availability of accessible, private, and confidential counseling for physicians through medical societies, such as those provided by organizations like the Lane County Medical Society (Oregon), which has a program with several features identified as best practices for physician wellness by the Workgroup. Counseling via telehealth could also enhance access and provide greater assurance of privacy to those seeking care.

14. Given the prevalence of burnout, all physicians need to be educated about the resources currently available regarding burnout, including those referenced in Appendix A, for self-awareness, and for identification and referral of peer professionals who may have burnout. Medical societies are encouraged to partner with other organizations identified in this report to improve awareness of resources and their dissemination.

15. The FSMB recommends that professional medical societies and organizations representing physicians, such as the American Medical Association, the American Osteopathic Association, and the Council of Medical Specialty Societies work with state medical boards to raise awareness among the public of the importance of physician wellness not only because of its inherent value to physicians themselves but also as a significant contributor to patient safety.

Centers for Medicaid and Medicare Services:

16. The FSMB recommends careful analysis of any new requirements placed on physicians to determine their potential impact on physician wellness. Any new requirements that could serve as a driver of burnout in physicians must be supported by evidence and accompanied by a strong rationale that is based in improving patient care to justify any new burdens imposed on physicians.
State Government, Health Departments, and Legislatures:

17. As state government, health departments, and legislatures make decisions that can impact physicians, the FSMB recommends that they weigh the potential value of proposed new regulations against potential risks to the health of physicians and other clinicians.

Vendors of Electronic Health Records (EHR) systems and standard setting organizations:

18. As a promising advancement in the provision and documentation of care, but also a key driver of frustration with medical practice, EHRs need to be improved in a way that takes the user experience into greater consideration than it does currently. This experience may be improved through facilitating greater ease of data entry into the system, as well as ease of access to data from the system. Vendors are encouraged to include end-user physicians on their builder teams to optimize input about operability and interoperability.

19. Efforts to reduce redundant or duplicative entry should be required by standard setting organizations, such as the Office of the National Coordinator for Health IT (ONC), and reflected in the EHR systems ultimately designed by vendors.

20. EHR vendors are encouraged to focus future improvements on facilitating and improving the provision of patient care. The primary purposes of an EHR relate to documentation of care received by a patient, retrieval of patient care related information and data, and patient communication.

Medical Schools and Residency Programs:

21. The FSMB encourages the Accreditation Council for Graduate Medical Education, the Association of American Medical Colleges, the American Association of Colleges of Osteopathic Medicine, the American Medical Association, the American Osteopathic Association and the institutions they represent, to continue their laudable efforts at improving the culture of medicine and facilitating open conversations about illness and wellness in order to promote positive change.

22. The FSMB recommends continued efforts to encourage medical students and residents to value self-care and understand the positive impacts that physician wellness can have on patient care.

23. The FSMB recommends that medical schools, residency programs, and their accrediting bodies consider ways of amplifying the medical student and
resident voice on systemically induced pressures and support trainees by providing means for raising issues related to medical student and resident health and well-being anonymously.

**Hospitals/Employers:**

24. The FSMB recommends that hospitals revise, where necessary and appropriate, their questions asked as part of their credentialing process according to the recommendations made above for the medical licensing community to ensure that these are not discouraging physicians or other health professionals from seeking needed treatment.

25. The FSMB recommends that hospitals and health systems assess physician health at regular intervals using a validated instrument and act upon the results. Employers should keep results of these assessments internal to the organization or health system in order to promote workplace change, while avoiding threatening or punitive cultures.

26. Hospitals, as well as the American Hospital Association and related organizations, are encouraged to officially adopt the “Quadruple Aim” to demonstrate the importance they place in the health and wellness of the physicians and all other health professionals they employ and recognize the impact of provider health on safe patient care.

27. Hospitals should ensure that their policies and procedures are adopted with consideration given to the impact they have on the health of the hospital workforce. Decisions impacting hospital the health of hospital and health system employees should be made with adequate input from individuals representing the impacted sectors of that workforce.

28. While acknowledging the need for hospitals to acknowledge all staff in their programmatic development, employers are encouraged to make resources and programs available to physicians, including time and physical space for making connections with colleagues and pursuing personal goals that add meaning to physicians’ work lives. Resources and programs should not always be developed and implemented in a “one size fits all” manner, but should incorporate consideration of the different stressors placed on male and female physicians, within and outside of the workplace, and be tailored appropriately. Resources related to EHR implementation and use should also be made available by employers, including training to optimize use and support for order-entry such as scribes or other technological solutions aimed at restoring time available to physicians.
29. Hospitals should ensure that mandatory reports related to physician competence and discipline are made available to state medical boards and other relevant authorities.

**Insurers:**

30. The FSMB recommends that insurance carriers revise, where necessary and appropriate, their questions on applications for professional liability insurance according to the recommendations made above for the medical licensing community to ensure that these are not discouraging physicians or other health professionals from seeking needed treatment.

31. In evaluating the quality of care provided by physicians, insurers should look beyond cost-saving measures and use metrics related to physician health and incentivize practice patterns that contribute to physician wellness.

**Accrediting Organizations:**

32. In its ongoing development of standards for the accreditation of undergraduate medical education programs, graduate medical education training programs, hospitals and healthcare facilities, the FSMB encourages those organizations charged with the accreditation of institutions and educational programs to include standards related to required resources and policies aimed at protecting medical student, medical resident and attending physician health.

**Physicians:**

33. Physician wellness is a complex issue, made up of system-wide and individual components. However, physicians have a responsibility to attend to their own health, well-being, and abilities in order to provide care of the highest standard.\(^{61}\) This involves a responsibility to continually self-assess for indicators of burnout, discuss and support the identification of health issues with peers, and seek help or treatment when necessary. Physicians are encouraged to make use of services of state Physician Health Programs, which, where available, can be accessed confidentially in instances where patient harm has not occurred.

34. Physicians are encouraged to inform themselves about their ethical duty, oftentimes codified in state statutes, to report issues related to incompetence and unsafe care delivered by their peers. They are also encouraged to engage in open dialogue with peers about the importance of self-care, treatment-seeking, and the threats to themselves and their patients presented by burnout.

35. Physicians are also encouraged to seek an appropriate balance between time spent on practice and related work and activities external to work, particularly ones with restorative potential.

Conclusion

The duty of state medical boards to protect the public includes a responsibility to ensure physician wellness and to work to minimize the impact of policies and procedures that impact negatively on the wellness of licensees, both prospective and current. The rationale for this duty is based on the link between physician burnout and its intendant risks to patient safety, the fact that some regulatory processes employed by state medical boards can have negative impacts on the health and wellness of physicians themselves, and the potential for regulatory change to support physician wellness and help prevent further instances of burnout.

The information and recommendations in this Report of the FSMB’s Workgroup on Physician Wellness and Burnout are meant to support initial steps in the medical regulatory community and to contribute to ongoing conversation about patient safety and physician health.
FSMB WORKGROUP ON PHYSICIAN WELLNESS AND BURNOUT

Arthur S. Hengerer, MD, FACS, Chair
Immediate Past-Chair, Federation of State Medical Boards

Mohammed A. Arsiwala, MD
Vice Chair, Michigan Board of Medicine

Amy Feitelson, MD
Former Member, New Hampshire Board of Medicine

Doris C. Gundersen, MD
Federation of State Physician Health Programs

Kathleen Haley, JD
FSMB Director-at-Large
Executive Director, Oregon Medical Board

Brian J. Miller
Individual Member

Roger M. Oskvig, MD
Former Chair, New York State Board for Medicine

Michael R. Privitera Jr., MD
University of Rochester Medical Center

Jean L. Rexford
FSMB, Director-at-Large
Board Member, Connecticut Medical Examining Board

Dana C. Shaffer, DO
Secretary Treasurer, National Board of Osteopathic Medical Examiners

Scott A. Steingard, DO
FSMB Director-at-Large
Past President, Arizona Board of Osteopathic Examiners in Medicine and Surgery

Barbara E. Walker, DO
President-elect, North Carolina Medical Board

EX OFFICIOS:

Gregory B. Snyder, MD, DABR
Chair, FSMB

Patricia A. King, MD, PhD, FACP
Chair-elect, FSMB

Humayun J. Chaudhry, DO, MS, MACP, MACOI
President and CEO, FSMB

STAFF SUPPORT:

Mark L. Staz, MA
Director, Continuing Professional Development, FSMB
APPENDIX A: SAMPLE RESOURCE LIST

The following list is offered as a sample of resources available to support and facilitate the understanding, diagnosis, treatment, and prevention of symptoms of burnout or to maintain and improve physician wellness. The FSMB has not conducted an in-depth evaluation of individual resources, and inclusion herein does not indicate, nor is it to be interpreted as, an endorsement or guarantee of quality. Further, while some resources listed below are available free of charge, others are only accessible through purchase.

Federation of State Medical Boards, Policy on Physician Impairment, 2011.


The standard tool used to evaluate rates of burnout is the Maslach Burnout Inventory, developed in the 1980s by Christina Maslach, PhD, a psychologist at the University of California Berkeley.

The HappyMD.com – in particular, the burnout prevention matrix, 117 ways to prevent burnout

Accreditation Council for Graduate Medical Education – Physician Wellbeing Resources

American Academy of Family Physicians - Physician Burnout Resources Page:

American College of Emergency Physicians (ACEP) – ACEP Wellness Resource page

American College of Physicians – Resources on Physician Well-Being and Professional Satisfaction

American Medical Association Steps Forward website:

American Osteopathic Association – AOA Physician Wellness Strategy

Association of American Medical Colleges – Wellbeing in Academic Medicine

Federation of State Physician Health Programs

Mayo Physician Well-being Program:

National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience
Remembering the Heart of Medicine

Stress Management and Resiliency Training (SMART) program

SuperSmartHealth

The Studer Group

The Well-Being Index (Mayo Clinic)
REPORT OF THE BOARD OF DIRECTORS

Subject: Guidelines for the Structure and Function of a State Medical and Osteopathic Board

Referred to: Reference Committee A

Since 1988, the FSMB’s Guide to the Essentials of a Modern Medical Practice Act and Elements of a State Medical and Osteopathic Board have functioned as companion documents to provide state medical boards a useful blueprint for their structure and functions as stated in their medical practice act. These policies have served as a highly effective stimulus to medical boards and state legislatures for periodic review and revision of their statutes. The policies are revised every three years. The Advisory Council of Board Executives is charged with updating the policies to ensure currency and recommending the revisions to the Board of Directors. The 2017 Advisory Council includes Kimberly Kirchmeyer, Micah T. Matthews, MPA, Maegan Martin, JD, Frank B. Meyers, JD, Kathleen Seltzer Lippert, JD, Kevin D. Bohnenblust, JD, Mark E. Bowden, MPA, Kathleen Haley, JD, and Ian Marquand.

The Advisory Council of Board Executives met on August 17, 2017 in Washington, DC, to revise the Elements and Essentials for consideration by the FSMB House of Delegates at its Annual Meeting in April 2018. At this meeting the Council considered a full agenda in meeting its charge to conduct a review and revision of the Essentials and Elements of a State Medical and Osteopathic Act. As part of its meeting, the Council conducted a thorough review of the licensure by endorsement provisions in accordance with Resolution 17-3, Review of Model Guidelines for State Medical Boards Granting Licensure by Endorsement and Assessment of the Standards of ACGME International.

As a result of in person discussions and in response to feedback from member state boards, the Council agreed to condense the Elements and Essentials into one document, Guidelines for the Structure and Function of a State Medical and Osteopathic Board (Attachment 1). The Council determined that a singular guidance document on state medical board structure would reduce redundancies inherent in the original two documents and allow for a more dynamic and user-friendly resource for member state boards. The Council recommended that existing FSMB policy regarding licensure by endorsement not be amended to include reference to ACGME-International.

Guidelines for the Structure and Function of a State Medical and Osteopathic Board incorporates the contents of prior Elements and Essentials, containing the principles of state medical board responsibility, duty, empowerment, and accountability that the initial documents outlined, as well as detailing the essential components for the structure and function of a state medical board. This
guidance document reflects not only relevant characteristics of effective modern medical boards, but also a number of innovative concepts not yet widely implemented. Though presented for consideration as an integrated whole, the guidelines offer significant approaches to a variety of issues that concern many boards, including: funding and budgeting, confidentiality, board authority, personnel and staffing, administration, emergency powers, training of board members, immunity and indemnity, standards of evidence, and the public’s right to know.

Recognizing the differences among jurisdictions, this document is designed with the flexibility to accommodate as many of those differences as possible, while maintaining the integrity of the overall concept. Some sections empower boards to adopt alternatives of their choice, provided they are in accord with other state statutes, while other sections are phrased loosely to allow boards necessary discretionary authority. These guidelines may thus be seen not as one proposal but as various proposals.

A draft of the *Guidelines for the Structure and Function of a State Medical and Osteopathic Board* was distributed to FSMB member boards and other key stakeholder organizations in December 2017 with comments due January 31, 2018. There were no suggestions for modification received. No comments were received. The FSMB Board of Directors considered the draft *Guidelines for the Structure and Function of a State Medical and Osteopathic Board* at its meeting on February 7, 2018 in Washington D.C. and discussed clarifications to the document.

**ITEM FOR ACTION:**

The Board of Directors recommends that:

The House of Delegates ADOPT *Guidelines for the Structure and Function of a State Medical and Osteopathic Board*, superseding *Guide to the Essentials of a Modern Medical Practice Act (HOD 2015)* and *Elements of a State Medical and Osteopathic Board (HOD 2015).*

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Guidelines for the Structure and Function of a State Medical and Osteopathic Board

Introduction

As early as 1914, the Federation of State Medical Boards (FSMB), which now represents 70 state and territorial medical and osteopathic licensing and disciplinary boards (hereafter referred to as “state medical board(s)” or “Board(s)”), recognized the need for a guidance document supporting U.S. states and territories in their development, and updating as needed, of their medical practice acts, and the corresponding structures and functions of their medical boards.

Following extensive consultations with members and staff of state medical boards, and a review of emerging best practices, the FSMB first issued *A Guide to the Essentials of a Modern Medical Practice Act* in 1956. The stated purposes of this guidance document were:

1. To serve as a guide to those states that may adopt new medical practice acts or may amend existing laws; and
2. To encourage the development and use of consistent standards, language, definitions, and tools by boards responsible for physician and physician assistant regulation.

Over the years, dynamic changes in medical education, in the practice of medicine, and in the diverse responsibilities that face medical boards have necessitated frequent revision of a state or territory’s medical practice act. *The Essentials* has since undergone numerous revisions to respond to these changes and assist member boards to be consistent with best practices in the interests of public protection and patient safety.

In 1988, the Division of Medicine of the Bureau of Health Professions, Health Resources and Services Administration (HRSA), in the U.S. Department of Health and Human Services, requested proposals for the development of a parallel document on a state medical board’s structure and function. The FSMB proposed a new guidance document in response, called the *Elements of a State Medical and Osteopathic Board*. The Bureau of Health Profession and HRSA accepted the FSMB’s proposal, and the document was soon developed and made available for consideration by the public, state medical boards, medical organizations, and other relevant groups.

The primary focus of the *Elements* document was to develop a blueprint of the structure and function of a modern state medical board. It detailed the powers, duties, and protections that are basic to a state medical board’s structure and function. In that context, it reflected the understanding, concepts, opinions, knowledge and experience of the individuals comprising the work panel, which included members, attorneys and staff of state medical boards. The *Elements* presented a blueprint that was consistent with the principles expressed in the *Essentials*, and was offered as a stimulus for discussion of several issues vital to improving the regulation of the medical profession in the United States.

The *Elements* and *Essentials* have, since 1988, functioned as companion documents to provide state
medical boards a useful blueprint for their structure and functions as stated in their medical practice act. Revised by the FSMB’s Advisory Council of Board Executives every three years to remain current, the model policies have served as a highly effective stimulus to medical boards and state legislatures for periodic review and revision of their statutes.

In 2017, the Advisory Council met to revise the *Elements* and *Essentials* for consideration by the FSMB House of Delegates at its Annual Meeting in April 2018. At this meeting and in response to feedback from member state boards, the Advisory Council considered and agreed to condense the two model policies into one document. The Advisory Council determined that a singular guidance document on state medical board structure would reduce redundancies inherent in the original two documents and allow for a more dynamic and user-friendly resource for member state boards.

The guidance document that follows incorporates the contents of prior *Elements* and *Essentials* documents, containing the principles of state medical board responsibility, duty, empowerment, and accountability that the initial documents outlined, as well as detailing the essential components for the structure and function of a state medical board.

This guidance document reflects not only relevant characteristics of effective modern medical boards, but also a number of innovative concepts not yet widely implemented. The result is a document worthy of consideration for adaptation to the requirements of any state or territorial jurisdiction. Although it could hardly be expected that any one jurisdiction would accept every component of this model, it should lead every jurisdiction to assess its present board structure and function. Does the status quo provide maximum potential for protection of the public interest? Though presented for consideration as an integrated whole, the guidelines offer significant approaches to a variety of issues that concern many boards, including: funding and budgeting, confidentiality, board authority, personnel and staffing, administration, emergency powers, training of board members, immunity and indemnity, standards of evidence, and the public’s right to know.

Recognizing the differences among jurisdictions, this document is designed with the flexibility to accommodate as many of those differences as possible, while maintaining the integrity of the overall concept. Some sections empower boards to adopt alternatives of their choice, provided they are in accord with other state statutes, while other sections are phrased loosely to allow boards necessary discretionary authority. These guidelines may thus be seen not as one proposal but as various proposals. Each is applicable in one form or another to a diversity of settings, and all are aimed at increasing or refining the ability of state medical boards to better protect the health, safety and welfare of the public.

The Federation urges member boards to consider including any recommendations contained herein in their respective medical practice acts, rules, or their own guidance documents.

The following guidelines apply equally to boards that govern physicians who have acquired the M.D. or D.O. degree, and the terms used herein should be interpreted throughout with this understanding.
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Section I. Definitions

The following terms have the following meanings:

“Assessment Program” means a formal system to examine or evaluate a physician’s competence within the scope of the physician’s practice.

“Competence” means possessing the requisite abilities and qualities (cognitive, non-cognitive, and communicative) to perform effectively within the scope of the physician’s practice while adhering to professional ethical standards.

“Dyscompetence” means failing to maintain acceptable standards in one or more areas of professional physician practice. (HOD 1999)

“Impairment” means a physician’s inability to practice medicine with reasonable skill and safety due to:

1. Mental, psychological, or psychiatric illness, disease, or deficit;
2. Physical illness or condition, including, but not limited to, those illnesses or conditions that would adversely affect cognitive, motor, or perceptive skills; or
3. Habitual, excessive, or illegal use or abuse of drugs defined by law as controlled substances, illegal drugs, alcohol, or of other impairing substances.

“Incompetence” means lacking the requisite abilities and qualities (cognitive, non-cognitive, and communicative) to perform effectively in the scope of the physician’s practice.

“License” means any license, certificate, or other practice authorization granted by the Board pursuant to the medical practice act, or any other applicable statute.

“Licensee” means the holder of any license, certificate, or other practice authorization granted by the Board.

“Licensed physician” means a physician licensed to practice medicine in the jurisdiction.

“Medical Practice Act” means the statute that determines the structure and function of a state medical or osteopathic board. Section II below addresses categories that the medical practice act does not typically apply to.

“Physician assistant” means a skilled person who by training, scholarly achievements, submission of acceptable letters of recommendations, and satisfaction of other requirements of the Board has been licensed for the provision of patient services under the supervision and direction of a licensed physician who is responsible for the performance of that person.

“Physician Assistant Council” means a council appointed by the Board or other means that reviews matters relating to physician assistants, reports its findings to the Board, and makes recommendations for action.

“Practice of medicine” is consistent with the following:
1. Advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine in the jurisdiction;

2. Offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person;

3. Offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;

4. Offering or undertaking to perform any surgical operation upon any person;

5. Rendering a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient or the actual rendering of treatment to a patient within a state by a physician located outside the state as a result of transmission of individual patient data by electronic or other means from within a state to such physician or the physician’s agent;

6. Rendering a determination of medical necessity or a decision affecting the diagnosis and/or treatment of a patient; and

7. Using the designation Doctor, Doctor of Medicine, Doctor of Osteopathic Medicine/Doctor of Osteopathy, Physician, Surgeon, Physician and Surgeon, Dr., M.D., D.O., or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in the jurisdiction where the patient is located.

The definition of the practice of medicine may also include several exceptions, which exempt certain activities from the categorization of the practice of medicine.

The practice of medicine is determined to occur where the patient is located in order that the full resources of the state are available for the protection of that patient.

“Remediation” means the process whereby deficiencies in physician performance identified through an examination or assessment program are corrected, resulting in an acceptable state of physician competence.

“Supervising physician” means a licensed physician in good standing in the same jurisdiction as the physician assistant who the Board approved to supervise the services of a physician assistant, and who has in writing formally accepted the responsibility for such supervision.

“Telemedicine” means the practice of medicine using electronic communications, information technology, or other means between a licensee in one location, and a patient in another location, with or without an intervening healthcare provider. Generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax. It typically involves the application of secure videconferencing or store and forward technology to provide or support healthcare delivery by replicating the interaction of a traditional, encounter in person between a provider and a patient. (HOD 2014)
Section II. The Medical Practice Act

The structure and function of each of the 70 medical regulatory boards (allopathic, osteopathic and composite) within the United States and its territories are determined by a unique state statute (or group of statutes), usually referred to as a medical practice act. The differences among these statutes are related to the general administrative structure of each jurisdiction and to the needs of the public as they are perceived by each responsible legislative body.

The following section is not intended to encourage movement toward total uniformity among these statutes. Given the diversity of administrative structures and the variations in perceived needs, that would be a futile exercise. The existing differences do have a positive creative value, allowing the evolution and testing of a range of new approaches in a number of jurisdictions concurrently. Rather, it is intended to nurture that creativity by encouraging the public, state legislators, medical boards, medical societies, and others who have an interest in the regulation of the medical profession to reexamine existing practice acts as they relate to the composition, structure, functions, responsibilities, powers, and funding of medical boards.

The medical practice act should provide for a separate state medical board, acting as a governmental agency to regulate the practice of medicine, in order to protect the public from unlawful, incompetent, unqualified, impaired, or unprofessional practitioners of medicine, through licensure, regulation, and rehabilitation of the medical profession in the state.

Generally, the medical practice act should authorize Boards to promulgate rules and regulations to facilitate the enforcement of the act. Boards should be authorized to adopt and enforce rules and regulations to carry out the provisions of the medical practice act and to fulfill their duties under the act. Boards should adopt rules and regulations in accord with administrative procedures established in the respective jurisdiction.

Statement of purpose

The medical practice act should be introduced by a statement of policy specifying the purpose of the act. This statement should include language expressing the following concepts:

- The practice of medicine is a privilege granted by the people acting through their elected representatives.
- In the interests of public health, safety, and welfare, and to protect the public from the unprofessional, improper, incompetent, unlawful, fraudulent, and/or deceptive practice of medicine, it is necessary for the government to provide laws and regulations to govern the granting and subsequent use of the privilege to practice medicine.
- The primary responsibility and obligation of the state medical board is to act in the sovereign interests of the government by protecting the public through licensing, regulation and education as directed by the state government.

Sample Statement of Purpose:
As a matter of public policy, the practice of medicine is a privilege granted by
the people of the State acting through their elected representatives by their
adoption of the Medical Practice Act. It is not a natural right of individuals.
Therefore, in the interests of public health, safety and welfare, and to protect
the public from the unprofessional, improper, incompetent, unlawful,
fraudulent, and/or deceptive practice of medicine, it is necessary to provide
laws and regulations to govern the granting and subsequent use of the privilege
to practice medicine and to ensure, as much as possible, that only qualified and
fit persons hold that privilege. The Board’s primary responsibility and obligation
is to protect the public, and any license, certificate or other practice
authorization issued pursuant to this statute shall be a revocable privilege and
no holder of such a privilege shall acquire thereby any irrevocable right.

Exemptions

The medical practice act should not apply to:

1. Students while engaged in training in a medical school approved or recognized by the state
   medical board, unless the board licenses the student;
2. Those providing service in cases of emergency where no fee or other consideration is
   contemplated, charged or received by the physician or anyone on behalf of the physician;
3. Commissioned medical officers of the armed forces of the United States and medical officers of
   the United States Public Health Service or the Veterans Administration of the United States in
   the discharge of their official duties and/or within federally controlled facilities, provided that
   such persons who hold medical licenses in the jurisdiction should be subject to the provisions of
   the act and provided that all such persons should be fully licensed to practice medicine in one or
   more jurisdictions of the United States. Further, the military physician should be subject to the
   Military Health System Clinical Quality Assurance (CQA) Program 10 U.S.C.A. § 1094; Regulation
   DOD 6025.13-R;
4. Those practicing dentistry, nursing, optometry, psychology, or any other of the healing arts in
   accord with and as provided by the laws of the jurisdiction;
5. Those practicing the tenets of a religion or ministering religious based medical procedures or
   ministering to the sick or suffering by mental or spiritual means in accord with such tenets;
6. Those administering a lawful domestic or family remedy to a member of one’s own family;
7. Those fully licensed to practice medicine in another jurisdiction of the United States who briefly
   render emergency medical treatment or briefly provide critical medical service at the specific
   lawful direction of a medical institution or federal agency that assumes full responsibility for
   that treatment or service and is approved by the state medical board; and
8. Those fully licensed to practice medicine in another jurisdiction of the United States who is
   employed or formally designated as the team physician by an athletic team visiting the
   jurisdiction for a specific sporting event, and the physician limits the practice of medicine in the
   jurisdiction to medical treatment of the members, coaches, and staff of the sports entity that
   employs (or has designated) the physician.
Unlawful Practice of Medicine

The medical practice act should provide a definition of the unlawful practice of medicine and penalties for such unlawful practice. These provisions of the act should implement or be consistent with the following:

1. It should be unlawful for any person, corporation, or association to perform any act constituting the practice of medicine as defined in the medical practice act without first obtaining a medical license in accord with that act and the rules and regulations of the Board. Other licensed health care professionals may provide medical services within the scope of their authorizing license.

2. The Board should be authorized to issue a cease-and-desist order\(^1\) and/or obtain injunctive relief against the unlawful practice of medicine by any person, corporation, or association.

3. It should be a felony for any person, corporation, or association that performs any act constituting the practice of medicine as defined in the medical practice act, or causing or aiding and abetting such actions.

4. A physician located in another state practicing within the state by electronic or other means without a license (full, special purpose or otherwise) issued by the Board should be deemed guilty of a felonious offense.

Section III. State Medical Board Duty, Responsibility, and Power

In some states, responsibility for licensing and disciplinary functions is divided between two separate Boards. In others, Boards are subject to supervision or, in some cases, complete control by larger administrative or umbrella agencies. In a few states, the Board is simply an advisory body. In most states, the Board regulates both allopathic and osteopathic physicians; in others, separate boards exist. And in some states, narrow constitutional restrictions inhibit effective Board funding. Clearly, the following section proposes a true working board with real and effective power and support, a proposal some states are much better prepared to implement than others. But it is also a reflection of those principles the authors consider to be basic to the operation of any accountable medical board, regardless of the administrative structure of the state, the size or distribution of the physician population being regulated, the form of legislation required for funding, or the title of the body to which responsibility and power for regulation have been entrusted. It may be drawn upon by both allopathic and osteopathic boards, making appropriate adaptations in the area of Board membership. Larger administrative agencies can use it to better assess their own structures and functions and to explore the broader roles their medical boards might play in meeting public expectations.

It is necessary that Boards have the responsibilities and powers necessary to fulfill the duties conferred on the Board by the medical practice act. These duties, responsibilities, and powers are to be liberally construed to protect the health, safety, and welfare of the people of the Board’s State. It is the duty of Boards to determine a physician’s initial and continuing qualification and fitness for the practice of medicine. Boards should be empowered to initiate proceedings against the unprofessional, improper,

\(^1\) In light of the recent U.S. Supreme Court case, *North Carolina Board of Dental Examiners v. Federal Trade Commission*, it is currently unclear whether the reliance on cease-and-desist orders to regulate the unlicensed practice of medicine by state medical boards is a best practice.
incompetent, unlawful, fraudulent, deceptive, or unlicensed practice of medicine, and enforce the medical practice act and related rules. Boards should discharge these duties and responsibilities in accord with the medical practice act and other governing laws.

In addition to any other duty, responsibility, and power provided to the Board in the medical practice act, the Board, acting in accord with its medical practice act and the requirements of due process, should:

1. Enforce the provisions of the medical practice act;
2. Develop, adopt and enforce rules and regulations to affect the provisions of medical practice act and to fulfill the Boards duties there under;
3. Select and/or administer licensing examination(s);
4. Employ or contract with one or more organizations or agencies known to provide acceptable examinations for the preparation, administration, and scoring of required examinations;
5. Prepare, select, conduct, or direct the conduct of, set passing requirements for, assure security of, and impose conditions for (e.g., time or attempt limits) successful completion of the licensing and other required examinations;
6. Impose conditions, sanctions, deny licensure, levy fines, seek appropriate civil and/or criminal penalties, or any combination of these, against those who violate or attempt to violate examination security, those who obtain or attempt to obtain licensure by fraud or deception, and those who knowingly assist in such activities;
7. Acquire information about and evaluate medical education and training of applicants;
8. Determine which professional schools, colleges, universities, training institutions, and educational programs are acceptable relating to licensure under the medical practice act and are appropriately preparing physicians for the practice of medicine, and to accept the approval of such facilities and programs by Board-recognized accrediting bodies in the United States and Canada;
9. Develop and use applications and other necessary forms and related procedures it finds appropriate for purposes of the medical practice act;
10. Require supporting documentation or other acceptable verifying evidence of any information provided the Board by an applicant or licensee;
11. Require information on and evaluate an applicant’s or a licensee’s fitness, qualification, and previous professional record and performance from recognized data sources, including, but not limited to, the Federation of State Medical Boards’ Federation Physician Data Center, other national data repositories, licensing and disciplinary authorities of other jurisdictions, professional education and training institutions, liability insurers, health care institutions, and law enforcement agencies;
12. Issue, condition, or deny initial or endorsement licenses;
13. Maintain secure and complete records on individual licensees including, but not limited to license application, verified credentials, disciplinary information, and malpractice history;
14. Provide the public with a profile of all licensed physicians;
15. Process and approve or deny applications for license renewal and review of a licensee’s...
16. Develop and implement methods to identify physicians who are in violation of the medical practice act;

17. Require the self-reporting by applicants or licensees of any information the Board determines may indicate possible deficiencies in practice, performance, fitness, or qualification.

18. Require all licensees, healthcare professionals, healthcare facilities, and medical societies and organizations to report to the Board information that appears to show another licensee is, or may be, professionally incompetent, guilty of unprofessional conduct, or mentally or physically unable to engage safely in licensed practice, and to report to the Board and/or to an agency designated by the Board a licensee’s possible dependence on alcohol or other addictive substances which have the potential to impair. Require licensees, malpractice insurance companies, attorneys, and healthcare facilities to report any payments on a demand, claim, settlement, arbitration award or judgment by or on behalf of a licensee;

19. Develop and implement methods to identify and rehabilitate, if appropriate, physicians with an alcohol, drug, and/or psychiatric illness;

20. When deemed appropriate by the Board to do so, require professional competency, physical, mental or chemical dependency examination, and evaluations of any applicant or licensee, including withdrawal and laboratory examination of bodily fluids;

21. Establish a mechanism, which at the Board’s discretion, may involve cooperation with and/or participation by one or more Board-approved professional organizations, for the identification and monitored treatment of licensees who are dependent on or abuse alcohol or other addictive substances which have the potential to impair;

22. Establish a mechanism by which licensees who believe they abuse or may be dependent on or addicted to alcohol or other addictive substances which have the potential to impair, and who have not been identified by the Board through other sources of information, will be encouraged to report themselves voluntarily to the Board and/or, at the Board’s discretion, to a professional organization approved by the Board to seek assistance and monitored treatment;

23. Receive, review, and investigate complaints and adverse information about licensees, including sui sponte complaints;

24. Review and investigate reports received from entities having information pertinent to the professional performance of licensees;

25. Act to halt the unlicensed or illegal practice of medicine; review, investigate, and take appropriate action to enjoin reports received concerning the unlicensed practice of medicine; and seek penalties against those engaged in such practices;

26. Adjudicate those matters that come before it for judgement under the medical practice act and issue final decisions on such matters;

27. Share investigative information at the early stages of a complaint investigation with other Boards;

28. Issue cease and desist orders and to obtain court orders and injunctions to halt unlicensed practice, violation of this statute or the rules of the Board;

29. Institute actions in its own name and enjoin violators of the medical practice act;

30. Act on its own motion in disciplinary matters, administer oaths, issue notices, issue subpoenas in...
the name of the state including for patient records, receive testimony, conduct hearings, institute court proceedings for contempt to compel testimony or obedience to its orders and subpoenas, take evidentiary depositions, and perform such other acts as are reasonably necessary under the medical practice act or other laws to carry out its duties;

31. Issue subpoenas in the course of an investigation, including for *duces tecum* to compel production of documents or testimony to any party or entity that may possess relevant information regarding the subject of the investigation;

32. Institute proceedings in courts of competent jurisdiction to enforce its orders and the provisions of the medical practice act;

33. Use preponderance of the evidence as the standard of proof and to issue final decisions;

34. Present to the proper authorities information it believes indicates an applicant or licensee may be subject to criminal prosecution;

35. Discipline licensees found in violation of the medical practice act;

36. Issue conditioned, restricted, or otherwise circumscribed licenses as it determines necessary;

37. Take the following actions, in accord with applicable state statutes, alone or in combination, against those found in violation of the medical practice act:
   a. Revoke, suspend, condition, restrict, and/or otherwise limit the license;
   b. Place the licensee on probation with conditions;
   c. Levy fines and/or assess the costs of proceedings against the licensee;
   d. Censure, reprimand and/or otherwise admonish the licensee;
   e. Require the licensee to provide monetary redress to another party, and/or provide a period of free public or community service;
   f. Require the licensee to satisfactorily complete an educational, training, and/or treatment program or programs; and
   g. Require the licensee to successfully complete an examination, examinations, or evaluations designated by the Board; and

38. Summarily suspend a license when there is imminent risk of the public health and safety prior to hearing and final adjudication;

39. Enforce final disciplinary action against a licensee as deemed necessary to protect public health and safety;

40. Report all final disciplinary actions, non-administrative license withdrawals as defined by the Board, license denials, and voluntary license limitations or surrenders related to physicians, with any accompanying license limitations or surrenders related to physicians, with any accompanying Board orders, findings of fact and conclusions of law, to the Federation Physician Data Center of the Federation of State Medical Boards of the United States and to any other data repository required by law, and report all such actions, denials and limitations or surrenders related to other licensees, with the same supporting documentation, to the National Practitioner Data Bank as required by law;

41. Develop policies for disciplining or rehabilitating physicians who demonstrate inappropriate sexual behavior with patients or other professional boundaries violations;

42. Acknowledge receipt of complaints or other adverse information to persons or entities reporting to the Board and to the physician, and inform them of the final disposition of the matters.
449 reported;
450 43. Develop and implement methods to identify dyscompetent physicians and physicians who fail to
451 meet acceptable standards of care;
452 44. Develop or identify and implement methods to assess and improve physician practice;
453 45. Develop or identify and implement methods to ensure the ongoing competence of licensees;
454 46. Determine and direct the Board’s operating, administrative, personnel, and budget policies and
455 procedures in accord with applicable state statutes;
456 47. Acquire real property or other capital for the administration and operation of the Board;
457 48. Set necessary fees and charges to ensure active and effective pursuit of all of its responsibilities,
458 legal and otherwise;
459 49. Develop and adopt its budget;
460 50. Employ, direct, reimburse, evaluate, and dismiss when appropriate the Board’s executive
461 director, in accord with the Board’s state’s procedures; Supervision of staff is the purview of the
462 executive director.
463 51. Develop, recommend, and adopt rules, standards, policies, and guidelines related to
464 qualifications of physicians and medical practice;
465 52. Engage in a full exchange of information with the licensing and disciplinary boards of other
466 states and jurisdictions of the United States and foreign countries;
467 53. Direct the preparation and circulation of educational material, policies, and guidelines the Board
determines is helpful and proper for licensees;
468 54. Develop educational programs to facilitate licensee awareness of provisions contained in the
469 medical practice act and to facilitate public awareness of the role and function of state medical
470 boards;
471 55. Delegate to the executive director the Board’s authority to discharge its duties as appropriate;
472 and
473 56. Recommend to the Legislature those changes in, or amendments to, the medical practice act
474 that the Board determines would benefit the health, safety, and welfare of the public.

Section IV. State Medical Board Membership

Whatever the professional regulatory structure established by the government of the jurisdiction, the
state medical board bears the primary responsibility for licensing and regulating the medical profession
for the protection of the public. Every Board should include both physician and public members. All
Board members should act to further the interest of the state, and not their personal interests.

Composition and Size

The Board should consist of enough members to appropriately discharge the duties of the Board, at
least 25% of whom should be public members. The Board should consider several factors when
determining the appropriate size and composition of a Board, including the size of a state’s physician
population, the composition and functions of Board committees, adequate separation of prosecutorial
and judicial powers, and the other work of the Board envisions throughout this document. The Board
should be of sufficient size to allow for recusals due to conflicts of interest and other occasional member
absences without concentrating final decisions in the hands of too few members or loss of quorum.
Qualifications

The membership of the Board should be drawn from as many different regions of the State, as many different specialties as possible, and should reflect the licensee population.

Members should be citizens of the United States who have attained the age of majority as defined in the statutes of the State.

Sex, race, national or ethnic origin, creed, religion, disability, or age above majority shall not be used as the sole reason for making an individual eligible or ineligible to serve on the Board.

All physician members of the Board should be in active practice\(^2\) (HOD 2012), hold full and unrestricted medical licenses in the jurisdiction, be persons of recognized professional ability and integrity, and should have resided or practiced in the jurisdiction long enough to have become familiar with the laws, policies, and practice in the jurisdiction (e.g., five years).

Public members of the Board should reside in the Board's respective jurisdiction and be persons of recognized ability and integrity; are not licensed physicians, providers of health care, or retired physicians or health care providers; have no past or current substantial personal or financial interests in the practice of medicine or with any organization regulated by the Board (except as a patient or care giver of a patient); and have no immediate familial relationships with individuals involved in the practice of medicine or any organization regulated by the Board, unless otherwise required by law.

Members of the Board should not be registered as a lobbyist representing any health care interest or association nor be an officer, Board member, or employee of a statewide or national organization established for advocating the interests of individuals involved in the practice of medicine or any organization regulated by the Board.

Terms

Members of the Board, whether appointed or elected, should serve staggered terms to ensure continuity. All appointments and elections should be confirmed through the legislative branch of the jurisdiction. The length of terms on the Board should be set to permit development of effective skill and experience by members (e.g., three or four years). However, a limit should be set on consecutive terms of service (e.g., two or three consecutive terms).

The term of Board service shall be three to four years.

A person should not serve as a member of the Board for more than three consecutive full terms, but may be reappointed two years after completion of such service. A person who serves more than two

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\(^2\) FSMB Report of the Special Committee on Reentry to Practice (HOD 2012) defines the clinically active physician as one who, at the time of license renewal, is engaged in direct, consultative, or supervisory patient care, or as further defined by the states. Clinically inactive physician is defined as one who is not engaged in direct, consultative or supervisory patient care at the time of license renewal, but who, as a result of their professional activities, influences the care provided by clinically active practitioners.
years of an un-expired term should be considered to have served a full term.

Terms of service should be staggered, one fourth of the Board’s membership being appointed each year.

In order to ensure there is continual representation of public members, for Boards with up to four public members, the term of no more than one public member should expire in any one year. For Boards with more than four public members, the terms of no more than two public members should expire in any one year.

Requirements

Before assuming the duties of office, the following should be required of each member of the Board:

1. Take a constitutional oath or affirmation of office;
2. Swear or affirm that he/she is qualified to serve under all applicable statutes;
3. Sign a statement agreeing that he/she will disclose any potential conflicts of interest that may arise for that member in the conduct of Board business;
4. Sign a confidentiality and ethics statement agreeing to maintain the confidentiality of confidential Board business and patient identification and uphold high ethical standards in discharging Board duties.

The Board should also conduct, and new members should attend, a training program designed to familiarize new members with their duties and ethics of public service. The Board should hold an annual training program for new members.

Appointment

The members of the Board should be appointed by the Governor, who should make each appointment at least 30 calendar days prior to the beginning of the Board term being filled. The Governor should fill an unexpired term within 30 calendar days of the vacancy’s occurrence. The incumbent should serve until the Governor names a replacement. Should the Governor not act as such, the Board, by majority vote, should select a qualified person to serve in the interim until the Governor acts. Any individual, organization or group should be permitted to suggest potential Board appointees to the Governor.

Removal

A Board member should be automatically removed from the Board if the Board member:

1. Ceases to be qualified;
2. Submits written resignation to the Board Chair or to the Governor;
3. Is absent from the state for a period of more than six months;
4. Is found guilty of a felony or an unlawful act involving moral turpitude by a court of competent jurisdiction;
5. Is found guilty of malfeasance, misfeasance, or nonfeasance in relation to the Board member’s Board duties by a court of competent jurisdiction;
6. Is found to be mentally incompetent by a court of competent jurisdiction;
7. Fails to attend three successive Board meetings without just cause as determined by the Board,
or, if a new member, fails to attend the new members’ training program without just cause as
determined by the Board;
8. Is found to be in violation of the medical practice act; or
9. Is found to be in violation of the conflict of interest/ethics law.

Compensation/Reimbursement
Members of the Board should receive appropriate compensation for services and reimbursement for
expenses at the respective state’s current approved rate.

- Compensation: Service on the Board should not present an undue economic hardship. Board
members should therefore receive compensation in an amount sufficient to allow full
participation and not preclude qualified individuals from serving.
- Expenses: Each Board member’s travel and expenses necessarily and properly incurred for
active Board service should be paid at the respective state’s current approved rate.
- Education/Training: Travel, expenses, and daily compensation should also be paid for each
Board member’s attendance, in or out of the Board’s jurisdiction, for education or training
purposes approved by the Board and directly related to Board duties.

Section V. State Medical Board Structure

Officers
The Board should elect annually from its members a president/chair, a vice president/vice- chair, a
secretary-treasurer, and those other officers it determines are necessary to conduct its business. The
officers shall serve for a one-year term.

- President/Chair: The president/chair should approve Board meeting agendas, preside at Board
meetings, appoint Board committees and their chairs, and perform those other duties assigned
by the Board and this statute.
- Vice President/Vice-Chair: The vice president/vice-chair should assist the president/chair in all
duties as requested by the president/chair and should perform the duties of the president/chair
in that officer’s absence.
- Secretary/Treasurer: The secretary-treasurer should ensure the maintenance of the minutes of
all meetings of the Board and that the expenditure of funds complies with respective state law.

Committees
To effectively facilitate its work, fulfill its duties and exercise its powers, the Board should be authorized
to appoint committees from its membership, establish standing committees, including, but not limited
to, licensing, investigation, finance, administration, personnel, rules, legislative communications, and
public information committees. The chair should also be empowered to name ad hoc committees as
required. Changes in membership should not be deemed to affect or hinder the continuing business or
activity of any committee.

Other committees created by the Board should have responsibilities, consistent with the medical
practice act, delegated to them by the Board.

**Funding**

The medical practice act should provide that Board fees be adequate to fund the Board’s ability to effectively regulate the practice of medicine under the act, and that those fees paid by licensees be used only for purposes related to licensee licensure, discipline, education and Board administration. A designated officer of the Board or employee, at the direction of the Board, should oversee the collection and disbursement of funds, and the State Auditor’s Office (or the equivalent State office) should routinely audit the financial records of the Board and report to the Board and the Legislature.

**Revenues**

The Board should be fully supported by the revenues generated from its activities, including fees, charges and reimbursed costs, which the Board should deposit in an appropriate account, and the Board should also receive all interest earned on the deposit of such revenues. Such funds should be appropriated continuously and used by the Board only for administration and enforcement of the medical practice act. All fines levied by the Board may be deposited in the State General Fund, unless otherwise allowed by law. All administrative, investigative and adjudicatory costs recoupment should be deposited in the Board’s account.

In the event the legislature imposes additional responsibilities on the Board beyond the Board’s statutory responsibilities for licensure and discipline, the legislature should appropriate additional funds to the Board sufficient to carry out such additional responsibilities.

**Budget**

The Board should develop and adopt its own budget reflecting revenues, including the interest thereon, and costs associated with each health care field regulated. Revenues and interest thereon, from each health care field regulated should fully support Board regulation of that field. The budget should include allocations for establishment and maintenance of a reasonable reserve fund.

**Setting Fees and Charges**

All Board fees and charges should be set by the Board pursuant to its proposed budget needs. The Board should provide reasonable notice to the regulated healthcare professional and the public of all increases or decreases in fees and charges.

**Fiscal Year**

The Board should operate on the same fiscal year as the State.
Telephone or other telecommunication conference is an acceptable form of Board meeting if the president/chair alone or another officer and two Board members believe the Board’s business can be properly conducted by teleconference. The Board should be authorized to establish procedures by which its committees may meet by telephone or other telecommunication conference system.

**Frequency, Duration**

The Board should meet at least bimonthly for a period sufficient to complete the work before it at that time. One meeting per quarter may be sufficient for states with small physician populations. Committees should meet as directed by the Board.

**Special Meetings, Conferences**

Emergency meetings of the Board may be called at any time by the president/chair or at the request of an officer and two Board members if required to enforce the medical practice act. The Board may establish procedures by which its committees may call emergency meetings in accordance with the State’s open meeting laws.

Informal conferences of an investigation committee may be called by the chair of the committee for the purpose of holding discussions with licensees, accused or otherwise, who seek or agree to such conferences. Any disciplinary action taken as a result of such a conference and agreed to in writing by the Board and licensee should be binding and a matter of public record. The holding of an informal conference should be at an investigation committee’s discretion and should not preclude formal disciplinary investigation, proceedings, or action.

**Notice**

The Board should establish a system for giving all Board and committee members reasonable notice of all Board and committee meetings. The Board should comply with the State’s open meeting laws.

**Quorum**

A majority of members constitutes a quorum for the transaction of business by the Board or any committee of the Board. The business of the Board and its committees should be conducted in accord with the medical practice act and with rules of parliamentary procedure adopted by the Board.

**Conflict of Interest**

No member of the Board, acting in that capacity or as a member of any Board committee, shall participate in the deliberation, making of any decision, or the taking of any action affecting the Board member’s own personal, professional, or pecuniary interest, or that of a known relative or of a business or professional associate. With advice of legal counsel, the Board shall adopt and annually review a conflict of interest policy to enforce this section.

**Minutes**

Minutes of all Board and committee meetings and proceedings, and other Board and committee materials, shall be prepared and kept in accord with the Board’s adopted rules of parliamentary procedure and other applicable State laws.
Open Meetings

All meetings of the Board and its committees should be open to the public in accordance with the State’s Open Meeting laws, with the following exceptions:

1. Meetings or portions of meetings of the Board, acting in its capacity as a hearing or adjudicatory body, held to receive testimony or evidence the public disclosure of which the Board determines would constitute an unreasonable invasion of personal privacy, to consult with legal counsel, to deliberate issues, and to arrive at disciplinary judgments;

2. Meetings or portions of meetings regarding investigations;

3. Meetings or portions of meetings regarding license applications; and

4. Meetings or portions of meetings regarding personnel actions.

The Board should ratify all recommendations or decisions made in nonpublic meetings in public, which should be matters of public record.

Confidentiality

The minutes and all records of nonpublic meetings are privileged and confidential and should not be disclosed, except to the Board or its designees for the enforcement of the medical practice act, except that all licensing decisions made by the Board and all disciplinary orders, with the associated findings of fact and conclusions of law and order, issued by the Board should be matters of public record.

The following should be privileged and confidential:

1. Application and renewal forms and any evidence submitted in proof or support of an application to practice, except that the following items of information about each applicant or licensee included on such forms should be matters of public record:
   a. Full name;
   b. Date of birth;
   c. Name(s) and location(s) of professional schools attended;
   d. School awarding professional degree, date of award, and designation of degree;
   e. Site(s) and date(s) of graduate certification(s) held and date(s) granted;
   f. Specialty certifications;
   g. Year of initial licensure in the State;
   h. Other states in which licensed to practice; and
   i. Current office address and telephone number.

2. All investigations and records of investigations;

3. Any report from any source concerning the fitness of any person to receive or hold a license;

4. Any communication between or among the Board and/or its committees, staff, advisors, attorneys, employees, hearing officers, consultants, experts, investigators and panels occurring outside public meetings; and

5. A complaint and the identity of an individual or entity filing an initial complaint with the Board.

Notwithstanding the foregoing provisions, the Board may cooperate with and provide documentation to
other boards, agencies or law enforcement bodies of the State, other states, other jurisdictions, or the United States upon written official request by such entity(s). The Board should share investigative information at the early stages of a complaint investigation in order to reduce the likelihood that a licensee may become licensed in one state while under investigation in another state.

These provisions should not be construed as prohibiting a respondent or the respondent’s legal counsel from exercising the respondent’s right of due process under the law.

Section VII. Administration of the State Medical Board

Offices
The Board should maintain offices it determines are adequate in size, staff, and equipment to effectively carry out the provisions of the medical practice act. At its discretion, it may establish branch offices, staffed and equipped as it finds necessary, in as many areas of the State as it believes require such branch offices to facilitate the work of the Board.

Administration
The Board should set out the function, operation, and administration structure of its offices.

Staff, Special Personnel
To effectively perform its duties under the medical practice act, the Board should be empowered to determine its staff needs and to employ, fix compensation for, evaluate, discipline, and remove its own full-time, part-time and temporary staff in accord with the statutory requirements of the State. The Board should also be assigned adequate legal counsel by the office of the attorney general and/or be authorized to employ private counsel or its own full-time attorney. The Board should define the duties of and qualifications for the executive director. Staff benefits should be provided in accord with the statutes of the State.

The Board’s staff may include, but need not be limited to, the following:

- An executive director, who, among administrative and other delegated responsibilities, may assist, at the Board’s discretion, in the discharge of the duties of the secretary-treasurer and if one exists, the licensing committee, the investigation committee, and any other standing or ad hoc committee;
- One or more assistant executive directors;
- One or more medical consultants, who shall be licensed to practice medicine in the State without restriction;
- Office and clerical staff;
- One or more attorneys, who may be full-time employees of the Board, contractors of the Board, or assigned from the Office of the State Attorney General by agreement between the Board and that office, or in private practice; and/or
- One or more investigators, who shall be trained in and knowledgeable about the investigation of medical and related health care practice.
Special Support Personnel

The Board may enlist, at its discretion, the services of experts, advisors, consultants, and others who are not part of its staff to assist it in more effectively enforcing the medical practice act. Such persons may serve voluntarily, be reimbursed for expenses in accord with State law and policy, or be compensated at a level commensurate with services rendered in accord with state law and policy. When acting for or on behalf of the Board, such persons should benefit from the same immunity and indemnification protections afforded by this statute to the members and staff of the Board.

Section VIII. Immunity, Indemnity, Protected Communication

The medical practice act should provide legal protection for the members of the Board and its staff and for those providing information to the Board in good faith.

Immunity

There shall be no liability, monetary or otherwise, on the part of, and no cause of action for damages shall arise against any current or former member, officer, administrator, staff member, committee member, examiner, representative, agent, employee, consultant, witness, or any other person serving or having served the Board, either as a part of the Board’s operation or as an individual, as a result of any act, omission, proceeding, conduct, or decision related to the duties undertaken or performed in good faith and within the scope of the function of the Board.

Qualified Immunity and Indemnity

The medical practice act should provide the following:

1. There shall be no liability on the part of, and no action for damages against, any member of the Board, its agents, its employees, or any member of an examining committee of physicians appointed or designated by the Board, for any action undertaken or performed by such person within the scope of the duties, powers, and functions of the Board or such examining committee when such person is acting in good faith and in the reasonable belief that the action taken by such person is warranted.

2. If a current or former member, officer, administrator, staff member, committee member, examiner, representative, agent employee, consultant, or any other person serving or having served the Board requests the State to defend them against any claim or action arising out of any act, omission, proceeding, conduct, or decision related to their duties undertaken or performed in good faith in furtherance of the purposes of the medical practice act and within the scope of the function of the Board, and if such a request is made in writing at a reasonable time before trial, and if the person requesting defense cooperates in good faith in the defense of the claim or action, the State shall provide and pay for such defense and shall pay any resulting judgment, compromise, or settlement.

3. No person, committee, association, organization, firm, or corporation providing information to the Board in good faith and in the reasonable belief that such information is accurate and, whether as a witness or otherwise, shall be held, by reason of having provided such information, to be liable in damages under the law of the state or any political subdivision thereof.
4. In any suit brought against the Board, its employees or agents, any member of an examining committee appointed by the Board or any person, firm, or other entity providing information to the Board, when any such defendant substantially prevails in such suit, the court shall, at the conclusion of the action, award to any such substantially prevailing party defendant against any such claimant the cost of the suit attributable to such claim, including a reasonable attorney’s fee, if the claim was frivolous, unreasonable, without foundation, or in bad faith. For the purposes of this Section, a defendant shall not be considered to have substantially prevailed when the plaintiff obtains an award for damages or permanent injunctive or declaratory relief.

5. There shall be no liability on the part of and no action for damages against any corporation, foundation, or organization that enters into any agreement with the Board related to the operation of any committee or program to identify, investigate, counsel, monitor, or assist any licensed physician who suffers or may suffer from alcohol or substance abuse or a physical or mental condition which could compromise such physician’s fitness and ability to practice medicine with reasonable skill and safety to patients, for any investigation, action, report, recommendation, decision, or opinion undertaken, performed, or made in connection with or on behalf of such committee or program, in good faith, and in the reasonable belief that such investigation, action, report, recommendation, decision, or opinion was warranted.

