Maine Board of Osteopathic Licensure

(affiliated with the Department of Professional & Financial Regulation)

Agency Evaluation Report

Required by the Government Evaluation Act
(pursuant to 3 MRS Chapter 35, §959 Section 1.C.)

Submitted to the

Joint Standing Committee on Health Coverage, Insurance & Financial Services

November 1, 2019

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Enabling or Authorizing Law(s)

The Board of Osteopathic Licensure is authorized through the following section of Maine law:

10 MRS § 8001 (7) establishes the Board of Osteopathic Licensure as a board affiliated with the Department of Professional & Financial Regulation;

32 MRS § 2561 – 2600-C – Osteopathic Physicians;

32 MRS Chapter 1A – General Provisions Concerning Licenses

Section 59 – Temporary Licenses

Section 60-A – Consumer Complaints of Board Procedure;

10 MRS § 8003-A – Complaint Investigations;

10 MRS Chapter 901, Part 9 – Commerce and Trade;

24 MRS § 2502 – 2511 – Maine Health Security Act;

5 MRS Chapter 379 § 12004-A (29) Occupations & Professional Licensing Boards

42 USC Chapter 7.11320A – Uniform Reporting Systems for Health Services Facilities and Organizations

42 USC Chapter 117.11132 – Reporting of Sanctions Taken by Boards of Medical Examiners

45 CFR Part 60.1 – National Practitioners Data Bank

45 CFR Part 61.1 – Healthcare Integrity and Protection Data Bank

Description of Program

The Board of Osteopathic Licensure (affiliated with the Department of Professional & Financial Regulation) was created by the Legislature in 1919 and consisted of five physicians, each appointed by the Governor to serve a 5-year term.

Now, in 2019, the Board is comprised of ten members. Six must be graduates of a legally chartered college of osteopathic medicine and must also have been actively engaged in the practice of osteopathic medicine in Maine for a minimum of 5 years. Three must be members representing the interests of the public, and in 2017, a physician assistant (PA-C) member was appointed. All members are appointed by the Governor.

From the membership, a Board Chair, Vice-Chair and Secretary are elected for a minimum of 2 years.

The Board holds at least 11 meetings each year with additional days, if necessary, for hearings.

Board agendas include the review of complaints, reports from mandated reporters and other investigative matters, review of completed applications, rulemaking matters, financial reviews, general correspondence and information from those agencies with which the Board works closely.

Board staff includes its Executive Secretary and a portion of the Consumer Assistant position (as allowed by statute).

The Board's web address is: www.maine.gov/osteo. Licensing is done via the ALMS (Agency License Management System) and updates are in real time.

Board Priorities

Public Protection

The Board has met and will continue to strive to meet this priority by licensing and renewing the licenses of only those who have the necessary education and post-graduate training, experience and credentials and by regulating its licensees through disciplinary and non-disciplinary processes as allowed by statute.

Initial Licensure and License Renewal

The Board has established standards/requirements for each category of licensure to ensure that the public is served by only skilled professionals[1]. Among other process requirements, the Board verifies credentials, obtains references and queries databanks (Federation of State Medical Boards (FSMB) and National Practitioner Data Bank (NPDB)) prior to licensure or license renewal.

For renewal, licensees must certify that they have obtained 100 hours of Continuing Medical Education ('CME') every two (2) years when they renew by the end of their birth month (hours due is prorated for new licensees). Random CME audits are performed periodically. If a licensee has indicated they have not met their statutory requirement, an administrative agreement will generally be entered into to ensure that the requirement is met; hours obtained to meet the requirement cannot be used toward the next renewal period.

A physician who has not practiced since his or her last renewal period either for disciplinary or other reasons, will be required to demonstrate clinical competence. In this instance, there are two exams the Board considers requiring the physician to take one of two exams:

[1] Osteopathic physicians and physician assistants licensed by this Board.

- *COMVEX* – An exam through the National Board of Osteopathic Medical Examiners for physicians so that they may demonstrate current osteopathic medical knowledge and competency to practice;

- *SPEX* – The Special Purposes Examination is intended specifically to re-examine the general medical knowledge of physicians currently licensed or wishing to be reinstated following a period of no practice. This exam is administered through the Federation of State Medical Boards.

Regulation

The Board is responsible for regulating the practice of those to whom it has issued licenses. Methods of regulation are:

Disciplinary Action

Enforcement of minimum standards of conduct, competency and ethics is expected of all licensees to ensure that the public is served by skilled and responsible professionals. The Board adheres to statutory guidelines for the filing and processing of all complaints. Complaint forms and instructions as well as HIPAA compliant authorization forms are available to via the Board's website (www.maine.gov/osteo), or by contacting the Boards' Consumer Assistant or its Executive Secretary. Complaints can be submitted online (web address noted above) or on paper. The Consumer Assistant has software in place for taking a verbal complaint from a caller who is without sight.

Discipline may be imposed through various means such as adjudicatory hearings, consent agreements, and referral of matters to other agencies. Potential disciplinary actions include but may not be limited to warnings, censures, reprimands, license suspension, revocation, voluntary surrender, probation, additional specific CME and recovery of costs. Information regarding disciplinary actions in the past 5 years can be found at **Tab 1**.

Non-Disciplinary Action

Letters of Guidance are often issued to licensees to help them avoid similar complaints in the future. These are issued when a situation does not rise to a level of misconduct sufficient to merit disciplinary action. Many such letters have been issued and while they are not published on the Board's website, they are not confidential and anyone inquiring about whether a specific physician has received a letter of guidance is offered a copy, if one has been issued.

Board Rules & Regulatory Agenda

The Board has established the following rules:

Chapter 2 – Physician Assistants (*joint with the Board of Licensure in Medicine*)

Chapter 6 – Telemedicine Standards of Practice (*joint with the Board of Licensure in Medicine*)

Chapter 10 – Sexual Misconduct (*joint with the Board of Licensure in Medicine*)

Chapter 14 – Continuing Medical Education

Chapter 16 - Prescribing and Treatment for Self and Family Members

Chapter 17 - Physician / Physician Assistant - Patient Boundaries – Gifts

Chapter 19 - Physician Schedule for License Renewal

Chapter 21 - Use of Controlled Substances for Treatment of Pain (*joint with the Board of Nursing, the Board of Licensure in Medicine and the Board of Licensure of Podiatric Medicine*)

A copy of each can be found under **Tab 2**.

Board Goals

1. To ensure that the board is protecting the health and safety of both the public and its licensees to the best of its ability, the Board has the following goals:
2. Ensure that all licensees have been appropriately trained and qualified to practice osteopathic medicine and with a clear understanding of the Board, its governing statute and rules in order to promote their best possible practice;
3. Ensure public accessibility to Board information;
4. Promote the Board, it's mission and responsibilities;
5. Respond to issues specific to osteopathic medicine that may affect the public;
6. Establish current standards of medical conduct and practice;
7. Continue to update its website and move to having all applications submitted online.