6. There shall be no liability on the part of and no action for damages against any person who serves as a director, trustee, officer, employee, consultant, or attorney for or who otherwise works for or is associated with any corporation, foundation, or organization that enters into any agreement with the Board related to the operation of any committee or program to identify, investigate, counsel, monitor, or assist any licensed physician who suffers or may suffer from alcohol or substance abuse or a physical or mental condition which could compromise such physician’s fitness and ability to practice medicine with reasonable skill and safety to patients, for any investigation, action, report, recommendation, decision, or opinion undertaken, performed, or made in connection with or on behalf of such committee or program, in good faith and in the reasonable belief that such investigation, action, report, recommendation, decision, or opinion was warranted.

7. In any suit brought against any corporation, foundation, organization, or person described in Subsection 4 or 5 of this Section, when any such defendant substantially prevails in the suit, the court shall, at the conclusion of the action, award to any substantially prevailing party defendant against any claimant the cost of the suit attributable to such claim, including reasonable attorney fees, if the claim was frivolous or brought without a reasonable good faith basis. For purposes of this Subsection, a defendant shall not be considered to have substantially prevailed when the plaintiff obtains a judgment for damages, permanent injunction, or declaratory relief.

8. The state should defend a current or former member, officer, administrator, staff member, committee member, examiner, representative, agent, employee, consultant, witness, contractor, or any other person serving or having served the Board against any claim or action arising out of the medical practice act, omission, proceeding, conduct, or decision related to the person’s duties undertaken or performed in good faith and within the scope of the function of the Board. The State should provide and pay for such defense and should pay any resulting judgment, compromise, or settlement.
Protected Communication

Every communication made by or on behalf of any person, institution, agency, or organization to the Board or to any person designated by the Board, relating to an investigation or the initiation of an investigation, whether by way of report, complaint, or statement, should be privileged. No action or proceeding, civil or criminal, should be permitted against any such person, institution, agency, or organization by whom or on whose behalf such a communication was made in good faith.

The protections afforded in this provision should not be construed as prohibiting a respondent or the respondent’s legal counsel from exercising the respondent’s constitutional right of due process under the law.

Section IX. Reports of the Board

Annual Report

The Board should present to the Governor, the Legislature and the public, at the end of each fiscal year, a formal report summarizing its licensing and disciplinary activity for that year. The report should include, but not limited to, the following information about each of the Board’s regulated professions:

1. The total number of persons fully licensed by the State and the number of those licensees currently practicing in the State;
2. The number of licensees holding each form of limited license authorized by this statute;
3. The number of persons granted a full license by the State for the first time in the past year, the number of those licensees currently practicing in the State, and the number of full licenses denied in the past year;
4. The number of licensees currently practicing in-state about whom a complaint, a charge or an adverse item of information required by law was received in the past year;
5. The number and the source, by category, of complaints, charges and adverse items of information required by law received about licensees practicing in-state in the past year and the number of these found not to warrant action under this statute and the rules of the Board;
6. The number of disciplinary investigations conducted by the Board or its representatives concerning licensees practicing in-state in the past year;
7. The number of disciplinary actions, by category, taken by the Board in the past year against all licensees;
8. A ranking, by frequency, of primary causes for disciplinary action against all licensees in the past year;
9. A review of disciplinary activity related to holders of limited forms of license in the past year;
10. A review of the operations of the Board’s current mechanisms for dealing with a licensee dependent on or addicted to alcohol or other addictive substances which have the potential to impair;
11. A schedule of all current fees and charges;
12. A revenue and expenditure statement for the past year indicating the percentage of revenue from and expenditures for each regulated profession;
13. A summary of other Board activities and a schedule of days met by the Board and each of its...
committees during the year;
14. A summary of administrative and legislative activity in the past year;
15. A summary of the goals and objectives established by the Board for the coming fiscal year; and
16. A copy of the Board’s strategic plan.

Public Record, Action Reports
Each of the Board’s non-administrative license application withdrawals, license denials and final
disciplinary orders, including any associated findings of fact and conclusions of law, should be matters of
public record. Voluntary surrenders of or limitations on licenses shall also be matters of public record.
The Board should promptly report all denials, orders, surrenders, and limitations to the public, all health
care institutions in the State, appropriate State and federal agencies, related professional societies or
associations in the State, and any data repository. The Board should make the information readily
accessible to the public via the physician’s profile. The Board should update the profile at least annually
and offer the licensee an opportunity to correct erroneous information. A licensee’s profile shall
contain, but not be limited to:

1. Demographic Information: name and license number, gender, business or practice address, and
birth date.
2. Medical Education: medical school(s)’ name, address, year of graduation and degree, post-
graduate training program(s)’ name, address, years attended, and year completed.
3. License and Board Certification Information: license status, license type, original license date,
license renewal date, specialty and type of practice, and board certification by a certifying
authority recognized by the Board.
4. Criminal Convictions: a description of any conviction of a felony or a misdemeanor involving
moral turpitude within the last five years, including cases with a deferred adjudication or
expungement.
5. Malpractice History:
   a. The number of awards or judgments within the past 10 years;
   b. When the number exceeds 3, the number of demands, claims, and/or settlements paid
      by the licensee or on behalf of the licensee in the past 5 years; and
   c. A statement that malpractice payments do not necessarily demonstrate the quality of
      care provided by a physician, and that the Board independently investigates all reports
      of payment in malpractice cases, which will appear in the licensee’s disciplinary history if
      the Board completed the investigation and took disciplinary action.
6. Disciplinary History:
   a. All disciplinary actions taken by the Board;
   b. A brief description of the reason for a disciplinary action;
   c. All disciplinary actions taken by other state medical/osteopathic boards and a brief
description of the reason for discipline if available;
   d. All disciplinary actions taken by hospitals;
   e. An explanation of the types of discipline the Board takes and its effects on the licensee’s
      ability to practice; and
f. A statement that hospitals may take disciplinary actions for reasons that do not violate the governing statutes.

Section X. Examinations

The medical practice act should provide for the Board’s authority to approve an examination(s) of medical knowledge satisfactory to inform the Board’s decision to issue a full, unrestricted license to practice medicine and surgery in the jurisdiction.

In order to ensure a high quality, valid, and reliable examination of physician preparedness to practice medicine, the Board may delegate the responsibilities for examination development, administration, scoring, and security to a third party or nationally recognized testing entity. Such an examination should be consistent with recognized national standards for professional testing such as those reflected in Standards for Educational and Psychological Testing.

No person should receive a license to practice medicine in the jurisdiction unless he or she has successfully completed all components of an examination(s) identified as satisfactory to the Board:

- The currently administered United States Medical Licensing Examination (USMLE) Steps 1,2,3 or The Comprehensive Osteopathic Medical Licensing Examination of the United States (COMLEX-USA) Levels 1,2,3; or
- Previously administered examinations such as the Federation Licensing Examination (FLEX), National Board of Medical Examiners (NBME) Parts or National Board of Osteopathic Medical Examiners (NBOME) Parts; or
- A combination of these examinations identified as acceptable by the Board.

The examination(s) approved by the Board should be in the English language and designed to ascertain an individual’s fitness for an unrestricted license to practice medicine and surgery.

The Board may stipulate the numeric score or performance level required for passing the examination(s) or accept the recommended minimum passing score as determined by the developers of the examination.

The Board should be authorized to limit the number of times an examination may be taken, to require applicants to pass all examinations within a specified period, and to specify further medical education required for applicants unable to do so.

In order to support periodic or mandated reviews of its approved examination(s), the Board should be provided with reasonable access by the third party or testing entity in order to review the examination design, format, and content, as well as performance data and relevant procedures for test administration, security, and scoring.

Section XI. Requirements for Full Licensure

The medical practice act should provide minimum requirements for full licensure for the independent practice of medicine that bear a reasonable relationship to the qualifications and fitness necessary for
such practice. These provisions of the act should implement or be consistent with the following:

1. The applicant should provide the Board, or its agent, and attest to, or provide the means to obtain and verify the following information and documentation in a manner required by the Board:
   a. The applicant’s full name and all aliases or other names ever used, current address, Social Security number, and date and place of birth;
   b. A signed photograph not more than two (2) years old and, at the Board’s discretion, other documentation of identity;
   c. Originals of all documents and credentials required by the Board, notarized photocopies, or other verification acceptable to the Board of such documents and credentials;
   d. A list of all jurisdictions, United States or foreign, in which the applicant is licensed or has ever applied for licensure to practice medicine or is authorized or has ever applied for authorization to practice medicine, including all jurisdictions in which any license application or authorization has been withdrawn;
   e. A list of all jurisdictions, United States or foreign, in which the applicant has been denied licensure or authorization to practice medicine or as any other health care professional or has voluntarily surrendered a license or an authorization to practice medicine or as any other health care professional;
   f. A list of all sanctions, judgments, awards, settlements, or convictions against the applicant in any jurisdiction, United States or foreign, that would constitute grounds for disciplinary action under the medical practice act or the Board’s rules and regulations;
   g. A detailed educational history, including places, institutions, dates, and program descriptions of all the applicant’s education including all college, pre-professional, professional, and professional postgraduate education;
   h. A detailed chronological life history, including places and dates of residence, employment, and military service (United States or foreign) including periods of absence from the active practice of medicine;
   i. All Web sites associated with the applicant’s practice and professional activities;
   j. A list and current status of all specialty certifications and the name of certifying organization; and
   k. Any other information or documentation the Board determines necessary.

2. The applicant should possess the degree of Doctor of Medicine or Doctor of Osteopathic Medicine/Doctor of Osteopathy from a medical college or school located in the United States, its territories or possessions, or Canada that was approved by the Board or by a private nonprofit accrediting body approved by the Board at the time the degree was conferred. No person who graduated from a medical school that was not approved at the time of graduation should be examined for licensure or be licensed in the jurisdiction based on credentials or documentation from that school nor should such a person be licensed by endorsement.

3. Should the applicant graduate from a medical school in a foreign country, other than Canada, the applicant should meet all the requirements established by the Board to determine the
applicant’s fitness to practice medicine.

4. The applicant should have satisfactorily completed at least thirty-six (36) months of progressive postgraduate medical training (also termed graduate medical education, or GME) accredited by the Board, the Accreditation Council for Graduate Medical Education (ACGME), or the American Osteopathic Association (AOA).

5. The applicant should have passed the USMLE Steps 1, 2, 3 or COMLEX Levels 1, 2, 3 or a predecessor examination (FLEX, NBME Parts, NBOME Parts) or a combination of these examinations identified as accredited by the Board.

6. The applicant should have demonstrated a familiarity with the statutes and regulations of the jurisdiction relating to the practice of medicine and the appropriate use of controlled or dangerous substances.

7. The applicant should be physically, mentally, and professionally capable of practicing medicine in a manner acceptable to the Board and should be required to submit to a physical, mental, professional competency, or chemical dependency examination(s) or evaluation(s) if deemed necessary by the Board.

8. The applicant should not have been found guilty by a competent authority, United States or foreign, of any conduct that would constitute grounds for disciplinary action under the regulations of the Board or the act. The Board may be authorized, at its discretion, to modify this restriction for cause, but it should be directed to use such discretionary authority in a consistent manner.

9. If the applicant’s license is denied or in accordance with Board policy, the applicant should be allowed a personal appearance before the Board or a representative thereof for interview, examination or review of credentials. At the discretion of the Board, the applicant should be required to present the applicant’s original medical education credentials for inspection at the time of personal appearance.

10. The applicant should be held responsible for verifying to the satisfaction of the Board the validity of all credentials required for the applicant’s medical licensure. The Board or its agent should verify medical licensure credentials directly from primary sources, and utilize recognized national physician information services (e.g., the Federation of State Medical Boards’ Physician Data Center (PDC), which includes its Board Action Data Bank, and Federation Credentials Verification Service (FCVS); the files of the American Medical Association and the American Osteopathic Association; and other national data banks and information resources.)

11. The applicant should have paid all fees and have completed and attested to the accuracy of all application and information forms required by the Board before the Board’s verification process begins. The Board should require the applicant to authorize the Board to investigate and/or verify any information provided to it on the licensure application.

12. Applicants should have satisfactorily passed a criminal background check.

13. Pay appropriate fees.

Graduates of Foreign Medical Schools

The medical practice act should provide minimum requirements, in addition to those otherwise established, for full licensure of applicants who are graduates of schools located outside the United
States, its territories or possessions, or Canada. These provisions of the act should implement or be consistent with the following:

1. Such applicants should possess the degree of Doctor of Medicine, Bachelor of Medicine, or a Board-approved equivalent based on satisfactory completion of educational programs acceptable to the Board.
2. Such applicants should be eligible by virtue of their medical education, training, and examination for unrestricted licensure or authorization to practice medicine in the country in which they received that education and training.
3. Such applicants should have passed an examination acceptable to the Board that adequately assesses the applicants’ medical knowledge.
4. Such applicants should be certified by the Educational Commission for Foreign Medical Graduates or its Board-approved successor(s), or by an equivalent Board-approved entity.
5. Such applicants should have a demonstrated command of the English language satisfactory to the Board.
6. Such applicants should have satisfactorily completed at least thirty-six (36) months of progressive post-graduate medical training accredited by the Board, the Accreditation Council for Graduate Medical Education (ACGME), or the American Osteopathic Association (AOA).
7. All credentials, diplomas, and other required documentation in a foreign language submitted to the Board by or on behalf of such applicants should be accompanied by certified English translations acceptable to the Board.
8. Such applicants should have satisfied all applicable requirements of the United States Immigration and Naturalization Service.

Section XII. Licensure by Endorsement, Expedited Licensure by Endorsement, and Temporary and Special Licensure

The medical practice act should provide for licensure by endorsement, expedited licensure by endorsement, and in certain clearly defined cases, for temporary and special licensure.

Endorsement for Licensed Applicants

The Board should be authorized, at its discretion, to issue a license by endorsement to an applicant who:

1. Has complied with all current medical licensing requirements save that for examination administered by the Board;
2. Has passed a medical licensing examination given in English by another state, the District of Columbia, or a territory or possession of the United States or Canada, provided the Board determines that examination was equivalent to its own current examination, or an independent testing agent designated by the Board; and
3. Has a valid current medical license in another state, the District of Columbia, or a territory or possession of the United States or Canada.
Expedited Licensure by Endorsement

The Board should be authorized, at its discretion, to issue an expedited license by endorsement to an applicant who provides documentation of:

1. Identity as required by the Board;
2. All jurisdictions in which the applicant holds a full and unrestricted license;
3. Graduation from an approved medical school:
   a. Liaison Committee on Medical Education (LCME) or Commission on Osteopathic College Accreditation (COCA) of the American Osteopathic Association (AOA) approved medical school;
   b. Fifth Pathway certificate; or
   c. Educational Commission for Foreign Medical Graduates (ECFMG) certificate.
4. Passing one or more of the following examinations acceptable for initial licensure within three attempts per step/level:
   a. United States Medical Licensing Examination (USMLE) Steps 1-3 or its predecessor examinations, the National Board of Medical Examiners (NBME) I-III or the Federation Licensing Examination (FLEX);
   b. Comprehensive Osteopathic Medical Licensure Examination (COMLEX-USA) Levels 1-3 or its predecessor examinations, the National Board of Osteopathic Medical Examiners Levels 1-3 or its predecessor examination(s); and/or
   c. Medical Council of Canada Qualifying Examinations (MCCQE) or its predecessor examination(s) offered by the Licentiate Medical Council of Canada.
5. Successful completion of the total examination sequence within seven (7) years, except when in combination with a Ph.D. program;
6. Successful completion of three (3) years of progressive postgraduate training in a program accredited by the Accreditation Council on Graduate Medical Education (ACGME) or the AOA; and/or
7. Certification or recertification by a medical specialty board recognized by the American Board of Medical Specialties (ABMS) or the AOA within the previous ten (10) years. Lifetime certificate holders who have not passed a written specialty recertification examination must demonstrate successful completion of the Special Purpose Examination (SPEX), Comprehensive Osteopathic Medical Variable Purpose Examination (COMVEX) or applicable specialty recertification examination.

Boards should obtain supplemental documentation including, but not limited to:

1. Criminal background check;
2. Absence of current/pending investigations in any jurisdiction where licensed;
3. Verification of specialty board certification; and
4. Professional experience.

Physicians desiring an expedited process for licensure may utilize the Federation Credentials Verification Service (FCVS), or credentials verification meeting equivalent standards for verification of core
credentials, or rely on the primary source verification of the state board of first licensure for:

1. Medical school diploma;
2. Medical school transcript;
3. Dean’s certificate;
4. Examination history;
5. Disciplinary history;
6. Identity (photograph and certified birth certificate or original passport);
7. ECFMG certificate, if applicable; and
8. Fifth Pathway certificate, if applicable, and postgraduate training verification.

Temporary Licensure
The Board should be authorized to establish regulations for issuance of a temporary medical license for the intervals between Board meetings. Such a license should:

1. Be granted only to an applicant demonstrably qualified for a full and unrestricted medical license under the requirements set by the medical practice act and the regulations of the Board; and
2. Automatically terminate within a period specified by the Board.

Special Licensure
The Board should be authorized to issue conditional, restricted, probationary, limited or otherwise circumscribed licenses as it determines necessary. It is up to the discretion of the state medical board to set the criteria for issuing special purpose licenses. This provision should include, but not be limited to, the ability to issue a special license for the following purposes:

1. To provide medical services to a traveling sports team, coaches, and staff for the duration of the sports event;
2. To provide volunteer medical services to under-insured/uninsured patients;
3. To provide medical services to youth camp enrollees, counselors, and staff for the duration of the youth camp; and
4. To engage in the limited practice of medicine in an institutional setting by a physician who is licensed in another jurisdiction in the United States.

Section XIII. Limited Licensure for Physicians in Postgraduate Training
The medical practice act should provide that all physicians in all postgraduate training in the state or jurisdiction who are not otherwise fully licensed to practice medicine should be licensed on a limited basis for educational purposes. These provisions of the act should implement or be consistent with the following:

1. To be eligible for limited licensure, the applicant should have completed all the requirements for full and unrestricted medical licensure except postgraduate training or specific examination
2. Issuance of a limited license specifically for postgraduate training should occur only after the applicant demonstrates that he/she is accepted in a residency program. The application for limited licensure should be made directly to the Board in the jurisdiction where the applicant’s postgraduate training is to take place.

3. The Board should establish by regulation restrictions for the limited license to assure that the holder will practice only under appropriate supervision and within the confines of the program within which the resident is enrolled.

4. The limited license should be renewable annually and upon the written recommendation of the supervising institution, including a written evaluation of performance, until the Board regulations require the achievement of full and unrestricted medical licensure.

5. The disciplinary provisions of the medical practice act should apply to the holders of the limited and postgraduate training license as if they held full and unrestricted medical licensure.

6. The issuance of a limited license should not be construed to imply that a full and unrestricted medical license would be issued at any future date.

Postgraduate Training Program Reporting Requirements

Program directors responsible for postgraduate training should be required annually to provide the Board a written report on the status of program participants having a limited license.

The report should inform the Board about program participants who have successfully completed the program, have departed from the program, have had unusual absences from the program, or have had problematic occurrences during the course of the program.

The report should include an explanation of any disciplinary action taken against a limited licensee for performance or behavioral reasons which, in the judgment of the program director, could be a threat to public health, safety, and welfare; unapproved or unexplained absences from the program; resignations from the program or nonrenewal of the program contract; dismissals from the program for performance or behavioral reasons; and referrals to substance abuse programs not approved by the Board.

Failure to submit the annual program director’s report shall be considered a violation of the mandatory reporting provisions of the medical practice act and shall be grounds to initiate such disciplinary action as the Board deems appropriate, including fines levied against the supervising institution and suspension of the program director’s medical license.

Section XIV: Periodic Renewal

The medical practice act should provide for the periodic renewal of medical licenses to permit the Board to review the qualifications of licensees on a regular basis. These provisions of the act should implement or be consistent with the following:

At the time of periodic renewal, the Board should require the licensee to demonstrate to its satisfaction the licensee’s continuing qualification for medical licensure. The Board should design the application for licensure renewal to require the licensee to update and/or add to the information in the Board’s file.
relating to the licensee and the licensee’s professional activity. It should also require the licensee to report to the Board the following information:

1. Any action taken for acts or conduct similar to acts or conduct described in the medical practice act as grounds for disciplinary action against a licensee by:
   a. Any jurisdiction or authority (United States or foreign) that licenses or authorizes the practice of medicine or participation in a payment or practice program;
   b. Any peer review body;
   c. Any specialty certification board;
   d. Any health care organization;
   e. Any professional medical society or association;
   f. Any law enforcement agency;
   g. Any health insurance company;
   h. Any malpractice insurance company;
   i. Any court; and
   j. Any governmental agency.

2. Any adverse judgment, settlement, or award against the licensee or payment by or on behalf of the licensee arising from a professional liability demand, claim, or case.

3. The licensee’s voluntary surrender of or voluntary limitation on any license or authorization to practice medicine in any jurisdiction, including military, public health, and foreign.

4. Any denial to the licensee of a license or authorization to practice medicine by any jurisdiction, including military, public health, and foreign.

5. The licensee’s voluntary resignation from the medical staff of any health care organization or voluntary limitation of the licensee’s staff privileges at such an organization if that action occurred while the licensee was under formal or informal investigation by the organization or a committee thereof for any reason related to possible medical incompetence, unprofessional conduct, or mental, physical, alcohol, or drug impairment.

6. The licensee’s voluntary resignation or withdrawal from a national, state, or county medical society, association, or organization if that action occurred while the licensee was under formal or informal investigation or review by that body for any reason related to possible medical incompetence, unprofessional conduct, mental, physical, alcohol, or drug impairment.

7. Whether the licensee is currently suffering from any condition that adversely affects or impairs the licensee’s practice of medicine.

8. The licensee’s completion of continuing medical education or other forms of professional maintenance and/or evaluation, including specialty board certification or recertification, within the renewal period.

The Board should be authorized, at its discretion, to require continuing medical education for license renewal and to require documentation of that education. The Board should have the authority to audit, randomly or specifically, licensees for compliance.

The Board should require the licensee to apply for license renewal in a manner prescribed by the board and attest to the accuracy and truthfulness of the information submitted. The Board should be
authorized to collect a fee for renewal of a license.

The Board should be directed to establish an effective system for reviewing renewal forms. It should also be authorized to initiate investigations and/or disciplinary proceedings based on information submitted by licensees for license renewal.

Failure to report fully and correctly as outlined above should be grounds for disciplinary action by the Board.

Section XV. Disciplinary Process

The medical practice act should provide for disciplinary and/or remedial action against licensees and the grounds on which such action may be taken. These provisions of the act should implement or be consistent with the following:

Range of Actions

A range of progressive disciplinary and remedial actions should be made available to the Board. The Board should be authorized, at its discretion, to take disciplinary, non-disciplinary, public or non-public actions, singly or in combination, as the nature of the violation requires and to promote public protection. These include, but are not limited to, the following:

1. Revocation of the medical license;
2. Suspension of the medical license;
3. Probation;
4. Stipulations, limitations, restrictions, probation, and conditions relating to practice;
5. Censure (including specific redress, if appropriate);
6. Reprimand;
7. Letters of concern and advisory letters:
   a. The Board should be authorized to issue a confidential (if allowed by state law), non-reportable, non-disciplinary letter of concern, or advisory letter to a licensee when evidence does not warrant formal discipline, but the Board has noted indications of possible errant conduct by the licensee that could lead to serious consequences and formal action if the conduct were to continue. In its letter of concern or advisory letter, the Board should also be authorized, at its discretion, to request clarifying information from the licensee.
8. Monetary redress to another party;
9. A period of free public service, either medical or non-medical;
10. Satisfactory completion of an educational, training and/or treatment program(s), or professional developmental plan:
   a. The Board should be authorized, at its discretion, to require professional competency, physical, mental, or chemical dependency examination(s) or evaluation(s) of any applicant or licensee, including withdrawal and laboratory examination of bodily fluids, tissues, hair, or nails.
11. Levy fines; and
12. Payment of administrative and disciplinary costs.

Grounds for Action
The Board should be authorized to take disciplinary action for unprofessional or dishonorable conduct, which should be defined to mean, but not be limited to, the following:

1. Fraud or misrepresentation in applying for or procuring a medical license or in connection with applying for or procuring periodic renewal of a medical license;
2. Cheating on or attempting to subvert the medical licensing examination(s);
3. The commission or conviction or the entry of a guilty, nolo contendere plea, or deferred adjudication (without expungement) of:
   a. A misdemeanor related to the practice of medicine and any crime involving moral turpitude; or
   b. A felony related to the practice of medicine. The Board shall revoke a licensee’s license following conviction of a felony, unless a 2/3 majority vote of the board members present and voting determined by clear and convincing evidence that such licensee will not pose a threat to the public in such person’s capacity as a licensee and that such person has been sufficiently rehabilitated to warrant the public trust;
4. Conduct likely to deceive, defraud, or harm the public;
5. Disruptive behavior and/or interaction with physicians, hospital personnel, patients, family members, or others that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;
6. Making a false or misleading statement regarding the licensee’s skill or the efficacy or value of the medicine, treatment, or remedy prescribed by the licensee or at the licensee’s direction in the treatment of any disease or other condition of the body or mind;
7. Representing to a patient that an incurable condition, sickness, disease, or injury can be cured;
8. Willfully or negligently violating the confidentiality between physician and patient except as required by law;
9. Professional incompetency as one or more instances involving failure to adhere to the applicable standard of care to a degree which constitutes negligence, as determined by the Board;
10. Being found mentally incompetent or of unsound mind by any court of competent jurisdiction;
11. Being physically or mentally unable to engage in the practice of medicine with reasonable skill and safety;
12. Practice or other behavior that demonstrates an incapacity or incompetence to practice medicine;
13. The use of any false, fraudulent, or deceptive statement in any document connected with the practice of medicine;
14. Giving false, fraudulent, or deceptive testimony while serving as an expert witness;
15. Practicing medicine under a false or assumed name;
16. Aiding or abetting the practice of medicine by an unlicensed, incompetent, or impaired person;
17. Allowing another person or organization to the licensee’s license to practice medicine;
18. Commission of any act of sexual misconduct, including sexual contact with patient surrogates or key third parties, which exploits the physician-patient relationship in a sexual way;
19. Habitual or excessive use or abuse of drugs, alcohol, or other substances that impair ability;
20. Failing or refusing to submit to an examination or any other examination that may detect the presence of alcohol or drugs upon Board order or any other form of impairment;
21. Prescribing, selling, administering, distributing, diverting, ordering or giving any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug for other than medically accepted therapeutic purposes;
22. Knowingly prescribing, selling, administering, distributing, ordering, or giving to a habitual user or addict or any person previously drug dependent, any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug, except as otherwise permitted by law or in compliance with rules, regulations, or guidelines for use of controlled substances and the management of pain as promulgated by the Board;
23. Prescribing, selling, administering, distributing, ordering, or giving any drug legally classified as a controlled substance or recognized as an addictive drug to a family member or to the licensee themselves;
24. Violating any state or federal law or regulation relating to controlled substances;
25. Signing a blank, undated, or predated prescription form;
26. Obtaining any fee by fraud, deceit, or misrepresentation;
27. Employing abusive, illegal, deceptive, or fraudulent billing practices;
28. Directly or indirectly giving or receiving any fee, commission, rebate, or other compensation for professional services not actually and personally rendered, though this prohibition should not preclude the legal functioning of lawful professional partnerships, corporations, or associations;
29. Disciplinary action of another state or federal jurisdiction against a license or other authorization to practice medicine or participate in a federal program (payment or treatment) based upon acts or conduct by the licensee similar to acts or conduct that would constitute grounds for action as defined in this section, a certified copy of the record of the action taken by the other state or jurisdiction being conclusive evidence thereof;
30. Failure to report to the Board any adverse action taken against oneself by another licensing jurisdiction (United States or foreign), by any peer review body, by any health care institution, by any professional or medical society or association, by any governmental agency, by any law enforcement agency, or by any court for acts or conduct similar to acts or conduct that would constitute grounds for action as defined in this section;
31. Failure to report or cause a report to be made to the Board of any physician upon whom a physician has evidence or information that appears to show that the physician is incompetent, guilty of negligence, guilty of a violation of this act, engaging in inappropriate relationships with patients, is mentally or physically unable to practice safely, or has an alcohol or drug abuse problem;
32. Failure of physician who is the chief executive officer, medical officer, or medical staff to report to the Board any adverse action taken by a health care institution or peer review body, in addition to the reporting requirement in 31. (Note: a report under 31 may need to wait until the peer review and due process procedures are completed, but the report under 30 must be
reported immediately without waiting for the final action of the health care institution and
applies to all physicians not just staff physicians);

33. Failure to report to the Board surrender of a license limitation or other authorization to practice
medicine in another state or jurisdiction, or surrender of membership on any medical staff or in
any medical or professional association or society has surrendered the authority to utilize
controlled substances issued by any state or federal agency, or has agreed to a limitation to or
restriction of privileges at any medical care facility while under investigation by any of those
authorities or bodies for acts or conduct similar to acts or conduct that would constitute
grounds for action as defined in this section;

34. Failure to report any adverse judgment, award, or settlement against the licensee resulting from
a medical liability claim related to acts or conduct similar to acts or conduct that would
constitute grounds for action as defined in this section;

35. Failure to report to the Board any adverse judgment, settlement, or award arising from a
medical liability claim related to acts or conduct similar to acts or conduct that would constitute
grounds for action as defined in this section;

36. Failure to provide pertinent and necessary medical records to another physician or patient in a
timely fashion when legally requested to do so by the subject patient or by a legally designated
representative of the subject patient regardless of whether the patient owes a fee for services;

37. Improper management of medical records, including failure to maintain timely, legible,
accurate, and complete medical records and to comply with the Standards for Privacy of
Individually Identifiable Health Information, 45 CFR Part 160 and 164, of the Health Insurance
Portability and Accountability Act of 1996;

38. Failure to furnish the Board, its investigators, or representatives information legally requested
by the Board or failure to comply with a Board subpoena or order;

39. Failure to cooperate with a lawful investigation conducted by the Board;

40. Violation of any provision(s) of the medical practice act or the rules and regulations of the Board
or of an action, stipulation, or agreement of the Board;

41. Engaging in conduct calculated to, or having the effect of, bringing the medical profession into
disrepute or conduct unbecoming of the medical profession, including but not limited to,
violation of any provision of a national code of ethics acknowledged by the Board and/or failing
to uphold the standards of the profession;

42. Failure to follow generally accepted infection control procedures;

43. Failure to comply with any state statute or board regulation regarding a licensee’s reporting
responsibility for HIV, HVB (hepatitis B virus), seropositive status or any other reportable
condition (including child abuse and vulnerable adult abuse) or disease;

44. Practicing medicine in another state or jurisdiction without appropriate licensure;

45. Conduct which violates patient trust, exploits the physician-patient relationship, or violates
professional boundaries, regardless of the medium;

46. Failure to offer appropriate procedures/studies, failure to protest inappropriate managed care
denials, failure to provide necessary service, or failure to refer to an appropriate provider within
such actions are taken for the sole purpose of positively influencing the physician’s or the plan’s
financial wellbeing;
47. Providing treatment or consultation recommendations, including issuing a prescription via
electronic or other means, unless the physician has obtained a history and physical evaluation of
the patient adequate to establish diagnosis and identify underlying conditions and/or
contraindications to the treatment recommended/provided;
48. Violating a Board formal order, condition of probation, consent agreement, or stipulation;
49. Representing, claiming, or causing the appearance that the physician possesses a particular
medical specialty certification by a Board recognized certifying organization (ABMS, AOA) if not
true;
50. Failing to obtain adequate patient informed consent;
51. Using experimental treatments without appropriate patient consent and adhering to all
necessary and required guidelines and constraints;
52. Any conduct that may be harmful to the patient or the public;
53. Failing to divulge to the Board upon legal demand the means, method, procedure, modality, or
medicine used in the treatment of an ailment, condition, or disease;
54. Conduct likely to deceive, defraud, or harm the public;
55. The use of any false, fraudulent, or deceptive statement in any document connected with the
practice of the healing arts including intentional falsifying or fraudulent altering of a patient or
medical care facility record;
56. Failure to keep written medical records which accurately describe the services rendered to the
patient, including patient histories, pertinent findings, examination results, and test results;
57. Delegating professional responsibilities to a person when the licensee knows or has reason to
know that such person is not qualified by training, experience, or license to perform them;
58. Using experimental forms of therapy without proper informed patient consent, without
conforming to generally accepted criteria or standard protocols, without keeping detailed
legible records, or without having periodic analysis of the study and results reviewed by a
committee or peers; and
59. Failing to properly supervise, direct, or delegate acts which constitute the healing arts to
persons who perform professional services pursuant to such licensee’s direction, supervision,
order, referral, delegation, or practice protocols.

Enforcement and Disciplinary Action Procedures
The medical practice act should provide for procedures that will permit the Board to take appropriate
enforcement and disciplinary action when and as required, while assuring fairness and due process to
licensees. These provisions of the act should implement or be consistent with the following:

Board Authority: The Board should be empowered to commence legal action to enforce the provisions
of the medical practice act and to exercise full discretion and authority with respect to disciplinary
actions. In the course of an investigation, the Board’s authority should include the ability to issue
subpoenas to licensees, health care organizations, complainants, patients, and witnesses to produce
documents or appear before the Board or staff to answer questions or be deposed. The Board should
have the power to enforce its subpoenas, including disciplining a non-compliant licensee, and it is
incumbent upon the subpoenaed party to seek a motion to quash the subpoena.
Administrative Procedures: The existing administrative procedures act or similar statute, in whole or in part, should either be applicable to or serve as the basis of the procedural provisions of the medical practice act. The procedural provisions should provide for Board investigation of complaints; notice of formal or informal charges or allegations to the licensee; a fair and impartial hearing for the licensee before the Board, an examining committee or hearing officer; an opportunity for representation of the licensee by counsel; the presentation of testimony, evidence and arguments; subpoena power and attendance of witnesses; a record of the proceedings; and judicial review by the courts in accordance with the standards established by the jurisdiction for such review. The Board should have subpoena authority to conduct comprehensive reviews of a licensee’s patient and office records and administrative authority to access otherwise protected peer review records. The Board should not need the patients’ consent to obtain copies of medical records, nor shall health care institutions’ peer-review privilege bar the Board from obtaining copies of peer review information. Once in the Board’s possession, the patient records and peer review records should have the same legal protection from disclosure as they have when in the possession of the licensee, the patient or the peer-review organization.

Standard of Proof: The Board should be authorized to use preponderance of the evidence as the standard of proof in its role as trier of fact for all levels of discipline.

Informal Conference: Should there be an open meeting law, an exemption to it should be authorized to permit the Board, at its discretion, to meet in informal conference with a licensee who seeks or agrees to such a conference. Disciplinary action taken against a licensee because of such an informal conference and agreed to in writing by the Board and the licensee should be binding and a matter of public record. However, license revocation and suspension should be held in open formal hearing, unless executive session is permitted by the State’s open meetings law. The holding of an informal conference should not preclude an open formal hearing if the Board determines such is necessary.

Summary Suspension: The Board should be authorized to summarily suspend or restrict a license prior to a formal hearing when it believes such action is required to protect the public from an imminent threat to public health and safety. The Board should be permitted to summarily suspend or restrict a license by means of a vote conducted by telephone conference call or other electronic means if appropriate Board officials believe such prompt action is required. Proceedings for a formal hearing should be instituted simultaneously with the summary suspension. The hearing should be set within a reasonable time of the date of the summary suspension. No court should be empowered to lift or otherwise interfere with such suspension while the Board proceeds in a timely fashion.

Cease and Desist Orders/Injunctions: The Board should be authorized to issue a cease-and-desist order and/or obtain an injunction to restrain any person or any corporation or association and its officers and directors from violating any provision of the medical practice act. Violation of an injunction should be punishable as contempt of court. No proof of actual damage to any person should be required for issuance of a cease-and-desist order and/or an injunction, nor should issuance of an injunction relieve those enjoined from criminal prosecution, civil action, or administrative process for violation of the medical practice act.
Board Action Reports: All the Board’s final disciplinary actions, non-administrative license withdrawals, and license denials, including related findings of fact and conclusions of law, should be matters of public record. The Board should report such actions and denials to the National Practitioner Data Bank and Board Action Data Bank of the Federation of State Medical Boards of the United States within 30 days of the action being taken, to any other data repository required by law, and to the media. Voluntary surrender of and voluntary limitation(s) on the medical license of any person should also be matters of public record and should also be reported to the Federation of State Medical Boards of the United States and to any other data repository by law. The Board should have the authority to keep confidential practice limitations and restrictions due to physical impairment when the licensee has not violated any provision in the medical practice act.

Tolling Periods of License Suspension or Restriction: The Board should provide, in cases of license suspension or restriction, that any time during which the disciplined licensee practices in another jurisdiction without comparable restriction shall not be credited as part of the period of suspension or restriction.

Section XVI: Compulsory Reporting and Investigation

The medical practice act should provide that certain persons and entities report to the Board any possible violation of the act or of the Board’s rules and regulations by a licensee. These provisions of the act should implement or be consistent with the following:

Any person should be permitted to report to the Board in a manner prescribed by the Board, any information he or she believes indicates a medical licensee is or may be dyscompetent, guilty of unprofessional conduct, or mentally or physically unable to engage safely in the practice of medicine.

The following should be required to report to the Board promptly and in writing any information that indicates a licensee is or may be dyscompetent, guilty of unprofessional conduct, or mentally or physically unable to engage safely in the practice of medicine; and any restriction, limitation, loss or denial of a licensee’s staff privileges or membership that involves patient care:

1. All licensees licensed under the act,
2. All licensed health care providers,
3. The state medical associations and its components,
4. All hospitals and other health care organizations in the state, to include hospitals, medical centers, long term care facilities, managed care organizations, ambulatory surgery centers, clinics, group practices, coroners, etc.,
5. All chiefs of staff, medical directors, department administrators, service directors, attending physicians, residency directors, etc.,
6. All liability insurance organizations,
7. All state agencies,
8. All law enforcement agencies in the state,
9. All courts in the state,
10. All federal agencies (e.g., Drug Enforcement Administration, Food and Drug Administration,
11. All peer review bodies in the state, and
12. All resident training program directors.

A licensee’s voluntary resignation from the staff of a health care organization or voluntary limitation of a
licensee’s staff privileges at such an organization should be promptly reported to the Board by the
organization if that action occurs while the licensee is under formal or informal investigation by the
organization or a committee thereof for any reason related to possible medical incompetence,
unprofessional conduct, or mental, physical, alcohol or drug impairment.

Malpractice insurance carriers, the licensee’s attorney, a hospital, a group practice, and the affected
licensees should be required to file with the Board a report of each final judgment, settlement,
arbitration award, or any form of payment by the licensee or on the licensee’s behalf by any source
upon any demand, claim, or case alleging medical malpractice, battery, dyscompetence, incompetence,
or failure of informed consent. Licensees not covered by malpractice insurance carriers should be
required to file the same information with the Board regarding themselves. All such reports should be
made to the Board promptly (e.g., within 30 days).

The Board should be permitted to investigate any evidence that appears to show a licensee is or may be
medically incompetent, guilty of unprofessional conduct, or mentally or physically unable to engage
safely in the practice of medicine.

Any person, institution, agency, or organization who reports in good faith and not made in bad faith, a
licensee pursuant to paragraphs 2 and 3 of this section should not be subject to civil damages or criminal
prosecution for so reporting. A bad faith report is grounds for disciplinary action under the medical
practice act. There should be no monetary liability on the part of, and no cause of action for damages
should arise against, any person, institution, agency, or organization for reporting in good faith.

To assure compliance with compulsory reporting requirements, specific civil penalties should be
established for demonstrated failure to report (e.g., up to $10,000 per instance).

The Board should promptly acknowledge all reports received under this section. The Board should
promptly notify persons or entities reporting under this section of the Board’s final disposition of the
matters reported.

Section XVII. Impaired Physicians

The medical practice act should provide for the limitation, restriction, conditioning, suspension or
revocation of the medical license of any licensee whose mental or physical ability to practice medicine
with reasonable skill and safety is impaired.

The Board should have available to it a confidential impaired physician program approved by the Board
and charged with the evaluation and treatment of licensees who are in need of rehabilitation. The Board
may directly provide such programs or through a formalized contractual relationship with an
independent entity whose program meets standards set by the Board. The Board shall have the ability
to monitor or audit the program to ensure the program meets the requirements of the Board.

The Board should be authorized, at its discretion, to require a licensee or applicant to submit to a
mental or physical examination, body fluid, nail, or hair follicle test, or a chemical addiction, abuse, or
dependency evaluation conducted by an independent evaluator designated or approved in advance by
the Board. The results of the examination or evaluation should be admissible in any hearing before the
Board or hearing officer, despite any claim of privilege under a contrary rule or statute. Every person
who receives a license to practice medicine or who files an application for a license to practice medicine
should be deemed to have given consent to submit to mental or physical examination or a chemical
addiction, abuse, or dependency evaluation, and to have waived all objections to the admissibility of the
results in any hearing before the Board. If a licensee or applicant fails to submit to an examination or
evaluation when properly directed to do so by the Board, the Board should be permitted to enter a final
order upon proper notice, hearing, and proof of refusal.

If the Board finds, after an evaluation, examination or hearing, that a licensee is mentally, physically, or
chemically impaired, it should be authorized to take one or more of the following actions:

1. Direct the licensee to submit to therapy, medical care, counseling, or treatment acceptable to
the Board and comply with monitoring to ensure compliance;
2. Suspend, limit, restrict, or place conditions on the licensee's medical license for the duration of
the impairment and monitoring or treatment; and/or
3. Revoke the licensee's medical license.

Any licensee or applicant who is prohibited from practicing medicine under this provision should be
afforded, at reasonable intervals, an opportunity to demonstrate to the satisfaction of the Board that he
or she can resume or begin the practice of medicine with reasonable skill and safety. A license should
not be reinstated, however, without the payment of all applicable fees and the fulfillment of all
requirements as if the applicant had not been prohibited from practicing medicine.

While all impaired licensees should be reported to the Board in accord with the mandatory reporting
requirements of the medical practice act, unidentified and unreported impaired licensees should be
encouraged to seek treatment. To this end, the Board should be authorized, at its discretion, to establish
rules and regulations for the review and approval of a medically directed Physician Health Program
(PHP). Those conducting a Board-approved PHP should be exempt from the mandatory reporting
requirements relating to an impaired licensee who is participating satisfactorily in the program, or the
Board should hold its report in confidence and without action, unless or until the impaired licensee
ceases to participate satisfactorily in the program. The Board should require a PHP to report any
impaired licensee whose participation is unsatisfactory to the Board as soon as that determination is
made. Participation in an approved PHP should not protect an impaired licensee from Board action
resulting from a report of licensee impairment from another source or resulting from an investigation of
other medical practice violations. The Board should be the final authority for approval of a PHP, should
conduct a review of its approved program(s) on a regular basis and should be permitted to withdraw or
deny its approval at its discretion. The PHP should be required to report to the Board information regarding any violation of the medical practice act by a PHP participant, other than the impairment, even if the violation is unrelated to the licensee’s impairment.

Section XVIII: Dyscompetent and Incompetent Licensees

The medical practice act should provide for the restriction, conditioning, suspension, revocation, or denial of the medical license of any licensee who the Board determines to be dyscompetent or incompetent. These provisions of the act should implement or be consistent with the following:

The Board should be authorized to develop and implement methods to identify dyscompetent or incompetent licensees and licensees who fail to provide the appropriate quality of care. The Board should also be authorized to develop and implement methods to assess and improve licensee practices.

The Board should have access to a Board-approved assessment program charged with assessing licensees’ clinical competency.

The Board should be authorized, at its discretion, to require a licensee or an applicant for licensure to undergo a physician competency evaluation conducted by a Board-designated independent evaluator at licensee’s own expense. The results of the assessment should be admissible in any hearing before the Board or hearing officer, despite any claim of privilege under a contrary rule or statute. Every person who receives a license to practice medicine or who files an application for a license to practice medicine should be deemed to have given consent to submit to a physician competency evaluation, and to have waived all objections to the admissibility of the results in any hearing before the Board or hearing officer. If a licensee or applicant fails to submit to a competency assessment when properly directed to do so by the Board, the Board should be permitted to enter a final order upon proper notice, hearing, and proof of refusal to submit to such an evaluation.

If the Board finds, after evaluation by the assessment program, that a licensee or applicant for licensure is unable to competently practice medicine, it should be authorized to take one or more of the following actions:

1. Suspend, revoke, or deny the licensee’s medical license or application;
2. Restrict or limit the licensee’s practice to those areas of demonstrated competence and comply with monitoring to ensure compliance;
3. Place conditions on the licensee’s license; and/or
4. Direct the licensee to submit to a Board approved remediation program and comply with monitoring to ensure compliance to resolve any identified deficits in medical knowledge or clinical skills acceptable to the Board.

Any licensee or applicant for licensure who is prohibited from practicing medicine, or who has had restrictions or conditions placed upon their license, under the above section, should be afforded, at reasonable intervals, an opportunity to demonstrate to the satisfaction of the Board that he/she can resume or begin the practice of medicine, or can practice without the restrictions or conditions, with reasonable skill and safety. A license should not be reinstated, however, without the payment of all
applicable fees and the fulfillment of all requirements as if the applicant had not been previously prohibited.

The Board should be authorized to require the assessment program to provide to the Board a written report of the results of the assessment with recommendations for remediation of the identified deficiencies.

The Board should have access to Board approved remedial medical education programs for referral of licensees in need of remediation. Such programs shall incorporate and comply with standards set by the Board. During remediation, the program shall provide, at Board determined intervals, written reports to the Board on the licensee’s progress. Upon completion of the remediation program, the program shall provide a written report to the Board addressing the remediation of the previously identified areas of deficiency. The Board should be authorized to mandate that the licensee undergo post-remediation assessment to identify areas of continued deficit. The licensee shall be responsible for all expenses incurred as part of the assessment and the remediation.

Section XIX: Physician Assistants

The medical practice act should provide for the Board to license and regulate physician assistants.

Administration

The Board should administer and enforce these provisions of the medical practice act with the advice and assistance of the Physician Assistant Council.

Licensing

No person should perform or attempt to practice as a physician assistant without first obtaining a license from the Board and having a supervising physician.

An applicant for licensure as a physician assistant should complete all Board application forms and pay a nonrefundable fee. The forms should request the applicant provide their name and address and such additional information as the Board deems necessary. The Board may issue a license to a physician assistant applicant who fulfills all board requirements for licensure. However, a licensed physician assistant is prohibited from practicing until they have an agreement with a supervising physician(s).

Each licensed physician assistant should renew their license and file updated documentation stating their name and current address and any additional information as required by the Board. A fee set by the Board should accompany each renewal and filing of updated documentation.

The Board may require written notification by the supervising physician and the physician assistant if the relationship is changed or severed for a reason that would have an adverse effect for patient care.

Persons not licensed by the Board who hold themselves out as physician assistants should be subject to penalties applicable to the unlicensed practice of medicine.
Rules and Regulations
The Board should be empowered to adopt and enforce rules and regulations for:

1. Setting qualifications of education, skill, and experience for the licensing of a person as a physician assistant and providing forms and procedures for licensure and for renewal; and
2. Evaluating applicants for licensure as physician assistants.

Disciplinary Actions
The Board should be empowered to deny, revoke, or suspend any license, to limit or restrict the location of practice, to issue reprimands, to remove the authorization of a supervising physician, and to limit or restrict the practice of a physician assistant upon grounds and according to procedures similar to those for such disciplinary actions against licensed physicians. Such actions should be reported to the National Practitioner Databank and the Federation of State Medical Boards.

Duties and Scope of Practice
A physician assistant should be permitted to provide those medical services delegated to them by the supervising physician that are within their training and experience.

Responsibility of Supervising Physician
Every physician supervising or employing a physician assistant should be legally responsible for the delegation of health care tasks, the performance and the acts and omissions of the physician assistant. Nothing in these provisions, however, should be construed to relieve the physician assistant of any responsibility for any of their own acts and omissions. No physician should have under their supervision more staff, physician assistant, or otherwise than the physician can adequately supervise. In the event the supervising physician is absent, he or she must provide for appropriate supervision of the physician assistant by another licensed physician. Each and every relationship should adhere to all statutory requirements for licensure.

Renewal
The Board should be authorized, at its discretion, to require evidence of satisfactory completion of continuing medical education for license renewal.
FSMB Advisory Council of Board Executives

2017-2018 Members:

Kimberly Kirchmeyer, Medical Board of California
Kathleen Szelzer Lippert, JD, CMBE Kansas State Board of Healing Arts
Maegan Carr Martin, JD, Tennessee State Board of Medical Examiners
Micah Matthews, MPA, Washington Medical Quality Assurance Commission
Frank Meyers, JD, District of Columbia Board of Medicine

Ex Officio Members:

Kevin Bohnenblust, JD, President, Administrators in Medicine
Mark Bowden, MPA, CMBE, Vice President, Administrators in Medicine
Kathleen Haley, JD, CMBE, FSMB BOD, Oregon Medical Board
Ian Marquand, FSMB BOD, Montana Board of Medical Examiners

FSMB Staff Support:

Shiri A. Hickman, JD
REPORT OF THE BOARD OF DIRECTORS

Subject: Report on Resolution 17-2: Advocacy for Professional Licensure of Emergency Medical Service Providers

Referred to: Reference Committee A

In April 2017, the Federation of State Medical Boards House of Delegates referred Resolution 17-2, Advocacy for Professional Licensure of Emergency Medical Service (EMS) Providers, to the Board of Directors for study. The Resolution, submitted by the Montana Board of Medical Examiners, states:

Resolved, that the Federation of State Medical Boards (FSMB) adopt a position supporting professional licensure of paramedics and other advanced life support EMS providers under the authority of state medical boards; and be it further

Resolved, that the FSMB coordinate and collaborate with individual state medical boards and other stakeholders to develop model statutory language for states to utilize in adopting a professional licensing process and standards for EMS providers.

The Board of Directors considered the Resolution and tasked the Advisory Council of Board Executives to evaluate the regulatory oversight of paramedics and make a recommendation as to the position of the FSMB. The Board noted that the Advisory Council of Board Executives would be reviewing and recommending revisions to the Essentials of a State Medical and Osteopathic Medical Practice Act and the Elements of a State Medical and Osteopathic Board and would therefore be well positioned to study this issue and draft model statutory language, if the resolution was to be recommended for adoption.

Background
Each state, territory and the District of Columbia has a lead EMS agency, according to the National Association of State Emergency Medical Services Officials (NASEMSO). These agencies are usually a part of the state health department, but in some states they are part of a multidisciplinary state public safety department, or are an independent state agency. State EMS agencies are responsible for the overall planning, coordination, and regulation of the EMS system within the state as well as licensing local EMS agencies and personnel.

1 https://www.nasemso.org/About/StateEMSAgencies/StateEMSAgencyListing.asp
There is longstanding history of state regulation of EMS providers, with promulgation and execution of state laws and rules regarding EMS provider requirements for practice dating as far back as 1972. This includes accreditation of educational programs, use of a valid, reliable and legally defensible examination, criminal history checks, and ongoing competency maintenance requirements such as minimum continuing education credits and skill proficiency demonstration.

Additionally, recent developments in critical care transport and community paramedicine has served as a catalyst to the adoption of state laws and rules requiring physician oversight of EMS providers. These rules typically entail physician oversight and review of patient care, physician review of written patient care protocols, and when necessary, physician contact during patient care via radio or telephone.

State Medical Boards

Today only four state medical boards have oversight of EMS professionals: Alaska State Medical Board; Hawaii Medical Board; Commonwealth of the Northern Mariana Islands; and the Montana Board of Medical Examiners. According NASEMSO, the licensing and regulation of EMS personnel began in the 1970’s and has steadily migrated away from state boards of medicine to separate State EMS regulatory boards. These EMS boards are not only responsible for the licensing of EMS personnel, but also the nation’s 21,000 EMS agencies that respond to 911 emergencies and provide transport, including specialty care air medical transport, and ground transport. This regulatory scheme is similar to the boards of pharmacy that license not only the individual pharmacists but also pharmacies, distributors, manufactures, and wholesalers.

The number of non-physician health care providers that are under the purview of state medical boards varies significantly throughout the country, from athletic trainers to polysomnography techs. The FSMB has not heretofore taken a position on what professions should be regulated by the medical board, with the exception of physician assistants for whom the medical and osteopathic boards license the majority, and therefore a specific recommendation and practice act for EMS personnel would not be in keeping with current policy or practice. Additionally, state medical boards would require extra human and financial resources to take on the licensure and regulation of another health occupation, and boards have not indicated their desire to do so. However, it should be noted that state medical boards have an indirect role in the oversight of EMS personnel through the licensure and regulation of the EMS associated physician medical directors.

Advisory Council of Board Executives

The FSMB Advisory Council of Board Executives (Council) is made up of nine executive directors, including the two associate members of the FSMB Board of Directors and the

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president and vice president of Administrators in Medicine. The Council provides guidance to the Board and FSMB staff on FSMB projects and services, state and federal legislative agenda, and is responsible for the three year review and revision of the Essentials of a State Medical and Osteopathic Practice Act and Elements of a State Medical and Osteopathic Board. The Board of Directors tasked the Council to evaluate Resolution 17-2 and make its recommendation to the Board. The Council met on August 17, 2017 at the FSMB office in Washington, D.C.

The Council noted the limited resources of state medical boards and the capacity of boards to take on additional regulated professions. The Council recognized the authority and discretion of the state to delegate oversight of the health occupation to best protect the public within their individual state structures. The Advisory Council recommended the Board of Directors not pursue policy in favor of Resolution 17-2, primarily due to the additional responsibilities and resources that would be required for the licensing of EMS providers, investigation and adjudication of complaints, and standard enforcement. Additionally, the Council noted current political pressures and criticisms of state occupational licensure generally and were concerned policy proposals for additional layers of oversight would be ill advised.

As an alternative approach to Resolution 17-2, the recommendations contained in FSMB’s policy, Regulatory Strategies for Achieving Greater Cooperation and Collaboration Among Health Professional Boards (HOD 2017) may address the concerns expressed in Resolution 17-2. The policy recommends that state medical boards establish procedures for exchanging information with other boards, agencies, and departments responsible for regulating health-related occupations, facilities, and programs, and for coordinating investigations involving matters within the jurisdiction of more than one regulatory body. These procedures would apply to exchanging information between the state medical board and the state EMS agency to 1) conduct joint investigations; 2) share investigatory data; and create or develop processes to facilitate communication and collaboration between the board/agency.

Resolution 17-2 also speaks to the need for standardization of licensing and practice standards among the states. While there are variances in state licensure requirements for EMS personnel based on the needs and available resources in individual states, the majority require passage of a national examination and certification from the National Registry of Emergency Medical Technicians. Additionally, the NASEMSO, with support from the U.S. Department of Homeland Security, has initiated an interstate licensure compact that should further standardize licensing requirements among states. To participate in the compact, EMS personnel must have passed the National Registry of Emergency Medical Technicians (NREMT) examination for initial licensure and have an unrestricted license in his/her home state.
Conclusion

In conclusion, the Board of Directors concurs with the Advisory Council of Board Executives and does not recommend a policy change at this time regarding the licensure and regulation of EMS personnel. The Board further finds that the policy, *Regulatory Strategies for Achieving Greater Cooperation and Collaboration Among Health Professional Boards* (HOD 2017), applies and is a more feasible approach to Resolution 17-2.

ITEM FOR ACTION:

For information.
REPORT OF THE BYLAWS COMMITTEE

SUBJECT: PROPOSED AMENDMENTS TO THE FEDERATION BYLAWS

REFERRED TO: REFERENCE COMMITTEE

The Bylaws Committee, chaired by Jerry G. Landau, JD, met on September 27-28, 2017 in Washington, D.C. and extended its discussion on January 9 and February 21, 2018 via videoconference to consider the current Bylaws and proposed amendments thereto and make recommendations for any necessary changes. In keeping with its charge, the Committee also discussed the FSMB Articles of Incorporation as they relate to the Bylaws. Members of the Committee include: Charles A. Castle, MD; Erich W. Garland, MD; Eric R. Groce, DO; W. Reeves Johnson, Jr., MD; and Ian Marquand. Ex officio members include FSMB Chair Gregory B. Snyder, MD; FSMB Chair-elect Patricia A. King, MD, PhD; and FSMB President-CEO Humayun J. Chaudhry, DO.

The Bylaws Committee is presenting twenty-five (25) proposed amendments for consideration. Proposed amendments #1-7 are contained in Bylaws Proposal #1; proposed amendments #8-23 are contained in Bylaws Proposal #2; proposed amendment #24 is contained in Bylaws Proposal #3; and proposed amendment #25 is contained in Bylaws Proposal #4. Each Bylaws Proposal will be addressed separately.

The Bylaws may be amended at any annual meeting of the House of Delegates by two-thirds of those present and voting.

BYLAWS PROPOSAL #1/ PROPOSED AMENDMENTS #1-7 (PROPOSED BY THE FSMB BOARD OF DIRECTORS)

In July 2017, the FSMB Board of Directors approved a resolution directing the Bylaws Committee to explore changes to the Bylaws that would enhance the role of state medical board executive directors in FSMB governance. The catalyst prompting the resolution was the FSMB’s commitment to enhancing its effectiveness in supporting its state medical and osteopathic boards (SMBs) and its awareness that the institutional knowledge, historical perspective and political savvy of SMB executive directors are invaluable to the creation of FSMB work products and positions statements.

The Board of Directors acknowledges that since the inception of the FSMB there has been ongoing review and periodic revisions to the bylaws to allow for appropriate evolution of the organization. In its current form, executive directors as ‘Associate Members’ cannot be utilized to their full potential to benefit the organization.
After extensive discussion and careful consideration, the concept of creating a new category of Fellow was advanced which would allow for both appropriate recognition of the significant contribution that executive directors provide to medical regulation as well as allow the organization to more fully benefit from their expertise on our various committees, work groups and task forces.

In September 2017, the Bylaws Committee met to develop a draft Bylaws proposal for the Board’s consideration, as well as to consider other potential amendments to the Bylaws. At this time, the Bylaws Committee determined that potential amendments designed to create a new category of Fellow could be drafted within the structure of the Bylaws and were feasible to consider. The Committee began to draft recommended revisions. In furtherance of this effort, the Bylaws Committee also sought input from Administrators in Medicine (AIM). In December 2017, the Bylaws Committee distributed proposed revisions to the FSMB Member Medical Boards for comment.

In January 2018, the Bylaws Committee discussed the feedback received from the Member Medical Boards and AIM, all of which was favorable, and the draft proposal was then forwarded, with no additional changes, to the Board of Directors for final review at its February 2018 meeting. On February 21, the Bylaws Committee discussed the Board’s feedback and finalized its position on the proposal.

Bylaws Proposal #1 can be found in its entirety behind Attachment 1 and contains seven (7) proposed amendments (#1-7) within Article II. Classes of Membership, Election and Membership Rights; Article III. Officers: Election and Duties; and Article IV. Board of Directors. The Bylaws Committee recommends the House of Delegates ADOPT proposed Amendments #1-7 as follows:

PROPOSED AMENDMENT #1

Article II. Classes of Membership, Election and Membership Rights
Section B. Fellows

There shall be two categories of Fellow of the FSMB:

1. Board Member Fellow. A Board Member Fellow is an individual member who as a result of appointment or confirmation is designated to be a member of a Member Medical Board. A Board Member Fellow shall be a Fellow of the FSMB during the member’s period of service on a Member Medical Board, and for a period of 36 months thereafter, and

2. Staff Fellow. A Staff Fellow is an individual hired or appointed and who is responsible for the day-to-day supervision and performance of the administrative duties and functions for which a medical board is responsible. Each member board may denote only one individual to serve as a Staff Fellow of the FSMB. No individual shall
continue as a Staff Fellow upon termination of employment by or service to the Member Medical Board.

PROPOSED AMENDMENT #2
Article II. Classes of Membership, Election and Membership Rights
Section C. Honorary Fellows

Thirty-six months after completion of service on a Member Medical Board, a Board Member Fellow as defined in section B, paragraph 1 shall become an Honorary Fellow of the FSMB thirty-six months after completion of service on a Member Medical Board. A Staff Fellow as defined in Section B, paragraph 2 shall become an Honorary Fellow of the FSMB upon termination of employment by or service to the Member Medical Board. An Honorary Fellow of the FSMB may be appointed by the Chair to serve as a member of any committee or in any other appointive capacity.

PROPOSED AMENDMENT #3
Article II. Classes of Membership, Election and Membership Rights
Section D. Associate Members

A Member Medical Board may designate one or more employees or staff members, other than an individual designated as a Staff Fellow, to be an Associate Member of the FSMB. No Associate Member individual shall continue in that capacity as an Associate Member upon termination of employment by or service to the Member Medical Board.

PROPOSED AMENDMENT #4
Article III. Officers: Election and Duties
Section A. Officers of the FSMB

1. OFFICERS. The officers of the FSMB shall be that of Chair, Chair-elect, Treasurer and Secretary.

2. Only an individual who is a Fellow as defined in Article II, Section B, Paragraph 1 at the time of the individual’s election or appointment shall be eligible for election or appointment as an Officer of the FSMB, except for the position of Secretary.

3. The position of Secretary shall be an ex-officio office, without vote, and the President of the FSMB shall serve as Secretary.

PROPOSED AMENDMENT #5
Article IV. Board of Directors
Section A. Membership and Terms

1. MEMBERSHIP: The Board of Directors shall be composed of the Officers, the Immediate Past Chair, nine Directors-at-Large and two Associate Members Staff Fellows. At least
two members of the Board, who are not Associate Members Staff Fellows, shall be non-physicians, at least one of whom shall be a public/consumer member.

2. NOMINATION OF ASSOCIATE MEMBERS STAFF FELLOWS: Nominations for Associate Member Staff Fellow positions shall be accepted from Member Boards, the Board of Directors and the Administrators in Medicine (AIM). Associate Members Staff Fellows shall be elected appointed by the Board of Directors in staggered terms in accordance with policies and procedures established by the Board of Directors.

3. TERMS: Directors-at-Large shall each serve for a term of three years and shall be eligible to be reelected to one additional term. Staff Fellows shall serve for a term of two years and shall be eligible to be reappointed to one additional term. A partial term totaling one-and-a-half years or more shall count as a full term. Associate Members shall each serve for a term of two years. Associate Members shall not be eligible to serve consecutive terms.

PROPOSED AMENDMENT #6

Article IV. Board of Directors
Section F. Vacancies

1. DIRECTORS-AT-LARGE: In the event of a vacancy in the membership of the Directors-at-Large, the Board of Directors may appoint a Fellow who meets the qualifications for the position to serve until the next Annual Meeting of the House of Delegates, at which time an individual shall be nominated and, if elected, shall serve for the remainder of the unexpired term. In the event a Director-at-Large is elected to the office of Treasurer or Chair-elect, that vacancy shall be filled by an election at the same Annual Meeting of the House of Delegates.

2. ASSOCIATE MEMBERS STAFF FELLOWS: In the event of a vacancy of an Associate Member a Staff Fellow, the Board of Directors may appoint a substitute to complete the Associate Member’s Staff Fellow’s term in accordance with the policies established by the Board of Directors.

PROPOSED AMENDMENT #7

Article IV. Board of Directors
Section G. Executive Committee of the Board

1. MEMBERSHIP: The Board of Directors shall establish an Executive Committee of the Board, which shall consist of the Chair as Chair, Chair-elect, Treasurer, Immediate Past Chair and two three Directors-at-Large. The Directors-at-Large shall be elected for a one-year term by majority vote of the Directors-at-Large and the Associate Members of Staff Fellows serving on the Board of Directors at the first regular meeting of the Board following the annual meeting of the House of Delegates. In the event of a vacancy in a Director-at-Large position, the Directors-at-Large and the Associate Members of Staff Fellows serving on the Board, by majority vote, shall choose another Director-at-Large to serve the remainder of the one-year term. A Staff Fellow may serve in one of the
Director-at-Large positions. No more than one Staff Fellow may serve on the Executive Committee at any one time. In the event of vacancy in the position of Immediate Past Chair, this position shall remain vacant until the next Annual Meeting of the House of Delegates.

**BYLAWS PROPOSAL #2/ PROPOSED AMENDMENTS #8-23 (PROPOSED BY THE BYLAWS COMMITTEE)**

Bylaws Proposal #2 can be found in its entirety behind Attachment 2 and contains sixteen (16) proposed amendments (#8-24) within Article II. Classes of Membership, Election and Membership Rights; Article III. Officers: Election and Duties; Article IV. Board of Directors; Article V. Nomination by Petition for Board of Directors and Nominating Committee; and Article VII. Meetings. For discussion purposes, these proposed amendments are divided into three sections.

1) **Proposed Amendments #8-13** to Articles III and IV address the Bylaws Committee’s recommendation that the Bylaws be changed so that the FSMB Immediate Past Chair is considered an Officer of the corporation given that when a Fellow is elected Chair-elect, the individual is expected to serve for three years: one year as Chair-elect; one year as Chair; and one year as Immediate Past Chair. The individual is also a standing member of the Executive Committee during those three years.

Accordingly, the Bylaws Committee recommends the House of Delegates ADOPT proposed Amendments #8-13 as follows:

**PROPOSED AMENDMENT #8**

Article III. Officers: Election and Duties
Section A. Officers of the FSMB

1. OFFICERS. The officers of the FSMB shall be that of Chair, Chair-elect, **Immediate Past Chair**, Treasurer and Secretary.

**PROPOSED AMENDMENT #9**

Article III. Officers: Election and Duties
Section B. Election of Officers

1. The Chair-elect shall ascend to the position of Chair at the Annual Meeting following the meeting in which the Chair-elect was elected.
2. The Chair-elect shall be elected at each Annual Meeting of the House of Delegates.
3. **The Immediate Past Chair assumes that position upon the Chair-elect ascending to the position of Chair.**
34. The Treasurer shall be elected every third year at the Annual Meeting of the House of Delegates.

45. Officers shall be elected by a majority of the members of the House of Delegates present and voting.

56. In any election, should no candidate receive a majority of the votes cast, a runoff election shall be held between the two candidates who receive the most votes for that office on the first ballot. Up to two additional runoff elections shall be held.

67. Prior to each election, the presiding officer shall cast a sealed vote that shall be counted only to resolve a tie that cannot be decided by the process set forth in this section.

PROPOSED AMENDMENT #10
Article III. Officers: Election and Duties
Section C. Duties of Officers

3. The duties of the Immediate Past Chair shall be as follows:
   a. Assist the Chair in the transition from Chair-elect to Chair;
   b. Serve as chair of the Nominating Committee; and
   c. Perform such other duties and responsibilities as the Chair shall determine.

34. The duties of the Treasurer shall be as follows:
   a. Perform the duties customary to that office;
   b. Perform such other duties as the Bylaws and custom and parliamentary usage may require or as the Board of Directors shall deem appropriate;
   c. Serve as an ex officio member of the Audit Committee; and
   d. Serve as chair of the Finance Committee.

45. The duties of the Secretary shall be as follows:
   a. Administer the affairs of the FSMB; and
   b. Such duties and responsibilities as the FSMB and the Board of Directors shall determine.

PROPOSED AMENDMENT #11
Article III. Officers: Election and Duties
Section D. Terms of Office and Succession

1. The Chair and Chair-elect shall serve for single terms of one year or until their successors assume office.

2. The Immediate Past Chair shall serve until a successor to the current Chair assumes office.

23. The Treasurer shall serve for a single term of three years or until the Treasurer’s successor assumes the office.

34. Officers shall assume office upon final adjournment of the Annual Meeting of the House of Delegates at which they were elected.

45. The term of the Secretary is co-terminus with that of the President.
PROPOSED AMENDMENT #12

Article III. Officers: Election and Duties
Section E. Vacancies

3. In the event of a vacancy in the office of Immediate Past Chair, the office shall remain open until a new Chair assumes the office.

34. In the event of a vacancy in the office of the Treasurer, the Board of Directors shall elect one of the Directors-at-Large to serve as Treasurer, with one vote on the Board of Directors and one vote on the Executive Committee, until the next year’s Annual Meeting of the House of Delegates, at which time a Treasurer shall be elected.

PROPOSED AMENDMENT #13

Article IV. Board of Directors
Section A. Membership and Terms

1. Membership: The Board of Directors shall be composed of the Officers, the Immediate Past Chair, nine Directors-at-Large and two Associate Members. At least two members of the Board, who are not Associate Members, shall be non-physicians, at least one of whom shall be a public/consumer member.

2) Proposed Amendment #14 to Article IV addresses the Bylaws Committee’s recommendation that the Bylaws be changed to offer greater clarity about the process for removing an individual from the Board of Directors. Accordingly, the Bylaws Committee recommends the House of Delegates ADOPT proposed Amendment #14 as follows:

PROPOSED AMENDMENT #14

Article IV. Board of Directors
Section E. Removal from Office

1. Removal: Any officer or member of the Board of Directors may be removed for any cause deemed sufficient by an affirmative vote of two-thirds of the total members of the Board of Directors entitled to vote and who are not subject to removal from office.

2. Procedure: The procedure for removal shall be as follows:
   a. The Board shall file with the Secretary of the Board and deliver a written statement of the cause for removal to the officer or board member in sufficient detail as to state the grounds for the removal. Delivery to the officer or board member shall be by certified mail, return receipt requested, to the last address known to the Board and is effective upon mailing.
   b. The officer or board member shall deliver a sworn written response to the Board, no later than thirty calendar days after the written statement of the cause for removal is delivered to the officer or board member in question. Delivery to the Board shall be by certified mail, return receipt requested,
directed to the Secretary of the Board at the FSMB corporate office. **Delivery is effective upon mailing.**

c. At the next Board meeting following the date the response is due, the Board shall determine whether or not to proceed with removal. Notice of the Board’s action shall be delivered to the officer or board member by certified mail, return receipt requested. If the officer or board member did not file a written response the Board shall proceed with a determination. **Delivery is effective upon mailing.**

d. If the Board votes to proceed with removal of the officer or board member, at a Board meeting held no less than thirty days after delivery of the notice, the officer or board member shall be afforded the opportunity to address the Board on the merits of the allegations and produce any relevant information to the Board after which the Board shall make a determination. **The Board meeting at which the officer or board member has the opportunity to address the Board shall be held no less than thirty days after delivery of the notice of removal.**

3. **APPEAL:** Any officer or member of the Board of Directors removed by the Board of Directors may appeal to the House of Delegates at its next business meeting. The officer or member may be reinstated by a two-thirds vote of the House of Delegates.

4. **DELIVERY:** For the purposes of this section, “Delivery” is effective upon mailing.

3) **Proposed Amendments #15-24** to Articles II, IV, V and VII address the Bylaws Committee’s recommendation that the Bylaws be changed to reflect an increase in the Executive Committee from two to three Directors-at-Large, minor editorial improvements. Accordingly, the Bylaws Committee recommends the House of Delegates **ADOPT proposed Amendments #15-24** as follows:

**PROPOSED AMENDMENT #15**

Article II. Classes of Membership, Election and Membership Rights

Section B. Fellows

An individual member who as a result of appointment or confirmation is designated to be a member of a Member Medical Board shall be a Fellow of the FSMB during the member’s period of service on a Member Medical Board, and for a period of 36 **thirty-six** months thereafter.

**PROPOSED AMENDMENT #16**

Article IV. Board of Directors

Section B. Nominations

2. The Nominating Committee shall mail its roster of candidates to Member Boards not fewer than 60 **sixty** days prior to the Annual Meeting of the House of Delegates.
PROPOSED AMENDMENT #17

Article IV. Board of Directors
Section D. Duties of the Board of Directors

2. The Board of Directors shall carry out the mandates of the FSMB as established by the House of Delegates, and it shall have full and complete power and authority to perform all acts and to transact all business for and on behalf of the FSMB.

PROPOSED AMENDMENT #18

Article IV. Board of Directors
Section F. Vacancies

1. DIRECTORS-AT-LARGE: In the event of a vacancy in the membership of the Directors-at-Large, the Board of Directors may appoint a Fellow who meets the qualifications for the position to serve until the next Annual Meeting of the House of Delegates, at which time an individual a Fellow shall be nominated and, if elected, and shall serve for the remainder of the unexpired term. In the event a Director-at-Large is elected to the office of Treasurer or Chair-elect, that vacancy shall be filled by an election at the same Annual Meeting of the House of Delegates.

PROPOSED AMENDMENT #19

Article IV. Board of Directors
Section G. Executive Committee of the Board

1. MEMBERSHIP: The Board of Directors shall establish an Executive Committee of the Board, which shall consist of the Chair as Chair, Chair-elect, Treasurer, Immediate Past Chair and two three Directors-at-Large. The Directors-at-Large shall be elected for a one-year term by majority vote of the Directors-at-Large and the Associate Members of the Board of Directors at the first regular meeting of the Board following the Annual Meeting of the House of Delegates. In the event of a vacancy in a Director-at-Large position, the Directors-at-Large and the Associate Members of the Board, by majority vote, shall choose another Director-at-Large to serve the remainder of the one-year term. In the event of vacancy in the position of Immediate Past Chair, this position shall remain vacant until the next Annual Meeting of the House of Delegates.

PROPOSED AMENDMENT #20

Article V. Nomination by Petition for Board of Directors and Nominating Committee
Section A. Submission of a Petition

3. The deadline to submit petitions to the Administrative Staff is 21 twenty-one days prior to the Annual Meeting.
PROPOSED AMENDMENT #21

Article V. Nomination by Petition for Board of Directors and Nominating Committee
Section B. Validation and Placement on Ballot

3. The names of those seeking to run by petition whose petitions are deemed valid shall be
distributed to the Voting Delegates not fewer than fourteen days prior to the Annual Meeting.

PROPOSED AMENDMENT #22

Article VII. Meetings
Section A. Annual Meeting of the House of Delegates

The annual meeting of the House of Delegates of the FSMB, which shall be called the House of Delegates, shall be held at such time and place as may be fixed by the Board of Directors. Written notice of the time and place of the meeting shall be given to all Member Medical Boards by mail not fewer than ninety days prior to the date of the meeting. Notice is effective upon mailing.

PROPOSED AMENDMENT #23

Article VII. Meetings
Section B. Special Meetings of the House of Delegates

Special meetings of the House of Delegates may be called at any time by the Chair, on the written request of ten Member Medical Boards or by action of the Board of Directors. Written notice of the time and place of such meetings shall be given to all Member Medical Boards by mail not fewer than thirty days prior to the date of the meeting. Notice is effective upon mailing.

PROPOSED AMENDMENT #24

Article XIV. Adoption and Amendment of Bylaws, Effective Date
Section A. Amendment

These Bylaws may be amended at any annual meeting of the House of Delegates by two-thirds of those present and voting. Bylaws changes may be proposed only by the Board of Directors, Member Medical Boards or the Bylaws Committee and its members. All such proposals must be submitted in writing to the Bylaws Committee, in care of the Secretary of the FSMB. The Bylaws Committee shall inform the Member Medical Boards of its meeting dates not fewer than sixty days in advance of the meeting. The recommendations of the Bylaws Committee and the full texts of all proposed amendments recommended to the Committee shall be sent to each Member Medical Board not fewer than sixty days prior to the Annual Meeting of the House of Delegates at which they are to be considered.
**Bylaws Proposal #3/ Proposed Amendment #25 (Proposed by the Bylaws Committee)**

Bylaws Proposal #3 can be found in its entirety behind Attachment 3 and contains one (1) proposed amendment (#25) within Article VIII. Standing and Special Committees.

The Bylaws Committee proposes that Article VIII be changed to allow the FSMB Chair an opportunity to appoint an Associate Member to the Editorial Committee should the Chair so choose. Accordingly, the Bylaws Committee recommends the House of Delegates **ADOPT** proposed Amendment #25 as follows:

**Proposed Amendment #25**

Article VIII. Standing and Special Committees

Section D. Editorial Committee

1. An Editorial Committee, not to exceed twelve Fellows and three *non-member subject matter experts* non-Fellows, at least two of whom shall be *subject matter experts*, shall advise the Editor-in-Chief on editorial policy for the FSMB’s official publication, and shall serve as the editorial board of that publication and otherwise assist the Editor-in-Chief in the performance of duties as appropriate and necessary. No officer or member of the Board of Directors shall serve on this Committee.

**Bylaws Proposal #4/ Proposed Amendment #26 (Proposed by the Tennessee Board of Medical Examiners)**

Bylaws Proposal #4 can be found in its entirety behind Attachment 4 and contains one (1) proposed amendment (#26) within Article IV. Board of Directors.

The Tennessee Board of Medical Examiners proposes that Article IV be changed to allow the inclusion of two (2) public/consumer members, who are not Associate Members, to serve on the Board of Directors as follows:

**Proposed Amendment #26**

Article IV. Board of Directors

Section A. Membership and Terms

1. **MEMBERSHIP**: The Board of Directors shall be composed of the Officers, the Immediate Past Chair, nine Directors-at-Large and two Associate Members. At least two members of the Board, who are not Associate Members, shall be *non-physicians*, at least one of whom shall be a public/consumer member.

The Tennessee Board suggests that this modification to the Bylaws makes clear that the public/consumer members’ participation and perspective on the Board is valued and aligned with
the Member Medical Boards of the FSMB, and notes that non-physician members can still be
elected to the Board if they are Fellows of the FSMB.

The Bylaws Committee considered the Tennessee Board’s position and discussed the current
process for electing Fellows to the Board of Directors, which begins with the election of the
requisite number of non-physicians and public/consumer members and a ballot that only includes
the non-physician and public/consumer member candidates. After those positions are filled, any
non-physician or public/consumer member candidate not elected at that time is included on the
next ballot with the physician candidates.

The Bylaws Committee opined that while it is true that the Tennessee Board’s proposed change
to the Bylaws would still provide an opportunity for non-physicians (who are not
public/consumer members because of their nexus to healthcare) to be elected to the Board, they
would not have the added benefit of being considered independently of physicians, which might
discourage a non-physician, such as a physician assistant, from running for election because of a
perception that voting delegates would likely favor the physicians.

Given the importance of this issue, the Bylaws Committee agreed that additional discussion is
needed to consider all of the possible ramifications of this proposed change as well as how it
might affect the rest of the Bylaws. The Committee also concurred that because of the
significance of the changes being presented to the House of Delegates in Proposal 1, it would be
best to act on Proposal 4 in 2019. Therefore, the Bylaws Committee recommends the House of
Delegates **TABLE proposed Amendment #26 until the Bylaws Committee can make its final
recommendation to the House in 2019.**
ARTICLE I. NAME

The corporation shall be known as the Federation of State Medical Boards of the United States, Inc. (“FSMB”).

ARTICLE II. CLASSES OF MEMBERSHIP, ELECTION AND MEMBERSHIP RIGHTS

SECTION A. MEMBER MEDICAL BOARDS

The term “Member Medical Board” as used in the Articles of Incorporation and in these Bylaws shall refer to any board, committee or other group in any state, territory, the District of Columbia or possession of the United States of America that is empowered by law to pass on the qualifications of applicants for licensure to practice allopathic or osteopathic medicine or to discipline such licensees. If a state or other jurisdiction has more than one such entity and if each is an independent agency unrelated to the others, each is eligible for membership. Any eligible Medical Board may become a Member Medical Board upon approval of its application by the Board of Directors.

SECTION B. FELLOWS

There shall be two categories of Fellow of the FSMB:

1. Board Member Fellow. A Board Member Fellow is an individual member who as a result of appointment or confirmation is designated to be a member of a Member Medical Board. A Board Member Fellow shall be a Fellow of the FSMB during the member’s period of service on a Member Medical Board, and for a period of 36 months thereafter, and

2. Staff Fellow. A Staff Fellow is an individual hired or appointed and who is responsible for the day-to-day supervision and performance of the administrative duties and functions for which a medical board is responsible. Each member board may denote only one individual to serve as a Staff Fellow of the FSMB. No individual shall continue as a Staff Fellow upon termination of employment by or service to the Member Medical Board.
SECTION C. HONORARY FELLOWS

Thirty-six months after completion of service on a Member Medical Board, a Member Fellow as defined in section B, paragraph 1, shall become an Honorary Fellow of the FSMB, thirty-six months after completion of service on a Member Medical Board. A Staff Fellow as defined in Section B, paragraph 2, shall become an Honorary Fellow of the FSMB upon termination of employment by or service to the Member Medical Board. An Honorary Fellow of the FSMB may be appointed by the Chair to serve as a member of any committee or in any other appointive capacity.

SECTION D. ASSOCIATE MEMBERS

A Member Medical Board may designate one or more employees or staff members, other than an individual designated as a Staff Fellow, to be an Associate Member of the FSMB. No Associate Member individual shall continue in that capacity as an Associate Member upon termination of employment by or service to the Member Medical Board.

SECTION E. COURTESY MEMBERS

Any physician or physician assistant licensed by a Member Medical Board or an Affiliate Member Board and not eligible for any other type of membership may become a Courtesy Member of the FSMB upon approval of the candidate’s application. A Courtesy Member may serve as a member of a committee and in any other capacity upon appointment by the Chair.

SECTION F. AFFILIATE MEMBERS BOARDS

A board or authority that is not otherwise eligible for membership may become an Affiliate Member Board of the FSMB upon approval of its application by the Board of Directors if the board or authority licenses either:

1. Allopathic or osteopathic physicians or physician assistants in the United States; or
2. Allopathic or osteopathic physicians if the board or authority is located in another country.

SECTION G. OFFICIAL OBSERVERS

An organization may apply for Official Observer status at meetings of the House of Delegates. The Board of Directors shall prescribe rules and procedures to govern the application for, the granting of, and the exercise of Official Observer status.
SECTION H. RIGHTS OF MEMBERS

Except as otherwise provided in these Bylaws, rights, duties, privileges and obligations of a member of the FSMB may be exercised only by a Member Medical Board.

SECTION I. METHODS OF NOMINATION TO ELECTED OFFICE

Nomination by the Nominating Committee or Nomination by Petition pursuant to Articles III, IV, V and VIII shall be the sole methods of nomination to an elected office of the FSMB. A candidate who runs for and is not elected to an elected office shall be ineligible to be nominated for any other elected office during the same election cycle.

ARTICLE III. OFFICERS: ELECTION AND DUTIES

SECTION A. OFFICERS OF THE FSMB

1. OFFICERS. The officers of the FSMB shall be that of Chair, Chair-elect, Treasurer and Secretary.

2. Only an individual who is a Fellow as defined in Article II, Section B, Paragraph 1 at the time of the individual's election or appointment shall be eligible for election or appointment as an Officer of the FSMB, except for the position of Secretary.

3. The position of Secretary shall be an ex-officio office, without vote, and the President of the FSMB shall serve as Secretary.

SECTION B. ELECTION OF OFFICERS

1. The Chair-elect shall ascend to the position of Chair at the Annual Meeting following the meeting in which the Chair-elect was elected.

2. The Chair-elect shall be elected at each Annual Meeting of the House of Delegates.

3. The Treasurer shall be elected every third year at the Annual Meeting of the House of Delegates.

4. Officers shall be elected by a majority of the members of the House of Delegates present and voting.

5. In any election, should no candidate receive a majority of the votes cast, a runoff election shall be held between the two candidates who receive the most votes for that office on the first ballot. Up to two additional runoff elections shall be held.
6. Prior to each election, the presiding officer shall cast a sealed vote that shall be counted only to resolve a tie that cannot be decided by the process set forth in this section.

SECTION C. DUTIES OF OFFICERS

1. The duties of the Chair shall be as follows:
   a. Preside at all meetings and sessions of the House of Delegates and the Board of Directors;
   b. Perform the duties customary to the office of the Chair;
   c. Make appointments to committees and define duties of committee members in accordance with these Bylaws, except as otherwise provided herein;
   d. Serve, ex officio, on all committees except as otherwise provided herein; and
   e. Exercise such other rights and customs as the Bylaws and parliamentary usage may require or as the FSMB or the Board of Directors shall deem appropriate.

2. The duties of the Chair-elect shall be as follows:
   a. Assist the Chair in the discharge of the Chair’s duties; and
   b. Perform the duties of the Chair at the Chair’s request or, in the event of the Chair’s temporary absence or incapacitation, at the request of the Board of Directors.

3. The duties of the Treasurer shall be as follows:
   a. Perform the duties customary to that office;
   b. Perform such other duties as the Bylaws and custom and parliamentary usage may require or as the Board of Directors shall deem appropriate;
   c. Serve as an ex officio member of the Audit Committee; and
   d. Serve as chair of the Finance Committee.

4. The duties of the Secretary shall be as follows:
   a. Administer the affairs of the FSMB; and
   b. Such duties and responsibilities as the FSMB and the Board of Directors shall determine.
SECTION D. TERMS OF OFFICE AND SUCESSION

1. The Chair and Chair-elect shall serve for single terms of one year or until their successors assume office.

2. The Treasurer shall serve for a single term of three years or until the Treasurer’s successor assumes the office.

3. Officers shall assume office upon final adjournment of the Annual Meeting of the House of Delegates at which they were elected.

4. The term of the Secretary is co-terminus with that of the President.

SECTION E. VACANCIES

1. In the event of a vacancy in the office of the Chair, the Chair-elect shall assume the position of Chair for the remainder of the unexpired term, and shall then serve a full one-year term as Chair.

2. In the event of a vacancy in the office of the Chair-elect, the Board of Directors shall appoint a Director-at-Large to assume the duties, but not the office, of Chair-elect for the remainder of the unexpired term. At the next Annual Meeting of the House of Delegates, both a Chair and a Chair-elect shall be elected in accordance with the provisions in Section B of this Article.

3. In the event of a vacancy in the office of the Treasurer, the Board of Directors shall elect one of the Directors-at-Large to serve as Treasurer, with one vote on the Board of Directors and one vote on the Executive Committee, until the next year’s Annual Meeting of the House of Delegates, at which time a Treasurer shall be elected.

ARTICLE IV. BOARD OF DIRECTORS

SECTION A. MEMBERSHIP AND TERMS

1. MEMBERSHIP: The Board of Directors shall be composed of the Officers, the Immediate Past Chair, nine Directors-at-Large and two Associate Members Staff Fellows. At least two members of the Board, who are not Associate Members Staff Fellows, shall be non-physicians, at least one of whom shall be a public/consumer member.

2. NOMINATION OF ASSOCIATE MEMBERS STAFF FELLOWS: Nominations for Associate Member Staff Fellow positions shall be accepted from Member Boards, the Board of Directors and the Administrators in Medicine (AIM). Associate Members Staff Fellows shall be elected
appointed by the Board of Directors in staggered terms in accordance with policies and
procedures established by the Board of Directors.

3. TERMS: Directors-at-Large shall each serve for a term of three years and shall be eligible to be
reelected to one additional term. Staff Fellows shall serve for a term of two years and shall
be eligible to be reappointed to one additional term. A partial term totaling one-and-a-half
years or more shall count as a full term. Associate Members shall each serve for a term of
two years. Associate Members shall not be eligible to serve consecutive terms.

SECTION B. NOMINATIONS
1. The Nominating Committee shall submit a roster of one or more candidates for each of the
offices and positions to be filled by election at the Annual Meeting of the House of Delegates.
2. The Nominating Committee shall mail its roster of candidates to Member Boards not fewer
than 60 days prior to the Annual Meeting of the House of Delegates.

SECTION C. ELECTION OF DIRECTORS-AT-LARGE
1. At least three of the Directors-at-Large shall be elected each year at the Annual Meeting of the
House of Delegates by a majority of the votes cast.
2. If no candidate receives a majority of the votes on the first ballot, and one seat is to be filled, a
runoff election shall be held between the two candidates who received the most votes on the
first ballot.
3. If more than one seat is to be filled from a single list of candidates, and if one or more seats
are not filled by majority vote on the first ballot, a runoff election shall be held, with the ballot
listing candidates equal in number to twice the number of seats remaining to be filled. These
candidates shall be those remaining who received the most votes on the first ballot. The same
procedure shall be used for any required subsequent runoff elections. In the event of a tie vote
in a runoff election up to two additional runoff elections shall be held.
4. Prior to the election, the presiding officer shall cast a sealed vote, ranking each candidate in a
list. The presiding officer’s vote is counted for the candidate in the runoff election who is highest
on the list. The presiding officer’s vote is counted only to resolve a tie that cannot be decided
by the process set forth in this section.
5. Directors shall assume office upon final adjournment of the Annual Meeting of the House of
Delegates at which they were elected.
6. Only an individual who is a Fellow at the time of the individual's election shall be eligible for
election as a Director of the FSMB.

SECTION D. DUTIES OF THE BOARD OF DIRECTORS

1. The control and administration of the FSMB is vested in the Board of Directors and it shall act
for the FSMB between Annual Meetings.

2. The Board of Directors shall carry out the mandates of the FSMB as established by the House
of Delegates, and it shall have full and complete power and authority to perform all acts and to
transact all business for and on behalf of the FSMB.

3. The Board of Directors shall conduct and manage all property, affairs, work and activities of
the FSMB, subject only to the provisions of the Articles of Incorporation and these Bylaws and
to resolutions and enactments of the House of Delegates.

4. The Board of Directors shall be the fiscal agent of the FSMB.

5. The Board of Directors shall establish rules for its operations and meetings.

6. The FSMB shall indemnify Directors, Officers and other individuals acting on behalf of the
FSMB if such indemnification is in accordance with the laws of the State of Nebraska and the
operational policies and procedures of the Board of Directors, as adopted. The Board shall
report to the membership of the FSMB at the Annual Meeting of the House of Delegates.

7. The Board of Directors shall establish a strategic plan for the FSMB that states the FSMB
mission and objectives and shall submit that plan to the House of Delegates for ratification,
modification or rejection. The Board shall review the current strategic plan annually and
propose any amendments to the Annual Meeting of the House of Delegates for ratification,
modification or rejection. The President shall report to the Annual Meeting of the House of
Delegates on the extent to which the FSMB’s stated objectives have been accomplished in the
preceding year.

SECTION E. REMOVAL FROM OFFICE

1. REMOVAL: Any officer or member of the Board of Directors may be removed for any cause
deemed sufficient by an affirmative vote of two-thirds of the total members of the Board of
Directors entitled to vote and who are not subject to removal from office.

2. PROCEDURE: The procedure for removal shall be as follows:
a. The Board shall file with the Secretary of the Board and deliver a written statement of the cause for removal to the officer or board member in sufficient detail as to state the grounds for the removal. Delivery to the officer or member shall be by certified mail, return receipt requested, to the last address known to the Board and is effective upon mailing.

b. The officer or board member shall deliver a sworn written response to the Board no later than thirty calendar days after the written statement is filed with the Secretary of the Board. Delivery to the Board shall be by certified mail, return receipt requested, directed to the Secretary of the Board at the FSMB corporate office. Delivery is effective upon mailing.

c. At the next Board meeting, the Board shall determine whether or not to proceed with removal. Notice of the Board’s action shall be delivered to the officer or Board member by certified mail, return receipt requested. If the officer or board member did not file a written response the Board shall proceed with a determination. Delivery is effective upon mailing.

d. If the Board votes to proceed with removal of the officer or Board member, at a Board meeting held no less than thirty days after delivery of the notice, the Board member shall be afforded the opportunity to address the Board on the merits of the allegations and produce any relevant information to the Board after which the Board shall make a determination.

3. APPEAL: Any officer or member of the Board of Directors removed by the Board of Directors may appeal to the House of Delegates at its next business meeting. The officer or member may be reinstated by a two-thirds vote of the House of Delegates.

SECTION F. VACANCIES

1. DIRECTORS-AT-LARGE: In the event of a vacancy in the membership of the Directors-at-Large, the Board of Directors may appoint a Fellow who meets the qualifications for the position to serve until the next Annual Meeting of the House of Delegates, at which time an individual shall be nominated and, if elected, shall serve for the remainder of the unexpired term. In the event a Director-at-Large is elected to the office of Treasurer or Chair-elect, that vacancy shall be filled by an election at the same Annual Meeting of the House of Delegates.

2. ASSOCIATE MEMBERS STAFF FELLOWS: In the event of a vacancy of an Associate Member’s Staff Fellow, the Board of Directors may appoint a substitute to complete the Associate Member’s Staff Fellow’s term in accordance with the policies established by the Board of Directors.
SECTION G. EXECUTIVE COMMITTEE OF THE BOARD

1. MEMBERSHIP: The Board of Directors shall establish an Executive Committee of the Board, which shall consist of the Chair as Chair, Chair-elect, Treasurer, Immediate Past Chair and two Directors-at-Large. The Directors-at-Large shall be elected for a one-year term by majority vote of the Directors-at-Large and the Associate Members of Staff Fellows serving on the Board of Directors at the first regular meeting of the Board following the annual meeting of the House of Delegates. In the event of a vacancy in a Director-at-large position, the Directors-at-Large and the Associate Members of Staff Fellows serving on the Board, by majority vote, shall choose another Director-at-Large to serve the remainder of the one-year term. A Staff Fellow may serve in one of the Director-at-Large positions. No more than one Staff Fellow may serve on the Executive Committee at any one time. In the event of vacancy in the position of Immediate Past Chair, this position shall remain vacant until the next Annual Meeting of the House of Delegates.

2. DUTIES: In intervals between Board meetings, the Executive Committee shall act for and on behalf of the Board in any matters that require prompt attention. It shall not modify actions previously taken by the Board unless additional information or a change of circumstances is presented and warrants additional action.

3. MEETINGS: The Executive Committee may meet as often as it deems necessary or appropriate, either in person, telephonically, electronically or by unanimous written consent, and at such times and places and manner as the Chair may determine. Minutes must be kept of all meetings.

4. REPORTING: The Executive Committee shall report in writing all formal actions taken by it to the Board of Directors within five working days of taking those actions. At each meeting of the Board, the Executive Committee shall present to the Board a written report of all its formal actions since the previous meeting of the Board.

SECTION H. PUBLIC POLICY STATEMENTS

A “public policy” is defined as the official public position of the FSMB on a matter that may be reasonably expected to affect Member Boards when dealing with their licensees, other health care providers, health-related special interest groups, governmental bodies or the public. The House of Delegates is the official public policy-making body of the FSMB. When the interests of the FSMB require more immediate action, the Board of Directors, or the President in consultation with the
Chair, if feasible, is authorized to issue statements on matters of public policy between Annual Meetings.

**ARTICLE V. NOMINATION BY PETITION FOR BOARD OF DIRECTORS AND NOMINATING COMMITTEE**

**SECTION A. SUBMISSION OF A PETITION**

1. At the time the Nominating Committee’s roster of candidates is distributed to the Member Boards, the Boards will be informed that a Fellow who is qualified for nomination, but not otherwise nominated by the Nominating Committee, may seek to run for a position on the Board of Directors as an Officer or Director-at-Large, or for a position on the Nominating Committee.

2. In order to be placed on the ballot, the Fellow seeking nomination is required to present a petition to Administrative Staff that is signed by at least one Fellow from at least four Member Boards as well as a fellow from the Board of the member seeking nomination.

3. The deadline to submit petitions to the Administrative Staff is 21 days prior to the Annual Meeting.

**SECTION B. VALIDATION AND PLACEMENT ON BALLOT**

1. The Administrative Staff shall verify that all signatures on the petition are valid. “Valid” is defined as the person who is seeking nomination and the persons who signed the petition are Fellows as defined in the FSMB Bylaws.

2. Once verified, the petitions are deemed valid and the candidate is placed on the ballot.

3. The names of those seeking to run by petition whose petitions are deemed valid shall be distributed to the Voting Delegates not fewer than 14 days prior to the Annual Meeting.

4. Once a candidate seeking to run by petition is added to the ballot, the candidate shall be afforded the same privileges and be bound by the same rules in the campaign process as candidates who were nominated by the Nominating Committee.

**ARTICLE VI. PRESIDENT**

The Board of Directors may, by a two-thirds majority vote of the full Board, appoint a President of the FSMB, who shall be a physician, to serve without term. The President shall administer the affairs of the FSMB and shall have such duties and responsibilities as the Board of Directors and
the FSMB shall direct. The President shall serve as Secretary of the FSMB and shall be an ex-officio member, without vote, of the Board of Directors.

ARTICLE VII. MEETINGS

SECTION A. ANNUAL MEETING OF THE HOUSE OF DELEGATES

The annual meeting of the House of Delegates of the FSMB, which shall be called the House of Delegates, shall be held at such time and place as may be fixed by the Board of Directors. Written notice of the time and place of the meeting shall be given to all Member Medical Boards by mail not fewer than 90 days prior to the date of the meeting.

SECTION B. SPECIAL MEETINGS OF THE HOUSE OF DELEGATES

Special meetings of the House of Delegates may be called at any time by the Chair, on the written request of ten Member Medical Boards or by action of the Board of Directors. Written notice of the time and place of such meetings shall be given to all Member Medical Boards by mail not fewer than 30 days prior to the date of the meeting.

SECTION C. RIGHT TO VOTE

1. The right to vote at meetings of the House of Delegates is vested in, and restricted to, Member Medical Boards. Each Member Medical Board is entitled to one vote, said vote to be cast by the delegate of the Member Board. The delegate shall be the president of the Member Medical Board or the President’s designated alternate. In order for a delegate to be permitted to vote, the delegate shall present a letter of appointment to the Secretary of the Board of Directors.

2. All classes of membership shall have the right of the floor at meetings of the House upon request of a delegate and approval of the presiding officer; however, the right to introduce resolutions is restricted to Member Medical Boards and the Board of Directors and the procedure for submission of such resolutions shall be in accordance with FSMB Policy.

SECTION D. QUORUM

A majority of Member Medical Boards shall constitute a quorum at any meeting of the House of Delegates. A majority of the voting members of the Board of Directors or any committee or other constituted group shall constitute a quorum of the Board, committee or group.
SECTION E. RULES OF ORDER

Meetings of the House of Delegates, Board of Directors and all committees shall be conducted in accordance with the *American Institute of Parliamentarians Standard Code of Parliamentary Procedure*, current edition, except when in conflict with the Articles of Incorporation or these Bylaws, in which case the Articles of Incorporation or these Bylaws shall prevail.

ARTICLE VIII. STANDING AND SPECIAL COMMITTEES

SECTION A. STANDING COMMITTEES

1. The Standing Committees of the FSMB shall be:
   a. Audit Committee
   b. Bylaws Committee
   c. Editorial Committee
   d. Education Committee
   e. Ethics and Professionalism Committee
   f. Finance Committee
   g. Nominating Committee

2. ADDITIONAL STANDING COMMITTEES. Additional standing committees may be created by resolution of the FSMB and/or amendment to the Bylaws. Chairs and members of all standing committees, with the exception of the Nominating Committee, shall be appointed by the Chair, with the approval of the Board of Directors, for a term of one year, unless otherwise provided for in these Bylaws. Reappointment, unless specifically prohibited, is permissible.

3. MEMBERSHIP. Honorary Fellows, Associate Members and Courtesy Members may be appointed by the Chair to serve on a standing committee in addition to the number of committee members called for in the following sections of this chapter. No more than one Honorary Fellow, Associate or Courtesy Member or non-member subject matter expert may be appointed by the Chair to serve in such a capacity on any standing committee unless otherwise provided for in these Bylaws. All committee members shall serve with vote. Honorary Fellows, Associate or Courtesy Members, and non-members appointed to standing committees by the Chair shall serve for a term concurrent with the term of the Chair. No individual shall serve on more than one standing committee except as specified in the Bylaws. With the exception of the Nominating Committee and the Editorial Committee, the Chair and the Chair-elect shall serve, ex-officio, on all committees.
4. VACANCIES. In the event a vacancy occurs in an elected position on a standing committee, the Chair, with the approval of the Board of Directors, shall appoint a Fellow to serve on the committee until the next meeting of the House of Delegates, at which time an election will be held to fill the vacant position for the remainder of the unexpired term. In the event a vacancy occurs in an appointed position on a standing committee, the Chair, with the approval of the Board of Directors, shall appoint a Fellow to serve on the committee for the remainder of the unexpired term. In the event the Chairmanship of the Nominating Committee becomes vacant, the FSMB Chair, with the approval of the FSMB Board of Directors, shall appoint a Past Chair of the FSMB Board of Directors to serve in that capacity for the remainder of the unexpired term.

SECTION B. AUDIT COMMITTEE

The Audit Committee shall:

1. Be composed of five Fellows, three of whom shall be members of the Board of Directors. The Treasurer of the FSMB shall serve ex-officio without vote. The Chair of the FSMB shall appoint the Chair of the Audit Committee from one of the three sitting Board Members.

2. Ensure that an annual audit of the financial accounts and records of the FSMB is performed by an independent Certified Public Accounting firm.

3. Recommend to the Board of Directors the appointment, retention or termination of an independent auditor or auditors and develop a schedule for periodic solicitation of audit firms consistent with Board policies and best practices.

4. Oversee the independent auditors. The independent auditors shall report directly to the Committee.

5. Review the audit of the FSMB. Submit such audit and Committee's report to the Board of Directors.

6. Report any suggestions to the Board of Directors on fiscal policy to ensure the continuing financial strength of the FSMB.

7. When the finalized committee report to the Board of Directors is made, suggestions and feedback will be forwarded to the Finance Committee.
SECTION C. BYLAWS COMMITTEE

The Bylaws Committee, composed of five Fellows, shall continually assess the Articles of Incorporation and the Bylaws and shall receive all proposals for amendments thereto. It shall, from time to time, make recommendations to the House of Delegates for changes, deletions, modifications and interpretations thereto.

SECTION D. EDITORIAL COMMITTEE

1. An Editorial Committee, not to exceed twelve Fellows and three non-member subject matter experts, shall advise the Editor-in-Chief on editorial policy for the FSMB’s official publication, and shall serve as the editorial board of that publication and otherwise assist the Editor-in-Chief in the performance of duties as appropriate and necessary. No officer or member of the Board of Directors shall serve on this Committee.

2. Service on the Editorial Committee is by nomination and appointment by the FSMB Chair, subject to approval of the Board of Directors, immediately following the Annual Meeting of the House of Delegates. Candidates are allowed to express their interest in serving on the Committee through self-nomination. Committee members shall serve staggered three-year terms and shall be limited to two full terms.

3. The Editor-in-Chief shall be elected by the Editorial Committee to a three-year term beginning on the date of the annual Editorial Committee meeting, with the Editor-in-Chief’s term on the Editorial Committee being automatically extended to allow the Editor-in-chief to serve for three years. A member of the Editorial Committee whose term is expiring shall continue to serve until the member’s replacement meets at the next annual Editorial Committee meeting.

4. The Editorial Committee will elect its Chair, who will serve as the Editor-in-Chief of the Journal of Medical Regulation. The Editor-in-Chief will serve without compensation and will coordinate decisions on the Journal content, among other duties to be determined by the Bylaws Committee.

SECTION E. EDUCATION COMMITTEE

The Education Committee shall be composed of eight Fellows, to include the Chair as chair, the Immediate Past Chair and the Chair-elect. The Committee shall be responsible for assisting in the development of educational programs for the FSMB.
SECTION F. ETHICS AND PROFESSIONALISM COMMITTEE

The Ethics and Professionalism Committee shall be composed of up to five Fellows and up to two subject matter experts. The Ethics and Professionalism Committee shall address ethical and professional issues pertinent to medical regulation.

SECTION G. FINANCE COMMITTEE

The Finance Committee shall be composed of five Fellows, to include the Treasurer as Chair. The Finance Committee shall review the financial condition of the FSMB, review and evaluate the costs of the activities and programs to be undertaken in the forthcoming year, present a budget for the FSMB to the Board of Directors for its recommendation to the House of Delegates at the Annual Meeting and perform such other duties as are assigned to it by the Board of Directors. Except for the Treasurer, no Fellow shall serve on both the Audit and Finance Committees.

SECTION H. NOMINATING COMMITTEE: PROCESS FOR ELECTION

1. MEMBERSHIP: The Nominating Committee shall be composed of six Fellows and the Immediate Past Chair, who shall chair the Committee and serve without vote except in the event of a tie. At least one elected member of the Nominating Committee shall be a public member. With the exception of the Immediate Past Chair, no two Committee members shall be from the same member board and no officer or member of the Board of Directors shall serve on the Committee. A member of the Nominating Committee may not serve consecutive terms.

2. ELECTION: At least three Fellows shall be elected at each Annual Meeting of the House of Delegates by a plurality of votes cast, each to serve for a term of two years. Only an individual who is a Fellow at the time of the individual’s election shall be eligible for election as a member of the Nominating Committee. In the event of a tie vote in a runoff election, up to two additional runoff elections shall be held. Prior to the election, the presiding officer shall cast a sealed vote, ranking each candidate in a list. The presiding officer’s vote is counted for the candidate in the runoff election who is highest on the list. The presiding officer’s vote is counted only to resolve a tie that cannot be decided by the process set forth in this section.

3. Members of the Nominating Committee are not eligible for inclusion on the roster of candidates for offices and positions to be filled by election at the Annual Meeting of the House of Delegates.
SECTION I. SPECIAL COMMITTEES

Special committees may be appointed by the Chair, from time to time, as may be necessary for a specific purpose.

SECTION J. REPRESENTATIVES TO OTHER ORGANIZATIONS AND ENTITIES

Appointment of all representatives of the FSMB to other official organizations or entities shall be made or nominated by the Chair, with the approval of the Board of Directors, as applicable, and shall serve for a term of three years unless the other organization shall specify some other term of appointment. Representatives to these organizations shall be Fellows, Honorary Fellows, Associate Members or Courtesy Members at the time of their appointment or nomination.

ARTICLE IX. UNITED STATES MEDICAL LICENSING EXAMINATION (USMLE)

SECTION A. Except as otherwise set forth in this Article, the composition of committees and subcommittees for the USMLE are subject to agreements with and the advice and consent of the National Board of Medical Examiners (NBME) and/or the USMLE Composite Committee. The Chair, with the approval of the Board of Directors, shall make appointments to the following USMLE committees in appropriate numbers and at appropriate times as required by the FSMB/NBME Agreement establishing the USMLE and by other agreements as may apply:

1. USMLE Composite Committee, which shall be responsible for the development, operation and maintenance of policies governing the three-step USMLE. The President shall be one of the FSMB’s representatives on this Committee.

2. USMLE Budget Committee, which shall be responsible for the development and monitoring of USMLE revenues and expenses, including the establishment of fees. FSMB representatives on the Committee will be the Chair, Chair-elect, Treasurer, President and the senior FSMB financial staff member.

3. The USMLE Management Committee shall be responsible for overseeing the design, development, scoring and standard setting for the USMLE Step examinations, subject to policies established by and reporting to the USMLE Composite Committee. Appointments to the Management Committee shall be made consistent with the FSMB/NBME Agreement Establishing the USMLE.
SECTION B. The President shall provide FSMB advice and consent to the NBME for NBME’s appointments to the USMLE Management Committee and/or any appointments made jointly under the FSMB/NBME Agreement Establishing the USMLE.

ARTICLE X. POST-LICENSEURE ASSESSMENT SYSTEM

The Post-Licensure Assessment Governing Committee shall be responsible for the development, operation and maintenance of policies governing the Post-Licensure Assessment System (PLAS) established by joint agreement between FSMB and NBME. The Chair, with the approval of the Board of Directors, shall make appointments to the Post-Licensure Assessment Governing Committee and its program committees in appropriate numbers and at appropriate times as required by the FSMB/NBME joint agreement establishing the Post-Licensure Assessment System and by other agreements as may apply.