To assure that the above goals are met, the Board has and will continue to:

1. Require applicants to successfully pass a jurisprudence exam (which will continue to be updated, as needed) to assure the Board that they have read and understood their governing statute and applicable rules;

2. Improve public access to Board information by continuing to update its website with license and Board action information:

3. Continue to accept online complaints, updating forms as needed;

4. Continue to accept online initial license and license renewal applications;

5. Continue to hold Board meetings periodically at the University of New England, College of Osteopathic Medicine with the hope that students will gain some understanding of the Board process;

6. Continue to promulgate rules and adopt policies that will effectively regulate the practice of osteopathic medicine. The Board also reviews current rules and will continue to revise as necessary, having just recently worked on revisions to rules joint with the Boards of Nursing and Licensure in Medicine;

7. Continue to present, when invited, at Maine Osteopathic Association Conferences to help attendees better understand what happens at a Board meeting, including but not limited to the license and license renewal process and complaint reviews;

8. Continue to work with the American Osteopathic Association and the Maine Osteopathic Association and other relevant organizations to evaluate and provide appropriate continuing medical education and explore more programs for remedial education for those physicians who may need to be or have been disciplined;

9. The Board, through the Consumer Assistant distributes the Consumer's Guide to the Licensing, Regulation and Discipline of Physicians in Maine. This pamphlet is provided to both licensees and those requesting complaint paperwork. A pamphlet is also provided to the parties when the Board has voted to hold an Informal Conference or an Adjudicatory Hearing;

10. Continue its contact with osteopathic medical schools to address the osteopathic physician's ethical and professional responsibilities. The Board will continue to thoroughly review and investigate complaints to determine if there may be competency issues or if professional standards have been violated and disciplinary action may be necessary;

11. Continue to work with the Maine Medical Professionals Health Program which assists licensees with substance use issues.

Organizational Chart

Please see the Chart under **Tab 3**.

Compliance

The Board must follow procedures set by the State of Maine in reporting health and safety concerns and workplace injuries. The Board complies with the Americans with Disabilities Act. It's office and meeting spaces are state approved for ADA compliance.

The Board must also make certain that it's policies and procedures do not impact unfavorably on any person by restricting or categorizing applicants or potential employees. The Board is committed to providing satisfactory accommodations to qualified applicants and employees with disabilities in compliance with state and federal laws.

To that end, the Board recently updated its initial and license renewal applications to ensure that questions asked are in compliance with state and federal laws.

The Board must follow affirmative action requirements when hiring employees. Staff participates in the Workers Compensation Plan, offered to all State of Maine employees.

Board staff is familiar and compliant with the State's policy regarding the use of State owned or leased equipment.

Board staff is familiar and compliant with the Department of Professional & Financial Regulation policies.

Financial Summary

The Board functions solely on dedicated revenue.

The financial summary can be found at **Tab 4**.

Coordination with State, Federal and Other Agencies

The Office of the Attorney General

The AG's office provides legal counsel and investigative services to the Board through an agreement.

The Office of Substance Use

Board staff works with this office when there are questions or concerns regarding the Prescription Monitoring Program.

Maine Board of Pharmacy

The Board receives referrals from the Pharmacy Board and provides information to the Pharmacy Board if needed and as allowed by law.

The Federation of State Medical Boards (hereafter 'FSMB')

The Board and its staff work closely with the FSMB on a variety of issues including online applications, the FSMB Data Bank, the FSMB's FCVS (Federation Credentials Verification Service), Board Action alerts. At least one member of the Boar generally attends the FSMB's Annual Meeting (fully funded by the FSMB). A representative from the FSMB visits one monthly meeting every two years to observe and update the Board on new initiatives and provides other information of interest to licensing Boards.

The National Practitioner Databank (hereafter 'NPDB')

Each applicant for permanent licensure is required to do a self-query with the NPDB. The Board provides disciplinary updates as required and is compliant with the requirements set forth by the NPDB – see **Tab 5**.

Department of Human Services

The Board receives information from this Department regarding licensees who have defaulted on child support.

Department of Administrative & Financial Services

Board staff coordinates with and is assisted by the Department of Administrative & Financial Services regarding accounting procedures with additional assistance from staff members in the Office of the Budget and the Department's assigned Security & Employment Service Center.

Board of Licensure in Medicine

The Board shares a percentage of the Consumer Assistant position with the Board of Licensure in Medicine via agreement, pursuant to statute.

Constituents

Public: Because the Board is responsible for the regulation of those who practice osteopathic medicine in Maine, staff interacts with the public on a daily basis via phone, visits to the office, e-mail, fax, etc.

Licensees: The Board's Executive Secretary interacts daily with licensees and prospective applicants on a variety of levels via a variety of the above methods.

Alternative Delivery Systems

In coordination with the Office of Information Technology and inforME, online initial licensing, online license renewal services, downloadable forms, online licensee searches and other processes are available via the ALMS (Agency License Management System).

Comparison of State and Federal Laws

Confidentiality of Health Care Laws – Title 22 – MRS 1711-C

Privacy of Individual Identifiable Health Information – 4 CFR Part 164

Collection, Management and Disclosure of Personal Information

The Board collects personal information in a variety of ways. Personal information includes but is not limited to address, telephone number, financial and medical information. Social Security numbers and the above personal information are collected on license applications and during the review of complaints and investigations.

Board staff is well-versed regarding the proper use of Social Security numbers and personal information and has a procedure in place to ensure that the public is not erroneously provided access to such information. The Board also has a responsibility to ensure that Freedom of Access Act (FOAA) requests are made and responded to in accordance with Maine law.

Awareness of the confidentiality of the above information is of the utmost importance. State law provides that information in possession of the State of Maine is generally available to the public unless deemed confidential by statute.

List of Reports, Applications and Other Paperwork

A full list of the Board's reports and applications can be found at **Tab 6**.

The Board is currently working on updates to its governing statute with the hope of accomplishing many changes through this process.

The Board welcomes any questions the Committee may have. Board staff can be reached via e-mail at osteo.pfr@maine.gov or phone at 287-2480.

Complaints & Investigations Received

Calendar Year	Received	Dismissed	Board Action	Carried Over
2014	60	54	4	2
2015	54	49	4	5
2016	52	53	1	0
2017	52	48	4	7
2018	42	41	1	8

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

383 BOARD OF OSTEOPATHIC LICENSURE
a joint rule with
373 BOARD OF LICENSURE IN MEDICINE

Chapter 2: JOINT RULE REGARDING PHYSICIAN ASSISTANTS

SUMMARY: Chapter 2 is a joint rule pertaining to the licensure, registration, scope of practice, supervision, notification, and continuing education requirements for physician assistants who are supervised by either an allopathic or osteopathic physician. Chapter 2 also establishes a Physician Assistant Advisory Committee.

SECTION 1. DEFINITIONS

1. "Active-Nonclinical" means the physician assistant cannot render medical services or prescribe medication to any person in Maine.

2. "Active Unrestricted License" means the physician possesses an active Maine license to practice medicine that does not include any restrictions or limitations on the scope of practice or ability to supervise physician assistants.

3. "Administratively Complete Application" is a uniform application for licensure, or certificate of registration as developed by the Boards, which when submitted to one of the Boards has: a) all questions on the application completely answered; b) signature and date affixed; c) all required notarizations included; d) all required supplemental materials provided in correct form; e) all requests for additional information submitted; and f) all fees, charges, costs or fines paid.

4. "AMA" means the American Medical Association.

5. "AOA" means the American Osteopathic Association.

6. "Board" means the Board of Licensure in Medicine or the Board of Osteopathic Licensure.

7. "BOL" means the Board of Osteopathic Licensure as defined in 32 M.R.S. §2561.

8. "BOLIM" means the Board of Licensure in Medicine as defined in 32 M.R.S. §3263.

9. "Certificate of Registration" means a document issued by the Board to a licensed physician assistant that authorizes the physician assistant to render medical services under the supervision of a licensed physician pursuant to a written plan of supervision that meets the requirements of this rule.

10. "Covering Supervising Physician" (CSP) means a physician who has an active, unrestricted license in good standing issued by either the Board of Licensure in Medicine or the Board of Osteopathic Licensure, and who has agreed in writing to provide

supervision of the physician assistant when the primary supervising physician is not available, and when actively engaged as a supervisor, to be legally liable and responsible for all delegated medical services rendered by the physician assistant pursuant to a written plan of supervision that meets the requirements of this rule. A covering supervising physician must hold an active, unrestricted permanent, temporary, or emergency license unless the Board has waived the requirement that the CSP license be unrestricted. A covering supervising physician shall accept supervisory responsibility for periods of time not to exceed the time period specified in the written plan of supervision, which time period may not exceed forty-five (45) consecutive calendar days.

11. "License" means a document issued by the Board to a physician assistant that identifies the physician assistant as qualified by training and education to render medical services under the supervision of a licensed physician pursuant to a written plan of supervision that meets the requirements of this rule.

12. "NCCPA" means the National Commission on Certification of Physician Assistants.

13. "Physician" means an individual with an active, unrestricted license in good standing to practice medicine in Maine issued by the Board of Licensure in Medicine or the Board of Osteopathic Licensure.

14. "Physician Assistant" means a person who has graduated from a physician assistant program accredited by the American Medical Association Committee on Allied Health Education and Accreditation, or the Commission for Accreditation of the Allied Health Education Programs, or the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or their successors; and/or who has passed the certifying examination administered by the National Commission on Certification of Physician Assistants (NCCPA) or its successor and possesses a current license and certificate of registration issued by the Board. Only physician assistants who are currently certified by the NCCPA may use the initials PA-C.

15. "Primary Supervising Physician" (PSP) means a physician who has an active, unrestricted license in good standing issued by either the Board of Licensure in Medicine or the Board of Osteopathic Licensure, and who has agreed in writing to provide supervision of a physician assistant and to be legally liable and responsible for all delegated medical services rendered by the physician assistant pursuant to a written plan of supervision that meets the requirements of this rule. A primary supervising physician must hold an active, unrestricted permanent, temporary, or emergency license, unless the Board has waived the requirement that the PSP license be unrestricted.

16. "Secondary Supervising Physician" (SSP) means a physician who has an active, unrestricted license in good standing issued by either the Board of Licensure in Medicine or the Board of Osteopathic Licensure, and who has agreed in writing to provide supervision of a physician assistant and, when actively engaged as a supervisor, to be legally liable and responsible for all delegated medical services rendered by the physician assistant pursuant to a written plan of supervision that meets the requirements of this rule. A secondary supervising physician must hold an active, unrestricted permanent, temporary, or emergency license, unless the Board has waived the requirement that the SSP license be unrestricted.

17. "Supervision" means that the supervising physician is responsible for overseeing, directing, and monitoring the medical services rendered by the physician assistant pursuant to a written plan of supervision that meets the requirements of this rule. Supervision shall be continuous, but does not require the physical presence of a supervising physician at the place where the physician assistant is rendering medical services; however, it is imperative that a supervising physician and a physician assistant are or can be in contact with each other by telecommunication.

18. "Written Plan of Supervision" means a document that meets the requirements of this rule and which identifies the physician assistant's scope of practice, delegates only those medical tasks appropriate to the physician assistant's level of competence, identifies the relationship of and access to the supervising physician(s), and describes the process for evaluating the physician assistant's performance.

SECTION 2. UNIFORM QUALIFICATIONS TO PRACTICE

1. License and Certificate of Registration Required

An individual must hold BOTH an active license and a current certificate of registration issued by the Board in order to render medical services as a physician assistant in the State of Maine.

2. Uniform Application for License/Certificate of Registration

A. The Boards shall develop a uniform application form for licensure and a uniform application form for a certificate of registration.

B. Applicants for physician assistant licensure and a certificate of registration shall complete the Board-approved forms, and submit them to the Board together with all required fees and required documentation.

3. Uniform Requirements for Temporary/New Graduate License

A. The Board, or if delegated, Board staff may issue a one-time, non-renewable temporary license to practice as a physician assistant to an applicant who:

(1) Submits an administratively complete application on forms approved by the Board;

(2) Pays the appropriate uniform licensure fee;

(3) Has successfully completed an educational program for physician assistants accredited by the American Medical Association Committee on Allied Health Education and Accreditation, or the Commission for Accreditation of the Allied Health Education Programs, or their successors;

(4) Has no license, certification or registration as a physician assistant, or any other type or classification of health care provider license, certification or registration under current discipline, revocation, suspension, restriction or probation;

(5) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law;

(6) Passes, at the time of license application, a jurisprudence examination administered by the Board; and

(7) Is currently scheduled to take, but has not yet taken, the national certifying examination administered by the NCCPA (NCCPA examination) or its successor organization, or has taken the NCCPA examination and is awaiting the results. **An applicant who has taken the NCCPA examination and failed to pass is not eligible to apply for a temporary license.**

B. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding the applicant's qualifications, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

C. A temporary license is valid until one of the following occurs:

(1) A period not to exceed six (6) months from the date of issuance has elapsed;

(2) The Board and/or physician assistant receive notice of the failure to pass the NCCPA examination; or

(3) Board staff receives notice of the passage of the NCCPA examination, upon which Board staff shall issue a full license so long as all other qualifications have been met and no cause exists that may be considered grounds for disciplinary action or denial of licensure as provided by law.

D. **Incomplete Application**

Any application for a temporary license that has been on file without action for four (4) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process in order to proceed to licensure.

4. **Uniform Requirements for Full License**

A. The Board, or if delegated, Board staff may issue a full license as a physician assistant to an applicant who:

(1) Submits an administratively complete application on forms approved by the Board;

(2) Pays the appropriate uniform licensure fee;

(3) Has successfully completed an educational program for physician assistants accredited by the American Medical Association Committee on

Allied Health Education and Accreditation, or the Commission for Accreditation of the Allied Health Education Programs, or their successors;

(4) Has no license, certification or registration as a physician assistant, or any other type or classification of health care provider license, certification or registration under current discipline, revocation, suspension, restriction or probation;

(5) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law;

(6) Passes, at the time of license application, a jurisprudence examination administered by the Board; and

(7) Has passed the NCCPA certification examination and holds a current certification issued by the NCCPA that has not been subject to disciplinary action by the NCCPA at the time the license application is acted upon by the Board.

B. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding the applicant's qualifications, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

C. **Incomplete Application**

Any application that has been on file without action for one (1) year shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process in order to proceed to licensure.

5. **Uniform Requirements for Certificate of Registration**

A. In order to render medical services, a physician assistant must have BOTH a current license and a certificate of registration issued by the Board for each primary supervising physician relationship. The Board may issue a certificate of registration to a physician assistant who:

(1) Possesses a temporary or full license issued by the Board;

(2) Submits an administratively complete application for a certificate of registration on a form approved by the Board;

(3) Pays the appropriate uniform fee for certificate of registration; and

(4) Submits a written plan of supervision that conforms to the requirements of this rule.

6. **Uniform Requirements for Active-Nonclinical License**

A. **Active-Nonclinical License**. The Board, or if delegated, Board staff shall issue an active-nonclinical license to an applicant who meets the qualifications for

licensure, but who does not have an active current certificate of registration or does not currently have a primary supervising physician registered with the Board.

B. **License Conversion**: The Board, or if delegated, Board staff shall convert an active license to an active-nonclinical license for any licensee who meets the qualifications for licensure, but who does not have a current certificate of registration issued by the Board or does not currently have a primary supervising physician registered with the Board.

7. **Uniform Process for Conversion of Active-Nonclinical License to Active License**

A. The Board, or if delegated, Board staff may convert the status of a physician assistant's license from active-nonclinical to active for an applicant who:

(1) Submits an administratively complete application for a certificate of registration on a form approved by the Board;

(2) Pays the appropriate uniform fee for a certificate of registration; and

(3) If not actively engaged in clinical practice for twelve (12) of the eighteen (18) months prior to submission of the administratively complete application, provides documentation to the satisfaction of the Board demonstrating current clinical competency. Such proof may include the completion of additional training or education.