ARTICLE XI. FINANCES AND DUES

SECTION A. SOURCES OF FUNDS

Funds necessary for the conduct of the affairs of the FSMB shall be derived from but not be limited to:

1. Annual dues imposed on the Member Medical Boards, Affiliate Members, Courtesy Members and Official Observers;
2. Special assessments established by the House of Delegates;
3. Voluntary contributions, devices, bequests and other gifts;
4. Fees charged for examination services, data base services, credentials verification services and publications.

SECTION B. ANNUAL DUES, ELIGIBILITY TO SERVE AS A DELEGATE

The annual dues for Member Medical Boards shall be established, from time to time, by a majority vote of the House of Delegates.

1. Annual dues for Member Medical Boards shall be the same for all Members regardless of their physician populations. Annual dues are due and payable not later than January 1.
2. Any Member Medical Board whose dues are in default at the time of the Annual Meeting of the House of Delegates shall be ineligible to have a seated delegate.
ARTICLE XII. DISCIPLINARY ACTION

SECTION A. MEMBER

For the purposes of this Article, a member shall be defined as a Member Medical Board, a Fellow, an Honorary Fellow, an Associate Member, an Affiliate Member, Courtesy Member or Official Observer.

SECTION B. AUTHORIZATION

The Board of Directors, on behalf of the House of Delegates, may enforce disciplinary measures, including expulsion, suspension, censure and reprimand, and impose terms and conditions of probation or such sanctions as it may deem appropriate, for any of the following reasons:

1. Failure of the member to comply or act in accordance with these Bylaws, the Articles of Incorporation of the FSMB, or other duly adopted rules or regulations of the FSMB;

2. Failure of the member to comply with any contract or agreement between the FSMB and such member or with any contract or agreement of the FSMB that binds such member;

3. Failure of the member to maintain confidentiality or security, or the permitting of conditions that allow a breach of confidentiality or security, in any manner dealing with the licensing examination process or the confidentiality of FSMB records, including the storage, administration, grading or reporting of examinations and information relating to the examination process; or

4. The imposition of a sanction, judgment, disciplinary penalty or other similar action by a Member Medical Board that licenses the member or by a state or federal court, or other competent tribunal, whether or not related to the practice of medicine and including conduct as a member of a Member Medical Board.

SECTION C. PROCEDURE

Any member alleged to have acted in such manner as to be subject to disciplinary action shall be accorded, at a minimum, the procedural protection set forth in the Manual for Disciplinary Procedures, which is available from the FSMB upon the written request of any member.

SECTION D. REINSTATEMENT

In the event a member is suspended or expelled from the FSMB, the member may apply to the President for reinstatement after one year following final action on expulsion. The President shall review the application and the reason for the suspension or expulsion and forward a report to the
Board. The Board may accept application for reinstatement under such terms and conditions as it may deem appropriate, reject the application or request further information from the President. The Board’s decision to accept or reject an application is final.

ARTICLE XIII. CORPORATE SEAL

The Board of Directors shall adopt a corporate seal that meets the requirements of the state in which the FSMB is incorporated.

ARTICLE XIV. ADOPTION AND AMENDMENT OF BYLAWS, EFFECTIVE DATE

SECTION A. AMENDMENT

These Bylaws may be amended at any annual meeting of the House of Delegates by two-thirds of those present and voting. Bylaws changes may be proposed only by the Board of Directors, Member Medical Boards or the Bylaws Committee. All such proposals must be submitted in writing to the Bylaws Committee, in care of the Secretary of the FSMB. The Bylaws Committee shall inform the Member Medical Boards of its meeting dates not fewer than 60 days in advance of the meeting. The recommendations of the Bylaws Committee and the full texts of all proposed amendments recommended to the Committee shall be sent to each Member Medical Board not fewer than 60 days prior to the Annual Meeting of the House of Delegates at which they are to be considered.

SECTION B. EFFECTIVE DATE

These Bylaws and any other subsequent amendments thereto, shall become effective upon their adoption, except as otherwise provided herein.

Bylaws last amended in April 2017
ARTICLE I. NAME
The corporation shall be known as the Federation of State Medical Boards of the United States, Inc. (“FSMB”).

ARTICLE II. CLASSES OF MEMBERSHIP, ELECTION AND MEMBERSHIP RIGHTS

SECTION A. MEMBER MEDICAL BOARDS
The term “Member Medical Board” as used in the Articles of Incorporation and in these Bylaws shall refer to any board, committee or other group in any state, territory, the District of Columbia or possession of the United States of America that is empowered by law to pass on the qualifications of applicants for licensure to practice allopathic or osteopathic medicine or to discipline such licensees. If a state or other jurisdiction has more than one such entity and if each is an independent agency unrelated to the others, each is eligible for membership. Any eligible Medical Board may become a Member Medical Board upon approval of its application by the Board of Directors.

SECTION B. FELLOWS
An individual member who as a result of appointment or confirmation is designated to be a member of a Member Medical Board shall be a Fellow of the FSMB during the member’s period of service on a Member Medical Board, and for a period of 36 thirty-six months thereafter.

SECTION C. HONORARY FELLOWS
Thirty-six months after completion of service on a Member Medical Board, a Fellow shall become an Honorary Fellow of the FSMB and may be appointed by the Chair to serve as a member of any committee or in any other appointive capacity.

SECTION D. ASSOCIATE MEMBERS
A Member Medical Board may designate one or more employees or staff members to be an Associate Member of the FSMB. No Associate Member shall continue in that capacity upon termination of employment by or service to the Member Medical Board.
SECTION E. COURTESY MEMBERS

Any physician or physician assistant licensed by a Member Medical Board or an Affiliate Member Board and not eligible for any other type of membership may become a Courtesy Member of the FSMB upon approval of the candidate’s application. A Courtesy Member may serve as a member of a committee and in any other capacity upon appointment by the Chair.

SECTION F. AFFILIATE MEMBERS BOARDS

A board or authority that is not otherwise eligible for membership may become an Affiliate Member Board of the FSMB upon approval of its application by the Board of Directors if the board or authority licenses either:

1. Allopathic or osteopathic physicians or physician assistants in the United States; or
2. Allopathic or osteopathic physicians if the board or authority is located in another country.

SECTION G. OFFICIAL OBSERVERS

An organization may apply for Official Observer status at meetings of the House of Delegates. The Board of Directors shall prescribe rules and procedures to govern the application for, the granting of and the exercise of Official Observer status.

SECTION H. RIGHTS OF MEMBERS

Except as otherwise provided in these Bylaws, rights, duties, privileges and obligations of a member of the FSMB may be exercised only by a Member Medical Board.

SECTION I. METHODS OF NOMINATION TO ELECTED OFFICE

Nomination by the Nominating Committee or Nomination by Petition pursuant to Articles III, IV, V and VIII shall be the sole methods of nomination to an elected office of the FSMB. A candidate who runs for and is not elected to an elected office shall be ineligible to be nominated for any other elected office during the same election cycle.

ARTICLE III. OFFICERS: ELECTION AND DUTIES

SECTION A. OFFICERS OF THE FSMB

1. OFFICERS. The officers of the FSMB shall be that of Chair, Chair-elect, Immediate Past Chair, Treasurer and Secretary.
2. Only an individual who is a Fellow at the time of the individual’s election or appointment shall be eligible for election or appointment as an Officer of the FSMB, except for the position of Secretary.

3. The position of Secretary shall be an ex-officio office, without vote, and the President of the FSMB shall serve as Secretary.

SECTION B. ELECTION OF OFFICERS

1. The Chair-elect shall ascend to the position of Chair at the Annual Meeting following the meeting in which the Chair-elect was elected.

2. The Chair-elect shall be elected at each Annual Meeting of the House of Delegates.

3. The Immediate Past Chair assumes that position upon the Chair-elect ascending to the position of Chair.

4. The Treasurer shall be elected every third year at the Annual Meeting of the House of Delegates.

5. Officers shall be elected by a majority of the members of the House of Delegates present and voting.

6. In any election, should no candidate receive a majority of the votes cast, a runoff election shall be held between the two candidates who receive the most votes for that office on the first ballot. Up to two additional runoff elections shall be held.

7. Prior to each election, the presiding officer shall cast a sealed vote that shall be counted only to resolve a tie that cannot be decided by the process set forth in this section.

SECTION C. DUTIES OF OFFICERS

1. The duties of the Chair shall be as follows:
   a. Preside at all meetings and sessions of the House of Delegates and the Board of Directors;
   b. Perform the duties customary to the office of the Chair;
   c. Make appointments to committees and define duties of committee members in accordance with these Bylaws, except as otherwise provided herein;
   d. Serve, ex officio, on all committees except as otherwise provided herein; and
e. Exercise such other rights and customs as the Bylaws and parliamentary usage may require or as the FSMB or the Board of Directors shall deem appropriate.

2. The duties of the Chair-elect shall be as follows:
   a. Assist the Chair in the discharge of the Chair’s duties; and
   b. Perform the duties of the Chair at the Chair’s request or, in the event of the Chair’s temporary absence or incapacitation, at the request of the Board of Directors.

3. The duties of the Immediate Past Chair shall be as follows:
   a. Assist the Chair in the transition from Chair-elect to Chair;
   b. Serve as chair of the Nominating Committee; and
   c. Perform such other duties and responsibilities as the Chair shall determine.

4. The duties of the Treasurer shall be as follows:
   a. Perform the duties customary to that office;
   b. Perform such other duties as the Bylaws and custom and parliamentary usage may require or as the Board of Directors shall deem appropriate;
   c. Serve as an ex officio member of the Audit Committee; and
   d. Serve as chair of the Finance Committee.

5. The duties of the Secretary shall be as follows:
   a. Administer the affairs of the FSMB; and
   b. Such duties and responsibilities as the FSMB and the Board of Directors shall determine.

SECTION D. TERMS OF OFFICE AND SUCESSION

1. The Chair and Chair-elect shall serve for single terms of one year or until their successors assume office.

2. The Immediate Past Chair shall serve until a successor to the current Chair assumes office.

3. The Treasurer shall serve for a single term of three years or until the Treasurer’s successor assumes the office.
3. Officers shall assume office upon final adjournment of the Annual Meeting of the House of Delegates at which they were elected.

4. The term of the Secretary is co-terminus with that of the President.

SECTION E. VACANCIES

1. In the event of a vacancy in the office of the Chair, the Chair-elect shall assume the position of Chair for the remainder of the unexpired term, and shall then serve a full one-year term as Chair.

2. In the event of a vacancy in the office of the Chair-elect, the Board of Directors shall appoint a Director-at-Large to assume the duties, but not the office, of Chair-elect for the remainder of the unexpired term. At the next Annual Meeting of the House of Delegates, both a Chair and a Chair-elect shall be elected in accordance with the provisions in Section B of this Article.

3. In the event of a vacancy in the office of Immediate Past Chair, the office shall remain open until a new Chair assumes the office.

4. In the event of a vacancy in the office of the Treasurer, the Board of Directors shall elect one of the Directors-at-Large to serve as Treasurer, with one vote on the Board of Directors and one vote on the Executive Committee, until the next year’s Annual Meeting of the House of Delegates, at which time a Treasurer shall be elected.

ARTICLE IV. BOARD OF DIRECTORS

SECTION A. MEMBERSHIP AND TERMS

1. Membership: The Board of Directors shall be composed of the Officers, the Immediate Past Chair, nine Directors-at-Large and two Associate Members. At least two members of the Board, who are not Associate Members, shall be non-physicians, at least one of whom shall be a public/consumer member.

2. Nomination of Associate Members: Nominations for Associate Member positions shall be accepted from Member Boards, the Board of Directors and Administrators in Medicine (AIM). Associate Members shall be elected by the Board of Directors in staggered terms in accordance with policies and procedures established by the Board of Directors.
3. TERMS: Directors-at-Large shall each serve for a term of three years and shall be eligible to be reelected to one additional term. A partial term totaling one-and-a-half years or more shall count as a full term. Associate Members shall each serve for a term of two years. Associate Members shall not be eligible to serve consecutive terms.

SECTION B. NOMINATIONS

1. The Nominating Committee shall submit a roster of one or more candidates for each of the offices and positions to be filled by election at the Annual Meeting of the House of Delegates.

2. The Nominating Committee shall mail its roster of candidates to Member Boards not fewer than 60 sixty days prior to the Annual Meeting of the House of Delegates.

SECTION C. ELECTION OF DIRECTORS-AT-LARGE

1. At least three of the Directors-at-Large shall be elected each year at the Annual Meeting of the House of Delegates by a majority of the votes cast.

2. If no candidate receives a majority of the votes on the first ballot, and one seat is to be filled, a runoff election shall be held between the two candidates who received the most votes on the first ballot.

3. If more than one seat is to be filled from a single list of candidates, and if one or more seats are not filled by majority vote on the first ballot, a runoff election shall be held, with the ballot listing candidates equal in number to twice the number of seats remaining to be filled. These candidates shall be those remaining who received the most votes on the first ballot. The same procedure shall be used for any required subsequent runoff elections. In the event of a tie vote in a runoff election up to two additional runoff elections shall be held.

4. Prior to the election, the presiding officer shall cast a sealed vote, ranking each candidate in a list. The presiding officer’s vote is counted for the candidate in the runoff election who is highest on the list. The presiding officer’s vote is counted only to resolve a tie that cannot be decided by the process set forth in this section.

5. Directors shall assume office upon final adjournment of the Annual Meeting of the House of Delegates at which they were elected.

6. Only an individual who is a Fellow at the time of the individual’s election shall be eligible for election as a Director of the FSMB.
SECTION D. DUTIES OF THE BOARD OF DIRECTORS

1. The control and administration of the FSMB is vested in the Board of Directors and it shall act for the FSMB between Annual Meetings.

2. The Board of Directors shall carry out the mandates of the FSMB as established by the House of Delegates, and it shall have full and complete power and authority to perform all acts and to transact all business for and on behalf of the FSMB.

3. The Board of Directors shall conduct and manage all property, affairs, work and activities of the FSMB, subject only to the provisions of the Articles of Incorporation and these Bylaws, and to resolutions and enactments of the House of Delegates.

4. The Board of Directors shall be the fiscal agent of the FSMB.

5. The Board of Directors shall establish rules for its operations and meetings.

6. The FSMB shall indemnify Directors, Officers and other individuals acting on behalf of the FSMB if such indemnification is in accordance with the laws of the State of Nebraska and the operational policies and procedures of the Board of Directors, as adopted. The Board shall report to the membership of the FSMB at the Annual Meeting of the House of Delegates.

7. The Board of Directors shall establish a strategic plan for the FSMB that states the FSMB mission and objectives and shall submit that plan to the House of Delegates for ratification, modification or rejection. The Board shall review the current strategic plan annually and propose any amendments to the Annual Meeting of the House of Delegates for ratification, modification or rejection. The President shall report to the Annual Meeting of the House of Delegates on the extent to which the FSMB’s stated objectives have been accomplished in the preceding year.

SECTION E. REMOVAL FROM OFFICE

1. REMOVAL: Any officer or member of the Board of Directors may be removed for any cause deemed sufficient by an affirmative vote of two-thirds of the total members of the Board of Directors entitled to vote and who are not subject to removal from office.

2. PROCEDURE: The procedure for removal shall be as follows:

   a. The Board shall file with the Secretary of the Board and deliver a written statement of the cause for removal to the officer or board member in sufficient detail as to state the grounds
for the removal. Delivery to the officer or board member shall be by certified mail, return receipt requested, to the last address known to the Board and is effective upon mailing.

b. The officer or board member shall deliver a sworn written response to the Board, no later than thirty calendar days after the written statement of the cause for removal is filed with the Secretary of the Board delivered to the officer or board member in question. Delivery to the Board shall be by certified mail, return receipt requested, directed to the Secretary of the Board at the FSMB corporate office. Delivery is effective upon mailing.

c. At the next Board meeting following the date the response is due, the Board shall determine whether or not to proceed with removal. Notice of the Board’s action shall be delivered to the officer or board member by certified mail, return receipt requested. If the officer or board member did does not file a written response the Board shall proceed with a determination. Delivery is effective upon mailing.

d. If the Board votes to proceed with removal of the officer or board member, at a Board meeting held no less than thirty days after delivery of the notice, the board member shall be afforded the opportunity to address the Board on the merits of the allegations and produce any relevant information to the Board after which the Board shall make a determination. The Board meeting at which the officer or board member has the opportunity to address the Board shall be held no less than thirty days after delivery of the notice of removal.

3. APPEAL: Any officer or member of the Board of Directors removed by the Board of Directors may appeal to the House of Delegates at its next business meeting. The officer or member may be reinstated by a two-thirds vote of the House of Delegates.

4. Delivery. For the purposes of this section, “Delivery” is effective upon mailing.

SECTION F. VACANCIES

1. DIRECTORS-AT-LARGE: In the event of a vacancy in the membership of the Directors-at-Large, the Board of Directors may appoint a Fellow who meets the qualifications for the position to serve until the next Annual Meeting of the House of Delegates, at which time an individual a Fellow shall be nominated and, if elected, and shall serve for the remainder of the unexpired term. In the event a Director-at-Large is elected to the office of Treasurer or Chair-elect, that vacancy shall be filled by an election at the same Annual Meeting of the House of Delegates.
2. **ASSOCIATE MEMBERS:** In the event of a vacancy of an Associate Member, the Board of Directors may appoint a substitute to complete the Associate Member’s term in accordance with the policies established by the Board of Directors.

**SECTION G. EXECUTIVE COMMITTEE OF THE BOARD**

1. **MEMBERSHIP:** The Board of Directors shall establish an Executive Committee of the Board, which shall consist of the Chair as Chair, Chair-elect, Treasurer, Immediate Past Chair and **two** Directors-at-Large. The Directors-at-Large shall be elected for a one-year term by majority vote of the Directors-at-Large and the Associate Members of the Board of Directors at the first regular meeting of the Board following the Annual Meeting of the House of Delegates. In the event of a vacancy in a Director-at-Large position, the Directors-at-Large and the Associate Members of the Board, by majority vote, shall choose another Director-at-Large to serve the remainder of the one-year term. In the event of vacancy in the position of Immediate Past Chair, this position shall remain vacant until the next Annual Meeting of the House of Delegates.

2. **DUTIES:** In intervals between Board meetings, the Executive Committee shall act for and on behalf of the Board in any matters that require prompt attention. It shall not modify actions previously taken by the Board unless additional information or a change of circumstances is presented and warrants additional action.

3. **MEETINGS:** The Executive Committee may meet as often as it deems necessary or appropriate, either in person, telephonically, electronically or by unanimous written consent, and at such times and places and manner as the Chair may determine. Minutes must be kept of all meetings.

4. **REPORTING:** The Executive Committee shall report in writing all formal actions taken by it to the Board of Directors within five working days of taking those actions. At each meeting of the Board, the Executive Committee shall present to the Board a written report of all its formal actions since the previous meeting of the Board.

**SECTION H. PUBLIC POLICY STATEMENTS**

A “public policy” is defined as the official public position of the FSMB on a matter that may be reasonably expected to affect Member Boards when dealing with their licensees, other health care providers, health-related special interest groups, governmental bodies or the public. The House
of Delegates is the official public policy-making body of the FSMB. When the interests of the FSMB require more immediate action, the Board of Directors, or the President in consultation with the Chair, if feasible, is authorized to issue statements on matters of public policy between Annual Meetings.

ARTICLE V. NOMINATION BY PETITION FOR BOARD OF DIRECTORS AND NOMINATING COMMITTEE

SECTION A. SUBMISSION OF A PETITION

1. At the time the Nominating Committee’s roster of candidates is distributed to the Member Boards, the Boards will be informed that a Fellow who is qualified for nomination, but not otherwise nominated by the Nominating Committee, may seek to run for a position on the Board of Directors as an Officer or Director-at-Large, or for a position on the Nominating Committee.

2. In order to be placed on the ballot, the Fellow seeking nomination is required to present a petition to Administrative Staff that is signed by at least one Fellow from at least four Member Boards as well as a fellow from the Board of the member seeking nomination.

3. The deadline to submit petitions to the Administrative Staff is twenty-one days prior to the Annual Meeting.

SECTION B. VALIDATION AND PLACEMENT ON BALLOT

1. The Administrative Staff shall verify that all signatures on the petition are valid. “Valid” is defined as the person who is seeking nomination and the persons who signed the petition are Fellows as defined in the FSMB Bylaws.

2. Once verified, the petitions are deemed valid and the candidate is placed on the ballot.

3. The names of those seeking to run by petition whose petitions are deemed valid shall be distributed to the Voting Delegates not fewer than fourteen days prior to the Annual Meeting.

4. Once a candidate seeking to run by petition is added to the ballot, the candidate shall be afforded the same privileges and be bound by the same rules in the campaign process as candidates who were nominated by the Nominating Committee.
ARTICLE VI. PRESIDENT

The Board of Directors may, by a two-thirds majority vote of the full Board, appoint a President of the FSMB, who shall be a physician, to serve without term. The President shall administer the affairs of the FSMB and shall have such duties and responsibilities as the Board of Directors and the FSMB shall direct. The President shall serve as Secretary of the FSMB and shall be an ex-officio member, without vote, of the Board of Directors.

ARTICLE VII. MEETINGS

SECTION A. ANNUAL MEETING OF THE HOUSE OF DELEGATES

The annual meeting of the House of Delegates of the FSMB, which shall be called the House of Delegates, shall be held at such time and place as may be fixed by the Board of Directors. Written notice of the time and place of the meeting shall be given to all Member Medical Boards by mail not fewer than 90 ninety days prior to the date of the meeting. Notice is effective upon mailing.

SECTION B. SPECIAL MEETINGS OF THE HOUSE OF DELEGATES

Special meetings of the House of Delegates may be called at any time by the Chair, on the written request of ten Member Medical Boards or by action of the Board of Directors. Written notice of the time and place of such meetings shall be given to all Member Medical Boards by mail not fewer than 30 thirty days prior to the date of the meeting. Notice is effective upon mailing.

SECTION C. RIGHT TO VOTE

1. The right to vote at meetings of the House of Delegates is vested in, and restricted to, Member Medical Boards. Each Member Medical Board is entitled to one vote, said vote to be cast by the delegate of the Member Board. The delegate shall be the president of the Member Medical Board or the President’s designated alternate. In order for a delegate to be permitted to vote, the delegate shall present a letter of appointment to the Secretary of the Board of Directors.

2. All classes of membership shall have the right of the floor at meetings of the House upon request of a delegate and approval of the presiding officer; however, the right to introduce resolutions is restricted to Member Medical Boards and the Board of Directors and the procedure for submission of such resolutions shall be in accordance with FSMB Policy.
SECTION D. QUORUM

A majority of Member Medical Boards shall constitute a quorum at any meeting of the House of Delegates. A majority of the voting members of the Board of Directors or any committee or other constituted group shall constitute a quorum of the Board, committee or group.

SECTION E. RULES OF ORDER

Meetings of the House of Delegates, Board of Directors and all committees shall be conducted in accordance with the *American Institute of Parliamentarians Standard Code of Parliamentary Procedure*, current edition, except when in conflict with the Articles of Incorporation or these Bylaws, in which case the Articles of Incorporation or these Bylaws shall prevail.

ARTICLE VIII. STANDING AND SPECIAL COMMITTEES

SECTION A. STANDING COMMITTEES

1. The Standing Committees of the FSMB shall be:
   a. Audit Committee
   b. Bylaws Committee
   c. Editorial Committee
   d. Education Committee
   e. Ethics and Professionalism Committee
   f. Finance Committee
   g. Nominating Committee

2. ADDITIONAL STANDING COMMITTEES. Additional standing committees may be created by resolution of the FSMB and/or amendment to the Bylaws. Chairs and members of all standing committees, with the exception of the Nominating Committee, shall be appointed by the Chair, with the approval of the Board of Directors, for a term of one year, unless otherwise provided for in these Bylaws. Reappointment, unless specifically prohibited, is permissible.

3. MEMBERSHIP. Honorary Fellows, Associate Members and Courtesy Members may be appointed by the Chair to serve on a standing committee in addition to the number of committee members called for in the following sections of this chapter. No more than one Honorary Fellow, Associate or Courtesy Member or non-member subject matter expert may be appointed by the Chair to serve in such a capacity on any standing committee unless otherwise
provided for in these Bylaws. All committee members shall serve with vote. Honorary Fellows, Associate or Courtesy Members, and non-members appointed to standing committees by the Chair shall serve for a term concurrent with the term of the Chair. No individual shall serve on more than one standing committee except as specified in the Bylaws. With the exception of the Nominating Committee and the Editorial Committee, the Chair and the Chair-elect shall serve, ex-officio, on all committees.

4. VACANCIES. In the event a vacancy occurs in an elected position on a standing committee, the Chair, with the approval of the Board of Directors, shall appoint a Fellow to serve on the committee until the next meeting of the House of Delegates, at which time an election will be held to fill the vacant position for the remainder of the unexpired term. In the event a vacancy occurs in an appointed position on a standing committee, the Chair, with the approval of the Board of Directors, shall appoint a Fellow to serve on the committee for the remainder of the unexpired term. In the event the Chairmanship of the Nominating Committee becomes vacant, the FSMB Chair, with the approval of the FSMB Board of Directors, shall appoint a Past Chair of the FSMB Board of Directors to serve in that capacity for the remainder of the unexpired term.

SECTION B. AUDIT COMMITTEE

The Audit Committee shall:

1. Be composed of five Fellows, three of whom shall be members of the Board of Directors. The Treasurer of the FSMB shall serve ex-officio without vote. The Chair of the FSMB shall appoint the Chair of the Audit Committee from one of the three sitting Board Members.

2. Ensure that an annual audit of the financial accounts and records of the FSMB is performed by an independent Certified Public Accounting firm.

3. Recommend to the Board of Directors the appointment, retention or termination of an independent auditor or auditors and develop a schedule for periodic solicitation of audit firms consistent with Board policies and best practices.

4. Oversee the independent auditors. The independent auditors shall report directly to the Committee.

5. Review the audit of the FSMB. Submit such audit and Committee’s report to the Board of Directors.
6. Report any suggestions to the Board of Directors on fiscal policy to ensure the continuing financial strength of the FSMB.

7. When the finalized committee report to the Board of Directors is made, suggestions and feedback will be forwarded to the Finance Committee.

SECTION C. BYLAWS COMMITTEE

The Bylaws Committee, composed of five Fellows, shall continually assess the Articles of Incorporation and the Bylaws and shall receive all proposals for amendments thereto. It shall, from time to time, make recommendations to the House of Delegates for changes, deletions, modifications and interpretations thereto.

SECTION D. EDITORIAL COMMITTEE

1. An Editorial Committee, not to exceed twelve Fellows and three non-member subject matter experts, shall advise the Editor-in-Chief on editorial policy for the FSMB’s official publication, and shall serve as the editorial board of that publication and otherwise assist the Editor-in-Chief in the performance of duties as appropriate and necessary. No officer or member of the Board of Directors shall serve on this Committee.

2. Service on the Editorial Committee is by nomination and appointment by the FSMB Chair, subject to approval of the Board of Directors, immediately following the Annual Meeting of the House of Delegates. Candidates are allowed to express their interest in serving on the Committee through self-nomination. Committee members shall serve staggered three-year terms and shall be limited to two full terms.

3. The Editor-in-Chief shall be elected by the Editorial Committee to a three-year term beginning on the date of the annual Editorial Committee meeting, with the Editor-in-Chief’s term on the Editorial Committee being automatically extended to allow the Editor-in-chief to serve for three years. A member of the Editorial Committee whose term is expiring shall continue to serve until the member’s replacement meets at the next annual Editorial Committee meeting.

4. The Editorial Committee will elect its Chair, who will serve as the Editor-in-Chief of the Journal of Medical Regulation. The Editor-in-Chief will serve without compensation and will coordinate decisions on the Journal content, among other duties to be determined by the Bylaws Committee.
SECTION E. EDUCATION COMMITTEE

The Education Committee shall be composed of eight Fellows, to include the Chair as chair, the Immediate Past Chair and the Chair-elect. The Committee shall be responsible for assisting in the development of educational programs for the FSMB.

SECTION F. ETHICS AND PROFESSIONALISM COMMITTEE

The Ethics and Professionalism Committee shall be composed of up to five Fellows and up to two subject matter experts. The Ethics and Professionalism Committee shall address ethical and professional issues pertinent to medical regulation.

SECTION G. FINANCE COMMITTEE

The Finance Committee shall be composed of five Fellows, to include the Treasurer as Chair. The Finance Committee shall review the financial condition of the FSMB, review and evaluate the costs of the activities and programs to be undertaken in the forthcoming year, present a budget for the FSMB to the Board of Directors for its recommendation to the House of Delegates at the Annual Meeting and perform such other duties as are assigned to it by the Board of Directors. Except for the Treasurer, no Fellow shall serve on both the Audit and Finance Committees.

SECTION H. NOMINATING COMMITTEE: PROCESS FOR ELECTION

1. MEMBERSHIP: The Nominating Committee shall be composed of six Fellows and the Immediate Past Chair, who shall chair the Committee and serve without vote except in the event of a tie. At least one elected member of the Nominating Committee shall be a public member. With the exception of the Immediate Past Chair, no two Committee members shall be from the same member board and no officer or member of the Board of Directors shall serve on the Committee. A member of the Nominating Committee may not serve consecutive terms.

2. ELECTION: At least three Fellows shall be elected at each Annual Meeting of the House of Delegates by a plurality of votes cast, each to serve for a term of two years. Only an individual who is a Fellow at the time of the individual’s election shall be eligible for election as a member of the Nominating Committee. In the event of a tie vote in a runoff election, up to two additional runoff elections shall be held. Prior to the election, the presiding officer shall cast a sealed vote, ranking each candidate in a list. The presiding officer’s vote is counted for the candidate in the runoff election who is highest on the list. The presiding officer’s vote is counted only to resolve a tie that cannot be decided by the process set forth in this section.
3. Members of the Nominating Committee are not eligible for inclusion on the roster of candidates for offices and positions to be filled by election at the Annual Meeting of the House of Delegates.

SECTION I. SPECIAL COMMITTEES

Special committees may be appointed by the Chair, from time to time, as may be necessary for a specific purpose.

SECTION J. REPRESENTATIVES TO OTHER ORGANIZATIONS AND ENTITIES

Appointment of all representatives of the FSMB to other official organizations or entities shall be made or nominated by the Chair, with the approval of the Board of Directors, as applicable, and shall serve for a term of three years unless the other organization shall specify some other term of appointment. Representatives to these organizations shall be Fellows, Honorary Fellows, Associate Members or Courtesy Members at the time of their appointment or nomination.

ARTICLE IX. UNITED STATES MEDICAL LICENSING EXAMINATION (USMLE)

SECTION A. Except as otherwise set forth in this Article, the composition of committees and subcommittees for the USMLE are subject to agreements with and the advice and consent of the National Board of Medical Examiners (NBME) and/or the USMLE Composite Committee. The Chair, with the approval of the Board of Directors, shall make appointments to the following USMLE committees in appropriate numbers and at appropriate times as required by the FSMB/NBME Agreement establishing the USMLE and by other agreements as may apply:

1. USMLE Composite Committee, which shall be responsible for the development, operation and maintenance of policies governing the three-step USMLE. The President shall be one of the FSMB’s representatives on this Committee.

2. USMLE Budget Committee, which shall be responsible for the development and monitoring of USMLE revenues and expenses, including the establishment of fees. FSMB representatives on the Committee will be the Chair, Chair-elect, Treasurer, President and the senior FSMB financial staff member.

3. The USMLE Management Committee shall be responsible for overseeing the design, development, scoring and standard setting for the USMLE Step examinations, subject to policies established by and reporting to the USMLE Composite Committee. Appointments to
SECTION B. The President shall provide FSMB advice and consent to the NBME for NBME’s appointments to the USMLE Management Committee and/or any appointments made jointly under the FSMB/NBME Agreement Establishing the USMLE.

ARTICLE X. POST-LICENSEURE ASSESSMENT SYSTEM

The Post-Licensure Assessment Governing Committee shall be responsible for the development, operation and maintenance of policies governing the Post-Licensure Assessment System (PLAS) established by joint agreement between FSMB and NBME. The Chair, with the approval of the Board of Directors, shall make appointments to the Post-Licensure Assessment Governing Committee and its program committees in appropriate numbers and at appropriate times as required by the FSMB/NBME joint agreement establishing the Post-Licensure Assessment System and by other agreements as may apply.

ARTICLE XI. FINANCES AND DUES

SECTION A. SOURCES OF FUNDS

Funds necessary for the conduct of the affairs of the FSMB shall be derived from but not be limited to:

1. Annual dues imposed on the Member Medical Boards, Affiliate Members, Courtesy Members and Official Observers;
2. Special assessments established by the House of Delegates;
3. Voluntary contributions, devices, bequests and other gifts;
4. Fees charged for examination services, data base services, credentials verification services and publications.

SECTION B. ANNUAL DUES, ELIGIBILITY TO SERVE AS A DELEGATE

The annual dues for Member Medical Boards shall be established, from time to time, by a majority vote of the House of Delegates.
1. Annual dues for Member Medical Boards shall be the same for all Members regardless of their physician populations. Annual dues are due and payable not later than January 1.

2. Any Member Medical Board whose dues are in default at the time of the Annual Meeting of the House of Delegates shall be ineligible to have a seated delegate.

**ARTICLE XII. DISCIPLINARY ACTION**

**SECTION A. MEMBER**

For the purposes of this Article, a member shall be defined as a Member Medical Board, a Fellow, an Honorary Fellow, an Associate Member, an Affiliate Member, Courtesy Member or Official Observer.

**SECTION B. AUTHORIZATION**

The Board of Directors, on behalf of the House of Delegates, may enforce disciplinary measures, including expulsion, suspension, censure and reprimand, and impose terms and conditions of probation or such sanctions as it may deem appropriate, for any of the following reasons:

1. Failure of the member to comply or act in accordance with these Bylaws, the Articles of Incorporation of the FSMB, or other duly adopted rules or regulations of the FSMB;

2. Failure of the member to comply with any contract or agreement between the FSMB and such member or with any contract or agreement of the FSMB that binds such member;

3. Failure of the member to maintain confidentiality or security, or the permitting of conditions that allow a breach of confidentiality or security, in any manner dealing with the licensing examination process or the confidentiality of FSMB records, including the storage, administration, grading or reporting of examinations and information relating to the examination process; or

4. The imposition of a sanction, judgment, disciplinary penalty or other similar action by a Member Medical Board that licenses the member or by a state or federal court, or other competent tribunal, whether or not related to the practice of medicine and including conduct as a member of a Member Medical Board.
SECTION C. PROCEDURE

Any member alleged to have acted in such manner as to be subject to disciplinary action shall be accorded, at a minimum, the procedural protection set forth in the Manual for Disciplinary Procedures, which is available from the FSMB upon the written request of any member.

SECTION D. REINSTATEMENT

In the event a member is suspended or expelled from the FSMB, the member may apply to the President for reinstatement after one year following final action on expulsion. The President shall review the application and the reason for the suspension or expulsion and forward a report to the Board. The Board may accept application for reinstatement under such terms and conditions as it may deem appropriate, reject the application or request further information from the President. The Board’s decision to accept or reject an application is final.

ARTICLE XIII. CORPORATE SEAL

The Board of Directors shall adopt a corporate seal that meets the requirements of the state in which the FSMB is incorporated.

ARTICLE XIV. ADOPTION AND AMENDMENT OF BYLAWS, EFFECTIVE DATE

SECTION A. AMENDMENT

These Bylaws may be amended at any annual meeting of the House of Delegates by two-thirds of those present and voting. Bylaws changes may be proposed only by the Board of Directors, Member Medical Boards or the Bylaws Committee and its members. All such proposals must be submitted in writing to the Bylaws Committee, in care of the Secretary of the FSMB. The Bylaws Committee shall inform the Member Medical Boards of its meeting dates not fewer than 60 sixty days in advance of the meeting. The recommendations of the Bylaws Committee and the full texts of all proposed amendments recommended to the Committee shall be sent to each Member Medical Board not fewer than 60 sixty days prior to the Annual Meeting of the House of Delegates at which they are to be considered.

SECTION B. EFFECTIVE DATE

These Bylaws and any other subsequent amendments thereto, shall become effective upon their adoption, except as otherwise provided herein.
2018 FSMB BYLAWS
PROPOSED AMENDMENTS
PROPOSAL #3

ARTICLE VIII. STANDING AND SPECIAL COMMITTEES

SECTION A. STANDING COMMITTEES

1. The Standing Committees of the FSMB shall be:
   
   a. Audit Committee
   b. Bylaws Committee
   c. Editorial Committee
   d. Education Committee
   e. Ethics and Professionalism Committee
   f. Finance Committee
   g. Nominating Committee

2. ADDITIONAL STANDING COMMITTEES. Additional standing committees may be created by resolution of the FSMB and/or amendment to the Bylaws. Chairs and members of all standing committees, with the exception of the Nominating Committee, shall be appointed by the Chair, with the approval of the Board of Directors, for a term of one year, unless otherwise provided for in these Bylaws. Reappointment, unless specifically prohibited, is permissible.

3. MEMBERSHIP. Honorary Fellows, Associate Members and Courtesy Members may be appointed by the Chair to serve on a standing committee in addition to the number of committee members called for in the following sections of this chapter. No more than one Honorary Fellow, Associate or Courtesy Member or non-member subject matter expert may be appointed by the Chair to serve in such a capacity on any standing committee unless otherwise provided for in these Bylaws. All committee members shall serve with vote. Honorary Fellows, Associate or Courtesy Members, and non-members appointed to standing committees by the Chair shall serve for a term concurrent with the term of the Chair. No individual shall serve on more than one standing committee except as specified in the Bylaws. With the exception of the Nominating Committee and the Editorial Committee, the Chair and the Chair-elect shall serve, ex-officio, on all committees.

4. VACANCIES. In the event a vacancy occurs in an elected position on a standing committee, the Chair, with the approval of the Board of Directors, shall appoint a Fellow to serve on the committee until the next meeting of the House of Delegates, at which time an election will be held to fill the vacant position for the remainder of the unexpired term. In the event a vacancy occurs in an appointed position on a standing committee, the Chair, with the approval of the Board of Directors, shall appoint a Fellow to serve on the committee for the remainder of the unexpired term. In the event
the Chairmanship of the Nominating Committee becomes vacant, the FSMB Chair, with the approval of the FSMB Board of Directors, shall appoint a Past Chair of the FSMB Board of Directors to serve in that capacity for the remainder of the unexpired term.

SECTION B. AUDIT COMMITTEE
The Audit Committee shall:
1. Be composed of five Fellows, three of whom shall be members of the Board of Directors. The Treasurer of the FSMB shall serve ex-officio without vote. The Chair of the FSMB shall appoint the Chair of the Audit Committee from one of the three sitting Board Members.
2. Ensure that an annual audit of the financial accounts and records of the FSMB is performed by an independent Certified Public Accounting firm.
3. Recommend to the Board of Directors the appointment, retention or termination of an independent auditor or auditors and develop a schedule for periodic solicitation of audit firms consistent with Board policies and best practices.
4. Oversee the independent auditors. The independent auditors shall report directly to the Committee.
5. Review the audit of the FSMB. Submit such audit and Committee’s report to the Board of Directors.
6. Report any suggestions to the Board of Directors on fiscal policy to ensure the continuing financial strength of the FSMB.
7. When the finalized committee report to the Board of Directors is made, suggestions and feedback will be forwarded to the Finance Committee.

SECTION C. BYLAWS COMMITTEE
The Bylaws Committee, composed of five Fellows, shall continually assess the Articles of Incorporation and the Bylaws and shall receive all proposals for amendments thereto. It shall, from time to time, make recommendations to the House of Delegates for changes, deletions, modifications and interpretations thereto.

SECTION D. EDITORIAL COMMITTEE
1. An Editorial Committee, not to exceed twelve Fellows and three non-Fellows, at least two of whom shall be subject matter experts, shall advise the Editor-in-Chief on editorial policy for the FSMB’s official publication, and shall serve as the editorial board of that publication and otherwise assist the Editor-in-Chief in the performance of duties as appropriate and necessary. No officer or member of the Board of Directors shall serve on this Committee.
2. Service on the Editorial Committee is by nomination and appointment by the FSMB Chair, subject to approval of the Board of Directors, immediately following the Annual
Meeting of the House of Delegates. Candidates are allowed to express their interest in serving on the Committee through self-nomination. Committee members shall serve staggered three-year terms and shall be limited to two full terms.

3. The Editor-in-Chief shall be elected by the Editorial Committee to a three-year term beginning on the date of the annual Editorial Committee meeting, with the Editor-in-Chief’s term on the Editorial Committee being automatically extended to allow the Editor-in-chief to serve for three years. A member of the Editorial Committee whose term is expiring shall continue to serve until the member’s replacement meets at the next annual Editorial Committee meeting.

4. The Editorial Committee will elect its Chair, who will serve as the Editor-in-Chief of the *Journal of Medical Regulation*. The Editor-in-Chief will serve without compensation and will coordinate decisions on the *Journal* content, among other duties to be determined by the Bylaws Committee.

**SECTION E. EDUCATION COMMITTEE**

The Education Committee shall be composed of eight Fellows, to include the Chair as chair, the Immediate Past Chair and the Chair-elect. The Committee shall be responsible for assisting in the development of educational programs for the FSMB.

**SECTION F. ETHICS AND PROFESSIONALISM COMMITTEE**

The Ethics and Professionalism Committee shall be composed of up to five Fellows and up to two subject matter experts. The Ethics and Professionalism Committee shall address ethical and professional issues pertinent to medical regulation.

**SECTION G. FINANCE COMMITTEE**

The Finance Committee shall be composed of five Fellows, to include the Treasurer as Chair. The Finance Committee shall review the financial condition of the FSMB, review and evaluate the costs of the activities and programs to be undertaken in the forthcoming year, present a budget for the FSMB to the Board of Directors for its recommendation to the House of Delegates at the Annual Meeting and perform such other duties as are assigned to it by the Board of Directors. Except for the Treasurer, no Fellow shall serve on both the Audit and Finance Committees.

**SECTION H. NOMINATING COMMITTEE: PROCESS FOR ELECTION**

1. **MEMBERSHIP:** The Nominating Committee shall be composed of six Fellows and the Immediate Past Chair, who shall chair the Committee and serve without vote except in the event of a tie. At least one elected member of the Nominating Committee shall be a public member. With the exception of the Immediate Past Chair, no two Committee members shall be from the same member board and no officer or member of the Board of Directors shall serve on the Committee. A member of the Nominating Committee may not serve consecutive terms.
2. **ELECTION**: At least three Fellows shall be elected at each Annual Meeting of the House of Delegates by a plurality of votes cast, each to serve for a term of two years. Only an individual who is a Fellow at the time of the individual’s election shall be eligible for election as a member of the Nominating Committee. In the event of a tie vote in a runoff election, up to two additional runoff elections shall be held. Prior to the election, the presiding officer shall cast a sealed vote, ranking each candidate in a list. The presiding officer’s vote is counted for the candidate in the runoff election who is highest on the list. The presiding officer’s vote is counted only to resolve a tie that cannot be decided by the process set forth in this section.

3. Members of the Nominating Committee are not eligible for inclusion on the roster of candidates for offices and positions to be filled by election at the Annual Meeting of the House of Delegates.

**SECTION I. SPECIAL COMMITTEES**

Special committees may be appointed by the Chair, from time to time, as may be necessary for a specific purpose.

**SECTION J. REPRESENTATIVES TO OTHER ORGANIZATIONS AND ENTITIES**

Appointment of all representatives of the FSMB to other official organizations or entities shall be made or nominated by the Chair, with the approval of the Board of Directors, as applicable, and shall serve for a term of three years unless the other organization shall specify some other term of appointment. Representatives to these organizations shall be Fellows, Honorary Fellows, Associate Members or Courtesy Members at the time of their appointment or nomination.
ARTICLE IV. BOARD OF DIRECTORS

SECTION A. MEMBERSHIP AND TERMS

1. MEMBERSHIP: The Board of Directors shall be composed of the Officers, the Immediate Past Chair, nine Directors-at-Large and two Associate Members. At least two members of the Board, who are not Associate Members, shall be non-physicians, at least one of whom shall be a public/consumer member.

TN Board Comment: This simple modification of the FSMB Bylaws makes clear that the Public/Consumer members’ participation and perspective on the Board of Directors is valued and aligned with the member medical boards of the FSMB.

It should be noted that non-physician members can be elected to the Board of Directors if they are fellows of the FSMB. This proposed change to the Bylaws would not alter that status.

There are nine Directors-at-Large and two Associate Members on the FSMB Board of Directors in addition to the Officers of the Board of Directors and the Immediate Past Chair. The Secretary (President) of the Board of Directors is ex officio and does not vote.
The Nominating Committee met on Friday, January 19, 2018 in Irving, Texas at 9:00 am CST. FSMB Immediate Past Chair Dr. Arthur Hengerer serves as Chair of the Committee. Other members of the Committee include Dr. Howard (Joey) Falgout, Dr. Jone Geimer-Flanders, Dr. Marilyn Heine, Dr. Stuart Mackler, Dr. Michelle Terry and Carmela Torrelli. Providing staff support were FSMB President and CEO Dr. Humayun Chaudhry, Director of Leadership Services Pat McCarty, and Governance Support Associate Pam Huffman.

Dr. Hengerer expressed his sincere appreciation for the Committee’s dedication and emphasized the importance of their work in selecting highly qualified candidates for the elected office positions.

The Committee reviewed all submitted nomination materials; considered the results of the one-on-one interviews between the Committee members and nominees; and discussed the importance of selecting candidates who fulfill the qualifications for FSMB leadership positions as outlined in the Committee’s charge. The Committee also shared ideas for strengthening the process of finding good candidates in the future. After thoughtful and careful deliberation throughout the vetting process, the Nominating Committee unanimously approved the following roster of candidates:

**Chair-elect** – 1 fellow, to be elected for three years; a one-year term as chair-elect; a one year term as chair; and a one-year term as immediate past chair

Assists the chair in the discharge of the chair’s duties; and performs the duties of the chair at the chair’s request or, in the event of the chair’s temporary absence or incapacitation, at the request of the Board of Directors.

**Scott A. Steingard, DO – Arizona Osteopathic**

With only one candidate for chair-elect, Dr. Steingard will be elected by acclamation; his current term on the FSMB Board of Directors does not expire until 2019, therefore his election as chair-elect will result in a partial term of one year to be filled.

**Treasurer** – 1 fellow, to be elected for a three-year term

The Treasurer shall perform the duties customary to that office and shall perform such other duties as the Bylaws and custom and parliamentary usage may require or as the Board of Directors shall deem appropriate; serves as chair of the Finance Committee and as an ex officio member of the Audit Committee.
Jerry G. Landau, JD – Arizona Osteopathic

With only one candidate for treasurer, Mr. Landau will be elected by acclamation; his current term as a director-at-large on the FSMB Board of Directors expires in May 2018 and is one of the full terms that will need to be filled.

**Board of Directors** – 4 fellows; three to be elected for a three-year term each; one to be elected for a one-year term.

Control and administration of the corporation is vested in the Board of Directors, which is the fiscal agent of the corporation; the Board acts for the FSMB between Annual Meetings.

Mohammed A. Arsiwala, MD – Michigan Medical
Anna Z. Hayden, DO – Florida Osteopathic
Shawn P. Parker, JD, MPA* – North Carolina
Anita M. Steinbergh, DO – Ohio
Sarvam P. TerKonda, MD – Florida Medical
Joseph R. Willett, DO - Minnesota

*In accordance with the FSMB bylaws, “At least two members of the Board, who are not Associate Members, shall be non-physicians, at least one of whom shall be a public/consumer member.” With Mr. Landau’s pending election as treasurer and the continued service of another public member on the Board, this bylaws requirement will be fulfilled. Therefore, there will be no need to address the public member candidacy separately. The public member and physician candidates will be included on the same slate.

One candidate will need to be elected to fill Mr. Landau’s expired term (a 3-year term). Dr. Hayden’s current term as director-at-large on the Board expires in May 2018 resulting in a 2nd full term to be filled. The term of another board member who is not eligible for re-election also expires in 2018 resulting in a 3rd full term to be filled. A fourth candidate will need to be elected to serve a partial term of 1 year due to Dr. Steingard’s pending election as chair-elect.

**Nominating Committee** – 3 fellows, each to be elected for a two-year term

Committee members select a roster of nominees for each of the elected positions to be filled at the annual business meeting of the House of Delegates.

Nathaniel B. Berg, MD – Guam [Dr. Berg has withdrawn his nomination]*
Ahmed D. Faheem, MD – West Virginia Medical
Robert P. Giacalone, RPh, JD – Ohio
Kenneth J. Walker, MD – Virginia
*In accordance with the FSMB bylaws, “At least one elected member of the Nominating Committee shall be a public member.”* The term of the one public member currently on the Nominating Committee will expire in May 2018; therefore the 2018 House of Delegates will be required to elect at least one public member. With only three candidates for the Nominating Committee, including the requisite public member, the three candidates will be elected by acclamation.

No two Nominating Committee members are to be from the same member board. Continuing members of the Committee are from Alabama, Pennsylvania Medical and Washington Medical.

Respectfully submitted,

Arthur S. Hengerer, MD, FACS
Chair, Nominating Committee
Memorandum

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

FROM: Sallie Debolt, Senior Counsel

RE: Proposed amendments to Rule 4731-31-01, OAC

DATE: March 22, 2018

Rule 4731-31-01 establishes standards for physicians who assess youth that sustain a concussion or head injury. As required by Section 3707.521, ORC, the standards are equal to or stronger than the guidelines developed by the Ohio Youth Sports Concussion and Head Injury Return-to-Play Guidelines Committee established by the Director of Health under a previous version of Section 3707.521, and which met during 2014 and 2015.

At the February meeting, the Policy Committee approved the proposed amendments for initial circulation to interested parties. The deadline for interested party comments was March 16, 2018. No comments were received.

The amendments to the rule are:

1. Changing the reference to the most recent “Consensus statement on concussion in sport” statement from the Zurich statement to the Berlin statement adopted in 2017, and

2. Moving the reference for the location of the model form developed by the Ohio Youth Sports Concussion and Head Injury Return-to-Play Guidelines Committee from the website of the Ohio Department of Health to the website of the Medical Board. No changes to the form are proposed.

The proposed amended rule is attached for your review.

REQUESTED ACTION: Recommend that the Medical Board approve Rule 4731-31-01, as presented, be filed with the Common Sense Initiative Office.
4731-31-01 Requirements for assessing and granting clearance for return to practice or competition.

(A) A physician holding a current license to practice medicine and surgery or osteopathic medicine and surgery issued under Chapter 4731. of the Revised Code meets the minimum education requirements to assess and clear athletes for return to practice or competition under section 3313.539 or 3707.511 of the Revised Code.

(B) A physician shall diagnose and treat concussions and determine the return-to-play protocol for athletes under section 3313.539 or 3707.511 of the Revised Code in accordance with the “Consensus Statement on Concussion in Sports” issued by the “4th International Conference on Concussion in Sport” held in Zurich, November 2012 “Consensus statement on concussion in sport – the 5th international conference on concussion in sport held in Berlin, October 2016’, and adopted on March 6, 2017. (Available from the website of the state medical board of Ohio at: med.ohio.gov.)

(C) A physician shall use the model form developed by the Ohio youth sports concussion and head injury return-to-play guidelines committee to document written clearance for the return to practice or competition. The model form may be found on the state medical board of Ohio’s website of the Ohio department of health at: http://www.healthy.ohio.gov/vipp/concussion.aspx–med.ohio.gov.
Dr. Soin called the meeting to order at 9:13 a.m.

MEETING MINUTES REVIEW

Dr. Soin asked for approval of the draft minutes of the February 14, 2018 meeting which were included in the agenda materials.

Mr. Giacalone moved to approve the Policy Committee minutes of the February 14, 2018 meeting. Dr. Schachat seconded the motion. Motion carried.

Rules Review Update

Ms. Anderson reported that the rules spreadsheet was included in the agenda materials for information. Several rules are at CSI and we are waiting for those to be released.

She reported that the Dietetics and Respiratory Care rules are essentially clean-up of the rules due to statute changes included in HB145 and the budget bill. These rules will be on the April agenda for the policy committee along with the Genetic Counselor rules.

One-bite draft rules and draft contract

Ms. Anderson noted that the information was included in the agenda materials. The information had been circulated for comments. We received several comments including those from Dr. Schottenstein and Board staff. The rules were updated to reflect the comments. Ms. Anderson said we were able to clarify several things. Information begins on page 512.
Ms. Anderson said there are five proposed rules. The one-bite rules will be included in OAC Chapter 4731-16, the treatment provider rules.

4731-16-17 Requirements for the one-bite program

This rule lays out the overview of the program. Ms. Anderson said that there are some entities that are different in this process. The first is a monitoring organization which will contract with the Medical Board. She said a draft contract is also included in the materials. It is our hope to get it to DAS in the next week or two for the competitive bid process for that contract. The one-bite treatment provider is also a new definition and it is explained more in one of the other rules. Essentially the one-bite treatment provider must meet current treatment provider requirements but must also have additional expertise in their medical director and staff to provide care for the one-bite individuals. Continuing care provider is new and it is slightly different from the aftercare that we currently have. The notable difference is that it is more like counseling with licensed counselors are part of the continuing care part of the program. All of this was developed with OPHP and the group facilitated by Representative Grossman.

The monitoring organization will be taking one-bite reports and making eligibility determinations. It is anticipated that the Board will also receive reports as we do now and if the individual is eligible for one-bite the Board will refer them to the monitoring organization.