(4) Submits a written plan of supervision that conforms to the requirements of this rule.

B. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding CME credits or active clinical practice, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

8. **Uniform Requirements for Renewal of License and Certificate of Registration**

A. **Uniform expiration**

Commencing January 1, 2016, regardless of the date of initial licensure or last license renewal, the license and certificate of registration of every physician assistant born in an odd-numbered year expires at midnight on the last day of the month of the physician assistant's birth every odd-numbered year. The license and certificate of registration of every physician assistant born in an even-numbered year expires at midnight on the last day of the month of the physician assistant's birth every even-numbered year. Prior to expiration of the license and certificate of registration, the physician assistant must renew the license and certificate of registration every two (2) years by the last day of the month of birth of the physician assistant seeking renewal, by means of application to the Board on forms prescribed and supplied by the Board.

CME may be pro-rated to accommodate the first transition cycle.

B. **Uniform license/certificate of registration renewal notification**

At least sixty (60) days prior to the expiration of a current license and certificate of registration, the Board shall mail or e-mail to each licensee, at the licensee's last known address, a notice of the requirement to renew the license and certificate(s) of registration.

C. **Uniform criteria for license renewal**

(1) The Board, or if delegated, Board staff may renew the license of a physician assistant who meets all of the following requirements:

(a) Submits an administratively complete license renewal application form;

(b) Pays the appropriate uniform license renewal fee;

(c) Affirms that the licensee has met the continuing medical education (CME) requirements. In the event that the required CME is not complete, the physician assistant may request an extension of time for good cause to complete the CME. The Board Secretary, Board Chair, or their designee has the discretion to grant or deny a request for an extension of time to complete the required CME credits;

(d) Maintains a copy of the current written plan of supervision for each practice location, which must be made available upon request by the Board or Board staff; and

(e) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of licensure as provided by law.

(2) In the event that the Board delegates licensing decisions to Board staff and there is any question regarding the applicant's qualifications, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

D. **Uniform criteria for renewal of certificate of registration**

(1) The Board, or if delegated, Board staff may renew a certificate of registration of a physician assistant who meets all of the following requirements:

(a) Submits an administratively complete renewal application form;

(b) Pays the appropriate uniform renewal of certificate of registration fee;

(c) Maintains a copy of the current plan of supervision for each practice location which must be made available upon request by the Board or Board staff; and

(d) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of the certificate of registration as provided by law.

(2) In the event that the Board delegates licensing decisions to Board staff and there is any question regarding renewal of the certificate of registration, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

E. **Uniform criteria for change of certificate of registration**

(1) The Board, or if delegated, Board staff may change a certificate of registration for a physician assistant who meets all of the following requirements:

(a) Submits an administratively complete certificate of registration application form;

(b) Pays the appropriate uniform fee for certificate of registration;

(c) Submits a written plan of supervision, if requested, that conforms to the requirements of this rule; and

(d) Has no cause existing that may be considered grounds for disciplinary action or denial of the certificate of registration as provided by law.

(2) In the event that the Board delegates licensing decisions to Board staff and there is any question regarding change of the certificate of registration, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

9. **Uniform Criteria for License Reinstatement**

A. The Board, or if delegated, Board staff may reinstate a lapsed or withdrawn license of a physician assistant who meets all of the following requirements:

(1) Submits an administratively complete reinstatement application form;

(2) Pays the appropriate uniform reinstatement fee;

(3) Provides a written statement explaining why he/she withdrew or allowed the license to lapse and a detailed listing of his/her activities since that time; and

(4) Has no cause existing that may be considered grounds for disciplinary action or denial of license reinstatement as provided by law.

B. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding reinstatement of the license, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

C. A physician assistant whose license has lapsed or been withdrawn for more than five (5) years shall apply for a new license.

D. The Board, at its discretion, may not reinstate the license of any physician assistant who has not provided evidence satisfactory to the Board of having actively engaged in the supervised rendering of medical services for at least twelve (12) of the eighteen (18) months prior to submission of the administratively complete reinstatement application under the license of another jurisdiction of the United States or Canada. The applicant may not be reinstated unless the Board is satisfied with the applicant's current clinical competence. If the applicant has not been in active practice, the Board may require the applicant to complete a competency update after review of the application. Possible competency updates may include programs as approved by the Board.

10. **Uniform Process for Withdrawal of License**

A physician assistant licensed by the Board may request to withdraw from licensure by submitting an administratively complete renewal application which states the reason for requesting withdrawal of licensure.

11. **Uniform Fees**

A. Board staff shall collect the following fees prior to the issuance of any license or certificate:

(1)	Initial License Application	$200
(2)	Initial Certificate of Registration (Not to exceed $250 per license biennium)	$50
(3)	License Renewal	$200
(4)	Certificate of Registration Renewal (Not to exceed $250 per license biennium)	$50
(5)	Certificate of Registration Change	$50
(6)	License Reinstatement after Withdrawal	$200
(7)	License Reinstatement after Lapse	$400

B. Board staff may prorate the fees for any license or registration that will expire less than twelve (12) months after its issuance.

SECTION 3. UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS

1. Delegated Authority

A. Physician assistants render medical services under physician supervision. Physician assistants may render only those medical services that have been delegated to the physician assistant by a supervising physician pursuant to a written plan of supervision.

B. Supervising physicians and the physician assistants whom they supervise are responsible for ensuring that any medical service that is delegated is:

(1) Within the scope of practice of the supervising physician;

(2) Suitable to be performed by the physician assistant, taking into account the physician assistant's education, training, and level of competence and experience; and

(3) Included in the written plan of supervision.

C. Medical services that may be delegated by a physician to a physician assistant pursuant to a written plan of supervision include:

(1) Ordering and performing diagnostic, therapeutic, and other medical services.

(2) Prescribing, administering, and dispensing of all medical devices and legend drugs, including all drugs in Schedules II-V, as defined in the *Controlled Substances Act*, 21 U.S.C. §801, *et seq.*, to the extent permitted by state and federal law and in accordance with the following:

(a) If authorized and delegated by the primary supervising physician, the delegation of the authority to prescribe, administer, or dispense scheduled drugs must be specifically included in the written plan of supervision and must identify which scheduled drugs (e.g. schedule II, schedule III, etc.) the physician assistant is authorized to prescribe, administer or dispense.

(b) The primary supervising physician shall perform a review of the physician assistant's scheduled drug prescribing practices every three months during the first year of the physician assistant's delegation of scheduled drug prescribing authority in the plan of supervision. Thereafter, the primary supervising physician shall conduct such a review every six months. All reviews shall include a review of patient charts and a review of the Prescription Monitoring Program reports. The primary supervising physician shall take corrective action regarding any deficiencies noted regarding the physician assistant's scheduled drug prescribing practices.

(c) Physician assistants may not prescribe Methadone, Suboxone (Buprenorphine), or Subutex unless allowed under state and federal laws. If permitted under state and federal laws, and if delegated by the primary supervising physician, the authority to prescribe Methadone, Suboxone (Buprenorphine), or Subutex must be specifically included in the written plan of supervision.

(d) Physicians are ultimately responsible for the prescribing practices of the physician assistants working under their delegation, and should closely monitor the prescribing of all scheduled drugs and controlled substances. Inappropriate prescribing practices by a physician assistant shall constitute grounds to discipline the physician assistant and supervising physicians(s).

(3) The rendering of medical services that are not routinely within the practice or regularly performed by the primary supervising physician so long as adequate oversight is ensured by a secondary supervising physician with the requisite training and experience to ensure competent provision of the medical services delivered by the physician assistant.

2. **Practice Setting**

A physician assistant may render medical services only in a practice setting in which the supervising physician agrees to provide supervision as documented in the written plan of supervision.

3. **Delegation by Physician Assistants**

A. Physician assistants rendering medical services under delegation from a supervising physician may delegate certain medical services to medical assistants when the medical services are under the control of the physician assistant or the supervising physician, one of whom must be present on the premises at the time the medical services are performed.

B. The supervising physician is ultimately responsible for any medical services delegated to the medical assistant by the physician assistant.

C. The medical services delegated by the physician assistant to a medical assistant must be described in the written plan of supervision.

D. The medical assistant may perform all assigned tasks authorized by the supervising physician as delegated by the physician assistant and identified in the physician assistant's plan of supervision, with the following exceptions:

(1) Patient triage;

(2) Patient examination; and

(3) Obtaining informed consent (except for immunizations)

SECTION 4. UNIFORM STANDARDS FOR PHYSICIAN SUPERVISION OF PHYSICIAN ASSISTANTS

1. **Supervising Physician Requirements**

A. Prior to supervising a physician assistant a physician must:

(1) Have an active, unrestricted permanent, temporary or emergency license to practice medicine in this state, unless the Board has waived the requirement that the PSP license be unrestricted;

(2) Prepare and sign a written plan of supervision that includes all of the elements and technical requirements of supervision as set forth in this rule; and

(3) Maintain a copy of the written plan of supervision on file at the location specified in the plan of supervision, which shall be immediately produced upon request of the Board or the Board staff.

B. **Prohibited physician conduct**

(1) No physician shall delegate to any person other than another physician licensed by the Board of Licensure in Medicine or the Board of Osteopathic Licensure the performance of medical services which constitute the practice of medicine or surgery, except in full compliance with this chapter or pursuant to 32 M.R.S. §3270-E or 32 M.R.S. §2594-E.

(2) No physician shall supervise a physician assistant who does not possess a valid license and certificate of registration issued by the Board.

(3) No physician shall supervise a physician assistant without complying with the requirements of this rule.

2. A supervising physician is responsible for observing, directing and evaluating the work, records and practices performed by the physician assistant pursuant to a written plan of supervision and is legally responsible for the practice of the physician assistant at all times.

3. A supervising physician may not permit a physician assistant to practice independently.

4. A supervising physician is responsible for providing continuous supervision of the physician assistant. Constant physical presence of the supervising physician at the time and place that the services are rendered by the physician assistant is not required:

A. So long as the supervising physician and the physician assistant are, or can be, easily in contact with one another by electronic communication, including but not limited to telecommunication; and

B. Unless physical presence is necessary to provide the same quality of patient care as provided by the physician.

5. Appropriate supervision shall include:

   A. Active and continuing overview of the physician assistant's activities to determine that the supervising physician's directions are being implemented;

   B. Immediate availability of the supervising physician, either in-person or by electronic communication, to the physician assistant for all necessary consultations;

   C. Personal and regular review, at least quarterly, by the supervising physician of selected patient records upon which entries are made by the physician assistant. The supervising physician shall select the patient records for review on the basis of written criteria established by the supervising physician and the physician assistant and the chart review will be sufficient in number to assure adequate review of the physician assistant's scope of practice; and

   D. Periodic, in person, education and review sessions discussing specific conditions, protocols, procedures and specific patients shall be held by the supervising physician for the physician assistant in accordance with the terms of the written plan of supervision. These sessions must occur at least twice each calendar year, and must be documented by the supervising physician and the physician assistant.

6. It is the responsibility of the primary supervising physician to ensure that supervision is maintained in his or her absence. A primary supervising physician may designate one or more covering supervising physicians. To serve as a covering supervising physician, a physician must hold an active, unrestricted license to practice medicine in this State. A covering supervising physician, jointly with the supervising physician, shall be legally responsible for the acts of the physician assistant which occur during periods of time when the covering supervising physician is providing supervision to the physician assistant. A covering supervising physician shall accept supervisory responsibility for periods of time not to exceed the time period specified in the written plan of supervision, which time period may not exceed forty-five (45) consecutive calendar days.

7. In the event of the sudden departure, incapacity, or death of the supervising physician, a registered secondary or covering supervising physician may assume the role of supervising physician in order to provide continuity of care for the patients of the former supervising physician.

SECTION 5. UNIFORM ELEMENTS OF WRITTEN PLANS OF SUPERVISION

1. All written plans of supervision shall include at a minimum:

   A. The physician assistant's scope of practice and practice setting, including the types of patients and patient encounters common to the practice, a general overview of the role of the physician assistant in the practice, and the tasks that the physician assistant may delegate to medical assistants.

   B. A description of the type and level of supervision, including:

(1) Whether the delegation of medical services is appropriate to the physician assistant's level of competence;

(2) If any medical services to be rendered are outside the normal practice of the primary supervising physician;

(3) The supervisory arrangements that assure appropriately trained supervision by a physician with the requisite specialty training if outside the normal practice of the primary supervising physician;

(4) A description of the relationship and ability to access the supervising physician(s); and

(5) A description of physician supervision when the primary supervising physician is not available. In such a circumstance, a covering supervising physician should be available for direct consultation with the physician assistant.

(6) A description of the mechanism and process for evaluating the physician assistant's performance. Such a process must include:

(a) **Primary Supervising Physician**. At least two documented meetings each licensure year between each primary supervising physician and the physician assistant during the physician assistant's two-year licensing cycle to evaluate the physician assistant's performance (semi-annual evaluations). All four semi-annual evaluations shall be documented on a form attached to the most current plan of supervision. If the primary supervising physician supervises the physician assistant for less than six months of a licensure year, only one evaluation need be completed for that licensure year. Semi-annual evaluations must be signed by the primary supervising physician and the physician assistant and the information must be kept by the physician assistant. Each semi-annual meeting evaluation shall address the following areas:

(i) clinical and procedural care delivery, including physician assistant supervision of medical assistants;

(ii) patient relations and professionalism;

(iii) documentation review. It is recommended that a representative sample of patient charts be reviewed on a routine basis; and

(iv) prescriptive practices. Special attention shall be devoted to the prescribing of controlled substances, if such prescribing is authorized. If controlled substances are prescribed a review of Prescription Monitoring Program reports shall be conducted.

(7) Secondary Supervising Physician. If the physician assistant is routinely working under the supervision of a secondary supervising physician who is a medical specialist (i.e. cardiologist, neurologist, etc.) outside of the primary supervising physician's field of practice, then the secondary supervising physician shall also perform semi-annual evaluations that shall address the following areas:

(a) clinical and procedural care delivery, including physician assistant supervision of medical assistants;

(b) patient relations and professionalism;

(c) documentation review. It is recommended that a representative sample of patient charts be reviewed on a routine basis; and

(d) prescriptive practices. Special attention shall be devoted to the prescribing of controlled substances, if such prescribing is authorized. If controlled substances are prescribed a review of Prescription Monitoring Program reports shall be conducted.

C. **Maintenance and production of plan of supervision**

(1) Physician assistants licensed and registered to practice in accordance with these rules and their supervising physicians must prepare and have on file in the main administrative office of the practice or practice location a written, dated plan of supervision that is signed by both the supervising physician(s) and the physician assistant and contains the elements of supervision as required by this rule. The plan of supervision shall specify at which location the plan of supervision will be maintained.

(2) The plan of supervision must be reviewed and updated as necessary but at least every two years at license/registration renewal. A statement shall be attached to the plan stating the date the plan was reviewed and any changes to the plan, and shall be signed by the physician assistant and supervising physicians(s).