Ms. Anderson said that another thing that is different with this program is the length of treatment for the licensee who is eligible for one-bite. In the one-bite program, the length of treatment is determined by the treatment provider and the current minimum 28-day treatment is no longer required.

Ms. Anderson said that as we work this process and these rules the board may want to discuss the length of treatment and determine if we want to have two different standards or the same standard. She said that decision does not need to be made now but it is something to keep in mind as it is different.

4731-16-18 Eligibility for the one-bite program

Ms. Anderson said this rule explains the eligibility for the one-bite program. A lot of the language is set in the statute. A licensee could be eligible for the one-bite program if the individual is diagnosed with a substance use disorder; they are impaired; they have not previously participated in the one-bite program or the prior reporting exemption; and the individual has no prior disciplinary action by the Medical Board for substance abuse.

One of the things that is different is the other things that can go along with impairment. Criminal acts/convictions or mental/physical health issues would be separated out and would follow a separate track so that it would not be folded into the impairment issue. So, the individual could be eligible for one-bite and get the confidential treatment but they could have a Board action for an out-of-state action or a criminal matter or some other non-impairment issue.

Dr. Steinbergh said that she understands bifurcating cases. She asked if the monitoring provider will be required to monitor the Medical Board’s citations and disciplinary actions. She understands what will come to the board as far as complaints. But will the contract require the monitoring organization to monitor the Board’s citations so a person in one-bite does not slip through? Does the provider have to report to the board if someone in one-bite has a new citation? Ms. Anderson said at this point the individual can proceed in the one-bite program and the monitoring organization would not be required
to report to the board that the individual is in the one-bite program. As a practical matter, she believed that the Board would find out that information anyway as the individual would tell us they are being monitored by the monitoring organization. She referred to a recent case where the doctor had an out-of-state action but was voluntarily participating in a monitoring program. So, the Board’s action was based on the out-of-state action.

Ms. Anderson noted that the monitoring organization is not providing the Board the identify of patients but only statistical information.

Dr. Steinbergh still had concern that the Board would cite a licensee who is in the one-bite program for any issue and the monitoring organization would not be aware of the Board action.

Ms. Marshall said it will probably unfold in several ways depending on the situation. If the licensee is in the one-bite program for impairment and the Board subsequently cites the licensee for something else, it would be up to the licensee to decide if they want to affirmatively raise their impairment as mitigating evidence as part of the administrative hearing regarding the citation. For instance, if we had information that an individual had forged prescriptions and the Board cited them for illegal processing of drug documents, she would expect that the licensee would see that it was in their best interest to say that was all part of their impairment, waive their Eastway rights, and we find out about it together.

On the other hand, if a licensee was cited for minimal standards or sexual relations with a patient, the licensee may choose to keep the impairment treatment private and just deal with the separate issue. If the licensee raises their impairment issues in an administrative hearing, it no longer remains confidential. If the licensee decides to keep their impairment treatment private, then they take the chance on what discipline they get by not putting forth all the mitigating evidence.

Dr. Steinbergh summarized it as it being up to the licensee not the monitoring organization. Ms. Marshall said she believed that it would work well for the licensee and the Board as the intent of the one-bite program is to be able for the licensee to keep their impairment treatment confidential if they are doing everything right according to the program.

Mr. Giacalone asked why the Board couldn’t send the citation letters to the monitoring organization as its public information. He said it would not take much to email them the information.

**4731-16-19 Monitoring organization for the one-bite program**

This rule has more information about the monitoring provider. Ms. Anderson said it is a bridge between the treatment provider and licensee and the Board. There are requirements for the organization to provide treatment provider information to the licensee and for getting the licensee to the evaluation. The licensee also enters into a monitoring agreement with the monitoring organization for a minimum of five years to do the drug screenings and AA meetings. The monitoring organization also provides statistical reports to the Board and education to licensees and treatment providers about the Medical Board’s rules and statutes regarding the one-bite program. There are also requirements that they work with the Board on the educational materials so that there is a consistent message.

Ms. Anderson said that relapse must be reported to the Board. She said we are working out some details of issues of reporting non-compliance. Some non-compliance is relatively minor such a one-time missed call-in versus actual relapse. She said we will develop a list of non-compliance issues that absolutely need to be reported to the Board and we will work with the selected monitoring organization. Dr. Steinbergh said it was very important that the non-compliance issues be identified.
and reported to the Board. Ms. Anderson indicated that any confirmed positive screen must be reported to the Board.

4731-16-20 Treatment providers in the one-bite program

Ms. Anderson said that this rule includes the additional requirements and qualifications such as having a medical director who is a board-certified addictionologist or addiction psychiatrist; having the medical director involved in the initial assessment, discharge planning, treatment planning, knowledge of prescribing medications for substance use disorder and interpretation of toxicology screens. We are also requiring a board-certified psychiatrist to be available, and group therapy that is supervised by a psychologist or a master’s level chemical dependency counselor, social worker or therapist. Quarterly training regarding one-bite eligibility to all staff of the treatment provider is required. Also, the treatment provider will work closely with the monitoring organization and the treatment provider is also required to report statistics to the board regarding one-bite participants.

4731-16-21 Continuing care for the one-bite program

The continuing care provider is like an aftercare provider. The minimum time is six months but it is set out by the continuing care agreement by the treatment provider with input from the monitoring organization.

Draft Monitoring Organization Contract

Ms. Anderson said the proposed contract was also available for committee review. We are finalizing it and getting it set for the competitive process.

Ms. Anderson said we are seeking approval today to send the draft rules to interested parties for comment.

Dr. Bechtel moved to approve sending the draft rules to interested parties for comment. Dr. Schachat seconded the motion. Motion carried.

Light based medical device and standards for surgery rules

Mr. Smith reported that the initial draft rules for light based medical device and standards for surgery were circulated on January 17th with a two-week comment period. The Board received 47 written comments from individuals, groups of individuals, and individuals writing on behalf of organizations. A spreadsheet summarizing each of the comments was included in the agenda materials. Mr. Smith reported that the comments had been categorized into a list of subject areas. He noted that the numbers are approximate and many of the written comments received addressed more than one subject area.

Mr. Smith reviewed the following with the committee:

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

4. Five comments sought a definition or clarification of the term "vascular laser".

5. Seven comments supported expanding the application of non-ablative light based medical devices beyond vascular lasers for dermatologic procedures and hair removal. Five of these seven comments supported expanding delegation to fractionated lasers often used for cosmetic procedures.

6. Four comments opposed expanding delegation of light based medical devices beyond hair removal to vascular lasers, or did not support physician’s delegating the application of light based medical devices at all.

Comments 7 through 10 focused on the difference in delegation between the different professions.

7. Two comments favored delegating light based medical device procedures to only physician assistants due to their more extensive education and training than that of other delegates. Two other comments were in favor of delegation to physician assistants and nurses, but not cosmetic therapists.

8. Three comments advocated delegating all light based medical device procedures, including ablative procedures, to physician assistants.

Mr. Smith pointed out that the first comment on the spreadsheet-Adamson-is a summary of what the OAPA believes about that topic. They believe PAs are authorized to delegate any service, including use of ablative and non-ablative light based medical devices if it is within the scope of their physician’s normal practice.

9. Three comments encouraged extending delegation of phototherapy and photodynamic therapy to cosmetic therapists.

On page 566 of the spreadsheet, the President of the Cosmetic Therapy Association of Ohio summarized the details of that comment.

10. Eight comments favored expanding off-site physician supervision beyond cosmetic therapists to all other delegates.

Comments 11 and 12 dealt with the evaluation of the patient. The proposed rules require an evaluation before and after the application of a specific type of treatment.

11. Nine comments did not agree with the requirements that the physician personally see patients before and after the initial application of a light based medical device, and sought to eliminate the initial evaluation, the follow-up evaluation, or both.

12. One comment requested clarification on whether the phrase “the physician has seen and personally evaluated the patient” allows for video or picture review by the physician instead of the physician being in the same room as the patient.

Several comments were received seeking changes to the rules regarding phototherapy for the treatment of hyperbilirubinemia in neonates.
13. Five comments sought various changes to the rule’s delegation of phototherapy in the treatment of hyperbilirubinemia in neonates.

Summaries of the comments can be found under Dr. Randy Miller on page 566, and the comments by Dr. Sequin.

14. One comment advocated extending the delegation of light based medical devices to tattoo removal, and allowing non-medical technicians to perform these procedures along with laser hair removal, skin rejuvenation, and acne treatment.

Mr. Smith said this comment was received from a representative of a laser company. Mr. Smith said he received additional comments yesterday from other laser companies checking on the updates and timeline for the rules.

15. One comment argued that the rules’ limited delegation of non-ablative dermatologic procedures was too restrictive and could possibly be in violation of antitrust laws.

Page 564 from John Irwin lays out the summary of the argument. Mr. Smith brought the committee’s attention to the comments of Eric Plinke on page 567 questioning the validity of the statement that the application of light based medical devices to the human body is the practice of medicine in light of 4731.34 and asking how the regulation of light based medical devices for aesthetic purposes is within the Board’s rule making authority. Both comments were from attorneys.

Comments 16 and 17 address training issues.

16. Four comments had questions about or suggested changes to the new training requirements for delegates applying light based medical devices.

17. One comments inquired into whether delegates who had been lawfully practicing laser hair removal could be exempted from the rule’s new education and training requirements. One other comment suggested a grandfather clause for practitioners who had been performing photodynamic therapy for years without regulation.

This comment related to the standards for surgery rule.

18. One comment suggested changing the surgery rule’s delegation of aspects of postoperative care to aspects of intra-and perioperative care, as well as inserting physician assistants as a separate and distinct provider of this care from allied healthcare personnel

Mr. Smith said he also presented the initial draft of the rules to the Physician Assistant Policy Committee in February. They had some good comments asking if the treatment of hyperbilirubinemia in neonates could be done by protocol. A second comment from PAPC encouraged adding continuing education to the training requirements to assure the practitioner’s knowledge is current and to guard against a practitioner who resumes practice after an extensive break from practice. This idea is to help assure the practitioner keeps up with the changes in technology.

Mr. Smith reported that the initial draft rules were circulated to two physician experts and their responses mirror the diversity of the comments received. Dr. Georgeann Poulos opposed the increased delegation for vascular lasers for non-ablative dermatologic procedures. While Dr. Stephen
Smith advocated broadening the language of the rules to include all nonablative laser and light therapies. Both experts supported the increased training requirements for delegates.

Mr. Smith said that Dr Bechtel worked with him on determining which of the comments would improve the rule. Starting on page 548 of the materials, some changes were made to the rule which are described below:

**18-01 definitions.**

1. In response to comments in #4 of the Comment List, added definition of vascular laser in 4731-18-01(K): “Vascular laser” means lasers and intense pulsed light apparatuses whose primary cutaneous target structures are telangiectasia, venulectasia, and superficial cutaneous vascular structures. In general, these lasers have wavelengths that correspond to the hemoglobin absorption spectrum.

2. In response to comments in #3 of the Comment List, clarified definition of phototherapy by separating phototherapy in the treatment of hyperbilirubinemia in neonates from phototherapy for dermatologic procedures in 4731-18-01(B). Also consolidated definition of phototherapy device within the definition of phototherapy.

   (B) “Phototherapy” means the following:
   
   (1) For paragraph (A) of rule 4731-18-04 of the Administrative Code, phototherapy means the application of light for the treatment of hyperbilirubinemia in neonates.

   (2) For paragraphs (B) and (C) of rule 4731-18-04 of the Administrative Code, phototherapy means the application of ultraviolet light for the treatment of psoriasis and similar skin diseases. This application can occur with any device cleared or approved by the United States food and drug administration for the indicated use that can be made to produce irradiation with broadband ultraviolet B (290-320nm), narrowband ultraviolet B (311-313 nm), excimer light based (308nm), ultraviolet A1 (340-400nm), or UVA (320-400nm) plus oral psoralen called PUVA.

3. In response to comments in #13 of the Comment List, tailored the requirements in 4731-18-04(A) for delegates applying phototherapy in the treatment of hyperbilirubinemia in neonates to follow the standard of care practiced in hospitals by aligning the requirements with hospital policies and protocols.

   (A) A physician may delegate to any appropriate person the application of light based medical devices cleared or approved by the United States food and drug administration for phototherapy in treatment of hyperbilirubinemia in neonates only if all the following conditions are met

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

   (2) The delegation and application of light based medical devices for phototherapy for this treatment is performed pursuant to hospital rules, regulations, policies, and protocols.

4. In response to comments in #11 and #12 of the Comment List, amended the language in the physician evaluation provisions in 4731-18-03(A)(3) and (4) and (B)(3) and (4) to: clarify that
the requirements for physician evaluation are per type of procedure delegated and applied rather than per procedure or just once per patient; and to make the rule clearer that the physician evaluation provisions require that the physician see and evaluate the patient in person for the initial evaluation and also for the follow-up to the initial application rather than see and evaluate by video or photograph.

For delegation of vascular lasers for non-ablative dermatologic procedures, proposed amended Rule 4731-18-03(A)(3) and (4) states:

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

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

For delegation of light-based medical devices for hair removal, proposed amended Rule 4731-18-03(B)(3) and (4) states:

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

(4) The physician has seen and personally evaluated the patient in person following the initial application of the specific light-based medical device, but prior to any continuation of treatment in order to determine that the patient responded well to that initial application of the specific light-based medical device; and,

5. In response to comments in #16 of the Comment List, added language in 4731-18-03(A)(6) and (B)(6) to clarify the requirements for education and training. In response to concerns that only inadequate manufacturer generated education would be taught, amended the rule to specify the list of topics that must be included in 8 hours of basic education. Also, spelled out that training must be done per type of procedure rather than per delegating physician in situations where a delegate has multiple delegating physicians. Also, amended rule to explain that the physician involved in the clinical procedure training does not need to be a delegating physician, but must be a physician who performs the type of procedure delegated in the normal course of their practice and expertise. Lastly, amended the rule to add documentation and retention of documentation responsibilities for each delegating physician.

Proposed amended Rule 4731-18-03(A)(6)(a)-(d) for vascular lasers states:

(6) The person to whom the delegation is made has received adequate education and training to provide the level of skill and care required including:

(a) Eight (8) hours of basic education that must include the following topics: light-based procedure physics, tissue interaction in light-based procedures, light-based procedure safety including use of proper safety equipment, clinical application of light-based procedures, pre and post-operative care of light-based procedure patients, and reporting of adverse events;

(b) Observation of fifteen (15) procedures for each specific type of vascular laser non-ablative procedure delegated. The procedures observed must be
performed by a physician for whom the use of this specific vascular laser procedure is within the physician’s normal course of practice and expertise; and

(c) Performance of twenty (20) procedures under the direct physical oversight of the physician on each specific type of vascular laser non-ablative procedure delegated. The physician overseeing the performance of these procedures must use this specific vascular laser procedure within the physician’s normal course of practice and expertise;

(d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in (a) must only be completed once by the delegate regardless of the number of types of specific vascular laser procedures delegated and the number of delegating physicians. The training requirements in (b) and (c) must be completed by the delegate once for each specific type of vascular laser procedure delegated regardless of the number of delegating physicians;

Proposed amended Rule 4731-18-03(B)(6)(a)-(d) states:

6) The person to whom the delegation is made has received adequate education and training to provide the level of skill and care required including:

(a) Eight (8) hours of basic education that must include the following topics: light based procedure physics, tissue interaction in light based procedures, light based procedure safety including use of proper safety equipment, clinical application of light based procedures, pre and post-operative care of light based procedure patients, and reporting of adverse events;

(b) Observation of fifteen (15) procedures for each specific type of light based medical device procedure for hair removal delegated. The procedures observed must be performed by a physician for whom the use of this specific light based medical device procedure for hair removal is within the physician’s normal course of practice and expertise; and

(c) Performance of twenty (20) procedures under the direct physical oversight of the physician on each specific type of light based medical device procedure for hair removal delegated. The physician overseeing the performance of these procedures must use this specific light based medical device procedure for hair removal within the physician’s normal course of practice and expertise;

(d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in (a) must only be completed once by the delegate regardless of the number of types of specific light based medical device procedures for hair removal delegated and the number of delegating physicians. The training requirements of (b) and (c) must be completed by the delegate once for each specific type of light based medical device procedure for hair removal delegated regardless of the number of delegating physicians;
6. In response to comments in #17 of the Comment List, added grandfather clause for the education and training requirements for delegates of light based medical devices for hair removal on a type of procedure basis in 4731-18-03(B)(6):

   (e) Delegates who, prior to the effective date of this rule, have been applying a specific type of light based medical device procedure for hair removal for at least two (2) years through a lawful delegation by a physician, shall be exempted from the education and training requirements of (a), (b), and (c) for that type of procedure provided that they obtain a written certification from one of their current delegating physicians stating that the delegate has received sufficient education and training to competently apply that type of light based medical device procedure. This written certification must be completed no later than sixty (60) days after the effective date of this provision, and a copy of the certification shall be retained by each delegating physician and each delegate.

Mr. Smith also noted that the 4731-25-08 Standards for Surgery had been moved from current Chapter 18-01 to chapter 25 (surgery chapter).

Dr. Bechtel said that it is important to note that Ohio and New Jersey have the most restrictions regarding delegation of lasers. It is much broader delegation in 48 states. He said the rules are driven by patient safety. He also said that the observation numbers required are not arbitrary but were based on conversations with those who are training physicians in laser procedures.

He also believed it critical that the physician evaluate the patient before the first laser treatment to be sure that it is appropriate for the patient and that after the first treatment the doctor examines the patient to be sure there were no complications. He believed that the rules included patient safety safeguards by requiring robust education, personal evaluations of the patient by the physician before and after the first treatment, and that the laser treatments be performed with the physician on site, except for laser hair removal.

Dr. Schachat moved to approve the proposed rules as amended and to recommend the Board approve the proposed rules for filing with the Common Sense Initiative (CSI) for an antitrust review. Mr. Giacalone seconded the motion. Motion carried.

Legislative Review

Mr. LaCross noted that the legislative report for Board members has been retooled. It will be sent to the Board the Thursday or Friday before the Board meeting.

Mr. LaCross said there are four bills we are currently watching.

Senate Bill 259, Physician Assistant Regulation

The legislation was introduced by Senator Hackett and is currently assigned to the Senate Health Committee. The first hearing was yesterday. The bill is supported by the Ohio Association of Physician Assistants (OAPA) and generally proposes to revise the laws regulating the practice of physician assistants. The Board is working with the OAPA on this bill.
• Removes requirement for physician assistant with out of state prescriptive authority to hold that authority for at least three years prior to obtaining prescriptive authority in Ohio, if the individual does not hold a master’s (4730.11).
• Increases the number of physician assistants a physician can supervise at any one time from 3 to 5 (4730.21)
• Removes PA formulary from statute and allows the PA to prescribe according to their supervision agreement and within the scope of practice of the supervising physician (4730.203)
• In a health care facility, the PA may perform rapid intubation and procedural sedation, order rapid intubation and procedural sedation, and order drugs needed to perform rapid intubation and procedural sedation (4730.201) The Ohio Hospital Association and the Anesthesiologist Association are working with the OAPA on this issue.

He indicated that the next steps include:

• An amendment proposed by the Board regarding supervision agreements which would allow on-site filing of the supervision agreement and CME style auditing. This change would require the Board to approve a reformatted supervision agreement.

Mr. LaCross reported that the implementation of the OH-ID program in late January caused difficulty with renewing PA supervision agreements by the January 31, 2018 deadline, so the deadline was pushed to mid-February and then again extended until August 30, 2018. The proposed change would make it much easier for hospitals and licensees to keep PA supervision agreements up-to-date.

• An amendment proposed by the Board on PAPC structure and operation; allowing for telecommunication of meetings for more flexibility in scheduling meetings. Since the formulary will be removed from the statute, the PAPC can help with rules review.

• An amendment proposed by the Board regarding active military, and VA licensure exemption which was explained by Ms. Debolt.

Ms. Debolt reported that currently Physician Assistants with prescriptive authority must have 500 hours of on-site supervision of their prescriptive decisions, but the 500 hour requirement does not apply to a newly licensed PA if they had already worked in another state and had 1000 hours of prescriptive experience. However, it does not currently count if you were a PA who worked in the military, veteran’s administration facilities, or public health services facilities. So, we are seeking an amendment that exempts PAs with prescriptive authority in the military, VA, or public health services from the 500 hour on-site requirement if they have 1000 hours of prescriptive experience.

Dr. Steinbergh wanted to comment on process, since the legislation was discussed in the PA/Scope of Practice Committee earlier this morning, and we are now discussing it in Policy Committee. She thinks it should be one discussion rather than multiple conversations on the same issue. Mr. LaCross said that we will try to coordinate conversations on shared topics.

Dr. Soin said there is some concern regarding the scope expansion allowing the physician assistant to do rapid intubation included in the bill.
House Bill 286, Palliative Care Programs

Mr. LaCross thanked the Board members for their comments regarding this issue. He said that Senator Burke had asked the Medical Board and the Pharmacy Board to look at the legislation before it was moved to committee for two reasons. The bill expanded the definition of palliative care to allow more people in the program and included a pain clinic exemption for hospice programs providing palliative care. The legislation was introduced by Representative LaTourette and is currently in the Senate Health, Human Services and Medicaid Committee on its second hearing.

The bill generally proposes to create the Palliative Care and Quality of Life Interdisciplinary Council, to establish the Palliative Care Consumer and Professional Information and Education Program, and to require health care facilities to identify patients and residents who could benefit from palliative care.

- The definition of palliative care is broadened to “serious illness,” to be provided at any stage (3712.01)
- Creates the Palliative Care Interdisciplinary Council and the Professional Information and Education Program (3701.36)
- The substitute bill proposes to amend the entities that can be exempted from the pain clinic law (4731.054) by allowing inpatient palliative care programs operated by a hospice to be exempted.

Mr. LaCross thanked Dr. Factora for his help. He also reported that the Medical Board agreed to all changes brought forth by Rep. LaTourette’s office. He has a final version of the bill that he will share with the Board members today.

Dr. Schachat asked about the definition of palliative care now including serious illness, so how is “serious illness” defined.

Mr. LaCross said we had concerns regarding the opioid prescribing issue as to which patients we would catch and who we would not catch. We were concerned if we would get the data regarding anyone in the outpatient setting. But the exemption would be only for inpatient palliative care programs operated by a hospice.

Dr. Steinbergh asked if life threatening was dropped. Mr. LaCross said he will verify. Mr. Groeber asked where do you draw the line between serious and life threatening. Dr. Schachat said most things are not life-threatening but he thinks “serious illness” needs to be defined. Dr. Schottenstein remarked that the palliative care definition can be expanded so much that it is just care.

Mr. Groeber reported that the change was made because a lot of non-health care professionals had the impression that palliative care was just hospice with another name. But others wanted to expand palliative care so people could get this care earlier in their illness and not just a month or so before the patient goes to hospice.

Dr. Factora said that hospice eligibility is defined as six-month life expectancy, but palliative medicine can be activated anytime before that. So, hospice patients can be palliative care patients, but not all palliative care patients are hospice patients. His impression was to allow patients greater access to palliative care before they enter hospice because the problem is that hospice care is utilized way too late. In many cases hospice is used just two weeks before the time of death. This change could allow a patient to enter care when they have a serious illness which can lead to life threatening illness to eventually a terminal diagnosis. Palliative care is going to deal with certain diagnoses, but you want a person to enter palliative care earlier in their disease progression so they do not have to suffer
needlessly. Dr. Factora believed that the palliative care medicine physician would determine what a serious illness was.

Mr. LaCross reported that the definition in the -7 version of the bill defines palliative care as:

Palliative care means specialized care for a patient of any age who has been diagnosed with a serious or life-threatening illness that is provided care at any stage of the illness by an interdisciplinary team working in consultation with health care professionals including those who may be seeking to cure the illness and needs to do all of the following. . .

Discussion was held regarding exemptions included in the Board’s prescribing rules and it was noted that palliative care is not exempted. It was noted that the Board did not want expanded palliative care services to be a gateway to increased opioid use.

It was noted that minimal standards of care apply to all patients.

Dr. Steinbergh asked if we had a definition for palliative care physician, as we do for pain management.

Dr. Schachat asked what are some of things that a palliative care physician could do that they can’t do now.

Dr. Factora said that the doctor can monitor the symptom management for the disease progression, such as late stage lung cancer or congestive heart failure. Many time the symptoms may be managed by the primary care physician but the symptoms may evolve and may require closer monitoring and adjustments for symptom management. It may be superseded by other clinical disease processes which the primary care doctor still must take care of. Often the symptoms may be put aside and unaddressed until the time they really become the dominant feature of that person’s clinical situation. Palliative care doctors really are meant to address these symptoms specifically.

Dr. Factora said he believes the legislation allows the introduction of appropriate patients into a pathway that is really focused on symptom management. He doesn’t think it opens Pandora’s box and allows a rate of prescribing freedom for any controlled substance relative to any other discipline.

Dr. Soin commented that we should be vigilant and that there are guardrails in place for patient safety.

Mr. LaCross said he would keep the board updated regarding the progress of this legislation.

House Bill 479, Pharmacy Drug Transparency

Mr. LaCross said Mr. Giacalone and Dr. Schachat wanted to put this bill on the board’s radar. It is supported by the pharmacist’s association.

Claw back is used by a pharmacy benefits manager to overinflate the cost of prescription medications at the point of sale transaction. Claw back forces the pharmacies to charge the customers more than the cash price, then the pharmacy benefit manager claws back the money that the customer was overcharged.
Gag restrictions is another practice by a pharmacy benefits manager. So, on top of overinflating the price of the medication, a contractual gag prohibits a pharmacy employee from telling the patient that the medication is cheaper if the patient pays in cash rather than using their prescription benefit.

Mr. LaCross said he wanted to bring this bill to the Board for their information. Mr. LaCross will provide some additional information received from the Pharmacy Association.

Mr. Giacalone was concerned about the gag order as it unacceptable and may interfere with patient care if the patient can't obtain their medication.

**HB 541 Health Services Volunteers**

Mr. LaCross reported that this bill would allow out-of-state doctors who hold a full license in another state to come to Ohio and work in a RAM clinic for seven days without remuneration but without getting any type of Ohio license. So basically, they treat patients and leave the state.

Mr. LaCross said that language will be added to the legislation: *the person must hold a valid, full and unrestricted license in another state and will be deemed as having a temporary license for a charitable event that will last not more than seven days subject to the authority of the State Medical Board and the provisions of Section 4731. ORC.*

He also said the RAM clinic would have to have information about the providers on file.

**Adjourn**

Due to time constraints, Dr. Soin reported that the remainder of the policy committee agenda items will be discussed by full the Board later today.

Dr. Bechtel moved to adjourn the meeting. Mr. Giacalone seconded the motion. Motion carried.

The meeting adjourned at 10:36 a.m.

jkw
Medical Board Legislative Report
April 05, 2018

Attached please find a list of all legislation being monitored by the Board. Below are updates on bills of interest.

**Senate Bill 259, Physician Assistant Regulation:**

The legislation was introduced by Senator Hackett and has currently been given sponsor testimony in Senate Health Committee. The bill is supported by the Ohio Association of Physician Assistants and generally proposes to revise the laws regulating the practice of physician assistants.

**Medical Board Members:** Dr. Steinbergh, Dr. Schachat

**Affected Code Sections:**

4730.06, 4730.11, 4730.15, 4730.201, 4730.203, 4730.21, 4730.38, 4730.39, 4730.40, 4730.41, 4730.42, 4730.43

**Legislative Analysis:**

- Eliminates provisions that limit the drugs a physician assistant may be authorized to prescribe to those included in a formulary established by the State Medical Board (4730.41(B)(1)).
- Explicitly prohibits a physician assistant from prescribing any drug in violation of state or federal law (4730.41(C)).
- Permits a physician assistant to delegate to another person the task of administering a drug only if the physician assistant is authorized to prescribe that drug (4730.203(C)).
- Authorizes a physician assistant to personally furnish samples of drugs and therapeutic devices that are not in the physician assistant's physician-delegated prescriptive authority (4730.41(A)).
- Authorizes a physician assistant working in a health care facility to perform rapid intubation and procedural sedation, as well as to order such procedures or the drugs needed to perform them (4730.201).
- Eliminates a requirement that a physician assistant seeking an Ohio license based on service in another jurisdiction, the U.S. armed forces, or the U.S. Public Health Service have practiced for at least three consecutive years in the other jurisdiction or service (4730.11).
- Increases to five (from three) the number of physician assistants a physician may supervise at any one time (4730.21(B)).
Next Steps:
- Board proposed amendment on supervision agreements – on site filing and CME style auditing
- Board proposed amendment on PAPC structure/operation – allow for telecommunication of meetings
- Board proposed amendment on Active Military, VA licensure jurisdiction exemption

House Bill 286, Palliative Care Programs:

The legislation was introduced by Representative LaTourette and has been heard for proponent testimony in Senate Health, Human Services and Medicaid Committee. The bill generally proposes to create the Palliative Care and Quality of Life Interdisciplinary Council, to establish the Palliative Care Consumer and Professional Information and Education Program, and to require health care facilities to identify patients and residents who could benefit from palliative care.

Medical Board Members: Dr. Factora, Dr. Schachat, Dr. Soin

Affected Code Sections:
3702.30, 3727.05, 3727.061, 3901.89, 4731.14, 4731.281, 4731.29, 4731.56, 4731.57, 5164.302

Legislative Analysis:
- Creates the Palliative Care and Quality of Life Interdisciplinary Council to consult with and advise the Department of Health on matters related to palliative care initiatives (3701.36(E)(1)).
- Establishes the Palliative Care Consumer and Professional Information and Education Program in the Department of Health and requires the Department to publish on its website certain information regarding palliative care (3701.361).
- Requires specified health care facilities and providers to establish a system for identifying patients or residents who could benefit from palliative care and to provide information on palliative care (3701.362(A)(1)).
- Authorizes a licensed hospice care program operating an inpatient hospice care facility or unit to provide palliative care to a patient other than a hospice patient (3712.063).

Next Steps:
- Rep. LaTourette’s office circulated a -8 version of the bill. All agreed upon changes are intact.
House Bill 479, Pharmacy Drug Transparency:

The legislation was introduced by Representative Lipps and Representative West and has been heard for sponsor testimony in House Government Accountability and Oversight. The bill generally proposes changes to health plan insurers, pharmacy benefit managers, and other administrators charging greater amounts than the actual cost of the drug. The bill also requires pharmacists, pharmacy interns, and terminal distributors to inform patients when using insurance to purchase a drug that it exceeds the amount it would cost without it; pharmacies may not charge the higher amount.

Medical Board Members: Dr. Schachat, Mr. Giacalone

Affected Code Sections:

1739.05, 1751.90, 3923.87, 3959.12, 3959.20, 4729.47

Legislative Analysis:

- Prohibits a plan issuer, pharmacy benefit manager, or other administrator to collect cost-sharing (The cost to an individual insured under a health benefit plan according to any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket expense requirement imposed by a plan) greater than the lesser of any of the following:
  - The amount an individual would pay for the drug if the drug were purchased without coverage
  - The net reimbursement paid to the pharmacy for the prescription drug by the health plan issuer
- A health plan issuer, pharmacy benefit manager, or other administrator cannot retroactively adjust a pharmacy claim for reimbursement unless a pharmacy audit is conducted in accordance with 3901.811 to 3901.814, or a technical billing occurred (3959.20).
- No health plan issuer, pharmacy benefit manager, or other administrator can charge a fee related to a pharmacy claim unless the fee can be determined at the time of claim adjudication (3959.20).
- Required the Department of Insurance to create a web form where consumers can submit complaints (3959.20).
- When filling a prescription, if a pharmacist, pharmacy intern, or terminal distributor of dangerous drugs has information indicating the cost-sharing amount exceeds what would otherwise be paid for the drug they must provide this information to the patient and the patient must not be charged the higher amount (4729.47).

Next Steps:
  - The Board will continue to watch this legislation and provide support where needed.
House Bill 541 Health Services Volunteers:

The legislation was introduced by Representative LaTourette and Representative Patterson and has been heard for sponsor testimony with a sub bill accepted House Health and Human Services Committee. The bill generally proposes that health professionals licensed in other states can provide health services during charitable events in Ohio.

Medical Board Members: Dr. Rothermel

Affected Code Sections:

4715.09, 4715.20, 4723.32, 4725.26, 4725.59, 4730.02, 4731.41, 4731.43, and 4731.60

Legislative Analysis:

- A physician’s assistant is exempt from ORC 4730.02 if the person holds a valid license or other form of authority to practice as a physician assistant issued by another state, and the person is practicing as a volunteer without remuneration during a charitable event that lasts not more than seven days (4730.02).
- An MD, DO, and DPM are exempt from 4731.41, 4731.43, and 4731.60 if the person holds a valid license or other form issued by another state, and the person is practicing as a volunteer without remuneration during a charitable event that lasts not more than seven days.
- When a person meets the allowed exemptions of 4730.02, 4731.41, 4731.43, and 4731.60 the person's scope of practice is limited to the procedures that a physician’s assistant, MD, DO, and DPM licensed under the chapters 4730.02, 4731.41, 4731.43, and 4730.60 is authorized to perform.
- A practicing individual is deemed authorized by the state medical board during the charitable event to practice medicine and surgery. The practitioner is subject to the provisions of medical board chapter and the board is authorized to take disciplinary action.

Next Steps:

- Proposed board amendment has been accepted clarifying that PA, MD, DO, and DPM's practicing in this state during the 7-day charitable event are subject to the authority of the State Medical Board and the provisions of chapter 4731 of the Revised Code has been accepted.
House Bill 535 Naloxone-Naltrexone Data Reporting:

The legislation was introduced by Representative Gavarone and has been heard for opponent testimony in House Community and Family Advancement. The bill generally proposes requiring certain reports regarding overdoses and naloxone, and to include naltrexone within OARRS.

Medical Board Members: TBD

Effecte Code Sections:

4729.01, 4729.44, 4729.75, 4729.79, 4729.85, 3727.25, and 4765.45

Legislative Analysis:

- Hospitals must report to the department of health on a monthly basis the total number of drug overdoses brought in for treatment, and the number of overdoses that resulted in and did not result in death (3727.25).
- Adds naltrexone to the list of drugs reported to OARRS (4729.79).
- The pharmacy board must provide reports detailing the number of prescribers who issued a prescription for or personally furnished naltrexone, the number of patients to whom the drug was dispensed or personally furnished, and the average quantity of the drug prescribed or personally furnished at one time (4729.85)

Next Steps:

- No action at this time

House Bill 546 Telemedicine-Health Benefit Plans:

The legislation was introduced by Representative Patton and has been referred to the House Health and Human Services Committee. The bill generally proposes the prohibition of health benefit plans from treating telemedicine services differently from in-person health care services solely because they are provided as telemedicine services.

Medical Board Members: TBD

Effecte Code Sections:

3902.30

Legislative Analysis:

- A health benefit must 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; a health benefit plan cannot exclude coverage for a service solely because it is provided as a telemedicine service (3902.30).
– A health benefit plan must not impose any annual or lifetime benefit maximum in relation to telemedicine services other than a benefit maximum imposed on all benefits offered under the plan (3902.30).

**Next Steps:**

– Board / Staff Review
HB75  PROFESSIONAL LICENSURE-ARMED FORCES (GAVARONE T, MERRIN D) To establish an expedited process to grant a professional license to an individual who is on active duty as a member of the armed forces of the United States, or is the spouse of such an individual, and holds a valid license in another state.

**Current Status:** 3/15/2017 - House Armed Services, Veterans Affairs and Homeland Security, (Second Hearing)


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HB131  PHYSICAL THERAPY LAWS (GAVARONE T, REINEKE W) To modify the laws governing the practice of physical therapy.

**Current Status:** 3/21/2018 - SUBSTITUTE BILL ACCEPTED & REPORTED OUT, House Health, (Seventh Hearing)


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HB146  CORONERS EDITING DEATH CERTIFICATES (HOUSEHOLDER L) To allow a coroner to change the cause, manner, and mode of death in a filed death certificate only after a hearing in the court of common pleas.

**Current Status:** 2/20/2018 - House State and Local Government, (Seventh Hearing)


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HB167  PHYSICIANS AND DENTISTS-OPIOIDS (EDWARDS J) Regarding addiction treatment and opioid prescribing by physicians and dentists.

**Current Status:** 5/17/2017 - House Health, (First Hearing)


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HB172  MEDICAL RECORD ACCESS (SCHURING K) To modify the laws governing access to a patient's medical records.

**Current Status:** 1/24/2018 - Re-Referred to Committee


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HB184  AUTHORIZE TELEDENTISTRY SERVICES (GAVARONE T, DEVITIS A) To authorize the provision of dental services through teledentistry, to require a proposal for creation of a primary care dental student component of the Choose Ohio First Scholarship Program, and to make other changes to the laws governing the practices of dentistry and dental hygiene.

**Current Status:** 12/5/2017 - Senate Health, Human Services and Medicaid, (First Hearing)

HB189  COSMETOLOGY LICENSING (ROEGNER K, REECE A) To make changes to the Cosmetology Licensing Law.

Current Status: 3/7/2018 - REPORTED OUT, House Government Accountability and Oversight, (Fifth Hearing)


HB191  REGISTERED NURSE ANESTHETISTS (GONZALES A) Regarding the practice of certified registered nurse anesthetists.

Current Status: 1/24/2018 - House Health, (Third Hearing)


HB231  CONTROLLED SUBSTANCES-LOCKABLE CONTAINERS (GINTER T, SPRAGUE R) To require pharmacists to offer to dispense controlled substances in lockable or tamper-evident containers


HB258  ABORTION-DETECTABLE HEARTBEAT (HAGAN C, HOOD R) To generally prohibit an abortion of an unborn human individual with a detectable heartbeat and to create the Joint Legislative Committee on Adoption Promotion and Support.

Current Status: 12/13/2017 - REPORTED OUT, House Health, (Fourth Hearing)


HB273  PHYSICIAN CERTIFICATION (GAVARONE T) To prohibit a physician from being required to secure a maintenance of certification as a condition of obtaining licensure, reimbursement, or employment or obtaining admitting privileges or surgical privileges at a hospital or health care facility.

Current Status: 10/25/2017 - House Health, (Third Hearing)


HB286  PALLIATIVE CARE PROGRAMS (LATOURRETTE S) To create the Palliative Care and Quality of Life Interdisciplinary Council, to establish the Palliative Care Consumer and Professional Information and Education Program, and to require health care facilities to identify patients and residents who could benefit from palliative care.

Current Status: 1/30/2018 - Senate Health, Human Services and Medicaid, (Second Hearing)


HB317  PRO BONO HEALTHCARE DEDUCTION (YOUNG R) To authorize, for six years, a personal income tax deduction for a physician based on the number of hours the physician provides uncompensated medical services through a hospital, free clinic, or nongovernmental medical organization.

HB326  **PSYCHOTROPICS-DRUG ADDICTION TREATMENT** (SEITZ B, GAVARONE T) To authorize certain psychologists to prescribe psychotropic and other drugs for the treatment of drug addiction and mental illness.

**Current Status:** 4/11/2018 - House Health, (Second Hearing)


HB348  **FENTANYL TRAFFICKING PENALTIES** (GINTER T) To provide that the penalty for trafficking in, possession of, or funding of trafficking in fentanyl or carfentanil is the same as the penalty for those crimes involving heroin, to increase to a third degree felony the trafficking in or possession of at least one gram but less than five grams of any of those drugs, to provide that deception to obtain a dangerous drug involving fentanyl or carfentanil is a third degree felony, and to provide a per se prohibited concentration of fentanyl and carfentanil regarding operating a vessel or motor vehicle that is the same as the per se prohibited concentration for heroin.

**Current Status:** 10/10/2017 - Referred to Committee House Criminal Justice


HB479  **PHARMACY DRUG PRICE TRANSPARENCY** (LIPPS S, WEST T) Regarding pharmacy benefit managers, pharmacists, and the disclosure to patients of drug price information.

**Current Status:** 3/20/2018 - House Government Accountability and Oversight, (First Hearing)


HB535  **NALOXONE-NALTREXONE DATA REPORTING** (GAVARONE T) To require certain reports regarding overdoses and naloxone, to include naltrexone within the Ohio Automated Rx Reporting System, and to name this act the “Opioid Data and Communication Expansion Act.”

**Current Status:** 3/21/2018 - House Community and Family Advancement, (Third Hearing)


HB536  **HEALTH INSURANCE-EMERGENCY COVERAGE** (REECE A) To prohibit health plan issuers, including those participating in the Medicaid care management system, from implementing any form of selective emergency services coverage.

**Current Status:** 3/21/2018 - House Insurance, (First Hearing)


HB541  **HEALTH SERVICES VOLUNTEERS** (PATTERSON J, LATOURETTE S) To authorize health professionals licensed in other states to provide volunteer health services during charitable events.

**Current Status:** 4/11/2018 - House Health, (Second Hearing)
HB546  **TELEMEDICINE-HEALTH BENEFIT PLANS** (PATTON T) To prohibit health benefit plans from treating telemedicine services differently from in-person health care services solely because they are provided as telemedicine services.

**Current Status:** 4/11/2018 - House Health, (First Hearing)


HB557  **ART THERAPY LICENSURE** (ANIELSKI M) To require the licensure of art therapists and to require the State Medical Board to regulate the licensure and practice of art therapists.

**Current Status:** 4/11/2018 - House Health, (Second Hearing)


HB565  **ABORTION BAN** (HOOD R, VITALE N) Regarding the abolition of abortion in the state of Ohio and the protection of unborn humans.

**Current Status:** 3/19/2018 - Introduced


SB55  **NURSE-PATIENT RATIOS** (SKINDELL M) To establish minimum ratios of direct-care registered nurses to patients in hospitals, to specify rights of registered nurses working in hospitals, and to prohibit retaliatory actions by hospitals against registered nurses.

**Current Status:** 3/21/2017 - Senate Health, Human Services and Medicaid, (First Hearing)


SB109  **MEDICAL INFORMATION-YELLOW DOT** (TAVARES C) To establish the "Yellow Dot" motor vehicle medical information program within the Department of Public Safety.

**Current Status:** 1/30/2018 - Senate Local Government, Public Safety and Veterans Affairs, (First Hearing)


SB110  **HEALTH CARE PROFESSIONALS-IDENTIFICATION** (TAVARES C) To require a health care professional to wear identification when providing care or treatment in the presence of a patient.

**Current Status:** 1/23/2018 - Senate Health, Human Services and Medicaid, (First Hearing)


SB119  **ADDICTION TREATMENT AND PRESCRIPTIONS** (HACKETT R, HOTTINGER J) Regarding addiction treatment and opioid prescribing by physicians and dentists.

**Current Status:** 6/27/2017 - Senate Health, Human Services and Medicaid, (First Hearing)
SB126 CONVERSION THERAPY BAN-MINORS (TAVARES C) To prohibit certain health care professionals from engaging in conversion therapy when treating minor patients.

Current Status: 9/26/2017 - Senate Health, Human Services and Medicaid, (First Hearing)


SB129 COSMETOLOGY LICENSING LAW CHANGES (JORDAN K, TAVARES C) To make changes to the Cosmetology Licensing Law.

Current Status: 12/12/2017 - Senate Government Oversight and Reform, (Second Hearing)


SB154 OPIOID ADDICTION RESPONSE (SCHIAVONI J, YUKO K) To provide for the prevention and treatment of opioid addiction, to make an appropriation, and to declare an emergency.

Current Status: 5/24/2017 - Referred to Committee Senate Finance


SB177 VOLUNTEER HEALTH CARE IMMUNITY (LEHNER P) To expand the circumstances in which qualified immunity from civil liability applies with respect to volunteer health care services provided to indigent and uninsured persons.

Current Status: 9/26/2017 - Senate Judiciary, (First Hearing)


SB178 MEDICAL TREATMENT ORDER PROCEDURES (LEHNER P) To establish procedures for the use of medical orders for life-sustaining treatment and to make changes to the laws governing DNR identification and orders.

Current Status: 9/7/2017 - Referred to Committee Senate Health, Human Services and Medicaid


SB221 RULE-MAKING AND REVIEW REFORM (UECKER J) To reform agency rule-making and legislative review thereof.

Current Status: 3/21/2018 - REPORTED OUT AS AMENDED, Senate Government Oversight and Reform, (Fourth Hearing)


SB229 CONTROLLED SUBSTANCES REGULATION (EKLUND J, LEHNER P) To modify laws pertaining to the State Board of Pharmacy and the regulation of controlled substances.

Current Status: 12/12/2017 - Senate Health, Human Services and Medicaid, (Second Hearing)
SB259  PHYSICIAN ASSISTANT REGULATION (HACKETT R) To revise the law regulating physician assistant practice.

Current Status: 3/13/2018 - Senate Health, Human Services and Medicaid, (First Hearing)


actionTRACK - Hannah News Service, Inc.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: FSMB Resolutions and Board Reports

DATE: April 6, 2018

Five (5) resolutions that will be presented to the 2018 FSMB House of Delegates for action on April 28 are included in the Policy Committee materials. Please note that prior Resolution 18-3 regarding physician assistants was withdrawn from consideration.

Following staff discussion with Mr. Giacalone, recommended action on each item is as follows:

Resolution 18-1: Acute Opioid Prescribing Workgroup and Guidelines (OH) – Reference Committee B
Recommended action: Support the resolution

Resolution 18-2: Testing Under Time Constraints of the Necessary and Explicit Component of the USMLE (MN) – Reference Committee B
Recommended action: Further clarification needed as the current USMLE bulletin describes the format and time limits of each step:

<table>
<thead>
<tr>
<th>Step 1</th>
<th>280 multiple choice questions Prometric test centers</th>
<th>7 blocks: 60 minutes each One day test session - 8 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2 Clinical Knowledge</td>
<td>318 multiple-choice questions Prometric test centers</td>
<td>8 blocks: 60 minutes each One day test session - 9 hours</td>
</tr>
<tr>
<td>Step 2 Clinical Skills</td>
<td>12 patient cases – administered at six test centers in US</td>
<td>15 minutes per patient with 10 minutes to record patient note One day test session – 8 hours</td>
</tr>
<tr>
<td>Step 3</td>
<td>Day 1 – 180 multiple-choice questions Prometric test centers</td>
<td>Day 1: 6 blocks: 45-minutes about 33 questions each block One day test session – 7 hours</td>
</tr>
<tr>
<td>Day 1 – Foundations of Independent Practice</td>
<td>Day 2 – 13 computer based case simulations Prometric test centers</td>
<td>Day 2 – each simulation is allotted a maximum of 10 or 20 minutes each One day test session – 9 hours</td>
</tr>
<tr>
<td>Day 2 – Advanced Clinical Medicine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Resolution 18-3: Permitting Out-of-State Practitioners to Provide Continuity of Care in Limited Situations (WA-M) – Reference Committee A
Recommended action: Support the resolution

Resolution 18-4: Interprofessional Continuing Education (FSMB BOD) – Reference Committee A
Recommended action: Support the resolution
Resolution 18-5: Workgroup on AI and Its Potential Impact on Patient Safety and Quality of Care in Medical Practice (PA-M) – Reference Committee B
   Recommended action: Support the resolution

The five (5) FSMB Board of Director Reports are also included in the Policy Committee materials
Recommended action is provided:

BRD RPT 18-1: Report of the Workgroup to Study Regenerative and Stem Cell Therapy Practices – Reference Committee B
   Recommended action: Support the FSMB Board of Directors recommendation to adopt the workgroup report.

   Recommended action: Support the FSMB Board of Directors recommendation to adopt the recommendations included in the report.

BRD RPT 18-3: Report of the FSMB Workgroup on Physician Wellness and Burnout – Reference Committee B
   Recommended action: Support the FSMB Board of Directors recommendation to adopt the recommendations included in the report.

BRD RPT 18-4: Guidelines for the Structure and Function of a State Medical and Osteopathic Board – Reference Committee A
   Recommended action: Support the FSMB Board of Directors recommendation to adopt the guidelines.

BRD RPT 18-5: Report on Resolution 17-2: Advocacy for Professional Licensure of EMS Providers – Reference Committee A
   Recommended action: Support the conclusion to not recommend a policy change at this time regarding the licensure and regulation of EMS personnel

Finally, the Report of the Bylaws Committee and a REVISED Report of the Nominating Committee are also included in the Policy Committee materials. Recommended action is provided.

FSMB Bylaws proposed amendments – Reference Committee A

   Proposed amendment #1 recommended by the FSMB Board of Directors: creates a Staff Fellow category of membership – such fellows are eligible to serve on the Board of directors (for executive Directors of Medical Boards); also allows member boards to name other staff members as Associate Members of the FSMB.
   Recommended action: Support the amendment

   Proposed amendment #2 recommended by Bylaws Committee: Immediate Past Chair of FSMB Board of Directors remains an officer of the corporation and is a standing member of the Executive Committee.
   Recommended action: Support the amendment

   Proposed amendment #3 recommended by the Bylaws Committee: Permits the FSMB Chair to appoint an Associate Member (the new category for Board staff other than Executive Director) to serve on the Editorial Committee.
   Recommended action: Support the amendment

FSMB Bylaws proposed amendments continued – Reference Committee A
Proposed amendment #4 offered by the Tennessee Board of Medical Examiners. Proposes to change Article IV: Board of Directors to allow the inclusion of (2) public/consumer members, who are not Associate Members, to serve on the Board of Directors.

Bylaws Committee recommendation to TABLE the amendment until the Bylaws Committee can make its final recommendation to the House in 2019.

Recommended action: Await results of discussion at Reference Committee.

Nominating Committee report – accepted as revised for information.
MEMORANDUM

TO:       Amol Soin, MD, Chair, Policy Committee
           Members, Policy Committee

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

DATE:    April 6, 2018

RE:       Dietetics and Respiratory Care rules

On January 21, 2018, the Medical Board added the licensees of the former boards of dietetics and respiratory care pursuant to the provisions of House Bill 49. Also, House Bill 145, which was signed into law on February 8, 2017, further aligned the dietetics and respiratory care statutes with the Medical Board statutes and processes. The statutory changes in these amended laws require corresponding changes to the rules for dietetics and respiratory care in chapters 4759 and 4761 respectively.

Many of the proposed changes involve requests to rescind rules where the Medical Board already has rules in areas such as disciplinary hearings, personal information systems, criminal record checks, rulemaking, notice of board meetings, and board operations. In addition, many rules have minor amendments that involve substituting State Medical Board of Ohio for the respective board.

There is also a substantial number of rules that are proposed to be filed as no change rules due to the five-year rule review date already having passed for most dietetics rules and many respiratory care rules.

Specific to dietetics, proposed rules reflect statutory changes to licensure including elimination of licensure by reciprocity, inactive status of licenses, and prorating of the initial license fee. In addition, the proposed rules include changes to the application and renewal procedures to reflect the electronic licensure and Board processes for other licensees. Also, proposed changes align the reinstatement and restoration processes for expired licenses with Board processes for other licensees. Lastly, a new rule 4759-11-01 Miscellaneous Provisions is proposed to incorporate dietetics licensees into the Medical Board rules for Criminal Record Checks (4731-4), Personal Information systems (4731-8), Hearings (4731-13), Reporting Requirements (4731-15), Impaired Practitioners (4731-16), Sexual Misconduct and Impropriety (4731-26), and Mental or Physical Impairment (4731-28). There will be corresponding minor changes forthcoming in these rule sets to reference dietitians and specific statutory citations in Title 4759 of the Ohio Revised Code.
As to respiratory care, proposed changes reflect the statutory elimination of inactive license status and lapsed license status, temporary non-resident practice of respiratory care, and collection of hyperbaric technologist certifications. Also, the respiratory care board had previously convened an education committee to monitor the respiratory care educational programs in Ohio. The proposed amended rule 4761-4-02 assigns an advisory role to the respiratory care advisory committee in this area consistent with its articulated statutory duties in R.C. 4761.032. In addition, the proposed rules align limited permit application procedures to electronic licensure processes and Board processes for other licensees. Lastly, a new rule 4761-15-01 Miscellaneous Provisions is proposed to incorporate respiratory care licensees into the Medical Board rules for Criminal Record Checks (4731-4), Personal Information systems (4731-8), Hearings (4731-13), Reporting Requirements (4731-15), Impaired Practitioners (4731-16), Exposure-Prone Invasive Procedure Precautions (4731-17), Sexual Misconduct and Impropriety (4731-26), and Mental or Physical Impairment (4731-28). There will be corresponding minor changes forthcoming in these rule sets to reference respiratory care professionals and specific statutory citations in Title 4761 of the Ohio Revised Code.

In addition, there will be additional proposed rules forthcoming for respiratory care in the areas of licensure and continuing education. The complexity of the processes in these areas for respiratory care merits further research and consultation with the respiratory care advisory council before these rules would be in suitable form for initial introduction to the Policy Committee.

PROPOSED ACTIONS:

1. Approve the rules for initial circulation to interested parties.

2. Refer the rules to the respective advisory councils for Dietetics and Respiratory Care for further review.
4759-1-01 Public notice of rule adoption. (Propose to rescind)

(A) Prior to adoption, amendment or rescission of any rule, except an emergency rule, the Ohio board of dietetics shall give public notice thereof as provided by section 119.03 of the Revised Code, at least thirty days prior to the date set for the public hearing. The board shall provide persons who are subject to, or may be affected by, the rules with reasonable notice by publication of that notice in the register of Ohio. Such notice shall contain a synopsis or general statement of the rule or rules to be adopted, amended, or rescinded, and the date, time, and place of the hearing on the proposed action.

(B) The board may give whatever other notice it reasonably considers necessary by mailing or faxing the notice one time to the following persons or organizations:

(1) Notice shall be sent to any person or organization included on the board's subscriber list during the past five years.

(2) Notice shall be sent to "The Ohio Academy of Nutrition and Dietetics" and such of their affiliate district associations as registered with the board.

(C) The board may post the notice on the board's web site as well as the full text of the proposed rules to be adopted, amended, or rescinded.

(D) The board may post the notice in the board's newsletter.

(E) Copies of the notice of the public hearing and the full text of the proposed rules shall be available at the board's offices at least thirty days prior to the date of the public rules hearing.

(F) The board may assess a reasonable fee, not to exceed the cost of copying and mailing, for notices sent to persons in accordance with this rule.
Notice of board meetings. (Propose to rescind)

(A) Any person may ascertain the time and place of all regularly scheduled meetings of the Ohio board of dietetics, and the time, place, and purpose of all special meetings of the board by any one of the following methods:

(1) Calling the board office by telephone during normal business hours (no collect calls will be accepted under any circumstances);

(2) Contacting the board office in person during normal business hours; or

(3) Providing the board with a written request for such notification and with a stamped self-addressed business-size envelope.

(4) Checking the board's website at www.dietetics.ohio.gov.

(B) Any person or organization who makes written request for routine notification of all regularly scheduled and special meetings of the board, shall be placed on the subscriber list maintained in the board office. Subscribers shall provide the board with one self-addressed stamped business-size envelope for each month during the time period that they wish to be notified. After the requested notification period has ended, such notification will cease, unless it is renewed in the manner set forth in this paragraph.

(1) Notices will be electronically disseminated at least seven calendar days prior to any regularly scheduled meeting, and at least four calendar days prior to any special meeting, unless the meeting is an emergency meeting. Notices of special meetings will include the type of business to be discussed.

(2) It is the responsibility of the person requesting notification to keep the board informed in writing of changes in the person's current mailing address.

(3) The obligation of the board under paragraph (B) of this rule to each person or organization fully complying with said requirements shall be deemed fully discharged with the mailing of notification to the most current mailing address and name on file with the board for this purpose, as of seven days prior to the particular regularly scheduled meeting.

(C) A representative of a news media organization, or of the business office of "The Ohio Academy of Nutrition and Dietetics," may receive notification of board meetings by making written request to the board office. The board will compile a mailing list and will mail notification of all regularly scheduled and special meetings to these representatives at their business addresses in accordance with the schedule in paragraph (B)(1) of this rule.

(1) Provided that not more than one representative of a radio or television station, newspaper, or other publication or of "The Ohio Academy of Nutrition and Dietetics" may receive such notification.
(2) It is the responsibility of the news media organization or "The Ohio Academy of Nutrition and Dietetics" to notify the board in writing of changes in the name or mailing address of the recipient of such information.

(3) Notification under paragraph (C) of this rule will remain in effect for one year from the date of the written request after which time the name of the organization will be removed from the mailing list unless the request is renewed in writing.

(4) The obligation of the board under paragraph (C) of this rule to each organization fully complying with said requirements shall be deemed fully discharged with the mailing of notification to the most current address and name on file with the board for this purpose, as of seven days prior to the particular regularly scheduled meeting, or four days prior to the particular special meeting.

(D) A representative of a news media organization may obtain telephone notification of emergency board meetings by making a written request to the board, including the name of the individual to be contacted, the individual's mailing address, and a maximum of two telephone numbers where the individual can be reached. The board will maintain a list of all representatives of the news media who request telephone notice of emergency meetings.

(1) In the event of an emergency meeting, the board shall immediately notify by telephone all representatives on the list of such meeting.

(2) Such telephone notice shall be complete if a message has been left for the media representative or if, after a reasonable effort, the board has been unable to provide such telephone notice.

(3) The media representative's name shall remain on the telephone notification list for one year from the date of the written request, after which time it will be removed unless the request is renewed in writing.

(4) It shall be the responsibility of the media representative or the media representative's organization to inform the board of any changes in telephone number or in the name of the person to be notified.

(E) The failure of any individual, organization, or organization representative to comply with the above requirements shall relieve the board of any obligation to provide advance notice of any kind of any public meeting to that individual, organization, or organization representative.
4759-1-03 Personal information systems. (Propose to rescind)

(A) The board shall appoint one employee to be directly responsible for each personal information system maintained by the board. Said employee shall:

(1) Inform all employees who have any responsibility for the operation or maintenance of said system or the use of personal information maintained in the system, of the applicable provisions of Chapter 1347. of the Revised Code and rules adopted thereunder; and

(2) Inform all persons requested to supply personal information for a system whether or not the person is legally required to provide such information; and

(3) Restrict the collection, maintenance, and use of personal information to only that which is necessary and relevant to functions of the board as required or authorized by statute or rule; and

(4) Provide all persons asked to supply personal information that will be placed in an interconnected or combined system, with information relevant to the system, including the identity of all other agencies or organizations that have access to the system; and

(5) Allow a person who is the subject of a record in a personal information system to inspect the record pursuant to section 1347.08 of the Revised Code. Upon the request and verification that the person requesting access to the record is the subject of information contained in the system, the employee shall:

(a) Inform the person of any personal information in the system of which the person is subject;

(b) Permit the person or the person's legal guardian, or an attorney who presents a signed authorization made by the person, to inspect all personal information in the system of which the person is subject, except where prohibited by law;

(c) Inform the person of the uses made of the personal information and identify other users who have access to the system;

(d) Allow a person who wishes to exercise rights as provided by this rule to be accompanied by one individual of that person's choice;

(e) Provide, for a reasonable charge, copies of any personal information the person is authorized to inspect; and

(6) Investigate disputes concerning the accuracy, relevance, timeliness, or completeness of personal information pursuant to section 1347.09 of the Revised Code and paragraph (D) of this rule.

(B) The board shall reprimand in writing any employee who initiates or otherwise contributes to any disciplinary or other punitive action taken against another individual who brings attention to the appropriate authorities, the press, or a member of the public, any evidence of unauthorized use
of any material contained in the personal information system. A copy of the reprimand shall be entered in the employee's personal file.

(C) The board shall monitor its personal information system by:

(1) Maintaining the personal information system with the accuracy, relevance, timeliness, and completeness necessary to assure fairness in any determination made by the board which is based on information contained in the system; and

(2) Eliminating unnecessary information from the system.

(D) The board shall investigate, upon request, the accuracy, relevance, timeliness, or completeness of personal information which is disputed by the subject of a record contained in the system, within ninety days after receipt of a request from the disputant; and

(1) Notify the disputant of the results of the investigation and any action the board intends to take with respect to the disputed information; and

(2) Delete any information the board cannot verify or finds to be inaccurate; and

(3) Permit the disputant, if the disputant is not satisfied with the determination made by the board, to include within the system:

(a) A brief statement of the person's position on the disputed information; or

(b) A brief statement that the person finds the information in the system to be inaccurate, irrelevant, outdated, or incomplete; and

(4) The board shall maintain a copy of all statements made by the disputant.

(E) The board shall not place personal information into an interconnected and combined system, unless said system contributes to the efficiency of the agencies or organizations authorized to use the system in implementing programs which are required or authorized by law.

(F) The board shall not use personal information placed into an interconnected or combined system by another state or local agency or organization, unless the personal information is necessary and relevant to the performance of a lawful function of the board.

(G) The board shall make available, upon request, all information concerning charges made by the board for reproduction of materials contained in its personal information system.
4759-2-01 Definitions.

The following meanings apply to all rules promulgated by the Ohio board of dietetics state medical board of Ohio, unless a specific paragraph explicitly defines or uses the word or term in a different manner.

(A) "Nutritional assessment" means the integrative evaluation of nutritionally relevant data to develop an individualized nutritional care plan. These data may include:

1. Nutrient intake;
2. Anthropometric measurements;
3. Biochemical values;
4. Physical and metabolic parameters;
5. Socio-economic factors;
6. Current medical diagnosis and medications; and
7. Pathophysiological processes.

The mere collection of these data for use in assessment is not nutritional assessment and does not require a dietitian licensed under section 4759.06 of the Revised Code.

(B) "Nutritional counseling" means the advising of individuals or groups regarding nutritional intake by integrating information from the nutritional assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status.

The distribution by an individual of written information prepared by a licensee is not nutritional counseling, and any person distributing the written information need not be licensed under section 4759.06 of the Revised Code.

(C) "Nutritional education" means a planned program based on learning objectives with expected outcomes designed to modify nutrition-related behaviors. This does not prohibit an individual from providing general non-medical nutrition information if the person does not violate division (B) of section 4759.02 of the Revised Code.

(D) "Nutritional care standards" means policies and procedures pertaining to the provision of nutritional care in institutional and community settings.

(E) "Nutritional care" means the application of the science of nutrition in the health and disease of people.
(F) "Board" means the Ohio board of dietetics, state medical board of Ohio.

(G) "Commission" means "The Commission on Dietetic Registration."

(H) "The Academy" means "The Academy of Nutrition and Dietetics."

(I) "Medical nutrition therapy" means the use of specific nutrition services to treat, or rehabilitate an illness, injury, or condition. Medical nutrition therapy includes nutrition assessment, intervention, education, and counseling.

(J) "Council on postsecondary accreditation" is synonymous with "Commission on recognition of post-secondary accreditation."

(K) For purposes of division (B)(2) of section 4759.02 of the Revised Code, the terms "Nutritionist", "Nutrition counselor" and like terms tend to indicate the person is practicing dietetics.

(L) "High nutritional risk" means, but is not limited to, an individual to whom one or more of the following apply:

1. Has a diagnosis of or presence of risk factors for malnutrition, dehydration, anemia, malabsorption disorders, vitamin and mineral deficiencies;

2. Receives enteral or parenteral nutrition;

3. Has pressure ulcer(s), open wounds(s), or non-healing wound(s);

4. Significantly low albumin or hemoglobin levels, or elevated blood urea nitrogen and electrolyte imbalances;

5. Severe chewing or swallowing problems;

6. Consistently poor food/fluid intakes;

7. Individuals who are less than ninety per cent of standard weight for height, or who exhibit significant weight changes as defined by accepted practice guidelines;

8. Decreased activities of daily living (ADL);

9. Decreased cognitive ability;

10. A pregnant female who was fifteen years of age or less at the time of conception;

11. Infants who are small for gestational age, or a pre-term infant of low birth weight.

(M) "General non-medical nutrition information" means information on the following:
(1) Principles of good nutrition and food preparation;
(2) Food to be included in the normal daily diet;
(3) The essential nutrients needed by the body;
(4) Recommended amounts of the essential nutrients;
(5) The actions of nutrients on the body;
(6) The effects of deficiencies or excesses of nutrients; or
(7) Food and supplements that are good sources of essential nutrients.
4759-3-01 Duties of board members. (Propose to rescind)

(A) Chairman:

(1) The chairman shall preside at all board meetings at which the chairman attends and perform all duties prescribed by law or board regulations; and

(2) The chairman is authorized by the board to make minor decisions regarding board activities in order to facilitate the responsiveness and effectiveness of the board.

(B) Vice chairman:

(1) The vice chairman shall perform the duties of the chairman if the chairman is absent or disabled; and

(2) If the office of chairman becomes vacant, the vice chairman will serve until a successor is elected.

(C) Board members:

The policy of the board is that members shall attend regular and special meetings as scheduled, and shall be compensated on a per diem basis when attending meetings or conducting official business for the agency.

(D) Election of officers:

Election of officers shall be conducted in accordance with the calendar year.
4759-3-02 Executive secretary/executive director. (Propose to rescind)

(A) The board shall designate an executive secretary who shall serve at the pleasure of the board. The executive secretary shall be the chief administrative officer of the board, may use the working title executive director, and shall be responsible to the board for the daily activities of its staff.

(B) The executive secretary/executive director shall be a licensee of the board but shall not engage in the practice of dietetics for compensation outside the scope of the duties of the executive secretary/executive director.

(C) In appointing an executive secretary/executive director, the board shall select a person of the highest available competence who has a minimum of five years of experience in the practice of dietetics and is the holder of a master's degree.
4759-3-03 Minutes of board meetings. (Propose to rescind)

(A) The unapproved minutes of all board meetings shall be recorded and open to public inspection in a binder located in the board office during normal business hours within ten business days of their recordation.

(B) Within ten business days after their approval by the board, the approved minutes of all board meetings shall be substituted for the unapproved minutes and shall be open to public inspection in the manner provided for in paragraph (A) of this rule and also posted to the board's web site within a reasonable time.
4759-3-04 Cooperation and communication with professional organizations.

The board shall maintain and foster communications between the board and all professional organizations in the state whose members are licensees. The board shall recognize "The Ohio Academy of Nutrition and Dietetics" for the purpose of requesting such state organization to designate an official liaison to the board. In the event such a liaison is designated by "The Ohio Academy of Nutrition and Dietetics," the board, the executive secretary/executive director, and the staff shall cooperate with the liaison in maintaining and fostering communication between the board and the association and the liaison may attend all board meetings and dietetics advisory council meetings or designate a substitute when unavailable to attend. The liaison shall be permitted to participate in board the dietetics advisory council discussions to the extent the board dietetics advisory council deems appropriate, except the liaison shall not participate in any deliberation on the discipline of a licensee.
4759-3-05 Advisory committees. (Propose to rescind)

The chairman of the board may appoint such advisory committees of board members and others as may assist the board in carrying out its responsibilities.
4759-3-06 Parliamentary procedures. (Propose to rescind)

Unless required otherwise by statute or rule, meetings of the board and committees shall be conducted according to the latest edition of "Robert's Rules of Order."
4759-3-07 Adjudication hearings. (Propose to rescind)

Any person receiving notice from the board of a violation of section 4759.02 of the Revised Code is entitled to a hearing if the person requests it within thirty days of the date of mailing the notice.
4759-4-01 Applications.

(A) Each applicant for initial licensure or renewal of a license or limited permit shall file a completed application with the board or submit to the board an application which demonstrates compliance with sections 4759.05 and 4759.06 of the Revised Code and this chapter. This application shall be submitted under oath in the manner determined by the board, and provide such other facts and materials as the board requires. No application shall be considered submitted to the board until the appropriate fee has been received by the board. Application fees are not refundable.

(B) Applications shall be completed in ink, signed by the applicant, accompanied by the appropriate fee and by such evidence, statements or documents as specified or required. An electronic signature may be used on applications submitted on line. No application for a license or permit submitted to the board shall be considered complete until the applicant has complied with the requirements of rule 4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks.

(C) The executive secretary/executive director, in consultation with staff, shall formulate the content of application forms to be used by applicants to the board. The board shall approve the content of the forms prior to their use. Applicants shall only submit applications on the forms approved by the board.

Each form shall contain, prior to the signature of the applicant, a statement that any applicant who knowingly makes a false statement on the application is guilty of a misdemeanor of the first degree under section 2921.13 of the Revised Code. If an applicant fails to complete the application process within six months of initial application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.

(D) Each applicant who is not a registered dietitian (RD) must forward an academic transcript from all degree granting institutions of higher education directly to the board or submit an official "student issued" copy.

(E) For the purpose of proving accreditation of a course of study at a foreign institution, an applicant shall have the applicant's academic credentials independently validated as equivalent by an accreditation agency that is recognized by the "Council for Higher Education Accreditation," or its predecessors, or have the applicant's academic credentials independently validated by an agency specializing in education evaluations which is acceptable to the board. A copy of the validation shall be attached to the application as part of the application.

(F) A licensee shall notify the board of a change of address providing at least a new address, telephone number, and signed request for the change. A licensee shall notify the board of a change of name by providing legal evidence of the name change and a signed request for the change.
(G) All applications, statements and documents submitted shall become the property of the board. No application being investigated under section 4759.07 of the Revised Code, may be withdrawn without approval of the board.
4759-4-02 Preprofessional experience. (Propose to file as no change rule)

(A) An applicant shall successfully complete a preprofessional dietetic experience that is approved by "The Academy of Nutrition and Dietetics" and is at least equivalent to the requirement for such programs adopted by "The Commission On Dietetic Registration."

(B) Doctoral degree alternative.

As an alternative to the requirements in paragraph (A) of this rule, the holder of a doctoral degree may meet the preprofessional dietetic experience by successfully completing a planned program of continuous experience in dietetic practice of not less than nine hundred hours under the supervision of a licensed dietitian in this state or a registered dietitian provided all the following conditions are satisfied:

(1) The applicant holds the doctoral degree from an accredited institution;

(2) The applicant has, as part of successfully completing either a baccalaureate or higher degree from an accredited institution, a major in any of the following subjects: human nutrition, food and nutrition, dietetics, food systems management, or public health nutrition;

(3) The applicant has submitted the program to the board for its approval and received approval prior to engaging in the planned program;

(4) The experience meets requirements that are at least equivalent to the requirements adopted by "The Commission On Dietetic Registration"; and

(5) Following completion of the program, the applicant shall submit a certificate of completion signed by the dietitian who supervised the program.

For purposes of this paragraph, an "accredited institution" is either: an institution accredited to grant the degree described in this paragraph by an accrediting agency that is recognized by the "Council for Higher Education Accreditation" or its predecessors; or an institution in a foreign country when the applicant presents evidence that the doctoral degree has been validated as equivalent to a degree under this paragraph by an institution accredited for such degrees in accordance with this paragraph or; by an agency specializing in educational credential evaluations which is acceptable to the board.
4759-4-03 Examination. (Propose to file as no change rule)

(A) As a prerequisite to the issuance of an initial license, the applicant shall provide evidence of passing the examination designated in paragraph (B) of this rule.

(B) The board selects and approves of the examination for dietitians offered by "The Commission On Dietetic Registration".
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) Be a registered dietitian; or

(2) If 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."

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 state medical board of Ohio 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 restoration 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.
4759-4-05 Licensure by reciprocity. (Propose to rescind)

If an applicant seeks licensure on the basis that the applicant has met equivalent requirements in another state or foreign country, the applicant shall attach to the application proof that the requirements of the other state or foreign country are equivalent to those of this state, unless the board has taken action recognizing that the requirements of the other state or foreign country to be waived are equivalent to similar requirements in this state.
4759-4-06 Status categories. (Propose to rescind)

(A) Inactive status.

A licensee may have a license placed in inactive status by written request to the board, signed by the holder of the license or the holder's legal guardian.

While a license is in inactive status, the licensee shall meet the cumulative continuing education/professional development requirements as required by rule 4759-4-04 of the Administrative Code, but is not required to pay the annual fee.

If a licensee fails to meet the continuing education/professional development requirements as prescribed in rule 4759-4-04 of the Administrative Code, the license may not be withdrawn from inactive status until any cumulative deficiency is corrected or waived by the board for good cause shown.

A license may be withdrawn from inactive status by completion of the application for reactivation, and providing evidence of compliance with cumulative continuing education/professional development requirements, and payment of the current reactivation fee.

An expired or lapsed license may not be placed in inactive status.

(B) Expired status.

A license not renewed by June thirtieth following its issuance is expired.

An expired license may not be placed in inactive status.

(C) Late status.

An application for renewal is late and the license is expired if it is postmarked after the thirtieth day of June but not later than the fifteenth day of August of the renewal year.

An individual seeking to renew an expired license during the late period shall complete the renewal application, and pay the current renewal and late fees.

An expired license may not be placed in inactive status during the late period.

(D) Lapsed status.

An expired license shall lapse after the fifteenth day of August of the renewal year.

An individual seeking to reinstate a lapsed, suspended, or revoked license shall complete the application for reinstatement, provide evidence of compliance with cumulative continuing education/professional development requirements as specified in rule 4759-4-04 of the
Administrative Code, and pay the current reinstatement fee. The license may not be reinstated until any cumulative deficiency is corrected or waived by the board for good cause shown.

A lapsed license may not be renewed or placed in inactive status.
4759-4-07 Failure to maintain licensure. (Propose to rescind)

An individual seeking to reinstate a license which has lapsed for more than two years shall meet the current licensure requirements including passing the examination, completion of the application for reinstatement, and payment of the reinstatement fee.

This rule does not apply to the holder of a license in inactive status, or a registered dietitian.

The board may waive the examination for good cause shown.
4759-4-08 Limited permit. (Propose to file as no change rule)

(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 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 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.

(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. 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 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.
4759-4-09 License certificates and permits.

(A) The board shall prepare and provide to each new licensee and limited permit holder a license certificate signed by the board’s president and secretary, and attested by its seal, and to each permittee a permit identification card. The identification card shall contain the person’s name, license number and date of expiration.

(B) Official certificates shall be signed by the chairman and be affixed with the raised seal of the board. Permit identification cards shall bear the signature of the chairman and/or the executive secretary/executive director.

(C) Any certificate and permit identification card issued by the board shall remain the property of the board and shall be surrendered to the board on demand.

(D) (B) Neither the holder nor anyone else shall make any alteration on a certificate or identification card issued by the board.

(E) (C) The board shall notify all licensees that licenses can be verified on the board’s website. Official verification letters will be issued by the board upon request only and with payment of the license verification fee specified in section 4759.08 of the Revised Code. Electronic verification of license or limited permit status shall be considered a primary source verification and shall be made available by the board.
4759-4-10 Prorated initial license fee. (Propose to rescind)

For the purposes of section 4759.08 of the Revised Code the board waives fifty per cent of the initial licensure fee if the license is only valid for the period between April first and June thirtieth.
4759-4-11 Criminal records check. (Propose to rescind)

(A) In addition to the requirements established in section 4759.06 of the Revised Code and agency 4759 of the Administrative Code, all applicants for an initial license or limited permit license to practice dietetics in the state of Ohio shall submit to a criminal records check conducted by the Ohio bureau of criminal identification and investigation in accordance with section 4759.06 1 of the Revised Code.

(B) The results of the criminal records check shall be received by the board prior to the issuance of an initial license to practice and the records check shall have been conducted no earlier that twelve months prior to the filing of the application with the board.

(C) An applicant requesting a criminal records check shall provide the Ohio bureau of criminal identification and investigation with the applicant's name, address, and any other information required by the bureau of criminal identification for the purpose of completing the criminal records check. In the request the applicant shall ask the superintendent of the bureau of criminal identification and investigation to obtain any information it has pertaining to the applicant from the federal bureau of investigation.

(D) The applicant shall cause the results of the criminal records check to be forwarded directly to the "Ohio Board of Dietetics at 77 South High St., Columbus, Ohio, 43215-6119." The board shall only accept results of a criminal records check submitted directly to the board from the Ohio bureau of criminal identification and investigation.

(E) The applicant shall bear all costs associated with the required criminal records check as determined by the Ohio bureau of criminal identification and investigation, the federal bureau of investigation, and by any agency with authority to charge a fee for fingerprint impressions.

(F) Prior to issuance of a license, the board will in its discretion evaluate the results of the criminal records check and information from any other source to determine if the applicant is eligible for a license.

(G) The results of the criminal records check are a confidential record and are not a public record for the purposes of section 149.43 of the Revised Code. Pursuant to section 4776.04 of the Revised Code the results are available for inspection by the applicant or applicant's legal representative during regular business hours. A legal representative requesting inspection of an applicant's criminal records shall have an appropriately filed letter of representation on file in the board office prior to inspecting the applicant's records.

(H) Background check reports will be retained in the board office for one year from the date of it's receipt or final action is taken upon the applicant's license, or until such time as the report is no longer of administrative value.
4759-4-12 Consideration of military experience, education, training and term of service.

(A) Eligibility for licensure.

In accordance with Chapter 5903. of the Revised Code, the board has determined that there are no military programs of training, military specialties and lengths of service that are substantially equivalent to or which exceed the educational and supervised training requirements for licensure as a dietitian.

(B) Definitions related to military service and veteran status.

(1) "Military," in accordance with division (A) of section 5903.03 of the Revised Code, means the armed forces of the United States or a reserve component of the armed forces of the United States, including the Ohio national guard or the national guard of any other state.

(2) "Member" means any person who is serving in the military,

(3) "Veteran" means any person who has completed service in the military, and who has been discharged under honorable conditions or who has been transferred to the reserve with evidence of satisfactory service.

(C) License renewal and continuing education.

(1) For military members in active duty, the board shall waive the requirements of paragraph (C) of rule 4759-4-04 of the Administrative Code for jurisprudence continuing education.

(2) In accordance with section 5903.10 of the Revised Code, a licensee whose license expired due to the licensee's service in the armed forces of the United States or a reserve component of the armed forces of the United States, including the Ohio national guard or the national guard of any other state, shall be eligible for renewal or restoration of the expired license at the same cost as if the license had not expired in accordance with section 4759.06 of the Revised Code, if the following conditions are met provided that the licensee presents the board with satisfactory evidence that, not more than twelve months prior to the date the evidence is submitted to the board, the licensee was honorably discharged or separated under honorable conditions.

(D) Prorated initial license fee.

In accordance with paragraph (D) of rule 4759.08 of the Revised Code, the board shall waive the prorated initial license fee for military service members.

(E) Prioritizing veterans and military members licensure applications.

Applications completed in accordance with section 4759.06 of the Revised Code will be receive priority processed within one to two business days in accordance with rule 4731-6-35 of the Administrative Code.
4759-4-13 Temporary license for military spouse.

(A) An individual whose spouse is ordered to active military duty in this state is eligible for a temporary military spousal license to practice as a licensed dietitian in accordance with section 4759.06 of the Revised Code.

(B) An application for a temporary military spousal license shall include the following:

(1) Proof that the applicant is married to an active duty service member of the armed forces of the United States;

(2) Proof that the applicant holds a valid, unrestricted license to practice dietetics in another jurisdiction of the United States;

(3) Proof that the applicant's spouse is assigned to a duty station in Ohio and the applicant is also assigned to a duty station in Ohio pursuant to the spouse's active duty military orders; and

(4) The initial application fee of one hundred twenty-five dollars pursuant to section 4759.08 of the Revised Code.

(C) A temporary military spouse license shall expire six months after the date of issuance and is not renewable.
4759-5-01 Supervision of persons claiming exemption. (Propose to file as no change rule)

For the purposes of the supervision requirement contained in divisions (B) and (E) of section 4759.10 of the Revised Code the dietitian who provides supervision shall be responsible for the supervision of the person claiming exemption from licensure as a dietetic technician, or dietetic technician registered, or nutrition associate and shall provide sufficient guidance and direction as to enable the person to perform competently. These individuals have completed at least a two-year associates degree or higher from a program in dietetic technology or dietetics that has been approved by the commission on accreditation for dietetics education of the "Academy of Nutrition and Dietetics." Dietetic technicians registered have also passed the national written examination administered by the commission on dietetic registration and maintain professional development / continuing education requirements for on-going registration.

The licensed dietitian is responsible and accountable for the nutrition care of patients / clients in all healthcare settings and must answer to patients, employers, licensure boards and the legal system if care is compromised.

The licensee shall not delegate the nutrition care process, but may assign tasks within the process to competent exempt practitioners for the purpose of providing the licensee with needed information and communicating with and educating patients / clients.

When supervising a person claiming exemption the licensee shall:

(A) Verify the credentials and competence of each individual exempt practitioner being supervised in the areas of dietetic practice as defined in section 4759.10 of the Revised Code. Those exempt practitioners who are competent to practice beyond minimum standards should be expected to demonstrate initial and on-going competence annually with documentation of successful audits.

The supervising dietitian can establish initial and on-going competency by individual means including but not limited to testing, evaluations, use of decision tree models and peer competency assessment. Engaging in on-going dietetics related continuing education is vital to competent practice.

(B) Provide the person being supervised with guidelines for appropriate assignments as part of the nutritional care process;

(C) Periodically establish performance criteria for the exempt practitioner, then assign tasks appropriately, direct and monitor the individual's practice. The supervising dietitian should compare actual performance with expected performance, document results and take appropriate action;

(D) Maintain written documentation of the initial and on-going competency assessment of the exempt practitioner, supervision being provided and performance of the individual, including participation in professional development / continuing education equivalent to the requirements of the commission on dietetic registration for dietetic technicians registered.
Documentation shall include, but is not limited to, dates of conferences, supervisory anecdotal notes, written evaluations and recommendations. Documentation should be maintained in the licensee's records and be available upon request of the board.

(E) The licensee shall provide supervision in a manner that protects the public. Direct supervision may be provided on-site, or supervision may be provided indirectly, as long as the licensee is immediately available by phone, e-mail, facsimile or other reliable means.
Student practice exemption. (Propose to file as no change rule)

(A) For purposes of divisions (D)(1) and (D)(2) of section 4759.02 of the Revised Code, a student dietitian may only engage in dietetic practice as defined in section 4759.01(A) of the Revised Code that is a part of the academic or pre-professional program.

(B) In order for student dietetic technicians to become qualified under the exemption for dietetic technicians contained in division (B) of section 4759.10 of the Revised Code, the board recognizes that pre-professional experiences are necessary. For this reason, dietetic practice by a student dietetic technician enrolled in a program that complies with the requirements in division (B) of section 4759.10 of the Revised Code, may be performed provided the student is actively pursuing the degree and the activity is performed under the supervision of a licensed dietitian or registered dietitian. A student dietetic technician may only engage in dietetic practice as defined in section 4759.01(A) of the Revised Code that is a part of the academic or pre-professional program.

(C) When supervising a student dietitian, a dietetic intern, or a student dietetic technician the licensee is responsible for providing appropriate training and guidelines for the student's clinical experiences, including ongoing close review of medical records and monitoring of student work performance. Documentation of such should be maintained in the licensee's records.
4759-5-03 Plan of treatment exemption.

For purposes of the exemption from licensure contained in division (F) of section 4759.10 of the Revised Code, a person when acting under the direction and supervision of a professional licensed under Chapters 4701. to 4755. Title 47 of the Revised Code, need not be a licensed dietitian if the person is executing a plan of treatment authorized by and within the scope of practice of the supervising licensed professional. The written plan of treatment shall include orders, goals, objectives, and appropriate treatments. Frequency of treatment and response to interventions shall be monitored and reviewed by the licensed practitioner. The licensed practitioner shall initiate the treatment plan and shall be on site when the plan is carried out by the unlicensed person.
4759-5-04 Additional nutritional activities exemption. (Propose to file as no change rule)

For purposes of division (D) of section 4759.10 of the Revised Code, the board hereby permits the woman, infant, and children's program which is part of the Ohio department of health and known as "W.I.C.", to designate a person to engage in providing such additional nutritional activities as are necessary to operate its programs, providing reasonable efforts to obtain the services of a licensee have failed. The department shall file the designation indicating the time period with the board. The designation shall expire at the end of one hundred eighty days. The designation may be renewed for additional one-hundred-eighty-day periods by action of the board.
4759-5-05 Distribution of literature exemption. (Propose to file as no change rule)

For purposes of division (G) of section 4759.10 of the Revised Code, the free distribution of literature includes its sale.
4759-5-06 Weight control program exemption. (Propose to file as no change rule)

For purposes of the exemption from licensure contained in division (J) of section 4759.10 of the Revised Code, a person presenting a general program of instruction for weight control need not be a licensed dietitian provided the general program of weight control is approved in writing by a licensed dietitian, physician licensed under Chapter 4731. of the Revised Code to practice medicine or surgery or osteopathic medicine or surgery, a person licensed in another state and approved by the board as having substantially equivalent licensure requirements as Ohio, or a registered dietitian.

A "general program of weight control" is a program designed for one or more population groups in order to achieve or maintain a healthy weight. It is not based on an individual nutrition assessment and does not provide medical nutrition therapy (MNT) as defined in rule 4759-2-01 of the Administrative Code. The program includes the diet plan and any information provided to customers including written guidelines for instruction to customers.

Persons presenting an approved general program of weight control are to adhere to the approved program content. The program shall be reviewed for re-approval in writing at least every two years.
4759-6-01 Standards of practice in nutrition care. (Propose to file as no change rule)

The standards of practice in nutrition care provide a common understanding about the profession's minimum expectations for practice, and form a basis for self-evaluation and improvement and an expectation about nutritional care and service delivery. The standards of practice in nutrition care are comprised of four standards representing the four steps of the nutrition care process.

The "nutrition care process" is a systematic problem-solving method that dietitians may use to critically think and make decisions when providing medical nutrition therapy or to address nutrition related problems and provide safe, effective, high quality nutrition care.

The nutrition care process shall consist of four distinct, but interrelated steps including nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation.

(A) The licensee uses accurate and relevant data and information to perform nutrition assessment and identify nutrition-related problems, as the foundation for nutrition diagnosis, the second step of the nutrition care process.

(1) "Nutrition assessment" means the same as "nutritional assessment" defined in paragraph (A) of rule 4759-2-01 of the Administrative Code.

(2) A nutrition assessment is initiated by referral and / or screening of individuals or groups for nutrition risk factors.

(3) The licensee systematically obtains, verifies and interprets data in order to make decisions about the nature and cause of nutrition-related problems.

(4) Nutrition assessment is an ongoing, dynamic process that involves not only initial data collection, but also reassessment and analysis of client or community needs.

(5) Problems that require consultation with or referral to another provider are recognized.

(6) Documentation and communication of nutritional assessment shall be complete, relevant, accurate and timely.

(B) The licensee determines a nutrition diagnosis to identify and label specific nutrition problem(s) that the dietitian is responsible for treating.

(1) "Nutrition diagnosis" is the identification and labeling that describes an actual occurrence, risk of, or potential for developing, a nutritional problem that dietetics practitioners are responsible for treating independently.

(2) The nutrition diagnosis is not a medical diagnosis. It results following nutrition assessment and the clustering, analysis, and synthesis of data and demonstrates a link to determining goals for outcomes, selecting appropriate interventions and tracking progress in attaining expected outcomes.
(3) Documentation of nutrition diagnosis(es) shall be relevant, accurate and timely and shall be revised and updated as additional assessment data become available.

(C) The licensee utilizes nutrition intervention as the third step in the nutrition care process to identify and implement appropriate, purposefully planned actions designed with the intent of changing a nutrition-related behavior, risk factor, environmental condition or aspect of health status for an individual, target group, or the community at large.

(1) "Nutrition Intervention" is a specific set of activities and associated materials used to address the problem; purposely planned actions designed with the intent of changing a nutrition-related behavior, risk factor, environmental condition, or aspect of health status for an individual, target group, or the community at large. It involves selection, planning, and implementing appropriate actions to meet patient / client / group's nutrition needs.

(2) "Intervention planning" involves prioritizing the nutrition diagnoses, conferring with the patient / client / and / or others, reviewing practice guides and policies, and setting goals and defining the specific nutrition intervention strategy.

(3) "Implementation of the nutrition intervention" is the action phase that includes carrying out and communicating the plan of care, continuing data collection, and revising the nutrition intervention strategy, as warranted, based on the patient / client response.

(4) The licensee performs the interventions or assigns the nutrition care that other competent practitioners may provide in accordance with federal, state and local laws and regulations.

(D) The licensee monitors and evaluates indicators and outcomes data directly related to the nutrition diagnosis, goals and intervention strategies to determine the progress made in achieving desired outcomes of nutrition care and whether planned interventions should be continued or revised.

(1) "Nutrition monitoring and evaluation" is the fourth step of the nutrition care process. Monitoring specifically refers to the review and measurement of the patient / client / group's status at a scheduled (preplanned) follow-up point with regard to the nutrition diagnosis, intervention plans / goals and outcomes, whereas evaluation is the systematic comparison of current findings with previous status, intervention goals, or a reference standard. Monitoring and evaluation use selected outcome indicators (markers) that are relevant to the patient / client / group's defined needs, nutrition diagnosis, nutrition goals, and disease state.

(2) The licensee uses standard nutrition care outcome indicator(s) to measure outcomes.

(3) Monitoring data should be compared with the nutrition prescription / goals / or reference standards to evaluate impact of the sum of all interventions on overall patient / client health outcomes.

(4) Documentation of nutrition monitoring and evaluation shall be comprehensive, specific, accurate, relevant and timely and reflect the indicators measured, results and method for obtaining
measurement. The criteria to which the indicator is compared and factors facilitating or hampering progress should be referenced in support of positive or negative outcomes. Future plans for nutrition care, monitoring and follow-up or discharge should be included.
**4759-6-02 Standards of professional performance.**

Every licensee shall comply with the following standards of professional performance in accordance with the "Code of Ethics of the Academy of Nutrition and Dietetics":

(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 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 (F) (E)(4) 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 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.
4759-6-03 Interpretation of standards. (Propose to file as no change rule)

The standards in this chapter are interpreted in a manner consistent with the "Standards of practice in nutrition care" and the "Standards of professional Performance" adopted by the "Academy of Nutrition and Dietetics."
4759-7-01 Filing of complaints. (Propose to rescind)

(A) Anyone may complain to the board alleging that a person has committed an action prohibited by Chapter 4759. of the Revised Code or the rules of the Ohio board of dietetics.

(B) A person wishing to complain about a violation of Chapter 4759. of the Revised Code or the rules of the board, may direct a complaint to the executive secretary/executive director; except a complaint regarding the executive secretary/executive director, the staff or the board may be directed to the chairman of the board or any board member.

(C) Upon receipt of a complaint, the executive secretary/executive director, unless the health and safety of the public otherwise requires, shall send to the complainant an acknowledgement letter, and request the complainant complete and return a complaint form.
Representatives; appearances communications; applicability. (Propose to rescind)

(A) As used in Chapter 4759-8 of the Administrative Code, "respondent" shall be defined as the person who is requesting or has requested a hearing as provided in Chapter 119. of the Revised Code.

(B) The respondent may represent himself or may be represented by an attorney admitted to the practice of law in Ohio. If the respondent does represent himself, he shall be deemed the representative of record for purposes of Chapter 4759-8 of the Administrative Code.

(C) The respondent is not required to personally appear at any hearing provided he has not been subpoenaed and has authorized his representative to represent him in all facets of a hearing before the board.

(D) The respondent or his representative may present his position, arguments, or contentions in writing rather than personally appearing at any hearing provided the respondent has not been subpoenaed.

(E) The representative of record for the respondent shall enter his appearance in writing.

(F) The representative of record from the office of the attorney general shall enter his appearance in writing.

(G) One who has entered an appearance as representative remains the representative of record unless and until a written withdrawal is filed with the board.

(H) Except as otherwise provided under Chapter 119. of the Revised Code, communications from the board or its attorney hearing examiner shall be sent to the representative of record.

(I) 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 only to the evidence of record.

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

(K) The attorney hearing examiner and members of the board shall disclose on the record the source and substance of any ex parte or attempted ex parte communications. That disclosure shall
be made at the earliest possible opportunity, but at least prior to deliberation on a pending or
impending adjudicatory proceeding.

(L) 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.
4759-8-02 Filing request for hearing. (Propose to rescind)

(A) In order to request a hearing under Chapter 119. of the Revised Code, a respondent or his representative must, in accordance with rule 4759-8-01 of the Administrative Code, file in writing a statement requesting such adjudication hearing within thirty days of the date of mailing of the board's notice of opportunity for hearing. The date of mailing shall be the date appearing on the certified mail receipt.

(B) A respondent or his representative properly filing a request for an adjudication hearing shall be entitled to such adjudication hearing within fifteen days but not sooner than seven days after such request has been filed unless both representatives agree otherwise or a continuance is granted pursuant to section 119.09 of the Revised Code and rule 4759-8-07 of the Administrative Code.
4759-8-03 Notice of hearings. (Propose to rescind)

Notice specifying the date, time and place set for hearing shall be mailed by certified mail to the representatives as identified in rule 4759-8-01 of the Administrative Code.
4759-8-04 Authority and duties of attorney hearing examiners. (Propose to rescind)

(A) Adjudication hearings may be conducted before the board or an attorney hearing examiner pursuant to sections 4759.07 and 4759.09 of the Revised Code. All attorney hearing examiners shall perform their duties in accordance with a current contract with the board.

(B) All hearings shall be open to the public, but the hearing examiner or presiding board member 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 is closed, the hearing examiner or presiding board member shall state the reasons therefore in the public record.

(C) Hearings shall be conducted 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 attorney hearing examiner or presiding board member 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 and to require the production of evidence for hearings and depositions;

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 and status conferences pursuant to rules 4759-8-17 and 4759-8-18 of the Administrative Code;

7. Request briefs before, during or following the hearing, as well as suggested findings, orders, and conclusions of law within such time limits as the attorney hearing examiner or presiding board member may determine;

8. Prepare entries, findings, orders, or reports and recommendations pursuant to rule 4749-8-15 of the Administrative Code;

9. Request preparation of entries, findings, or orders;

10. Make rulings on requests to broadcast, record, televise or photograph the hearing;

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

12. Determine the order in which any hearing shall proceed.
(E) The authority of the attorney hearing examiner or presiding board member shall not include authority to:

(1) Grant motions for dismissal of charges;

(2) Modify, compromise, or settle charges or allegations.

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

(G) If the hearing is held before an attorney hearing examiner, 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. When such rulings warrant, the matter may be remanded to the attorney hearing examiner.
4759-8-05 Consolidation. (Propose to rescind)

Upon motion by any representative of record, the attorney-hearing examiner or presiding board member may consolidate two or more hearings into a single hearing.
4759-8-06 Intervention.  (Propose to rescind)

Petitions to intervene shall not be permitted.
4759-8-07 Continuance of hearing. (Propose to rescind)

(A) The board or the board through its attorney hearing examiner, may continue a 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.

(B) The attorney hearing examiner or presiding board member may continue a hearing upon the motion of a representative of record.

(C) Hearings shall not be continued upon motion by a representative unless a showing of reasonable cause and proper diligence is presented. Before granting any continuance, consideration shall be given to harm to the public which may result from delay in proceedings. In no event will a motion for a continuance by a representative, requested less than five days prior to the scheduled date of the hearing, be granted unless it is demonstrated that an extraordinary situation exists which could not have been anticipated and which would justify the granting of a continuance.

(D) No continuance of an adjudicatory hearing under section 4759.09 of the Revised Code shall be granted without the written agreement of the respondent or his representative and the board.

(E) If a continuance is granted, the attorney hearing examiner or presiding board member shall immediately establish a new hearing date, unless circumstances prohibit.

(F) Hearings shall not be continued due to the unavailability of a subpoenaed witness without approval of the attorney hearing examiner or presiding board member. The hearing record may be held open to accept a deposition in lieu of oral testimony of a subpoenaed witness. The procedures set forth in rule 4759-8-19 of the Administrative Code shall apply to any deposition taken pursuant to this rule.

(G) No adjudication hearing shall be continued for more than ninety days for the purpose of exchanging witness or document lists to the extent provided in rule 4759-8-16 of the Administrative Code unless the board or attorney hearing examiner finds in writing that such exchange was diligently pursued but was not completed due to the unusual circumstances of the case.
4759-8-08 Motions. (Propose to rescind)

(A) Except as otherwise provided under Chapter 4759-8 of the Administrative Code or Chapter 119. of the Revised Code, all motions, unless made upon the record at the 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 therefor, and shall be filed in compliance with rule 4759-8-09 of the Administrative Code. A proposed entry may accompany any motion. All motions except those filed subsequent to the close of the hearing shall be made no later than fourteen days before the date of hearing unless express exception is granted by the attorney hearing examiner, the presiding board member, or by this chapter.

(B) All motions, together with supporting documentation, if any, shall be served as provided in rule 4759-8-10 of the Administrative Code.

(C) Within ten days after service of a written prehearing motion, or such other time as is fixed by the attorney hearing examiner or presiding board member, a response to that motion may be filed. A movant may reply to a response only with the permission of the attorney hearing examiner or presiding board member.

(D) Before ruling upon a written motion, all memoranda and supporting documents filed shall be considered. A written ruling shall be entered and copies shall be issued to the representatives as identified under rule 4759-8-01 of the Administrative Code. The ruling on all oral motions made at hearing shall be included in the record except where the board or the attorney hearing examiner elects to take the motion under advisement and issue a written ruling at a later time. The attorney hearing examiner or presiding board member shall include in each written ruling on a motion a short statement of the reasons therefor.

(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 the presiding board member acting on its behalf.
4759-8-09 Filing. (Propose to rescind)

(A) A document is "filed" when it is received and time-stamped in the offices of the board. The burden of ensuring proper filing of the document(s) is borne by the party filing the document(s).

(B) An original of any document required to be filed 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 executive secretary/executive director and shall contain the name, address, and telephone number of the person submitting the motion or brief and shall be appropriately captioned to indicate the name of the respondent.
4759-8-10 Service on parties. (Propose to rescind)

(A) Any document required by Chapter 4759-8 of the Administrative Code to be served by a representative of record may be served either personally, or by mail. Service shall be made upon the representative as identified in rule 4759-8-01 of the Administrative Code. Service is complete on the post-mark date or on personal service of the document.

(B) All motions and briefs shall contain the name, address, and telephone number of the person submitting the motion or brief and shall be appropriately captioned to indicate the name of the respondent.

(C) A motion shall be considered by the board or its attorney hearing examiner only if a certificate of service appears on it. Any signed statement is an acceptable certificate of service so long as it contains all of the following information:

(1) Date of service;

(2) Method by which service was made;

(3) Address where service was made; and

(4) Name of the person or authority who was served.
4759-8-11 Computation and extension of time.  (Propose to rescind)

(A) The date of occurrence of the event causing time to run is not counted in the computation of any time limit under Chapter 4759-8 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 attorney-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 4759-8-09 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 executive secretary/executive director and shall be served as provided in rule 4759-8-10 of the Administrative Code.
4759-8-12 Transcripts. (Propose to rescind)

(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.

(B) Upon request made to the board's executive secretary/executive director, a copy of original transcripts may be reviewed at the board offices. Additional copies may be prepared at the requestor's expense.

(C) Original transcripts shall not be removed from the board offices.
4759-8-13 Subpoenas for purposes of hearing. (Propose to rescind)

(A) Upon written request of either party, 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 the representatives as identified in rule 4759-8-01 of the Administrative Code.

(B) For purposes of a hearing conducted under Chapter 119. of the Revised Code, subpoena requests shall specify the name and address of the individual to be served and the date, time, and location at which they are to appear. With respect to the production of books, records and papers, such request may specify a date of compliance not more than seven days prior to hearing.

(C) Except upon leave of the board or its attorney hearing examiner or presiding board member, subpoena requests are to be filed with the board as provided in rule 4759-8-09 of the Administrative Code at least fourteen 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 attorney 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 five business 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 board or its attorney hearing examiner or presiding board member 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 the representatives as identified in rule 4759-8-01 of the Administrative Code.

(F) Upon motion and for good cause, the board or its attorney hearing examiner or presiding board member may order any subpoena be quashed. Motions to quash shall be made in the manner provided in rules 4759-8-08 and 4759-8-09 of the Administrative Code, except that motions to quash shall be filed at least five days prior to the date of compliance. The non-moving party may file a response no later than four 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 was subpoenaed. The board shall make a reasonable attempt to contact any witness whose subpoena has been quashed.

(G) Witnesses may not be subpoenaed to prehearing conferences.
4759-8-14 Mileage reimbursements and witness fees. (Propose to rescind)

(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 may not subpoena himself.

(C) Mileage and witness fees shall not be paid to anyone who fails to register at the hearing for which he was subpoenaed.
4759-8-15 Reports and recommendations. (Propose to rescind)

(A) Within thirty days following the close of an adjudication hearing conducted by an attorney hearing examiner pursuant to Chapter 119. of the Revised Code, the attorney 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 attorney hearing examiner.

(B) A copy of such written report shall be issued to the representatives of record as identified in rule 4759-8-01 of the Administrative Code. 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) The respondent's representative of record may, within ten days of his receipt of the attorney 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 attorney hearing examiner's recommendation.

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

(E) The board shall consider the attorney 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 order additional testimony to be taken or 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 attorney hearing examiner.

(F) Any motion to reopen the hearing record for purposes of introducing newly discovered material evidence which, with reasonable diligence could not have been discovered and produced at the hearing shall be made in the manner provided in rules 4759-8-08 and 4759-8-09 of the Administrative Code. Such motion to reopen shall be filed not later than ten days prior to the scheduled consideration by the board of the attorney hearing examiner's report and recommendation and any objections thereto. If such motion is filed prior to the issuance of the attorney hearing examiner's report and recommendation, the attorney hearing examiner shall rule on the motion. If such motion is filed subsequent to the issuance of the attorney hearing examiner's report and recommendation, the board shall rule upon the motion.

(G) Without leave of the board, the respondent or any representative of record shall not be permitted to address the board at the time of consideration of the attorney 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 and shall be served upon the representative of record.
(H) If a request to address the board is granted, the opposing representative may also address the board.
Exchange of documents and witness lists. (Propose to rescind)

(A) Any representative of record may serve upon the opposing representative of record a written request for a list of both the witnesses and the documents intended to be introduced at hearing. All lists requested under this rule shall be exchanged no later than seven days prior to the commencement of the administrative hearing.

(B) Failure without good cause to comply with paragraph (A) of this rule may result in exclusion from the hearing of such testimony or documents, upon motion of the representative to whom disclosure is refused.
4759-8-17 Pre-hearing conference. (Propose to rescind)

(A) At any time prior to hearing, the attorney hearing examiner or presiding board member may direct participation by the representatives of record in a prehearing conference. Such conference may be initiated by the attorney hearing examiner, by the board, or upon motion of either representative.

(B) Prehearing conferences may be held for the following purposes:

(1) Identification of issues;

(2) Obtaining stipulations and admissions;

(3) Agreements limiting the number of witnesses;

(4) Discussion of documents, exhibits, and witness lists;

(5) Estimating the time necessary for hearing;

(6) Discussion of any other matters tending to expedite the proceedings.

(C) All representatives of record shall attend the prehearing conference fully prepared to discuss the items enumerated in paragraph (B) of this rule.

(D) Procedural orders may be issued by the attorney hearing examiner or presiding board member based upon information obtained at a prehearing conference.
4759-8-18 Requirements for pre-hearing exchange of information. (Propose to rescind)

The hearing examiner or presiding board member shall, upon written motion of any representative of a party, issue an order setting forth a schedule by which the parties shall exchange hearing exhibits, identify lay and expert witnesses and exchange written reports from expert witnesses. Any written report by an expert required to be exchanged shall set forth the opinions to which the expert will testify and the bases for such opinions. The failure of a party to produce a written report from an expert under the terms of the order shall result in the exclusion of that expert's testimony at hearing. The failure of a party to produce an exhibit under the terms of the order shall result in the exclusion of that exhibit from evidence. The failure of a party to identify a lay or expert witness under the terms of the order may result in the exclusion of that witness' testimony at hearing.
4759-8-19 Status conference. (Propose to rescind)

With or without written motion from the representative of any party, the attorney hearing examiner or presiding board member may convene a status conference with representatives of the parties to address any matter related to preparation for hearing or the conduct of a hearing. The hearing examiner may issue such orders related to preparation for hearing and the conduct of the hearing which in the judgment of the hearing examiner facilitate the just and efficient disposition of the subject of the hearing.
4759-8-20 Depositions and transcripts of prior testimony. (Propose to rescind)

(A) Upon written motion of any representative of record, and upon service of that motion to all other representatives, the attorney hearing examiner may order that the testimony of a prospective witness be taken by deposition under such conditions and terms as specified in the order and that any designated books, papers, documents or tangible objects, not privileged, be produced at the same time and place 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; and

(3) The testimony of the prospective witness is necessary in order to prevent a failure of justice.

In the case of an expert witness, a showing of the unavailability of the expert shall not be necessary for consideration of the motion of a representative to take a deposition.

(B) The representatives shall agree to the time and place for taking the deposition in lieu of live testimony. Depositions shall be conducted in the same county in which the hearing is conducted unless otherwise agreed to by the representatives. If the representatives are unable to agree, the attorney hearing examiner or presiding board member shall set the time or fix the place of deposition. At a deposition taken pursuant to this rule, representatives shall have the right, as at hearing, to fully examine witnesses. The attorney hearing examiner has the discretion to be present at the deposition in lieu of testimony at hearing.

(C) A deposition taken under this rule shall be filed with the board not later than one day prior to hearing, and may be offered into evidence at hearing by either representative in lieu of the prospective witness’ personal appearance. The cost of preparing a transcript of any testimony taken by deposition in lieu of live testimony which is offered as evidence at the hearing shall be borne by the board. In the event of appeal, such costs shall be made a part of the cost of the hearing record. The expense of any video deposition shall be borne by the requestor.
4759-8-21 Prior action by the board. (Propose to rescind)

The attorney-hearing examiner or presiding board member shall admit evidence of any prior disciplinary action entered by the Ohio board of dietetics against the respondent.
Representatives of record may, by stipulation, agree on any or all facts involved in proceedings before the attorney-hearing examiner or presiding board member. Thereafter the attorney-hearing examiner or presiding board member may require development of any fact deemed necessary for just adjudication.
4759-8-23 Witnesses. (Propose to rescind)

(A) All witnesses 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' rights, and that legal counsel may neither examine nor cross-examine any witnesses.

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

(D) The presiding attorney hearing examiner or any board member, because of his duties, shall not be a competent witness nor subject to deposition in any adjudication proceeding. Unless the testimony of a board member or an attorney hearing examiner is material to the factual allegations set forth in the notice of opportunity for hearing, board members and attorney hearing examiners shall not be competent witnesses nor subject to deposition in any adjudication proceeding. Evidence from other persons relating to the mental processes of the presiding attorney hearing examiner or board members shall not be admissible.

(E) Any representative of record may move for a separation of witnesses. Expert witnesses shall not be separated.

(F) Each representative of record shall inform the attorney hearing examiner or presiding board member prior to the commencement of a hearing of the identity of each potential witness for his cause present in the hearing room. Failure to so identify potential witnesses at this time may be grounds for their later disqualification as witnesses.

(G) No witnesses shall be permitted to testify as to the nature, extent, or propriety of disciplinary action to be taken by the board. A witness may, in the discretion of the attorney hearing examiner or presiding board member, testify as to an ultimate issue of fact.
4759-8-24 Conviction of a crime. (Propose to rescind)

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.
4759-8-25 Rules of evidence. (Propose to rescind)

(A) The "Ohio Rules of Evidence" may be taken into consideration by the board or its attorney hearing examiner in determining the admissibility of evidence, but shall not be controlling.