(3) If a physician assistant is to be supervised by (a) secondary supervising physician(s), the secondary supervising physician(s) must accept delegation of supervision in writing as part of the plan of supervision.

(4) Failure to have a current written plan of supervision on file at the location specified in the plan of supervision and/or failure to produce a current written plan of supervision upon request of the Board or Board staff shall result in a citation and/or possible disciplinary action.

D. **Plan of supervision audit**

(1) Board staff may perform random audits of all plans of supervision by requesting that the physician assistant produce a copy of any plan of supervision.

(2) Upon request of the Board or Board staff, a physician assistant shall immediately provide a copy of the plan of supervision and, if applicable, the document showing the delegation of that plan to a secondary supervising physician, and/or copies of relevant performance review documentation. Such request may be made in writing or in person at the practice setting, in which case the plan shall be provided immediately. The Board may require the plan to be amended for purposes of ensuring public safety as required by law.

SECTION 6. UNIFORM NOTIFICATION REQUIREMENTS FOR PHYSICIAN ASSISTANTS

1. **Change of Primary Supervising Physician(S)**

A. A physician assistant licensed by the Board, upon changing a primary supervising physician, shall notify the Board in writing within ten (10) calendar days by submitting a uniform form approved by the Board, which shall include:

(1) The name, business address, and telephone number of the new primary supervising physician(s); and

(2) A statement that the new primary supervising physician has agreed to accept responsibility for all acts of the physician assistant and has signed a written plan of supervision that meets the requirements of this rule.

2. **Termination of Plan of Supervision**

A physician assistant licensed by the Board shall notify the Board in writing within ten (10) calendar days regarding the termination of any plan of supervision or supervisory relationship and the basis for the termination of the plan of supervision or supervisory relationship.

3. **Change of Contact Information**

A physician assistant licensed by the Board shall notify the Board in writing within ten (10) calendar days of any change in work or home address, email, phone, or other contact information.

4. **Death/Departure of Supervising Physician**

A physician assistant licensed by the Board shall notify the Board in writing within ten (10) calendar days of any death or permanent or long-term departure of the supervising physician from the practice location.

5. **Failure to Pass NCCPA Examination**

A physician assistant issued a temporary license by the Board shall notify the Board in writing within ten (10) calendar days of the failure to pass the NCCPA examination.

6. **Criminal Arrest/Summons/Indictment/Conviction**

A physician assistant shall notify the Board in writing within ten (10) calendar days of being arrested, summonsed, charged, indicted or convicted of any crime.

7. **Change in Status of Employment or Hospital Privileges**

A physician assistant shall notify the Board in writing within ten (10) calendar days of termination of employment, or any limitation, restriction, probation, suspension, revocation or termination of hospital privileges.

8. **Disciplinary Action**

A physician assistant shall notify the Board in writing within ten (10) calendar days of disciplinary action taken by any licensing authority including, but not limited to, warning, reprimand, fine, suspension, revocation, restriction in practice or probation.

9. **Material Change**

A physician assistant shall notify the Board in writing within ten (10) calendar days of any material change in qualifications or the information and responses provided to the Board in connection with the physician assistant's most recent application.

SECTION 7. UNIFORM CITATION

1. The board, or if delegated, board staff may issue citations in lieu of taking disciplinary action for:

   A. The failure to have a current plan of supervision that conforms to the requirements of this rule and performance review documentation on file at the location specified in the plan of supervision. The administrative fine for each violation is $200; or

   B. The failure to file a written notification form with the relevant Board as required by this rule. The administrative fine for each violation is $100.

2. **Service of Citation**

The citation may be served on the licensee by mail sent from the Board office.

3. **Right to Hearing**

The citation shall inform the licensee that the licensee may pay the administrative fine or request in writing a hearing before the Board regarding the violation. If the licensee requests a hearing, the citation shall be processed in the same manner as a complaint pursuant to 32 M.R.S. §3282-A, or 32 M.R.S. §2591-A except that the licensee's written response to the citation must be filed at the same time as the written request for hearing.

4. **Time for Payment or Request for Hearing**

The licensee shall either pay the administrative fine within thirty (30) days following issuance of the citation or request a hearing in writing within thirty (30) days following issuance of the citation. Failure to take either action within this thirty-day (30-day) period is a violation of the Board's rules that may subject the licensee to further disciplinary action by the Board for unprofessional conduct, including but not limited to an additional fine and action against the license.

5. **Citation Violations Not Reportable**

Administrative fines paid solely in response to citations issued pursuant to this rule do not constitute discipline or negative action or finding and shall not be reported to the Federation of State Medical Boards or the National Practitioner Databank or to any other person, organization, or regulatory body except as allowed by law. Citation violations and administrative fines are public records within the meaning of 1 M.R.S. §402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. §408-A.

SECTION 8. CONDUCT SUBJECT TO DISCIPLINE

Violation of this rule by a physician or physician assistant constitutes unprofessional conduct and is grounds for discipline of a physician's or physician assistant's license.

SECTION 9. UNIFORM CONTINUING MEDICAL EDUCATION (CME) REQUIREMENTS AND DEFINITIONS

In order to qualify to renew a license, a physician assistant must meet the following CME requirements:

1. **Requirements**

A. Each physician assistant who possesses an active license shall complete, during each biennial licensing period, a minimum of one hundred (100) credit hours of continuing medical education subject to the following:

(1) At least forty (40) hours must be in Category 1 (as defined by this rule);

(2) The total one hundred (100) hours may be in Category 1.

(3) Sixty (60) credit hours may be in Category 2 (as defined by this rule).

B. If the required CME is not completed and submitted, then an inactive status license renewal will be issued unless the Board has granted an extension of time or deferment as described in Subsection 2C below.

C. Proof of current NCCPA certification at the time an application for renewal is submitted satisfies CME requirements.

2. **Definitions of CME Categories**

A. Category 1 CME includes:

(1) CME programs sponsored or co-sponsored by an organization or institution accredited by: the American Academy of Physician Assistants (AAPA); the American Medical Association Council on Medical Education (AMA); the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Practice (AAFP); the Committee on Continuing Medical Education of the Maine Medical Association (MMA); the American Osteopathic Association (AOA); or the Maine Osteopathic Association (MOA). Programs will be properly identified as such by approved sponsoring or co-sponsoring organizations. VALUE: One (1) credit hour per hour of participation. VERIFICATION: Certificate of completion, if requested by the Board as part of a CME audit.

(2) Papers or articles published in peer reviewed medical journals (journals included in Index Medicus) VALUE: Ten (10) credit hours for each article. Limit one article per year. VERIFICATION: Copy of first page of article, if requested by the Board as part of a CME audit.

(3) Poster preparation for an exhibit at a meeting designated for AMA/AOA/AAPA category 1 credit, with a published abstract. VALUE: Five (5) credit hours per poster. Limit one poster per year. VERIFICATION: Copy of program with abstract and presenter identified, if requested by the Board as part of CME audit.

(4) Teaching or presentation in activities designated for AMA/AOA/AAPA category 1 Credit, VALUE: Two (2) credit hours for each hour of preparation and presentation of new and original material. Limit ten (10) hours per year. VERIFICATION: Copy of program from activity, if requested by the Board as part of CME audit.

(5) Medically related degrees, i.e. MPH, Ph.D. VALUE: Twenty five (25) credit hours per year. VERIFICATION: Certified copy of diploma or transcript, if requested by the Board as part of CME audit.

(6) Postgraduate training or advanced specialty training. VALUE: Fifty (50) credit hours per year. VERIFICATION: Certified copy of diploma or transcript, if requested by the Board as part of CME audit.