(B) The attorney hearing examiner or presiding board member may permit the use of electronic or photographic means for the presentation of evidence.
4759-8-26 Broadcasting and photographing administrative hearings. (Propose to rescind)

If the attorney hearing examiner or presiding board member determines that broadcasting, televising, recording or taking of photographs in the hearing room would not distract participants or 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 attorney hearing examiner or presiding board member 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 attorney hearing examiner and is made a part of the record of the proceedings;

(C) If the permission is granted, the place or places in the hearing room where operators and equipment are to be positioned shall be specified by the attorney hearing examiner or presiding board member.

(D) The filming, videotaping, recording or taking of photographs of witnesses who object thereto shall not be permitted.
4759-8-27 Sexual misconduct evidence. (Propose to rescind)

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 attorney hearing examiner or presiding board member 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 attorney hearing examiner or presiding board member.

(C) Nothing in this rule shall be construed as limiting the authority of the hearing examiner or presiding board member to close a hearing as provided paragraph (B) of rule 4759-8-04 of the Administrative Code.
4759-8-28 Reinstatement of license.  (Propose to rescind)

Any disciplinary action taken by the board pursuant to division (A) of section 4759.07 of the Revised Code which results in suspension from practice shall either lapse by its own terms or contain a written statement of the conditions under which the license may be reinstated.

Such conditions may include but are not limited to:

(A) Submission of a written application for reinstatement;

(B) Payment of all appropriate fees as provided in Chapter 4759. 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 applicant can resume practice in compliance with acceptable and prevailing standards.
4759-8-29 Settlements, dismissals, and voluntary surrenders. (Propose to rescind)

(A) Any matter which is the subject of a hearing may be settled at any time prior to the close of the hearing record. If settlement negotiations are to continue after the close of the hearing record, the representatives of record must, within ten days of the close of the hearing, jointly present the attorney hearing examiner or presiding board member with written notice specifying a period of time, not to exceed thirty days, for which the record is to be held open for purposes of negotiation. Such notice shall toll the thirty-day time period for issuance of findings of fact and conclusions of law pursuant to rule 4759-8-15 of the Administrative Code. If the attorney hearing examiner has not received appropriate written notice that a settlement agreement has been executed within the time period specified by the representatives’ joint notice, the tolling of the attorney 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 issuance of a final order by the board.

(B) Settlement shall be negotiated on behalf of the board by the probable review panel. Concurrence of the full board will be required prior to the execution of any settlement agreement containing terms not in conformity with disciplinary guidelines previously adopted.

(C) All settlement agreements shall be in writing and shall be signed by the respondent and chairman of the board. The representative from the office of the attorney general and the respondent's attorney, if any, shall sign the agreement in their representative capacities.

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

(E) Authorization to enter a notice of dismissal must be received from the presiding board member or chairman. Such a notice may be entered at any time prior to closing of the hearing record. If negotiations are to be continued and the hearing record has been closed, the procedures in paragraph (A) of this rule must be followed. Any notice of dismissal must be signed by the board's chairman.

(F) 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.
4759-9-01 Severability.

Each rule of Chapters 4759-1 to 4759-11 of the Administrative Code, and every part of each rule is declared to be an independent rule, and the holding of any rule or part thereof to be unconstitutional, void, or ineffective for any cause shall not affect the validity or constitutionality of any other rule or part thereof.
4759-10-01 Definitions. (Propose to rescind)

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 agency rule addressing requirements in section 1347.15 of the Revised Code.

(C) "Board" means the Ohio board of dietetics.

(D) "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.

(E) "Confidential personal information" (CPI) 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.

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

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

(H) "Individual" means a natural person or the natural person's authorized representative, legal counsel, legal custodian, or legal guardian.

(I) "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.

(J) "Person" means a natural person.

(K) "Personal information" has the same meaning as defined in division (E) of section 1347.01 of the Revised Code.

(L) "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.
(M) "Research" means a methodical investigation into a subject.

(N) "Routine" means commonplace, regular, habitual, or ordinary.

(O) "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 agency for internal administrative and human resource purposes.

(P) "System" has the same meaning as defined by division (F) of section 1347.01 of the Revised Code.

(Q) "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.
4759-10-02 Procedures for accessing confidential personal information. (Propose to rescind)

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

(A) 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 agency 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) 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) The board will comply with any written request from an individual for a list of confidential personal information that the board keeps on that individual unless the confidential personal information relates to an investigation about the individual based upon specific statutory authority. Additionally, the board will follow rule 4759-1-03 of the Administrative Code as it relates to personal information systems and sections 1347.08 and 1347.09 of the Revised Code. Any such requests shall be reviewed by the executive director in consultation with legal counsel. All requests will be processed without undue delay with a written response to the requestor.

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

(3) 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

(4) If all information relates to an investigation about that individual, inform the individual that the board has no confidential personal information about the individual that is responsive to the individual's request.

(C) Notice of invalid access:

(1) Upon discovery or notification that confidential personal information of a person has been accessed by an employee for an invalid reason, the board shall notify the person whose information was invalidly accessed as soon as practical and to the extent known at the time. However, the board shall delay notification for a period of time necessary to ensure that the notification would not
delay or impede an investigation or jeopardize homeland or national security. Additionally, 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 system.

"Investigation" as used in this paragraph means the investigation of the circumstances and involvement of an employee surrounding the invalid access of the confidential personal information. Once the board determines that notification would not delay or impede an investigation, the board shall disclose the access to confidential personal information made for an invalid reason to the person.

(2) Notification provided by the board shall inform the person of the type of confidential personal information accessed and 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) Appointment of a data privacy point of contact. The board director shall designate an employee of the agency to serve as the data privacy point of contact. The data privacy point of contact shall work with the chief privacy officer within the 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) Completion of a privacy impact assessment. The board director shall designate an employee of the agency to serve as the data privacy point of contact who shall timely complete the privacy impact assessment form developed by the office of information technology.
4759-10-03 Valid reasons for accessing confidential personal information. (Propose to rescind)

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 (CPI) regardless of whether the personal information system is a manual system or computer system:

Performing the following functions constitute valid reasons for authorized employees of the board to access confidential personal information:

(A) Responding to a public records request;

(B) Responding to a request from an individual for the list of CPI the agency 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 claims or otherwise administering a program with individual participants or beneficiaries;

(H) Auditing purposes;

(I) Licensure or eligibility for examination processes;

(J) Investigation or law enforcement purposes;

(K) Administrative hearings;

(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);

(N) Complying with an executive order or policy;

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

(P) Complying with a collective bargaining agreement provision.
4759-10-04 Confidentiality statutes. (Propose to rescind)

The following federal statutes or regulations or state statutes and administrative rules make personal information maintained by the board confidential and identify the confidential personal information within the scope of rules promulgated by this board in accordance with section 1347.15 of the Revised Code:

(A) Social security numbers: 5 U.S.C. 552 a., 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) Medical records: Health Insurance Portability and Accountability Act, Title II 45 CFR 160, 42 USC 1320.

(D) The Family Education Right to Privacy Act (FERPA), 20 U.S.C. 1232 g.

(E) Personal information systems, rule 4759-1-03 of the Administrative Code.

(F) Section 149.43 of the Revised Code.
4759-10-05 Restricting and logging access to confidential personal information in computerized personal information systems. (Propose to rescind)

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 modifies an existing computer system that stores, manages or contains confidential personal information, the board shall make a determination whether the modification constitutes an upgrade. Any upgrades to a computer system 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) The board shall require employees of the board who access confidential personal information within computer systems to maintain a log that records that access.

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

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

(3) For purposes of this paragraph, the board may choose the form or forms of logging, whether in electronic or paper formats.

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

(1) Who shall maintain the log;

(2) What information shall be captured in the log;

(3) How the log is to be stored; and

(4) How long information kept in the log is to be retained.

Nothing in this rule limits the board from requiring logging in any circumstance that it deems necessary.
4759-11-01 Miscellaneous Provisions.

For purposes of Chapter 4759. 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 4731-4, 4731-8, 4731-13, 4731-15, 4731-16, 4731-26, and 4731-28 of the Administrative Code are applicable to the holder of a license or limited permit issued pursuant to Chapter 4759. of the Revised Code, as though fully set forth in Chapter 4759 of the Administrative Code.
4761-1-01 Public hearings on adoption, amendment, or rescission of rules: methods of public notice. (Propose to rescind)

(A) Except in the case of an emergency rule authorized under division (F) of section 119.03 of the Revised Code, prior to the proposed adoption, amendment or rescission of any rule by the Ohio respiratory care board, public notice thereof shall be given at least thirty days prior to the date set for the public hearing thereon, by publication of that notice in the register of Ohio internet site at www.registerofohio.state.oh.us. Such notice shall include a statement of the board's intention to consider adopting, amending, or rescinding a rule; a synopsis of the proposed rule, amendment, or rule to be rescinded or a general statement of the subject matter to which the proposed rule, amendment or rescission relates; a statement of the reason or purpose for adopting, amending, or rescinding the rule; and the date, time, and place of the public hearing on said proposed action.

(B) The board may give whatever other notice it reasonably considers necessary including, but not limited to, the following:

(1) The board shall post the notice of the public rules hearing on the board's internet site at www.respiratorycare.ohio.gov. The board may also post the full text of the proposed rules on its internet site.

(2) The board may maintain a mailing list of all persons who have made a prior written request to receive a copy of each public notice provided for in paragraph (A) of this rule, and copies of such notices shall be sent by regular mail or electronic mail to each person on the mailing list at least thirty days prior to the date set for the hearing. Upon request, the board shall also promptly send a copy of any notice provided for in paragraph (A) of this rule by regular mail or electronic mail to any person not appearing on its mailing list. The board may assess a reasonable fee, not to exceed the cost of copying and mailing, for notices sent to persons in accordance with this rule.

(3) Copies of the notice of the public rules hearing and the full text of the proposed rules shall be available at the board's offices at least thirty days prior to the date of the public rules hearing.

(C) Prior to the effective date of a rule, amendment, or rescission, the board shall make a reasonable effort to inform those affected by the rule, amendment, or rescission. The method of notification may include posting the full text of the rule as adopted or amended on the board's internet site, publishing the rules in the board's electronic newsletter, and/or sending by regular mail or electronic mail a notice of the action to all persons whose name appears on the mailing list maintained by the board pursuant to paragraph (B)(2) of this rule, or to any person or his attorney who provided evidence, oral testimony, and/or a written statement which were made part of the record of the public hearing held pursuant to section 119.03 of the Revised Code. The board may assess a reasonable fee, not to exceed the cost of copying and mailing, for notices sent to persons in accordance with this rule.
4761-1-02 Notice of board meetings. (Propose to rescind)

(A) Any person or organization may ascertain the time and place of all regularly scheduled meetings of the Ohio respiratory care board, and the time, place, and purpose of all special meetings of the board by any one of the following methods:

(1) Calling the board office by telephone during normal business hours. No collect calls will be accepted under any circumstances.

(2) Inquiring in person at the board office during normal business hours, Monday through Friday, excluding recognized state holidays.

(3) Providing the board with a written request by mail or electronic mail.

(B) Any person or organization who makes written request for routine notification of all regularly scheduled and special meetings of the board by mail or by electronic mail shall be placed on a list. Notification will be made by one of the following methods:

(1) Sending written notice, which must be sent by regular mail or electronic mail no later than four calendar days prior to the day of a regular meeting.

(2) Notice by telephone no later than twenty-four hours prior to a special meeting. Telephone notice shall be complete if a message has been left for the representative, or if, after reasonable effort, the board has been unable to provide such telephone notice.

(C) A representative of a news media organization or of the business office of the Ohio society for respiratory care may obtain telephone or electronic mail notification of emergency board meetings by making written request to the board, including the name of the individual to be contacted, the individual’s electronic mailing address, and a maximum of two telephone numbers where the individual can be reached. The board will maintain a list of all representatives who request telephone notice of emergency meeting. Telephone notice shall be complete if a message has been left for the representative or if, after a reasonable effort, the board has been unable to provide such telephone notice. It shall be the responsibility of the news media organization or the business office of the Ohio society for respiratory care to inform the board of any changes in telephone number or electronic mailing address.
4761-2-01 Board organization. (Propose to rescind)

(A) The board shall hold an annual meeting in April, at which time it shall elect a president and secretary, who shall serve one year.

(B) The president shall preside at all meetings of the board. The president may appoint another board member to serve as vice-president to preside in the president's absence. In lieu of a hearing examiner for adjudication hearings, the president shall serve as the appointed hearing officer or the board may elect a hearing officer from among the other board members. The board may form committees as needed to fulfill its purpose under Chapter 4761. of the Revised Code and appoint qualified members.

(C) The board shall hold regular meetings as often as necessary to carry out its duties. Meetings shall be held in the Vern Riffe center for government and the arts or in such other places as deemed reasonable by the board.

(D) In the event of a vacancy, the board shall fill the office from among the members of the board at a regular or special meeting of the board.
4761-2-02 Personnel. (Propose to rescind)

The board shall:

(A) Employ an executive director who shall be the chief administrative officer of the board. The executive director shall be in the unclassified service of the state and shall be responsible for the daily activities of the board's office staff. The executive director shall assist the board in the administration and enforcement of Chapter 4761. of the Revised Code. If the executive director is a licensee of the board, he/she shall not engage in active practice of respiratory care while employed in this position.

(B) The executive director of the Ohio respiratory care board may, on behalf of the board, perform the following duties:

(1) Approve and issue, by signature authority, subpoenas pursuant to an investigation.

(2) Approve and issue, by signature authority, "Opportunity for Hearing Notices" that have been reviewed, moved and approved by majority vote of a quorum of the board during an open business meeting and "Allegations and Opportunity for Hearing Notices" moved and approved by the board during a telephonic conference pursuant to division (C) of section 4761.09 of the Revised Code, for the purpose of considering a summary suspension of a license.

(3) Approve and issue, by signature authority, initial licenses under section 4761.04 of the Revised Code, limited permits under section 4761.05 of the Revised Code and non-resident registrations under division (A)(4) of section 4761.11 of the Revised Code. The executive director must follow the rules adopted by the board under rules 4761-4-01, 4761-5-01, 4761-5-04, 4761-5-05 and 4761-6-01 of the Administrative Code when determining an applicant's qualification for issuance of the authorization to practice. Any application containing information indicating that the applicant is not fit to be licensed shall be held and reviewed by the board's probable review committee. If authorized for release by the committee, the executive director may issue the appropriate authorization to practice. The probable review committee may defer any application directly to the full board.

(C) Authorize the executive director to employ office staff and contract for services as necessary to carry out its responsibilities under Chapter 4761. of the Revised Code. The executive director may hire, discipline, or terminate board staff in accordance with the Ohio civil service employees association, AFSCME local 11, contract with the state of Ohio.

(D) The executive director may manage the staff and board resources as required to meet the obligations, goals and objectives of the agency. The executive director must report on the status of the agency at each regular board meeting, including fiscal, licensing and personnel status. All expenditure shall be monitored and reported to the board at each regular board meeting. Capital expenditures in excess of five hundred dollars must be approved by the board.
4761-2-03 Board records. (Propose to file as no change rule)

(A) The board shall maintain an electronic register of applicants for licenses and permits to practice respiratory care. It shall include the name, school of respiratory care from which the applicant graduated, if applicant is such a graduate, method and date the licenses or permits were issued and any other data the board shall require. If the applicant took the examination, the dates of examination shall be shown and scores attained where possible.

(B) The board shall maintain an electronically imaged or paper file containing the original license or limited permit application, verification of national credentialing in the profession of respiratory care, verification of previous or current licensing from other states, proof of successfully completing an accredited program in respiratory care, and any other documentation deemed necessary by the board for the issuance of an initial license or limited permit. The electronically imaged or paper file will also include disciplinary action orders or consent agreements approved by the board. An electronic imaged record shall constitute the official and original record of the board if the original record has been destroyed in accordance with the board's records retention schedule.

(C) A change in the name of the licensee, permit holder or applicant shall not be made on the board's records unless the request is accompanied by one of the following:

(1) A notarized personal affidavit.

(2) A certified copy of a court record.

(3) A certified copy of a marriage certificate.
4761-2-05 Personal information systems. (Propose to rescind)

(A) For the purpose of this rule and in accordance with Chapter 1347. of the Revised Code:

(1) "Personal information" means any information that describes anything about a person, or that indicates actions done by or to a person, or that indicates that a person possesses certain personal characteristics, and that contains, and can be retrieved from a system by, a name, identifying number, symbol, or other identifier assigned to a person. Personal information shall not include, in accordance with division (A)(1)(e) of section 1347.04 of the Revised Code, personal information systems that are comprised of investigatory material compiled for law enforcement purposes by the board.

(2) "System" means any collection or group of related records that are kept in an organized manner and that are maintained by a state or local agency, and from which personal information is retrieved by the name of the person or by some identifying number, symbol, or other identifier assigned to the person. "System" includes both records that are manually stored and records that are stored using electronic data processing equipment. "System" does not include published directories, reference materials or newsletters, or routine information that is maintained for the purpose of internal office administration, the use of which would not adversely affect a person.

(3) "Maintains" means board ownership of, control over, responsibility for, or accountability for systems and includes, but is not limited to, the board depositing of information with a data processing center for storage, processing, or dissemination. The board "maintains" all systems of records that are required by law to be kept by the agency.

(B) The personal information system of the board shall be maintained in accordance with Chapter 1347. of the Revised Code.

(C) The board shall collect, maintain, and use only personal information that is necessary and relevant to the functions that the board is required or authorized to perform by statute or rule. Personal information shall be eliminated from the system when it is no longer necessary and relevant to those functions in accordance with the board record retention policy established pursuant to section 149.34 of the Revised Code.

(D) The board shall identify a privacy officer to be directly responsible for the personal information system of the board. The privacy officer shall develop procedures for purposes of monitoring the accuracy, relevance, timeliness, and completeness of the personal information in the system, and, in accordance with the procedures, maintain the personal information in the system with the accuracy, relevance, timeliness, and completeness that is necessary to assure fairness in any determination made with respect to a person on the basis of the information.

(E) The board shall take reasonable precautions to protect personal information in the system from unauthorized modification, destruction, use, or disclosure.

(F) The board shall specify disciplinary measures to be applied to any 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 system.

(G) The board shall provide for the right of persons who are the subject of personal information to be informed about the personal information of which the person is the subject and to permit the person or the person's legal representative to inspect the personal information of which the person is the subject, in accordance with section 1347.08 of the Revised Code, including:

If any person disputes the accuracy, relevance, timeliness, or completeness of personal information that pertains to the person and that is maintained by the board in a personal information system, that person may request the board to investigate the current status of the information. The board shall comply with section 1347.09 of the Revised Code when the board receives such a request.

(H) The board shall not place personal information into an interconnected and combined system, unless the system contributes to the efficiency of the board or agencies using the system or organizations authorized to use the system in implementing programs which are required or authorized by law.

(I) The board shall not use personal information placed into an interconnected and combined system by another state or local agency or organization, unless the personal information is necessary and relevant to the performance of a lawful function of the board.
4761-3-01 Definitions of terms.

The following definitions shall apply to the Ohio respiratory care board state medical board of Ohio for the practice of respiratory care:

(A) "Board" means the Ohio respiratory care board state medical board of Ohio.

(B) "Licensee" means a respiratory care professional issued a license under section 4761.04 4761.05 of the Revised Code who can practice the full range of respiratory care as defined under division (A) of section 4761.01 of the Revised Code.

(C) "Limited permit holder" or "permit holder" means a person who holds a limited permit issued under Chapter 4761. of the Revised Code.

(D) "Not in active practice" means that a licensee has notified the board that he is temporarily not engaging in the practice of respiratory care.

(E) "Designate" means any person or group authorized by the board as its agent to handle testing or other functions.

(F) "Under the supervision" as it is used under division (B) of section 4761.17 of the Revised Code means that the prescribing physician or authorized nurse is available to provide direction to the respiratory care practitioner providing the respiratory care service.

(G) "Nonresident" as used under division (A)(4) of section 4761.11 of the Revised Code, means an individual holds a permanent residence outside the state of Ohio or holds a temporary residence within the state of Ohio for no more than thirty days in a year.

(H) "License", as it is used under division (A) of section 4761.05 of the Revised Code, means the license certificate or a notarized copy of the license certificate as issued by the board.

(I) "Conspicuous display" as it concerns the license certificate, means in a place accessible to the public during normal operating hours of the principal place of business.

(J) "National Board for Respiratory Care, Inc. (NBRC)" means the national credentialing board for pulmonary technology and respiratory therapy.

(K) "Lapsed" means a license or limited permit is no longer active according to the expiration date posted on the identification card.

(L) "Licensure by endorsement" means the issuance of a license based upon board approval of an examination recognized by the board as meeting the requirements of division (A)(3) of section 4761.04 of the Revised Code.
(M) (J) "Licensure by Ohio examination" means the issuance of a license based upon successfully passing an examination offered to individuals who qualify for an educational waiver provided for in Section 6 of Sub. House Bill 111 of the 118th General Assembly.

(N) (K) "A year" as the term is used in division (A)(4) of section 4761.11 of the Revised Code, means three hundred sixty five days from the approval date of the non-resident registration.

(L) (O) "A prescription or other order" means any verbal or written order or prescription for respiratory care services as defined under section 4761.01 of the Revised Code given in accordance with division (A) of section 4761.17 of the Revised Code.

(M) (P) "Organization" means any agency employing respiratory care providers.

(N) (Q) "Official transcript" means an official transcript from a respiratory care educational program approved by the board pursuant to rule 4761-4-01 of the Administrative Code which lists the courses taken to earn a degree or certificate of completion in respiratory care, the number of hours and grade earned for each course, and the date and type of degree or certificate of completion earned. The transcript must be marked "official" by the issuing institution.

(O) (R) "Minimal Sedation," as the term is used in rule 4761-7-05 of the Administrative Code, means a drug-induced state during which patients can respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular function are unaffected. "Minimal sedation" shall not include sedation achieved through intravenous administration of drugs.

(P) (S) "Moderate sedation/analgesia," as the term is used in rule 4761-7-05 of the Administrative Code, means a drug-induced depression of consciousness during which patients can respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained.

(Q) (T) "Deep sedation/analgesia," 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 patient airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

(R) (U) "General anesthesia," a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function 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. Cardiopulmonary function may be impaired.

(S) (V) "Off-site supervision," means that the authorized prescriber must be continuously available for direct communication with the respiratory care professional and must be in a location that under
normal conditions is not more than sixty minutes travel time from the respiratory care professional's location.

(W) (T) "Direct supervision," means that that the authorized prescriber is actually in sight of the respiratory care professional when the respiratory care professional is administering a medication to induce moderate sedation/analgesia in accordance with paragraph (B)(3)(c) of rule 4761-7-05 of the Administrative Code. Although the prescriber may be performing some other task at the same time, the prescriber is physically present in the same room, so that the prescriber may immediately provide direction or assume the performance of the task if difficulties arise. This does not require that the prescriber is watching "over the shoulder" of the respiratory care professional as would be required during the training period to ensure that the respiratory care professional is competent to perform the task.

(X) (U) "Authorized prescriber" or "prescriber," means an individual authorized to order or prescribe respiratory care pursuant to section 4761.17 of the Revised Code.

(Y) (V) "Regular employment" as the term is used in paragraph (A) of rule 4761-5-01 of the Administrative Code means having employment in the practice of respiratory care equaling no less than an average of twenty-five hours per week for a period of fifty-two weeks during the three consecutive years prior to the date of application for an initial license.

(Z) (W) "Active duty military service," means currently serving in the branches of the armed forces as defined in section 145.30 of the Revised Code.

(AA) (X) "Veteran," means any person who has completed service in the armed forces, including the national guard of any state, or a reserve component of the armed forces, who has been discharged under honorable conditions from the armed forces or who has been transferred to the reserve with evidence of satisfactory service.
4761-4-01 Approval of educational programs. (Propose to file as no change rule)

(A) The board hereby approves respiratory care educational programs that:

(1) Have been issued provisional accreditation, initial accreditation, continuing accreditation or other accreditation status conferred by the commission on accreditation for respiratory care (CoARC) or their successor organization(s) that permits the respiratory care educational program to continue to enroll and/or graduate students; and

(2) Require a minimum of an associate degree with a major in respiratory care.
4761-4-02 Monitoring of Ohio respiratory care educational programs by the education committee of the Ohio respiratory care board.

(A) Annually, each respiratory care educational program in Ohio shall submit proof of compliance with the accreditation standards developed by the commission on accreditation for respiratory care (CoARC) or their successor organization(s). At minimum, Ohio respiratory care programs shall provide the following:

1. A copy of the annual report submitted to CoARC.


3. A copy of any plan of corrective action for program deficiencies issued by CoARC in response to an official site visit or annual report.

(B) Each respiratory care program in Ohio shall also annually submit a current letter of good standing issued by CoARC.

(C) The board shall form an education committee consisting of at least two members from the board. The education committee respiratory care advisory council shall be responsible for monitoring advising the board on educational policy and issues affecting respiratory care educational programs in Ohio and reporting such matters to the board. The education committee respiratory care advisory council shall also review documentation filed by Ohio respiratory care educational programs in accordance with paragraph (A) of this rule. The committee shall address any matters of concern with programs and annually file a compliance report with the board. If matters of concern are unresolved, the education committee respiratory care advisory council may recommend to the Board that a recommendation to survey and investigate a respiratory care educational program. Survey and investigation findings shall be reported to the board. The board may contract independent expert services as needed to assist the education committee respiratory care advisory council and the board meets its responsibilities under this rule.
4761-4-03 Recognition of military educational programs for active duty military members and/or military veterans. (Propose to file as no change rule)

The board recognizes respiratory care educational programs offered by branches of the United States military that have been issued provisional accreditation, initial accreditation, continuing accreditation or other accreditation status conferred by the commission on accreditation for respiratory care (CoARC) or their successor organization that permits respiratory care programs offered by the United States military to continue to enroll and/or graduate students.
4761-5-05 Non-resident practice of respiratory care. (Propose to rescind)

(A) In accordance with division (A)(4) of section 4761.11 of the Revised Code, a non-resident, as defined under paragraph (G) of rule 4761-3-01 of the Administrative Code, may practice respiratory care in the state of Ohio under the supervision of a licensed respiratory care professional for no more than thirty days in a year if one of the following conditions are met:

(1) Qualifies for licensure in the state of Ohio, except for the passage of the examination as required under division (A)(3) of section 4761.04 of the Revised Code; or

(2) Holds a valid license issued by a state that has licensure requirements considered by the Ohio respiratory care board to be comparable to those of the state of Ohio and has not been issued a license in another state that has been revoked or is currently under suspension or probation.

(B) Prior to practicing in Ohio, non-residents must complete a non-resident registration form and file this form with the Ohio respiratory care board. Registrants must submit any documentation necessary to support either of the qualifications mentioned in paragraph (A)(1) or (A)(2) of this rule. Qualified registrants will be mailed a letter of authorization to practice in the state of Ohio. This letter must be shown to any employer offering to provide respiratory care in the state of Ohio with whom the registrant is employed. Registrants that fail to support meeting the qualifications for this exemption will be refused authorization to practice in the state of Ohio.

(C) Non-residents shall update the Ohio respiratory care board within five working days of any change in respiratory care employment in the state of Ohio or any change in residency status according to paragraph (G) of rule 4761-3-01 of the Administrative Code.

(D) Any registrant found practicing respiratory care in the state of Ohio after permanent residency is established or for more than thirty days in a year will be subject to action under section 4761.09 of the Revised Code, unless the registrant holds a valid Ohio license or limited permit.
4761-5-07 Criminal records check. (Propose to rescind)

(A) In addition to the requirements established in rules 4761-5-04 and 4761-6-01 of the Administrative Code, all applicants for an initial license or limited permit to practice respiratory care in the state of Ohio shall submit to a criminal records check completed by the Ohio bureau of criminal identification and investigation in accordance with section 4761.051 of the Revised Code. The results of the criminal records check shall be received by the board prior to processing of an initial application for license or limited permit.

(B) An applicant requesting a criminal records check shall provide the bureau of criminal identification and investigation with the applicant's name, address, and any other information required by the bureau of criminal identification and investigation for the purpose of completing the criminal background check. The applicant shall cause the results of the criminal background check to be forwarded to the "Ohio Respiratory Care Board at 77 South High Street, 16th Floor, Columbus, Ohio 43215."

(C) In the request, the applicant shall ask the superintendent of the bureau of criminal identification and investigation to obtain a civilian criminal background check and a criminal background check from the federal bureau of investigation.

(D) The Ohio respiratory care board will only accept the results of a criminal background check that is submitted to the board directly by the bureau of criminal identification and investigation in compliance with this rule.

(E) A criminal background check will not be required if the applicant has caused a criminal background check results report to be filed with the board in accordance with the requirements of this rule within one year prior to the date of initial application. A new criminal background check will be required if the applicant's criminal background check results report on file with the board is greater than one year old based on the filing date of the results report with the board.
4761-6-01 Limited permit application procedure.

(A) Limited permit—the board may issue a limited permit, to any applicant who is of good moral character, files an initial limited permit application form approved by the board, and pays the initial application fee prescribed by the board. An applicant for a limited permit shall submit to the board an application under oath in the manner determined by the board, and provide such other facts and materials as the board requires. No application shall be considered submitted to the board until the appropriate fee has been received by the board. Application fees are not refundable.

(1) An applicant for a limited permit must provide proof of meeting one of the following requirements:

(a) Is enrolled in and is in good standing in a respiratory care educational program that meets the requirements of rule 4761-4-01 of the Administrative Code; or

(b) Is a graduate of a respiratory care educational program that meets the requirements of rule 4761-4-01 of the Administrative Code and is making application within one year of such graduation date; or

(c) Is employed as a provider of respiratory care in this state and was employed as a provider of respiratory care in this state prior to March 14, 1989, as provided by division (B)(1)(b) of section 4761.05 of the Revised Code.

(2) An applicant meeting the requirements of paragraph (A)(1)(a) of this rule shall file with the application a verification of education form provided by the board as proof of his/her enrollment and good standing in an approved educational program.

(3) An applicant meeting the requirements of paragraph (A)(1)(b) of this rule shall submit an official transcript.

(4) An applicant meeting the requirements of paragraph (A)(1)(c) of this rule shall submit proof of his/her record of employment as a provider of respiratory care in this state.

(5) A person issued a limited permit under paragraph (A)(1)(a) or (A)(1)(b) of this rule shall practice respiratory care only under the supervision of a respiratory care professional until whichever of the following occurs first:

(a) Three years after the date the limited permit is issued; or

(b) until the holder discontinues enrollment in the educational program; or

(c) one year following the date of receipt of a degree or certificate of completion from a board-approved respiratory care education program;

(B) A person issued a limited permit under paragraph (A)(1)(a) or (A)(1)(b) of this rule may petition the board to extend the effective term of a limited permit in cases of unusual hardship. An
unusual hardship will be considered invalid if the events leading to the hardship did not occur within a reasonable timeframe from the date of petition for extension of the limited permit. A limited permit holder seeking an extension of a limited permit must file a written petition that describes the unusual hardship. The board may extend the term of a limited permit for periods of time deemed appropriate for the circumstances associated with the petition for extension.

(C) The respiratory care services which may be performed by the holders of a limited permit issued under paragraph (A)(1)(a) of this rule are limited to only those services which have been successfully completed by such persons as part of the curriculum of their respiratory care educational program, as certified by the director of the respiratory care educational program on the verification of education form filed with the board. A copy of the board approved verification of education form will be provided to the holder of a limited permit. The limited permit holder must provide a copy of the board approved verification of education form to all employers of respiratory care services. An updated verification of education form may be filed with the board upon successful completion of additional clinical courses.

(D) A person issued a limited permit under paragraph (A)(1)(c) of this rule shall practice respiratory care only under the supervision of a respiratory care professional and may practice for not more than three years, unless the holder has been employed as a provider of respiratory care for an average of not less than twenty-five hours per week for a period of not less than five years by a hospital certified or accredited pursuant to section 3727.02 of the Revised Code.

(E) Incomplete applications will be held open for ninety days following notification of incomplete requirements by regular mail. After sixty days, a final notice of incomplete application will be mailed by certified mail, return receipt requested. If, by the end of the ninety day period, the application remains incomplete, it will be considered abandoned. After ninety days, if desired, the applicant must submit a new application, including fee. If an applicant fails to complete the application process within six months of initial application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.

(F) No application being investigated under section 4761.09 of the Revised Code, may be withdrawn without approval of the board.

(G) A person issued a limited permit in accordance with this rule must file a completed supervisor registration form within fifteen days of the beginning date of employment in the practice of respiratory care. A limited permit holder must file a new form for any change in respiratory care employment or upon being employed by more than one respiratory care employer.
4761-7-01 Original license or permit, identification card or electronic license verification.

(A) The board shall prepare and provide to each initial license or permit holder a certificate stating the name of the license or limited permit holder, the license or limited permit number assigned and the initial issuance date. Additionally, the board may issue an identification card as proof of current authorization to practice. In lieu of an identification card, The board may permit the electronic verification of the each license or limited permit holder through a web-based verification system. An identification card or electronic verification shall contain the person's name, license or permit number, information as to the type of authorization under which they practice, and date of expiration.

(B) Official license or permit certificates shall be signed by the board president and secretary and be affixed with the attested by its seal of the board. Official identification cards, if used, shall bear the signature of the board president and/or the executive director. Electronic verification of license or limited permit status shall be considered a primary source verification. For the purpose of conspicuous display as set forth under division (A) of section 4761.05 of the Revised Code, a holder may make a notarized copy of the license or permit certificate. A written statement must be found on the document attesting that the certificate is a true copy.

(C) Neither the holder nor anyone else shall make any alterations on a certificate or identification card issued by the board.

(D) Regardless of the original issue date, all licenses shall expire on June thirtieth of each even numbered year, unless other limitations pursuant to law, board order, or consent agreement are in effect.

(E) Regardless of the original issue date, all limited permits will expire on June thirtieth of each year, unless other limitations pursuant to law, board order, or consent agreement are in effect.

(F) Identification cards or electronic verification are valid proof of current authorization.

(G) In accordance with division (C) of section 4761.05 of the Revised Code, holders of licenses and permits must display in a conspicuous place on their persons the information as to the type of authorization under which they practice. This information shall include the holder's name, title, and the type of authorization under which they practice, which shall state no less than "R.C.P." for a licensed respiratory care professional or "limited permit holder" for a limited permit holder. a wall certificate in their office or place where the majority of the holder’s practice is conducted.
4761-7-03 Scope of respiratory care defined. (Propose to file as no change rule)

(A) "Respiratory care" as employed in Chapter 4761. of the Revised Code, means engaging in respiratory care, as defined in division (A) of section 4761.01 of the Revised Code, as a clinician, an educator, a manager, and/or a consultant, excluding activities related to equipment maintenance, cleaning, and delivery.

(B) "Instructing in the use of medical gases" as it is used in division (A)(2) of section 4761.01 of the Revised Code, means the direct or indirect use of educational material, communicated in writing or otherwise, that explains the clinical indications or contraindications concerning a patient's prescription for a medical gas.

(C) "Administering of medical gases" as it is used in division (A)(2) of section 4761.01 of the Revised Code, means the direct application and quantitative adjustment of a medical gas to a patient regardless of the device used to administer the gas.

(D) "Monitoring and recording the results of medical gases" as it is used in division (A)(2) of section 4761.01 of the Revised Code, means assessing, evaluating and documenting the use of a medical gas, including measurements of fractional inspired concentrations, flow and volume; and a patient's physiologic or clinical response to a medical gas, including invasive or noninvasive sampling of blood or gas samples.

(E) "Any service" as it is used in division (A) of section 4761.01 of the Revised Code, means any practice performed by a competently trained licensed respiratory care professional or permit holder involving the evaluation of cardiopulmonary function, the treatment of cardiopulmonary impairment, the assessment of treatment effectiveness and the care of patients with deficiencies and abnormalities associated with the cardiopulmonary system.

(F) "Aspiration" as it is used in division (B)(1) of section 4761.10 of the Revised Code, means to remove bodily fluids or mucous from the pulmonary airway by means of a suction device. Included suctioning procedures are naso-pharyngeal, oral-pharyngeal, tracheal, and bronchial. Oral suctioning and suctioning of secretions external to the airway will not be considered aspiration as this term is defined in this rule.
4761-7-04 Supervision. (Propose to file as no change rule)

As provided for in division (B) of section 4761.05 of the Revised Code, a limited permit holder must work under the supervision of a respiratory care professional (RCP) and may not be supervised by any other person, including those persons licensed to practice in any other profession.

"To practice under the supervision of a respiratory care professional" as used in division (B) of section 4761.05 of the Revised Code requires that an RCP be readily available in the facility and responsible at all times for the direction and actions of a limited permit holder under their supervision. Three types of limited permits are issued by the board: student-based, employment-based, and graduate-based. The level of supervision and the duties assigned may vary based upon the type of limited permit holder that is being supervised. The RCP shall determine the appropriate level of supervision and assigned respiratory care duties for an employment-based limited permit holder taking into consideration institutional competency reviews and work performance. For student limited permit holders, the appropriate level of supervision and assigned respiratory care duties shall be based, in part, on competencies approved on the verification of education form completed by the student's respiratory care educational program director. At no time shall a supervising RCP assign duties that exceed the approved competencies documented on the verification of education form. Graduate-based limited permit holders may practice a full scope of respiratory care duties, but must still be supervised in accordance with this rule. Regardless of the type of limited permit held, an RCP shall not delegate to a less qualified person any service which requires the skill, knowledge and judgment of an RCP.
Administration of medications. (Propose to file as no change rule)

(A) Respiratory care professionals and limited permit holders must be able to document appropriate and successful training and proficiency on the route of medication delivery, drug pharmacology, and dosage calculations for any medication for the treatment and testing of cardiopulmonary impairment for which they are authorized to administer pursuant to division (A)(4) of section 4761.01 of the Revised Code. Appropriate training includes, but is not limited to, the following components:

(1) Pharmacology. Subject matter shall include terminology, drug standards, applicable laws and legal aspects, identification of drugs by name and classification, and the principles of pharmacodynamics of medications used in the treatment and testing of cardiopulmonary impairment.

(2) Techniques of drug administration. Subject matter shall include principles of asepsis, safety and accuracy in drug administration, applicable anatomy and physiology, and techniques of administration and any route of administration for any medications for the treatment and testing of cardiopulmonary impairment.

(3) Dosage calculations. Subject matter shall include a review of arithmetic and methods of calculation required in the administration of drug dosages.

(4) The role of the respiratory care professional or limited permit holder in the administration of any medication for the treatment and testing of cardiopulmonary impairment. Subject matter shall include constraints of medication administration under the legal scope of practice for respiratory care, the rationale for specific respiratory care in relation to drug administration; observations and actions associated with desired drug effects, side effects and toxic effects; communication between respiratory care professional or limited permit holder and other members of the health care team; respiratory care provider-client interactions; and the documentation of medication administration for any medication for the treatment and testing of cardiopulmonary impairment.

(B) Respiratory care professionals may administer medications to induce minimal sedation to moderate sedation/analgesia during diagnostic and therapeutic procedures relating to the testing and treatment of cardiopulmonary impairments. It is appropriate for respiratory care professionals to administer these medications if the following criteria are followed:

(1) Only a person authorized to prescribe or write orders pursuant to section 4761.17 of the Revised Code may select and order the drug to be administered to achieve the desired level of sedation/analgesia. The order shall include:

(a) Medication;
(b) Dosage;

(c) Frequency; and

(d) Method of administration.

(2) In addition to the general training requiring for medication administration contained in paragraphs (A)(1) to (A)(5) of this rule, a respiratory care professional shall also do the following:

(a) Complete the education and competency requirements of the employing facility on the administration of sedatives and analgesic medications;

(b) Understand the pharmacology, dosage, routes of administration, and adverse reactions of sedatives, analgesics, and antagonists. Identify the appropriate selection of monitoring equipment and be able to understand and interpret vital signs. Record patient's vital signs and medication in the medical record;

(c) Have current advanced cardiac life support (ACLS) or pediatric advanced life support (PALS) certification as appropriate and be able to perform rescue procedures;

(d) Meet competency guidelines, as determined by the facility, for the insertion and maintenance of artificial airways, assessing and maintaining ventilation, administration of oxygen, and

(e) Be able to insert and maintain an intravenous line when medications are administered by this route.

(3) The administration of medications to induce minimal to moderate sedation/analgesia shall be properly supervised by the authorized prescriber. Respiratory care professional must adhere to the following supervisory guidelines:

(a) Oral administration or aerosolized administration of medications to induce minimal to moderate sedation/analgesia may be performed with off-site supervision of the prescriber and do not require the respiratory care professional to be able to insert or maintain an intravenous line.

(b) Intravenous administration of medications to induce minimal sedation/analgesia for emergency intervention procedures, such as intubation may be performed with off-site supervision of the prescriber.

(c) Intravenous administration of medications to induce moderate sedation/analgesia for respiratory care procedures requires direct supervision of the prescriber.

(4) At no time shall a respiratory care professional administer a medication at a dosage and interval that is reasonably expected to induce deep sedation or general anesthesia.
(5) A respiratory care professional who administers a medication to induce minimal sedation to moderate sedation/analgesia shall have no other assignments during the course of administration, monitoring and recovery of the patient that would leave the patient unattended or unmonitored.

(6) Prior to administering a medication to induce minimal sedation to moderate sedation/analgesia, the respiratory care professional shall review the patient's pertinent medical history, including sedation-oriented aspects. The patient history should include a review of the medical history; current medications, herbal products, or vitamins; medication allergies; use of tobacco, alcohol, or substance abuse; last oral intake; and history of adverse reactions to sedatives, analgesics or anesthetics.

(7) Monitoring parameters shall minimally include:

(a) Baseline vital signs prior to and intermittently during the procedure;

(b) Pulmonary ventilation, including respiratory rate, depth of breathing, auscultation and, if appropriate, end tidal CO2 monitoring;

(c) Oxygenation via pulse oximetry;

(d) Electrocardiography for patient with history of cardiovascular disease or dysrhythmias, or hypertension;

(e) Response to verbal and tactile stimulation and commands;

(C) For each respiratory care professionals and limited permit holders respiratory care provider, the organization shall maintain a record that documents training and proficiency reviews. Documentation of periodic competency reviews shall be maintained by the organization. At the request of the board, records may be audited, reviewed, or copied.
4761-8-02 Licensees not in active practice. (Propose to rescind)

(A) A licensee shall be considered to be "inactive" upon written request to the board, signed by the holder of the license or the holder's legal guardian.

(B) An inactive license may be reinstated to active status by meeting the requirements of paragraph (G) of rule 4761-8-01 of the Administrative Code.
4761-9-01 Definition of respiratory care continuing education.

(A) "Respiratory care continuing education" (hereafter referred to as RCCE), as required under section 4761.06 of the Revised Code, means post-licensure learning experiences which are approved by the Ohio respiratory care state medical board of Ohio (hereafter referred to as the board) and which enhance or build upon the licensees current knowledge or educational background as it pertains to the practice of respiratory care, as set forth in section 4761.01 of the Revised Code.

(B) For the purposes of this chapter, the following definitions shall apply:

(1) "Post-licensure" means the period following the granting of a license under section 4761.04 of the Revised Code or a limited permit issued under division (B) of section 4761.05 of the Revised Code.

(2) "Learning experiences" means activities or programs which allow respiratory care providers to obtain or enhance skills, knowledge, or behavior needed to provide respiratory care.

(3) "Approved by the Ohio respiratory care state medical board of Ohio" means that the RCCE program or activity qualifies for official recognition by the board in accordance with one of the approval mechanisms set forth in rule 4761-9-05 of the Administrative Code.

(4) "Licensee" means the holder of a license issued under section 4761.04 of the Revised Code or a limited permit issued under division (B)(1)(b) of section 4761.05 of the Revised Code.

(a) Calculation of contact hours from credit hours earned in an academic institution shall be done using the following formula:

(i) Quarter system: one credit hour = ten contact hours;

(ii) Trimester system: one credit hour = twelve contact hours;

(iii) Semester system: one credit hour = fifteen contact hours.
Activities which do not meet the Ohio RCCE requirements. (Propose to file as no change rule)

(A) Activities which do not meet the Ohio RCCE requirement shall include but not be limited to:

(1) Basic life support (hereafter referred to as BLS) and cardiopulmonary resuscitation (hereafter referred to as CPR) provider courses;

(2) Repetition of any educational activity with identical objectives and content within the same reporting period;

(3) Employer specific orientation or inservice programs which do not significantly enhance the practice of respiratory care or related technologies;

(4) Self-directed independent study such as reading of texts or journal articles which have not been approved by any of the mechanisms listed under rule 4761-9-05 of the Administrative Code.

(5) Participation in clinical practice or research that is not part of an approved RCCE activity;

(6) Personal development activities not taken for the purpose of meeting RCCE requirements;

(7) Professional meetings and conventions except for those portions designated as approved RCCE activities;

(8) Community service and volunteer practice;

(9) Membership in a professional organization;

(10) RCCE contact hours ordered by the board, above and beyond the prescribed contact hours, as set forth under rule 4761-9-03 of the Administrative Code.
4761-9-04 Ohio respiratory care law and professional ethics course criteria. (Propose to file as no change rule)

(A) An acceptable course in Ohio respiratory care law or professional ethics shall meet the following criteria and be awarded or approved through an activity meeting the requirements of rule 4761-9-05 of the Administrative Code:

(1) The course shall be at least one contact hour in length; and

(2) The course content shall include one of the following:

(a) Standards of respiratory care practice and ethical conduct; or

(b) Acts that constitute violations of the respiratory care practice law under section 4761.09 of the Revised Code; or

(c) Obligations to report alleged violations of Chapter 4761 of the Revised Code or rules adopted thereunder; or

(d) Medical ethics.
4761-9-05 Approved sources of RCCE.

(A) Applicants for renewal shall successfully complete the required number of RCCE contact hours according to rule 4761-9-02 of the Administrative Code. RCCE earned from any combination of the following sources may be applicable towards meeting RCCE requirements:

1. Relevant college credit awarded by an academic institution accredited by its regional accrediting association.

2. RCCE contact hours awarded by respiratory care educational programs approved by the board in accordance with rule 4761-4-01 of the Administrative Code.

3. The successful completion of advanced life support programs and/or instructors for life support programs will qualify to meet the RCCE requirement. Those meeting this requirement are, but may not be limited to advanced cardiac life support (ACLS), pediatric advanced life support (PALS), neonatal resuscitation program (NRP), and advanced trauma life support (ATLS). The number of contact hours for each program must be assigned by the educational provider. Licensees will be responsible for acquiring documentation supporting completion of the program, the date of completion, and the number of contact hours earned.

4. Recertification for ACLS, PALS, NRP, or ATLS. The number of contact hours for each program must be assigned by the educational provider. Licensees will be responsible for acquiring documentation supporting completion of the program, the date of completion, and the number of contact hours earned.

5. All or portions of a continuing education activity relevant to the practice of respiratory care which meet the requirements of paragraph (A) of rule 4761-9-01 of the Administrative Code and which have been approved by a professional organization or association awarding continuing education contact hours, including, but not limited to the American association for respiratory care (A.A.R.C.), the American medical association (A.M.A.), the American nurses association (A.N.A.), the Ohio society for respiratory care (O.S.R.C.), the Ohio state medical association (O.S.M.A.), the Ohio nurses association (O.N.A.), the Ohio thoracic society (O.T.S.), the American college of chest physicians (A.C.C.P.), the American heart association (A.H.A.), the American lung association (A.L.A.), the Ohio lung association (O.L.A.), and the American association of critical care nurses (A.A.C.C.N.).

6. Relevant education and training provided by a branch of the U.S. military for active duty military service members.

7. Professional ethics or Ohio respiratory care law continuing education programs approved by the Ohio respiratory care state medical board for the purposes of meeting the requirements of rule 4761-9-04 of the Administrative Code. Providers must file a written request for approval with the Ohio respiratory care board, including a description of the course and qualifications of the course instructors. The Ohio respiratory care board, in its discretion, may approve or reject any course offering.
4761-10-01 Ethical and professional conduct.

A licensee and a permit holder shall provide professional services with objectivity and with respect for the unique needs and values of the health care recipient, as follows:

(A) A licensee or permit holder shall not discriminate on the basis of factors that are irrelevant to the provision of professional services including, but not limited to race, creed, sex, national origin, age or medical condition.

(B) Prior to a licensee or permit holder entering into a contractual relationship with a health care recipient, the licensee or permit holder shall provide sufficient information to enable the health care recipient to make an informed decision to enter into a contractual relationship. Sufficient information shall include any fees and arrangements for payment which might affect the decision.

(C) A licensee or permit holder shall not mislead the public and colleagues about services and shall not advertise in a misleading manner.

(D) A licensee or permit holder shall not engage in any activities that seek to meet their personal needs at the expense or detriment of the health care recipient.

(E) A licensee or permit holder shall not leave an assignment without being properly relieved by appropriate personnel.

(F) A licensee or permit holder shall not receive or give a commission or rebate or any other form of direct or indirect remuneration or benefit for the referral of patients/clients for professional services.

(G) A licensee or permit holder shall disclose to health care recipients any interest in commercial respiratory care enterprises which the licensee promotes for the purpose of direct or indirect personal gain or profit.

(H) A licensee or permit holder shall not accept gratuities for any reason including but not limited to preferential consideration of the health care recipient.

(I) A licensee or permit holder shall practice respiratory care within the scope of respiratory care as set forth in division (A) of section 4761.01 of the Revised Code and in accordance with acceptable and prevailing professional standards or guidelines and shall not endeavor to extend his/her practice beyond his/her competence and the authority vested in him/her under division (B) of section 4761.01 of the Revised Code.

(I) The board may determine adherence to acceptable and prevailing professional standards and guidelines for respiratory care practice by using:

(a) Current respiratory care literature recognized by the board;
(b) Position statements, standards of practice, or guidelines for respiratory care written by the board or other recognized national respiratory care professional organizations;

(c) Board member expertise;

(d) An expert witness;

(J) A licensee shall not employ, direct, or supervise a person who is not authorized to practice respiratory care under this chapter in the performance of respiratory care procedures.

(K) A licensee or permit holder shall cooperate to the extent permitted by law with other licensed health care professionals responsible for providing care to cardiopulmonary patients, including:

1) Consulting with appropriate licensed practitioners responsible for prescribing therapy, treatment, or diagnostic services;

2) Notifying other care givers and the prescribing practitioner when a prescribed therapy, treatment, or diagnostic service is not administered due to reasons contained in paragraph (L) of this rule;

3) Recommending to other care givers and the prescribing practitioner when prescribed therapy, treatment, or diagnostic service needs to be altered to obtain optimal patient care.

(L) A licensee or permit holder shall not implement an order that the respiratory care professional or limited permit holder believes or should have reason to believe is:

1) Inaccurate;

2) Not properly authorized;

3) Harmful, or potentially harmful to a health care recipient; or

4) Contraindicated by other documented information.

(M) A licensee or permit holder shall disclose health care recipient information only with other health care professionals responsible for providing care to the health care recipient with whom the licensee or permit holder is responsible. At all other times, a licensee or permit holder shall hold as confidential all patient information which the licensee or permit holder has knowledge.

(N) A licensee or permit holder shall access only health care recipient information which is necessary and relevant to their function and authority as a respiratory care provider.

(O) A licensee or limited permit holder shall not falsify any health care recipient record or any other document prepared or utilized in the course of treating or rendering respiratory care.
(P) A licensee or limited permit holder shall not engage in fraudulent billing for respiratory therapy or treatment.

(Q) A licensee or permit holder shall not engage in behavior that may cause physical, verbal, mental, or emotional abuse to a health care recipient.

(R) A licensee or permit holder shall not engage in behavior that may be reasonably interpreted as physical, verbal, mental, or emotional abuse to a health care recipient.

(S) A licensee or permit holder shall not:

(1) Engage in sexual conduct with a health care recipient under their care;

(2) Engage in conduct in the course of practice that may be reasonably interpreted as sexual conduct;

(3) Engage in verbal behavior in the course of practice that is seductive, or sexually demeaning to a health care recipient.
4761-10-02 Proper use of credentials. (Propose to file as no change rule)

(A) A licensee or permit holder shall not misrepresent any professional qualifications or credentials or provide any information that is false, deceptive or misleading in connection with his/her own application for employment or work as a respiratory care provider.

(B) A licensee or permit holder shall not delegate the use of his/her name or signature on documentation for services unless he/she actually provided these services and has given permission to another individual for such documentation, or unless he/she appropriately supervised those services.
4761-11-01 Filing of complaints. (Propose to rescind)

(A) Any person may file a complaint with the board that a licensee, permit holder, or other person has committed any act that is grounds for disciplinary action under section 4761.09 of the Revised Code or any act that violates section 4761.10 of the Revised Code or of Ohio respiratory care board rules.

(B) Upon receipt of a complaint, the investigator of the board shall send an acknowledgment letter to the complainant along with a request for any additional information, if deemed necessary.

(C) Anonymous complaints may be investigated if the executive director with the advice and consent of a board designee believes an investigation is justified.

(D) If the executive director of the board believes a complaint is justified, a report shall be filed with the board, who may draft an opportunity of hearing notice which shall be in accordance with Chapter 119. of the Revised Code.

(E) If a complaint is determined to be unfounded, the executive director with the approval and consent of the board may close the investigation.
4761-11-02 Administrative procedure for refusal to issue or renew a license or permit, deny, suspend, or revoke a certificate or license. (Propose to rescind)

Hearings held pursuant to proposed board action shall be in compliance with Chapter 119. of the Revised Code, including the following:

(A) A notice, to be given to the individual by certified mail, of his/her right to a hearing on the proposed board action.

(B) The notice shall include a reason or reasons for such proposed action, the law or rule allegedly violated, and a statement informing the individual of entitlement to a hearing, if requested, within thirty days of the time of mailing of the notice.

(C) The notice shall inform the individual that he/she may appear in person, submit contentions in writing, or be represented by an attorney, and that the individual may present evidence and examine witnesses at the hearing.

(D) In order to request a hearing under Chapter 119. of the Revised Code, a respondent or the respondent's representative must, in accordance with rule 4761-11-08 of the Administrative Code, file in writing a statement requesting such adjudication hearing within thirty days of the date of mailing of the board's notice of opportunity for hearing, or the date of personal service or final publication in a newspaper having general circulation in the respondent's county of residence. The date of mailing shall be the date appearing on the certified mail receipt.

(E) A respondent or the respondent's representative properly filing a request for an adjudication hearing shall be entitled to such adjudication hearing within fifteen days but not sooner than seven days after such a request has been filed, unless both representatives agree otherwise or a continuance is granted pursuant to section 119.09 of the Revised Code and rule 4761-11-06 of the Administrative Code.
4761-11-03 Board imposition of penalties. (Propose to rescind)

(A) Any licensee or permit holder found by the board to be in violation of section 4761.09 of the Revised Code may be reprimanded, placed on probation or have his license or permit suspended, refused for renewal, or revoked by the board. In addition, the board may fine violators as provided for in division (A)(6) of section 4761.03 of the Revised Code, not less than one hundred dollars nor more than one thousand dollars.

(B) Upon suspension, revocation or nonrenewal, the former license or permit holder shall return the license/permit certificate and I.D. card, if issued, to the board.

(C) If a suspension overlaps a license renewal period, the former license holder shall comply with the normal renewal procedures in agency level 4761 of the Administrative Code.
4761-11-04 Representation; appearance; communication; applicability. (Propose to rescind)

(A) As used in Chapter 4761-11 of the Administrative Code, "respondent" shall be defined as the person who is requesting or has requested a hearing as provided in Chapter 119. of the Revised Code.

(B) As used in Chapter 4761-11 of the Administrative Code, "hearing examiner" shall be defined as an attorney hearing examiner retained by the board to conduct hearings on its behalf.

(C) As used in Chapter 4761-11 of the Administrative Code, "appointed hearing officer" shall be defined as a member of the board elected to conduct a hearing should the hearing be held before the board and not a hearing examiner.

(D) The respondent may be self-represented or may be represented by an attorney admitted to the practice of law in Ohio. In the absence of an attorney, the respondent shall be deemed the representative of record for the purposes of Chapter 4761-11 of the Administrative Code. Any attorney shall be prepared to prove current law license at the time of the hearing.

(E) The respondent is not required to personally appear at any hearing provided he/she has not been subpoenaed. The respondent may authorize an attorney to represent him/her in all matters of the hearing before the board.

(F) The respondent or attorney representative may present positions, arguments, or contentions in writing rather than appear at any hearing provided that the respondent has not been subpoenaed.

(G) The representative of record for the respondent shall enter appearances in writing.

(H) The representative of record from the Ohio attorney generals office shall enter appearances in writing.

(I) The person entering an appearance as representative will remain the representative of record until a written withdrawal is filed with the board.

(J) Except as otherwise provided under Chapter 119. of the Revised Code, communications from the board, its appointed hearing officer, its hearing examiner, or representative from the Ohio attorney generals office shall be sent to the respondent's representative of record.

(K) The members of the board shall base their decisions on any matter subject to hearing only on the evidence contained in the record. No information acquired by a member of the board in any way other than by review of the evidence of the record shall be considered by such member in that member's decision on a matter subject to hearing. Any board member who participates in the probable review determination of will be recused from the adjudication hearing.

(L) 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 pending or impending
adjudicatory proceeding. Nothing contained herein, however, shall preclude the hearing examiner from nonsubstantative ex parte communications on procedural matters and matters affecting the efficient conduct of adjudicatory hearings.

(M) The hearing examiner and members of the board shall disclose on the record the source and substance of any ex parte or attempted ex parte communications. That disclosure shall be made at an adjudicatory hearing or at a board meeting prior to deliberation on a pending or impending adjudicatory proceeding.

(N) If any provision of the rules in this chapter is held invalid or if the application of any provision of the rules in this chapter to any person or circumstances is held invalid, the invalidity does 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 provision of the rules in this chapter are hereby declared severable.
4761-11-05 Authority and duties of the board or hearing examiner. (Propose to rescind)

(A) Adjudication hearings shall be conducted before the board or a hearing examiner. Adjudication hearings held before the board shall be conducted under the direction of an appointed hearing officer elected from among its members.

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

(C) In its discretion, the appointed hearing officer or hearing examiner may admit sensitive or confidential evidence into the hearing record under seal.

(D) The appointed hearing officer or 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.

(E) The authority of the appointed hearing officer or hearing examiner shall include, but not be limited to, authority to:

1. Administer oaths and affirmations, which may also be done by a notary public;

2. Order the issuance of subpoenas and subpoena duces tecum to require the attendance of witnesses at hearings and depositions and to require the production of evidence for hearings and depositions;

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. Prepare entries, findings, order, or reports and recommendations;

7. Request preparation of entries, findings, or orders;

8. Take such other actions as may be necessary to accomplish the purposes of paragraph (D) of this rule;

(F) The authority of the appointed hearing officer or hearing examiner shall not include authority to:

1. Grant motions for dismissal of charges;

2. Modify, compromise, or settle charges or allegations.
(G) The hearing examiner shall have other powers, duties, and authority as are granted by statutes or rules.
4761-11-06 Continuance of hearing. (Propose to rescind)

(A) Except in matters of summary suspension under division (C) of section 4761.09 of the Revised Code, the appointed hearing officer, or the board through its hearing examiner, shall initially continue a 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.

(B) The appointed hearing officer or the hearing examiner may continue a hearing upon the motion of a representative of record.

(C) Hearings shall not be continued upon motion by a representative unless showing of reasonable cause and proper diligence is presented. Before granting any continuance, consideration shall be given to harm to the public which may result from delay in proceedings.

(D) Upon proper motion, the hearing record may be held open to accept a deposition in lieu of oral testimony or a subpoenaed witness upon proper motion.

(E) Continuances whenever possible shall be sought no later than seven days before a hearing. Failure to request a continuance prior to that time will be denied without special necessity.
4761-11-07 Filing. (Propose to rescind)

(A) A document is "filed" when it is received and time-stamped in the offices of the Ohio respiratory care board.

(B) An original of any document required to be served by Chapter 4761-11 of the Administrative Code shall be filed with the Ohio respiratory care board not more than three days after service.

(C) All filings shall be addressed to the board to the attention of the executive director. A copy of all filings must be provided to the assistant attorney general representing the board as set forth in rule 4761-11-08 of the Administrative Code.
4761-11-08 Service. (Propose to rescind)

(A) Except as otherwise provided in Chapter 119. of the Revised Code or Chapter 4761-11 of the Administrative Code, any document required by this chapter of the Administrative Code to be served by the respondent, respondent’s counsel of record, assistant attorney general, or board representative may be served either personally or by first class mail service. Service is complete on the date it is received or on the date personal service of the document is made.

(B) All motions and briefs shall contain the name, address, and telephone number of the person submitting the motion or brief and shall be appropriately captioned to indicate the name of the respondent.

(C) A motion shall be considered by the board or its hearing examiner only if a certificate of service appears on it. Any signed statement is an acceptable certificate of service so long as it contains all of the following information:

(1) Date of service;

(2) Method by which service was made;

(3) Address where service was made; and

(4) Name of the person or authority who was served.
4761-11-09 Computation and extension of time. (Propose to rescind)

(A) The date of occurrence of the event causing time to run is not counted in the computation of any time limit under Chapter 4761-11 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 appointed hearing officer or the 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 4761-11-07 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 appointed hearing officer or hearing examiner.

(3) Requests for extension of time shall be served as provided in rule 4761-11-09 of the Administrative Code.
4761-11-10 Motions. (Propose to rescind)

(A) Except as otherwise provided under Chapter 119. of the Revised Code or Chapter 4761-11 of the Administrative Code, all motions, unless made upon the record at the 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 4761-11-07 of the Administrative Code. A proposed entry may accompany any motion. Except in cases of summary suspensions pursuant to division (C) of section 4761.09 of the Revised Code, all motions except those filed subsequent to the close of the hearing shall be made no later than fourteen days before the date of hearing unless express exception is granted by the appointed hearing officer or the hearing examiner or by this chapter.

(B) All motions, together with supporting documentation, if any, shall be served as provided in rule 4761-11-08 of the Administrative Code.

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

(D) Before ruling upon a written motion, the appointed hearing officer or hearing examiner shall consider all memoranda and supporting documents filed. The appointed hearing officer or hearing examiner shall enter a written ruling and shall issue copies to the representatives as identified under rule 4761-11-04 of the Administrative Code. The ruling on all oral motions made at hearing shall be included in the record except where the appointed hearing officer or hearing examiner elects to take the motion under advisement and issue a written ruling at a later time. The appointed hearing officer or hearing examiner shall include in each written ruling on a motion a short 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 by the hearing examiner shall be rendered by the board or, if the board is not in session, by the appointed hearing officer acting on its behalf.
4761-11-11 Transcripts. (Propose to rescind)

(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.

(B) Upon request made to the board, a copy of original transcripts, if the transcript is on file at the board office, may be reviewed at the board offices or signed out for a period of forty-eight hours. Additional copies may be prepared at the requestor's expense.

(C) Original transcripts, if the transcript is on file at the board office, shall not be removed from the board offices.
4761-11-12 Subpoenas for purposes of hearing. (Propose to rescind)

(A) Upon written request of any party, the board through its executive director 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 the representatives as identified in rule 4761-11-04 of the Administrative Code.

(B) For purposes of a hearing conducted under 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 they are to appear. With respect to the production of books, records and papers, such request may specify a date of compliance not more than seven days prior to hearing.

(C) Except upon leave of the appointed hearing officer or hearing examiner, subpoena requests are to be filed with the board as provided in rule 4761-11-07 of the Administrative Code at least fourteen 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 appointed hearing officer or 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 five 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 appointed hearing officer or the hearing examiner may order the issuance of subpoenas to compel the attendance and testimony of witnesses and production of books, records and papers. Copies of such subpoenas shall be issued to the representatives as identified in rule 4761-11-04 of the Administrative Code.

(F) Upon motion and for good cause, the appointed hearing officer or the hearing examiner may order any subpoena be quashed. Motions to quash shall be made in the manner provided in rules 4761-11-07 and 4761-11-08 of the Administrative Code, except that motions to quash shall be filed at least five days prior to the date of compliance. The non-moving party may file a response no later than four 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 the witness was subpoenaed. The board shall make a reasonable attempt to contact any witness whose subpoena has been quashed.
4761-11-13 Mileage reimbursement and witness fees. (Propose to rescind)

Each witness shall receive the following fees:

(A) Twelve dollars for each full day's attendance and six dollars for each half day's attendance at hearing or deposition. Each witness shall also receive fifty and one-half cents for each mile necessarily traveled to and from his place of residence to the place of giving testimony.

(B) As used in paragraph (A) of this rule, a "full day's attendance" means a day on which a witness is required or requested to be present at a proceeding before and after twelve o'clock noon regardless of whether the witness actually testifies. A "half day's attendance" means a day on which a witness is required to be present at a proceeding either before or after twelve o'clock noon, but not both, regardless of whether the witness actually testifies.

(C) A respondent may not subpoena him or herself.
4761-11-14 Reports and recommendations. (Propose to rescind)

(A) If the board uses a hearing examiner to hear a case, the hearing examiner shall submit a written report setting forth the proposed findings of fact and conclusions of law and recommendations of the action to be taken by the board within thirty days following the close of an adjudication hearing conducted pursuant to Chapter 119. of the Revised Code. 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 the representatives of record as identified in rule 4761-11-04 of the Administrative Code. 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) The respondent's representative of record may, within ten days of his 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.

(D) Upon written request, the board may grant extensions of the time within which to file objections. In the event that the full board is not in session, the appointed hearing officer may grant such extensions.

(E) 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 order additional testimony to be taken or 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 which, with reasonable diligence could not have been discovered and produced at the hearing shall be made in the manner provided in rules 4761-11-07, 4761-11-08, and 4761-11-10 of the Administrative Code. Such motion to reopen shall be filed not later than ten days prior to the scheduled consideration by the board of the hearing examiner's report and recommendation and any objections thereto. 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 upon the motion.

(G) Without leave of the board, the respondent or any representative of record shall not 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 has been actually notified of the request and given opportunity to respond.
(H) If a request to address the board is granted, the opposing representative may also address the board.
4761-11-15 Exchange of documents and witness lists. (Propose to rescind)

(A) Any representative of record may serve upon the opposing representative of record a written request for a list of both the names and addresses of witnesses and the documents intended to be introduced at hearing. Except in the case of summary suspensions, within seven days of the scheduled hearing the opposing representative shall supply such a list to the requesting representative. In cases of summary suspensions the exchange of lists of both witnesses and documents intended to be introduced at hearing shall be completed forthwith, but in no event less than three days prior to hearing.

(B) Without good cause, failure to comply with paragraph (A) of this rule may result in exclusion from the hearing of such testimony or documents, upon motion of the representative to whom disclosure is refused.
4761-11-16 Depositions and transcripts of prior testimony. (Propose to rescind)

(A) Upon written motion of any representative of record, and upon service of that motion to all other representatives, the appointed hearing officer or the hearing examiner may order that the testimony of a prospective witness be taken by deposition under such conditions and terms as the appointed hearing officer or the hearing examiner shall set and that any designated books, papers, documents or tangible objects, not privileged, be produced at the same time and place 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; and

(3) The testimony of the prospective witness is necessary in order to prevent a failure of justice.

In the case of an expert witness, a showing of the unavailability of the expert shall not be necessary for the appointed hearing officer or hearing examiner's consideration of the motion of a representative to take a deposition.

(B) The representatives shall agree to the time and place for taking the deposition in lieu of live testimony. Depositions shall be conducted in the same county in which the hearing is conducted unless otherwise agreed to by the representatives. If the representatives are unable to agree, the appointed hearing officer or hearing examiner shall set the time or fix the place of deposition. At a deposition taken pursuant to this rule, representatives shall have the right, as at hearing, to fully examine witnesses. A deposition taken under this rule may be offered into evidence at hearing by either representative in lieu of the prospective witness' personal appearance. The cost of preparing a transcript of any testimony taken by deposition in lieu of live testimony which is offered as evidence at the hearing shall be borne by the party that requested the deposition. In the event of appeal, such costs shall be made a part of the cost of the hearing record.

(C) Any deposition or 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 deposition is offered into evidence by a representative, the opposing representative may offer any other part. Nothing in this paragraph shall be construed to permit the taking of depositions for purposes other than those set forth in paragraph (A) of this rule.

(D) A transcript of testimony and exhibits from a prior proceeding may be introduced for any purpose if that prior proceeding forms the basis for the allegations. Upon offering part of a transcript or exhibit from a prior proceeding, the offering representative may be required by the opposing representative to present any other part of the offered item which should in fairness be
(A) All witnesses at any hearing before the board or its 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' rights, and that legal counsel may neither examine nor cross-examine any witnesses.

(C) Should a witness refuse to answer a question ruled proper at a hearing or disobey a subpoena, the Ohio respiratory care board may institute contempt proceedings pursuant to section 119.09 of the Revised Code.

(D) Neither board members nor the board's appointed hearing officer or hearing examiner, shall be a competent witness nor subject to deposition in any adjudication proceeding. Unless the testimony of a board member or hearing examiner is material to the factual allegations set forth in the notice of opportunity for hearing, board members or the hearing examiner shall not be competent witnesses nor subject to deposition in any adjudication proceeding. Evidence from other persons relating to the mental processes of the appointed hearing officer or the board's hearing examiner or board members shall not be admissible.

(E) Any representative of record may move for a separation of witnesses. Expert witnesses shall not be separated.

(F) Each representative of record at a hearing shall inform the board or hearing examiner prior to the commencement of a hearing of the identity of each potential witness for cause present in the hearing room. Failure to so identify potential witnesses at this time may be grounds for their later disqualification as witnesses.

(G) No witnesses shall be permitted to testify as to the nature, extent, or propriety of disciplinary action to be taken by the Ohio respiratory care board. A witness may, in the discretion of the appointed hearing officer or the hearing examiner, testify as to an ultimate issue of fact.
4761-11-18 Expert Testimony. (Propose to rescind)

Any party who intends to utilize expert testimony at hearing must provide a written report by the expert to the opposing party which sets forth the opinions to which the expert will testify and the bases for such opinions. Such report must be served upon the opposing party no later than five days prior to the hearing date, unless waived by both parties. Failure to produce and serve the expert's report within the prescribed time shall result in the exclusion of that expert's testimony and report at hearing.
4761-11-19 Exhibits. (Propose to rescind)

All exhibits will be labeled in advance of the hearing. Each party will provide ten copies of all exhibits to the appointed hearing officer or hearing examiner in advance of the hearing. Failure to provide exhibits in accordance with this rule may result in their exclusion.
4761-12-02 Renewal fees. (Propose to rescind)

(A) The following renewal fees apply:

(1) Respiratory care professional license fee, not to exceed one hundred dollars.

(2) Limited permit renewal:

(a) Limited permits issued in accordance with section 4761.05(B)(1)(a) of the Revised Code, as a currently enrolled student or graduate of an accredited respiratory care educational program, not to exceed ten dollars.

(b) Limited permits issued in accordance with section 4761.05(B)(1)(b) of the Revised Code, as a person employed as a provider of respiratory care in this state and employed as a provider of respiratory care in this state prior to March 14, 1989, not to exceed fifty dollars.

(B) A renewal penalty equal to one half the renewal fee will be assessed if the renewal application is not post marked by the renewal application deadline date provided for in paragraphs (B)(1) and (C)(1) of rule 4761-8-01 of the Administrative Code.
4761-12-03 Replacement of license or certificate. (Propose to rescind)

The respiratory care board may replace an identification card or certificate due to loss, theft, or destruction for the cost to print and mail this material. A certificate may also be reprinted due to name change, provided the original is returned to the board. A replacement fee will be required for an identification card, if issued, or a certificate issued in addition to those issued for initial application or renewal.

(A) A license card – six dollars;

(B) A license certificate – ten dollars.
4761-13-01 Definitions for accessing confidential personal information. (Propose to rescind)

(A) "Access" as a noun means an opportunity to copy, view, or otherwise perceive 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" (CPI) has the meaning as defined by division (A)(1) of section 1347.15 of the Revised Code and identified by rules promulgated by the agency 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 of the board" means each employee of the board regardless of whether he/she holds an elected or appointed office or position within the board. "Employee of the board" is limited to the Ohio respiratory care board.

(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 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 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 common place, 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 the board's employees that is maintained by the board for 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 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.
4761-13-02 Procedures for accessing confidential personal information. (Propose to rescind)

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

(A) 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) 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) If all information relates to an investigation about that individual, inform the individual that the board has no confidential personal information about the individual that is responsive to the individual’s request.

(C) Notice of invalid access.

(1) Upon discovery or notification that confidential personal information of a person has been accessed by an employee for an invalid reason, the board shall notify the person whose information was invalidly accessed as soon as practical and to the extent known at the time. However, the board shall delay notification for a period of time necessary to ensure that the notification would not delay or impede an investigation or jeopardize homeland or national security. Additionally, 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 system.

"Investigation" as used in this paragraph means the investigation of the circumstances and involvement of an employee surrounding the invalid access of the confidential personal information. Once the board determines that notification would not delay or impede an
investigation, the board shall disclose the access to confidential personal information made for an invalid reason to the person.

(2) Notification provided by the board shall inform the person of the type of confidential personal information accessed and 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) Appointment of a data privacy point of contact. The board director 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 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) Completion of a privacy impact assessment. The board director shall designate an employee of the board to serve as the data privacy point of contact who shall timely complete the privacy impact assessment form developed by the office of information technology.
4761-13-03 Valid reasons for accessing confidential personal information. (Propose to rescind)

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 (CPI) regardless of whether the personal information system is a manual system or computer system:

(A) Performing the following functions constitute valid reasons for authorized employees of the board to access confidential personal information:

1. Responding to a public records request;

2. Responding to a request from an individual for the list of CPI the agency maintains on that individual;

3. Administering a constitutional provision or duty;

4. Administering a statutory provision or duty;

5. Administering an administrative rule provision or duty;

6. Complying with any state or federal program requirements;

7. Processing or payment of claims or otherwise administering a program with individual participants or beneficiaries;

8. Auditing purposes;

9. Licensure [or permit, eligibility, filing, etc.] processes;

10. Investigation or law enforcement purposes;

11. Administrative hearings;

12. Litigation, complying with an order of the court, or subpoena;

13. Human resource matters (e.g., hiring, promotion, demotion, discharge, salary/compensation issues, leave requests/issues, time card approvals/issues);

14. Complying with an executive order or policy;

15. Complying with a board policy or a state administrative policy issued by the department of administrative services, the office of budget and management or other similar state agency; or

16. Complying with a collective bargaining agreement provision.
(D) To the extent that the general processes described in paragraph (A) of this rule do not cover the following circumstances, for the purpose of carrying out specific duties of the board, authorized employees would also have valid reasons for accessing CPI in these following circumstances:

(1) Conducting investigations of persons licensed by the board, including the review of information collected on subjects, witnesses, or records associated with the investigation;

(2) Reporting administrative actions and disciplinary records, pursuant to state or federal law;

(3) Monitoring compliance of board administrative actions, including the review of all internal and external reports and data used to facilitate the monitoring process;

(4) Records maintenance processes, including filing, copying, scanning, and monitoring, or

(5) Complying with criminal background check requirements pursuant to section 4761.051 of the Revised Code.
4761-13-04 Confidentiality statutes. (Propose to rescind)

The following federal statutes or regulations or state statutes and administrative rules make personal information maintained by the board confidential and identify the confidential personal information within the scope of rules promulgated by the board in accordance with section 1347.15 of the Revised Code:

(A) Social security numbers: 5 U.S.C. 552 a. as of 02/01/2010, 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) Confidential information obtained during an investigation: 4761.03(E) of the Revised Code.

(D) Medical records: health insurance portability and accountability act, 11 45, CFR 160, 42 USC 1320.

(E) College and university transcripts received by the board: per family educational rights and privacy act regulation 34 CFR Part 99 section 99.33 and 20 U.S.C. 1232 g(b)(4)(B) of 01/05/2009.
4761-13-05 Restricting and logging access to confidential personal information in computerized information systems. (Propose to rescind)

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 modifies an existing computer system that stores, manages or contains confidential personal information, the board shall make a determination whether the modification constitutes an upgrade. Any upgrades to a computer system 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) The board shall require employees of the board who access confidential personal information within computer systems to maintain a log that records that access.

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

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

(3) For purposes of this paragraph, the board may choose the form or forms of logging, whether in electronic or paper formats.

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

(1) Who shall maintain the log;

(2) What information shall be captured in the log;

(3) How the log is to be stored; and

(4) How long the information kept in the log is to be retained.

Nothing in this rule limits the board from requiring logging in any circumstance that it deems necessary.
4761-14-01 Accepting and storing hyperbaric technologist certifications. (Propose to rescind)

Pursuant to division (A)(12) of section 4761.03 of the Revised Code, the board is required to adopt rules prescribing the procedures for accepting and storing copies of hyperbaric technologist certifications filed with the board for purposes of acknowledging persons exempted under division (A)(11) of section 4761.11 of the Revised Code to administer hyperbaric oxygen. Accordingly, the following procedure shall be adopted:

(A) Persons certified as a hyperbaric technologist by the national board of diving and hyperbaric medical technology, or its successor organization shall complete the hyperbaric technologist filing form (form rcb-051, approved 8/20/2014) available on the board's website www.respiratorycare.ohio.gov.

(B) Persons filing the hyperbaric technologist filing form shall provide the following:

(1) Name and residential address.

(2) If employed as a hyperbaric technologist, the name and address of employer.

(3) The expiration date and hyperbaric technologist certification number issued by the national board of diving and hyperbaric medical technology, or its successor organization.

(4) A copy of the certificate of certification issued the national board of diving and hyperbaric medical technology, or its successor organization.

(5) A non-refundable twenty dollar filing fee.

(C) Upon receipt of the hyperbaric technologist filing form, the board shall review the form and enter the filer's information upon its license tracking system.

(D) The hyperbaric technologist filing form shall be scanned and the imaged document shall be stored in the board's electronic filing system. The original form may be scheduled for destruction pursuant to the board's records retention schedule.

(E) The board shall issue a letter to the filer acknowledging receipt and filing of the person's hyperbaric technologist certification.

(F) Persons acknowledged by the board as a certified hyperbaric technologist shall notify the board within sixty days of a change in residential address, employment, or hyperbaric technologist certification status.

(G) Persons certified as a hyperbaric technologist by the national board of diving and hyperbaric medical technology, or its successor organization, must maintain active certification to meet the definition of a certified hyperbaric technologist under division (G) of section 4761.01 of the Revised Code.

For purposes of Chapter 4761. 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 4731-4, 4731-8, 4731-13, 4731-15, 4731-16, 4731-17, 4731-26, and 4731-28 of the Administrative Code are applicable to the holder of a license or limited permit issued pursuant to Chapter 4761. of the Revised Code, as though fully set forth in Chapter 4761 of the Administrative Code.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: NaphCare Proposal Regarding Buprenorphine

DATE: April 4, 2018

NaphCare sent a letter dated January 26, 2018, which was provided to the Policy Committee at the February Board meeting. In that letter, NaphCare provides information as to how NaphCare will adhere to Rule 4731-11-12 in providing buprenorphine to patients in need of opioid withdrawal management in the Hamilton County Jail. The protocol would also be implemented in the jails in Franklin and Montgomery counties soon.

After receiving the January 26, 2018 letter, Dr. Schottenstein and I participated in a conference call with representatives from NaphCare to answer some questions we had. Attached you will find information outlining the questions and answers and some additional forms provided by NaphCare.

On March 27 and April 2, 2018, Brad McLane, Chief of Administration for NaphCare contacted me via e-mail to obtain a response from the Policy Committee to the January 26, 2018 letter. In addition, in the April 2, 2018, Mr. McLane asked for information regarding the administration of buprenorphine as a taper in appropriate circumstances for patient who come to the jail on an MAT program.

I have attached the January 26, 2018 letter, the questions and responses from the February 2, 2018 conference call, the March 27, 2018 and April 2, 2018 e-mails and Rule 4731-11-12. The MAT rule, proposed 4731-33-03 has recently been circulated for comment. This proposed rule would apply to office-based opioid treatment and will exempt jails.
January 26, 2018

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

Dear Ms. Anderson,

Many thanks to you, A.J. Groeber, and to the members of the Medical Board for braving the cold and snow last week to join us for a tour of the Franklin County Jail. I write to follow up on our discussion and outline NaphCare’s interest in increasing the administration of buprenorphine to better care for our opioid-addicted patient population during the dangerous process of withdrawal.

As per our discussion, NaphCare wishes to implement its “COWS-B” withdrawal protocol in our Ohio jails in order to provide better care for our opioid-dependent patients and to reduce the health risks associated with withdrawal. Our goal is to begin with a pilot of our protocol for the State of Ohio in Hamilton County as soon as possible. We then hope to implement the protocol in the Franklin County and Montgomery County jails in the near future. We seek the Board’s guidance in moving forward with this protocol consistent with applicable regulations. While we continue to respectfully disagree that the plain text of the Board’s Office Based Opioid Treatment (“OBOT”) Rule at OAC 4731-11-12 (which applies to “treatment of opioid addiction”) is applicable to management of opioid withdrawal in the jail setting, we believe that we can proceed with implementation of our protocol consistent with the rule as applicable to managing withdrawal in the jail setting. The following provides a step-by-step review of how NaphCare will adhere to OAC 4731-11-12.

1. Consistent with OAC 4731-11-12(B)(1), NaphCare will comply with all applicable federal and state laws applicable to OBOT. NaphCare will utilize physicians and nurse practitioners holding a valid DATA 2000 waiver (“X license”) who will treat no more than 30 patients each at any one time. The State of Ohio Board of Pharmacy has provided NaphCare with guidance to confirm that its OBOT regulations are inapplicable to NaphCare’s use of buprenorphine in the jails under these circumstances.

2. With regard to OAC 4731-11-12(B)(2), all patients who receive a buprenorphine taper as part of this protocol will receive an appropriate healthcare assessment conducted by qualified medical staff under the supervision of a physician who will meet the spirit of this requirement and will be appropriate as applicable to withdrawal management in the jail setting, including hepatitis screening as indicated. While all test results will not be available prior to commencing administration of buprenorphine, The Board’s FAQs for the rule dated February
23, 2015 clarify that a physician need not complete the assessment before administering the initial dose or doses of buprenorphine.

3. Consistent with OAC 4731-11-12(B)(3), NaphCare’s COWS-B protocol is based on SAMHSA’s 2004 “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction.”

4. Consistent with OAC 4731-11-12(B)(4) any patient diagnosed with Opioid Withdrawal based on DSM V criteria will be treated for their withdrawal symptoms using the COWS-B withdrawal protocol.

5. NaphCare views the requirements for an individualized treatment plan as set forth in OAC 4731-11-12(B)(5) and counseling as set forth in OAC 4731-11-12(B)(6) as inapposite to withdrawal management in the jail setting. However, NaphCare will work to connect appropriate patients to in-jail substance abuse treatment resources as well as connect them with community substance abuse treatment providers upon release.

6. NaphCare will utilize buprenorphine (Subutex), which has been approved for withdrawal management consistent with the requirements of OAC 4731-11-12(B)(7).

7. Consistent with OAC 4731-11-12(B)(8), NaphCare healthcare staff will only administer buprenorphine one dose at a time, and will ensure that the drug has completely dissolved to ensure no diversion. Because withdrawal management with buprenorphine will occur for a period of not more than seven days, the other provisions of this subsection are inapposite to the administration of buprenorphine in this setting.

8. Because incarcerated patients cannot obtain controlled substances from any other healthcare provider, the requirements of OAC 4731-11-12(B)(9) are easily met in the jail setting.

9. Consistent with OAC 4731-11-12(B)(10), which disallows administration of more than 16 milligrams of buprenorphine per day, NaphCare’s protocol administers no more than 8 milligrams of buprenorphine per day to nearly all patients and only goes above this, but never exceeding 16 milligrams per day, when a patient’s individual withdrawal symptoms warrant a higher dose.

10. Consistent with OAC 4731-11-12(B)(11) NaphCare will check OARRs on all patients receiving buprenorphine. The provision of this section requiring further review of OARRS information every ninety days is inapposite to the administration of buprenorphine in a jail over a short duration of time. There is no potential for a patient to obtain controlled drugs from another provider in the jail setting.
11. The requirements of OAC 4731-11-12(B)(12) respecting periodic toxicological testing are inapposite to the administration of a low dose of buprenorphine in the jail setting for a short duration of time to manage the risks of withdrawal.

12. NaphCare physicians will meet the requirements of OAC 4731-11-12(B)(13), which provides that each physician who provides OBOT shall “complete at least eight hours of ‘Category I’ continuing medical education related to substance abuse and addiction every two years.” NaphCare’s providers will be fully trained in the administration of buprenorphine to manage withdrawal, will maintain the requisite licensure, and NaphCare will maintain a consulting relationship with one or more addiction medicine specialists to advise NaphCare’s providers.

We appreciate your assistance as we endeavor to implement improved protocols to care for opioid-addicted patients during the dangerous process of withdrawal in Ohio. We respectfully request that you respond on or before February 2 to confirm that NaphCare may proceed with implementation of its COWS-B protocol as set forth above.

Respectfully,

Bradford T. McLane, J.D.
Chief of Operations for Administration

cc: Sheriff Jim Neil, Hamilton County Sheriff’s Office
Questions from Dr. Schottenstein:

Dr. Schottenstein and Kim Anderson participated in a conference call with Brad McLane, Dr. Bonner and Dr. Feely from NaphCare on 2-2-18. The answers to the questions were in red.

1. There is reference in the proposed Buprenorphine protocol to "Subutex protocol initial questionnaire," "Subutex protocol progress note," and "Subutex protocol final questionnaire." I would be glad if I could take a look at those actual forms.

See Attached.

2. There is a reference to the prescribing of additional Buprenorphine at the discretion of the provider if the patient continues to experience detox symptoms after completion of the Buprenorphine protocol. Is that just for days 6 and 7, as is implied in the Buprenorphine dosing table? Or is that indefinite, at the discretion of the provider?

The extension is only for days 6 and 7. This was extremely rare in the pilot program.

3. One of the listed contraindications to protocol inclusion is a positive pregnancy test. Buprenorphine is actually thought to be relatively safe for the mother and the baby. And opioid withdrawal potentially puts the pregnancy at risk. Why is pregnancy considered a contraindication to Buprenorphine protocol? And how do they propose to manage opioid withdrawal in pregnant women? I'm guessing they are currently using clonidine for detox in these cases. But it seems to me that the logic of extending the Buprenorphine protocol option to opioid addicted patients also could apply to those patients who are pregnant.

Pregnant women are excluded because they are not being withdrawn. Pregnant women will be on a maintenance track. If the woman is already participating in a methadone treatment program, methadone will be used. If not, then Subutex will be used.

Similarly, I'm curious as to the exclusion of patients with cirrhosis from the proposed Buprenorphine protocol. How are they treating those patients right now? And is the current treatment arguably substantially safer than Buprenorphine? Clonidine also has a hepatic metabolism, so either way there is potential stress on the liver.

The practice has been updated and patients with cirrhosis are not excluded from the COWS-B protocol. The buprenorphine is very low dose for a short period.

Along these lines, the patients that are withdrawing from benzodiazepines are no longer excluded from the COWS-B protocol, and may receive both protocols simultaneously.

4. In the COWS Buprenorphine protocol results, there are multiple results that are listed: decreased morbidity, decreased suicide risk, decreased mortality risk, decreased officer time, and no ER visits. Do they have actual data to show the difference in outcome between the patients on the Buprenorphine protocol, and the patients on the clonidine protocol? Are these theoretical benefits, or have they actually seen results to substantiate these claims?

Naphcare is just now gathering findings, and will be presenting them at the National Commission on Correctional Health Care conference this spring in Minnesota."
So for instance, where they state that there is a decreased suicide risk, have the actual number of documented suicide attempts decreased? Were there withdrawal related deaths prior to implementation of the Buprenorphine protocol? How often did patients have to go to the ER for dehydration prior to the implementation of the protocol? I'm just wondering if they have actual numbers regarding these claims, and if they do, I would be curious to see them.

Naphcare is just now gathering findings, and will be presenting them at the National Commission on Correctional Health Care conference this spring in Minnesota. These are expectations, not evidence based outcomes at this time. Per Dr. Feely, ER visits related to detox symptoms at the pilot sites are down 50%.

Detox symptoms are down significantly after the first administration of buprenorphine.

How often is the data-waived prescriber seeing the patient?

Data-waived prescriber is rounding daily with the patient.
Subutex Protocol

Initial Patient Questionnaire

Name: _____________________      Sex: ______
Race: _____________________      Age: ______

1. Opiate(s) used: _________________________________________________________________
   a. Frequency: ______________________________      b. Dose/Amount: _________________
   c. Length of time taking opiates regularly: ________________________________________

2. Additional substances used (drugs/alcohol) in the last 30 days:

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Amount and Frequency of Use</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

3. Withdrawal history:
   a. Any history of previous withdrawals: Yes No
   b. Name of substance that caused most recent withdrawal: ________________________________
   c. When was last occurrence of withdrawal: ___________________________________________
   d. Duration of those withdrawal symptoms: ___________________________________________
   e. Where were previous withdrawal symptoms treated (home, hospital, jail, etc.):
      ____________________________________________________________________________
   f. Were any medications used to treat withdrawal symptoms: Yes No
      If Yes, name any medications you recall taking for this: ________________________________
      ____________________________________________________________________________
   g. Typical number of days from last use to onset of withdrawal symptoms (in days): ______

4. Was drug use related to your current incarceration? Yes No

5. What is the number of incarcerations you have had that were drug or alcohol related: ______

6. Are you currently enrolled in a Methadone/Suboxone/Subutex/Vivitrol program in the community:
   Yes  No
   If Yes:
      a. How long have you been enrolled: ______________
      b. What is the name/where is the program: ______________
      c. When did you last go to the program: ______________
Buprenorphine Detox Protocol

Progress Note

What day number is the patient on in Subutex Protocol?

Are there any reported side effects to the Subutex?

Are there any current withdrawal symptoms being reported at this time (GI, nausea, sweating, etc.)?

Have any PRNs been used since the last assessment was performed?

Yes ☐ No ☐

Describe the patient's oral intake of food and fluids:

Document patient status/exam:

Document current vitals:

<table>
<thead>
<tr>
<th>Type</th>
<th>Last Update</th>
<th>Date/Time</th>
<th>Blood Pressure Systolic</th>
<th>Blood Pressure Diastolic</th>
<th>Temperature</th>
<th>Pulse</th>
<th>Respiration</th>
<th>Height in Feet</th>
<th>Height in Inches</th>
<th>Weight in Pounds</th>
<th>Weight in Quarters</th>
</tr>
</thead>
</table>
Subutex Protocol

Final Patient Questionnaire

Name: _____________________      Sex: ______
Race: _____________________      Age: ______

1. In general do you consider your recent withdrawal treatment to be:
   a. Better than past withdrawal treatment
   b. No different than past withdrawal treatment
   c. Worse than past withdrawal treatment

2. Rate the severity of withdrawal symptoms (0-10 scale, with 10 being worst):
   a. Past Opiate withdrawal events: _______
   b. Current Opiate withdrawal event: _______

3. Please report the duration (in number of days) of opiate withdrawal symptoms:
   a. Past Opiate withdrawal events: ______
   b. Current Opiate withdrawal event: ______

4. For this withdrawal event:
   a. What was the worst symptom you had: ______________
   b. What day into withdrawal did this occur on: ______________

5. Were the medications you received for withdrawal side effects such as stomach upset, diarrhea, etc. adequate to control the symptoms?  Yes   No
   a. If No – what symptom was not well controlled? _________________________________

6. Have you ever attempted to stop using opiates before:   Yes   No
   If Yes:
   a. Length of time before use re-started: ______
   b. Check the method(s) use (check all that apply):
      i. Methadone   _____
      ii. Suboxone   _____
      iii. Subutex   _____
      iv. Vivitrol   _____
      v. No medication   _____
   c. If you took one of the above listed medications before, how long did you take the medication: ______

7. How likely are you to start using opiates again when released from jail (0-10 scale with 10 being very likely): ______

8. Would you request the withdrawal treatment plan you just finished again if you came into the jail and needed opiate withdrawal treatment: Yes   No
   a. If Yes, Why: ______________________________________________________________
   b. If No, Why: ______________________________________________________________
From: Bradford McLane
To: Anderson, Kimberly
Cc: Groeber, AJ; Emily Feely; Steven Bonner; Shawn Ryan; RWinder@beneschlaw.com
Subject: RE: NaphCare Letter -- January 26, 2018
Date: Monday, April 2, 2018 10:08:01 AM
Attachments: image001.png

Dear Ms. Anderson,

Thank you for presenting this issue to the Policy Committee. In addition to our interest in starting our new protocol that provides for administration of buprenorphine as a taper in appropriate circumstances, we want to have the flexibility to maintain patients on buprenorphine who come into the jail on a MAT program. From our standpoint, this course of treatment is clinically appropriate and achieves greater consistency with the OBOT regulations as it continues a course of addiction treatment started in the free world setting. This issue has recently come up at Franklin County and we would like to be able to assure our providers that they can maintain patients on buprenorphine consistent with currently applicable Medical Board regulations.

Would it be possible for NaphCare to have one or more representatives present at the Policy Committee meeting to make our case?

Securing the regulatory clarity that we need to improve care of our patients in Ohio with opioid use disorder is my single highest priority.

Thank you for your help and for your attention to this important matter.

Brad

From: Kimberly.Anderson@med.ohio.gov [mailto:Kimberly.Anderson@med.ohio.gov]
Sent: Friday, March 30, 2018 4:17 PM
To: Bradford McLane
Cc: AJ.Groeber@med.ohio.gov
Subject: RE: NaphCare Letter -- January 26, 2018

Thank you. I will put this on the agenda for the April 11, 2018 Policy Committee meeting.

Confidentiality Notice: This message is intended for use only by the individual or entity to whom or which it is addressed and may contain information that is privileged, confidential and/or otherwise exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify me immediately by telephone.

Kimberly C. Anderson, Esq.
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
(614) 466-7207 (office)
(614) 230-9077 (cell)
Dear Ms. Anderson,

I write to follow up to my letter of January 26, 2018 as well as our correspondence and meetings dating back to October of last year.

In the January 26 letter, building on prior correspondence, I provided an outline of NaphCare’s intent to proceed with use of a buprenorphine taper to assist patients in the Hamilton County jail through opioid withdrawal, including detailed information on how we plan to proceed in keeping with the requirements of OAC 4731-11-12(B). I followed up to that letter on February 15, and you responded by voice mail that you discussed our letter with the policy committee but did not have a definitive answer at that time.

While we appreciate the Board proposing to exempt correctional facilities from these OBOT requirements, we do not want to wait for the new rules to go into effect in order to begin following our protocol in Ohio. I respectfully request a response to my January 26 letter as soon as possible.

Thank you for your consideration of this request.

Respectfully,

Brad

Bradford T. McLane
Chief of Administration
Direct Dial: (205) 536-8532
Fax: (205) 536-8404
4731-11-12 Office based opioid treatment.

(A) For the purposes of this rule:

(1) "Office Based Opioid Treatment," or "OBOT," means treatment of opioid addiction utilizing a "Schedule III, IV, or V" controlled substance narcotic.

(2) "Board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

(a) Subspecialty board certification in addiction psychiatry from the American board of psychiatry and neurology;

(b) Board certification in addiction medicine from the American board of addiction medicine;

(c) Certification from the American society of addiction medicine; or

(d) Board certification with additional qualification in addiction medicine from the American osteopathic association.

(B) A physician shall provide OBOT in compliance with all of the provisions of this rule.

(1) The physician shall comply with all federal and state laws applicable to OBOT;

(2) Prior to providing OBOT, the physician shall conduct an assessment meeting the following requirements:

(a) The assessment shall include, at a minimum, an appropriate history and physical, mental status exam, substance use history, appropriate lab tests, pregnancy test for women of childbearing years, toxicology tests for drugs and alcohol, and "hepatitis B" and "hepatitis C" screens.

(b) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, hepatitis "B" and "C" screens and the pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination of the patient that was conducted by a physician within a reasonable period of time prior to the visit. For purposes of this paragraph, "physician" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code, or an individual practicing in another state where the individual holds an active and unrestricted license to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice.

(3) The physician shall practice in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance and tapering. Acceptable protocols are any of the following:
(a) "Clinical Guidelines For the Use of Buprenorphine in the Treatment of Opioid Addiction" protocol approved by the substance abuse and mental health services administration in 2004, (available from the substance abuse and mental health services administration website at [http://samhsa.gov/](http://samhsa.gov/));

(b) The low dose protocol approved by the Ohio department of alcohol and drug addiction services in or about 2011 (available from the Ohio department of mental health and addiction services website at [http://mha.ohio.gov/](http://mha.ohio.gov/)); or

(c) Any protocol for OBOT approved by the Ohio department of mental health and addiction services and available from the Ohio department of mental health and addiction services website at [http://mha.ohio.gov](http://mha.ohio.gov).

(4) The physician shall diagnose an opioid disorder utilizing the criteria contained in the diagnostic and statistical manual of mental disorders, 4th or 5th edition.

(5) The physician shall develop an individualized treatment plan for each patient.

(6) The physician shall require each patient to actively participate in appropriate behavioral counseling or treatment for their addiction and shall document at each visit that the patient is attending sufficient behavioral health treatment.

(a) The physician shall maintain meaningful interactions with the qualified chemical dependency professional, addiction treatment provider, or other behavioral health professional who is treating the patient.

(b) If the physician is a psychiatrist, board certified addictionologist, or board certified addiction psychiatrist, the physician may personally provide behavioral health treatment for the addiction.

(c) If the physician determines that the patient cannot reasonably be required to obtain professional treatment or if the patient has successfully completed professional treatment, the physician shall require the patient to actively participate in a recovery care program such as alcoholics anonymous, narcotics anonymous, or other appropriate twelve step program, and to document attendance at program meetings.

(i) For at least the first year the physician shall require the patient to attend the meetings at least three times weekly.

(ii) Following the first year, the physician shall determine the frequency with which the patient shall be required to attend the meetings.

(iii) The physician shall document in the patient record the reasons that the patient cannot reasonably be required to obtain professional treatment.

(7) The physician shall provide OBOT utilizing a drug product that has been specifically approved by the United States food and drug administration for use in maintenance and detoxification treatment. A physician shall not provide OBOT utilizing a drug product that has not been specifically approved by the United States food and drug administration for use in maintenance and detoxification treatment.

(8) The physician shall comply with all of the following:

(a) During the first twelve months of treatment, the physician shall not prescribe, personally furnish, or administer more than a thirty day supply of OBOT medications at one time.

(b) The physician shall personally meet with and evaluate the patient at each visit during the first twelve months of OBOT, and shall document an assessment and plan for continuing treatment.

(c) After twelve months of OBOT, the physician shall personally meet with and evaluate the patient at least every three months, unless more frequent meetings are indicated.
(9) The physician shall not provide OBOT to a patient whom the physician knows or should know is receiving
other controlled substances for more than twelve consecutive weeks on an outpatient basis from any provider,
without having consulted with a board certified addictionologist or addiction psychiatrist, who has
recommended the patient receive OBOT. If the physician is a board certified addictionologist or addiction
psychiatrist, the consultation is not required.

(10) The physician shall not prescribe, personally furnish, or administer greater than 16 milligrams of
buprenorphine per day to a patient, except in one of the following situations:

(a) The dosage greater than 16 milligrams was established before the effective date of this rule;

(b) The physician is a board certified addictionologist or addiction psychiatrist and has determined that a dosage
greater than 16 milligrams is required for the patient, and has documented patientspecific reasons for the need
for a dosage greater than 16 milligrams in the patient's record;

(c) The physician has consulted with a board certified addictionologist or addiction psychiatrist who has
recommended a dosage greater than 16 milligrams and that fact is documented in the patient's medical record.

(11) The physician shall access OARRS for each patient no less frequently than every ninety days, and shall
document receipt and assessment of the information received.

(12) The physician shall provide ongoing toxicological testing in compliance with all of the following:

(a) The physician shall assure that any inoffice kit used is "Clinical Laboratory Improvement Amendments"
waived.

(b) The physician shall require toxicological testing be performed at least monthly for the first six months, then
randomly at least once every three months thereafter.

(c) The physician may accept the results of toxicological testing performed by a treatment program or pursuant
to a court order to satisfy the requirements of paragraph (B)(12)(b) of this rule.

(d) A screen is failed if the result is inconsistent with the treatment plan. A physician shall address failed screens
in a clinically appropriate manner.

(13) Each physician who provides OBOT shall complete at least eight hours of "Category I" continuing medical
education relating to substance abuse and addiction every two years. Courses completed in compliance with this
rule shall be accepted toward meeting the physician's "Category I" continuing medical education requirement for
biennial renewal of the physician's certificate.

(C) Notwithstanding the provisions of this rule, a physician may provide OBOT to a pregnant patient during the
term of her pregnancy and for two months thereafter, in compliance with the minimal standards of care.

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

(1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," and "failure to
employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as
those clauses are used in division (B)(2) of section 4731.22 of the Revised Code, and " a departure from, or the
failure to conform to, minimal standards of care of similar physicians under the same or similar circumstances,
whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section
4731.22 of the Revised Code.

(2) A violation of paragraph (B)(7) of this rule shall further constitute "selling, prescribing, giving away, or
administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division
(B)(3) of section 4731.22 of the Revised Code.
Effective: 1/31/2015
Five Year Review (FYR) Dates: 01/31/2020
Promulgated Under: 119.03.
Statutory Authority: 4731.05
Rule Amplies: 4731.22
MEMORANDUM

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

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

DATE: April 6, 2018

RE: Proposed Ohio Administrative Code Rule 4731-34-01 Standards and Procedures to be followed by physicians when prescribing a dangerous drug that may be administered by a pharmacist by injection.

Ohio Revised Code sections 4729.45 and 4731.057 were enacted in April 2017 as part of the enactment of Senate Bill 332. R.C. 4729.45 allows a pharmacist to administer injections, under certain conditions, of the following drugs: an opioid antagonist administered in a long-acting or extended release form; an antipsychotic drug administered in a long-acting or extended release form; Hydroxyprogesterone Caproate; Medroxyprogesterone Acetate; and Cobalamin. The conditions include that the drugs must be prescribed by a physician with whom the patient has an ongoing physician-patient relationship. Also, the pharmacist must complete training on the administration of these drugs and basic life support. Lastly, the pharmacist must practice in accordance with a physician-established protocol for the administration of these drugs by injection by a pharmacist. The requirements of this protocol are codified in R.C. 4729.45, rules promulgated by the Pharmacy Board pursuant to the statute (OAC 4729-5-40), and the proposed rule that follows.

R.C. 4731.057 states that “[t]he state medical board shall adopt rules establishing standards and procedures to be followed by a physician when prescribing a drug that may be administered by a pharmacist pursuant to section 4729.45 of the Revised Code.” The statute also requires the board to do so in consultation with the Pharmacy Board. The proposed rule is drafted pursuant to this statutory mandate. A summary of the rule follows.

Paragraph C of the proposed rule lays out the requirements that a physician must follow when prescribing these drugs. Of note is the requirement that the physician must specify the pharmacy where the prescription is to be administered. The physician must prescribe to a pharmacy where either the physician has written the protocol or personally reviewed the protocol on file. Further, the physician must obtain the consent of the patient.
In addition, paragraph D allows the physician to terminate the prescription under certain circumstances. Paragraph E lists the requirements for the physician-established protocol and in so doing ties in with the aforementioned statute and Pharmacy Board rule.

Also, paragraph F allows for biennial review and possible renewal by the physician that wrote the physician-established protocol. Lastly, paragraph G provides the disciplinary mechanism for a violation of this rule.

REQUESTED ACTION:

Approve that proposed rule 4731-34-01 be sent to interested parties for comment in initial circulation as well as to the Pharmacy Board for consultation.
4731-34-01 Standards and Procedures to be followed by physicians when prescribing a dangerous drug that may be administered by a pharmacist by injection

(A) As used in this rule,
(1) “Physician” means an individual authorized under Chapter 4731 of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.
(2) Pharmacist means an individual licensed under chapter 4729 of the Revised Code who has met the requirements in section 4729.45 of the Revised Code and rule 4729-5-40 of the Administrative Code to administer drugs by injection.

(B) Subject to paragraph (C) of this rule, a physician may prescribe any of the following dangerous drugs to be administered by injection by a pharmacist to a patient with whom the physician has an ongoing physician-patient relationship:
(1) An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form. An opioid antagonist may also be administered for the treatment of alcohol dependence in accordance with approved labeling by the United States Food and Drug Administration.
(2) An antipsychotic drug administered in a long-acting or extended-release form.
(3) Hydroxyprogesterone caproate for pregnant women.
(4) Medroxyprogesterone acetate for non-pregnant women.
(5) Cobalamin.

(C) If a physician chooses to prescribe the dangerous drugs in paragraph (B) of this rule to be administered by injection by a pharmacist, the physician shall comply with all the following:
(1) Maintain an ongoing physician-patient relationship with the patient to whom the drug is being prescribed.
(2) The physician’s scope of practice must include treatment of the condition for which the patient has been prescribed the drug.
(3) The physician’s prescription must specify the pharmacy where the drug is to be administered.
(4) The physician may only prescribe a drug to be administered at a pharmacy where the physician has either:
   (a) Written and established a current protocol on file at that pharmacy that meets the requirements in paragraph (E) of this rule and that is appropriate for the patient; or
   (b) Obtained and personally reviewed a current physician established protocol on file at that pharmacy that meets the requirements in paragraph (E) of this rule, and agrees that this protocol is appropriate for the patient.
(5) The physician shall inform the patient that the drug that the physician is prescribing will be administered at a pharmacy that meets the requirements in paragraph (C)(4) of this rule, and obtain patient’s consent to have the drug administered at that pharmacy. The patient’s consent shall be documented in the medical record. The physician may not prescribe in the manner described in this rule without the patient’s consent to both the manner and location of the administration of the prescription.
(6) If a physician chooses to prescribe an opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form to be administered by injection by a pharmacist, the physician shall also comply with all other applicable rules in Chapter 4731. of the Administrative Code for prescribing this type of drug.

(D) A physician may terminate a prescription, which may include refills, with a pharmacy under this section at any time for any of the following reasons:
(1) The patient or pharmacy is not following the physician established protocol with the pharmacy;
(2) Failure of the pharmacy to timely notify the physician within seven days of administration of the injection;
(3) Failure of the pharmacy to report an adverse event to the physician that occurred during the administration of the injection;
(4) In the case of an opioid antagonist, test results of the patient indicate that it is not appropriate to administer the drug;
(5) Discontinuation of the patient-physician relationship; or
(6) Any other medically appropriate reason.

(E) A physician-established protocol for the administration of the dangerous drugs by injection by a pharmacist must comply with the following:
(1) All requirements listed in section 4729.45 of the Revised Code and paragraph (F) of rule 4729-5-40 of the Administrative Code.
(2) The protocol shall be signed and dated by the physician prior to implementation and shall be readily available to the administering pharmacist.
(3) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.
(4) The protocol must be established by a physician who has a scope of practice that includes treatment of the conditions for which drugs administered under the protocol are intended to treat.

(F) The physician-established protocol shall be reviewed and may be renewed by the physician on a biennial basis.

(G) A violation of this rule, as determined by the Board, shall constitute for a physician "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.