(7) Other programs developed or approved from time to time by the Board. VALUE: Determined by the Board at the time of approval. VERIFICATION: Determined by the Board at the time of approval.

B. Category 2 CME includes:

(1) CME programs with non-accredited sponsorship, i.e. those not meeting the definition of Category 1 as defined in Subsection 2(A) above. VALUE: One (1) credit hour per hour of participation.

(2) Medical teaching of medical students, interns, residents, fellows, practicing physicians, or allied professionals. VALUE: One (1) credit hour per hour of teaching.

(3) Authoring papers, publications, books, or book chapters, not meeting the definition of Category 1 as defined in Subsection 2(A) above. VALUE: Ten (10) credit hours per publication. Limit ten (10) hours per year.

(4) Non-supervised individual activities, i.e. journal reading, peer review activities, self-assessment programs which are not sponsored by an accredited Category 1 organization. VALUE: One (1) credit hour per hour of participation.

C. **Exceptions to CME requirements**

(1) The Board, at its discretion, may grant an extension of time or deferment to a licensee who because of prolonged illness, undue hardship, or other extenuating circumstances has been unable to meet the requirements of CME.

(2) CME will be prorated during the first licensure period.

(3) CME requirements will be stayed for physician assistants called to active military duty according to current Board policy.

D. **Evidence of completion**

Board staff shall perform random audits of CME.

SECTION 10. IDENTIFICATION REQUIREMENTS

Physician assistants licensed under these rules shall keep their license and certificate of registration available for inspection at the location where they render medical services and shall, when rendering medical services, wear a name tag identifying themselves as a physician assistant.

SECTION 11. PHYSICIAN ASSISTANT ADVISORY COMMITTEE

1. The Boards shall appoint a Physician Assistant Advisory Committee (the Advisory Committee) comprised of such persons as it deems appropriate, but the Advisory Committee shall include at least two physicians and two physician assistants licensed by either the BOLIM or the BOL. The PA members of the BOL and the BOLIM shall also be members of the committee. The Boards may also appoint such Advisory Committee members it deems appropriate.

2. The duties of the Advisory Committee shall be to review matters and make recommendations pertaining to physician assistants and the supervision of physician assistants which the Boards request the Advisory Committee to consider.

3. Members of the Advisory Committee shall be appointed by the Boards for terms of up to four years. A member may be appointed by the Board for a second, and final four-year term. If a member is appointed to complete a term created by the premature departure of another member, the appointed member may still serve two full terms. The Boards may, at their discretion, remove any member from the Advisory Committee.

4. Members of the Advisory Committee shall not hold a leadership position or be an officer in a professional association regarding any professional occupation(s) licensed or regulated by the Boards.

5. The Chairperson of the Advisory Committee shall be a physician assistant member and shall not be a regular member of the Board of Licensure in Medicine or the Board of Osteopathic Licensure, and shall be elected by a vote of the members of the Advisory Committee. The Chairperson shall serve for a term of two years and may not be re-elected.

6. The Advisory Committee shall meet at the request of either Board. Five (5) members of the Advisory Committee shall constitute a quorum for the purpose of holding a meeting and conducting business.

STATUTORY AUTHORITY: 32 M.R.S. §§ 2562, 2594-E

EFFECTIVE DATE:
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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE
a joint rule with
383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 6: TELEMEDICINE STANDARDS OF PRACTICE

SUMMARY: Chapter 6 establishes standards for the practice of medicine using telemedicine in providing health care.

SECTION 1. STATEMENT REGARDING TELEMEDICINE

1. The Board recognizes that technological advances have made it possible for licensees in one location to provide health care to patients in another location with or without an intervening health care provider.

2 Telemedicine is a useful tool that, if applied appropriately, can provide important benefits to patients, including increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and potential cost savings.

3. The Board advises that licensees using telemedicine in providing health care will be held to the same standards of care and professional ethics as licensees providing traditional in-person health care.

4. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine in providing health care may subject the licensee to potential discipline by the Board.

SECTION 2. DEFINITIONS

1. "Asynchronous store-and-forward transmission" means the collection of a patient's relevant health information and the subsequent transmission of the information from an originating site to a health care provider at a distant site without the presence of the patient.

2. "Board" means the Maine Board of Licensure in Medicine or the Board of Osteopathic Licensure.

3. "Distant site" means the location of the licensee providing telemedicine services.

4. "In-person encounter" means that the licensee and the patient are in the physical presence of each other and are in the same physical location during the physician-patient encounter.

5. "Licensee" means a physician or physician assistant licensed or registered by the Board.

6. "Originating site" means the location of the patient at the time of the examination, diagnosis, consultation or treatment.

7. "Patient-Physician Relationship**"** has the same meaning as defined by Opinion 10.015 in the American Medical Association Code of Medical Ethics 2014-2015 Edition.

8. "Synchronous" means an interactive telemedicine encounter between a patient and a licensee that occurs at the same time.

9. "Telemedicine" means the practice of medicine or the rendering of health care services using electronic audio-visual communications and information technologies or other means, including interactive audio with asynchronous store-and-forward transmission, between a licensee in one location and a patient in another location with or without an intervening health care provider. Telemedicine includes asynchronous store-and-forward technologies, remote monitoring, and real-time interactive services, including teleradiology and telepathology. Telemedicine shall not include the provision of medical services only through an audio-only telephone, e-mail, instant messaging, facsimile transmission, or U.S. mail or other parcel service, or any combination thereof.

10. "Telemedicine technologies" means technologies and devices enabling secure electronic communications and information exchanges between a licensee in one location and a patient in another location with or without an intervening health care provider.

SECTION 3. PRACTICE GUIDELINES

1. A licensee who uses telemedicine shall utilize evidence-based telemedicine practice guidelines and standards of practice, to the degree they are available, to ensure patient safety, quality of care, and positive outcomes. The Board acknowledges that some nationally recognized medical specialty organizations have established comprehensive telemedicine practice guidelines that address the clinical and technological aspects of telemedicine for many medical specialties.

2. MAINE MEDICAL LICENSE REQUIRED

   A licensee who uses telemedicine in the examination, diagnosis, consultation or treatment of a patient located in Maine shall hold an active Maine medical license or shall hold an active registration in Maine to provide interstate consultative telemedicine services.

3. STANDARDS OF CARE AND PROFESSIONAL ETHICS

   A licensee who uses telemedicine in providing health care shall be held to the same standards of care and professional ethics as a licensee using traditional in-person encounters with patients. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine may be a violation of the laws and rules governing the practice of medicine and may subject the licensee to potential discipline by the Board.

4. SCOPE OF PRACTICE

A licensee who uses telemedicine in providing health care shall ensure that the services provided are consistent with the licensee's scope of practice, including the licensee's education, training, experience, ability, licensure, and certification.

5. IDENTIFICATION OF PATIENT AND PHYSICIAN

A licensee who uses synchronous telemedicine technology in providing health care shall verify the identity of the patient and ensure that the patient has the ability to verify the identity, licensure status, certification, and credentials of all health care providers who provide telemedicine services prior to the provision of care.

6. PHYSICIAN-PATIENT RELATIONSHIP

A. A licensee who uses telemedicine in providing health care shall establish a valid physician-patient relationship with the person who receives telemedicine services. The physician-patient relationship begins when:

(1) The person with a health-related matter seeks assistance from the licensee;

(2) The licensee agrees to undertake examination, diagnosis, consultation or treatment of the person; and

(3) The person agrees to receive health care services from the licensee whether or not there has been an in-person encounter between the licensee and the person.

B. A valid physician-patient relationship may be established between a licensee who uses telemedicine in providing health care and a patient who receives telemedicine services through any of the following circumstances:

(1) **Consultation with another licensee**. Through consultation with another licensee (or other health care provider) who has an established relationship with the patient upon agreement to participate in, or supervise, the patient's care; or

(2) **Telemedicine encounter**. Through telemedicine, if the standard of care does not require an in-person encounter, and in accordance with evidence-based standards of practice and telemedicine practice guidelines that address the clinical and technological aspects of telemedicine.

7. MEDICAL HISTORY AND PHYSICAL EXAMINATION

Generally a licensee shall perform an in-person medical interview and physical examination for each patient. However, the medical interview and physical examination may not be in-person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physician examination had been performed in-person. Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telemedicine in providing

health care shall interview the patient to collect the relevant medical history and perform a physical examination, when medically necessary, sufficient for the diagnosis and treatment of the patient. An internet questionnaire that is a static set of questions provided to the patient, to which the patient responds with a static set of answers, in contrast to an adaptive interactive and responsive online interview, does not constitute an acceptable medical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by the licensee.

8. NON-PHYSICIAN HEALTH CARE PROVIDERS

A. If a licensee who uses telemedicine in providing health care relies upon or delegates the provision of telemedicine services to a non-physician health care provider, the licensee shall:

(1) Ensure that systems are in place to ensure that the non-physician health care provider is qualified, trained, and authorized to provide that service; and

(2) Ensure that the licensee is available in person or electronically to consult with the non-physician health care provider, particularly in the case of injury or an emergency.

9. INFORMED CONSENT

A licensee who uses telemedicine in providing health care shall ensure that the patient provides appropriate informed consent for the health care services provided, including consent for the use of telemedicine to examine, consult, diagnose and treat the patient, and that such informed consent is timely documented in the patient's medical record.

10. COORDINATION OF CARE

A licensee who uses telemedicine in providing health care shall, when medically appropriate, identify the location and treating physician(s) for the patient, when available, where in-person services can be delivered in coordination with the telemedicine services. The licensee shall provide a copy of the medical records to the location or treating physician(s).

11. FOLLOW-UP CARE

A licensee who uses telemedicine in providing health care shall have access to, or adequate knowledge of, the nature and availability of local medical resources to provide appropriate follow-up care to the patient following a telemedicine encounter.

12. EMERGENCY SERVICES

A licensee who uses telemedicine in providing health care shall:

A. Obtain emergency contact information and/or telephone contact information of the patient; and

B. Refer a patient to an acute care facility or an emergency department when referral is necessary for the safety of the patient or in the case of an emergency.

13. MEDICAL RECORDS

A licensee who uses telemedicine in providing health care shall ensure that complete, accurate and timely medical records are maintained for the patient when appropriate, including all patient-related electronic communications, records of past care, physician-patient communications, laboratory and test results, evaluations and consultations, prescriptions, and instructions obtained or produced in connection with the use of telemedicine technologies. The licensee shall note in the patient's record when telemedicine is used to provide diagnosis and treatment. The licensee shall ensure that the patient or another licensee designated by the patient has timely access to all information obtained during the telemedicine encounter. The licensee shall ensure that the patient receives, upon request, a summary of each telemedicine encounter in a timely manner and in accordance with applicable law.

14. PRIVACY AND SECURITY

A. A licensee who uses telemedicine in providing health care shall ensure that all telemedicine encounters comply with the privacy and security measures of the Health Insurance Portability and Accountability Act and applicable law to ensure that all patient communications and records are secure and remain confidential.

(1) Written protocols shall be established that address the following:

(a) Privacy;

(b) Health care personnel who will process messages;

(c) Hours of operation;

(d) Types of transactions that will be permitted electronically;

(e) Required patient information to be included in any communication, including patient name, identification number and type of transaction;

(f) Archiving and retrieval; and

(g) Quality oversight mechanisms.

(2) The written protocols should be periodically evaluated for currency and should be maintained in an accessible and readily available manner for review. The written protocols shall include sufficient privacy and security measures to ensure the confidentiality and integrity of patient-identifiable information, including password protection, encryption or other reliable authentication techniques.

15. TECHNOLOGY AND EQUIPMENT

A. The Board recognizes that three broad categories of telemedicine technologies currently exist, including asynchronous store-and-forward technologies, remote monitoring, and real-time interactive services. While some telemedicine programs are multispecialty in nature, others are tailored to specific diseases and medical specialties. The technology and equipment utilized for telemedicine shall comply with the following requirements:

(1) The technology and equipment utilized in the provision of telemedicine services must comply with all relevant safety laws, rules, regulations, and codes for technology and technical safety for devices that interact with patients or are integral to diagnostic capabilities;

(2) The technology and equipment utilized in the provision of telemedicine services must be of sufficient quality, size, resolution and clarity such that the licensee can safely and effectively provide the telemedicine services;

(3) The technology and equipment utilized in the provision of telemedicine services must be compliant with the Health Insurance Portability and Accountability Act and other applicable law;

(4) The technology and equipment utilized in the provision of telemedicine services must be able to verify the identity and location of the patient; and

(5) The technology and equipment utilized in the provision of telemedicine services must be able to specify and disclose the identity and credentials of the health care provider(s).

16. DISCLOSURE AND FUNCTIONALITY OF TELEMEDICINE SERVICES

A. Except for health care provider to health care provider direct consultation, a licensee who uses telemedicine in providing health care shall ensure that the following information is clearly disclosed to the patient:

(1) Types of services provided;

(2) Contact information for the licensee;

(3) Identity, licensure, certification, credentials and qualifications of all health care providers who are providing the telemedicine services;

(4) Limitations in the drugs and services that can be provided via telemedicine;

(5) Fees for services, cost-sharing responsibilities, and how payment is to be made;

(6) Financial interests, other than fees charged, in any information, products, or services provided by the licensee(s);

(7) Appropriate uses and limitations of the technologies, including in emergency situations;

(8) Uses of and response times for e-mails, electronic messages and other communications transmitted via telemedicine technologies;

(9) To whom patient health information may be disclosed and for what purpose;

(10) Rights of patients with respect to patient health information; and

(11) Information collected and passive tracking mechanisms utilized.

17. PATIENT ACCESS AND FEEDBACK

A. A licensee who uses telemedicine in providing health care shall ensure that the patient has easy access to a mechanism for the following purposes:

(1) To access, supplement and amend patient-provided personal health information;

(2) To provide feedback regarding the quality of the telemedicine services provided; and

(3) To register complaints. The mechanism shall include information regarding the filing of complaints with the Board.

18. FINANCIAL INTERESTS

Advertising or promotion of goods or products from which the licensee(s) receives direct remuneration, benefit or incentives (other than the fees for the health care services) is prohibited to the extent that such activities are prohibited by state or federal law. Notwithstanding such prohibition, Internet services may provide links to general health information sites to enhance education; however, the licensee(s) should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, licensees should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of a preferred relationship with any pharmacy is prohibited unless pursuant to a collaborative practice agreement. Licensees shall not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit from the pharmacy unless pursuant to a collaborative practice agreement.

19. CIRCUMSTANCES WHERE THE STANDARD OF CARE MAY NOT REQUIRE A LICENSEE TO PERSONALLY INTERVIEW OR EXAMINE A PATIENT

A. Under the following circumstances, whether or not such circumstances involve the use of telemedicine in providing health care, a licensee may treat a patient who has not been personally interviewed, examined and diagnosed by the licensee:

(1) Situations in which the licensee prescribed medications on a short-term basis for a new patient and has scheduled an appointment to personally examine the patient;

(2) For institutional settings, including writing initial admission orders for a newly hospitalized patient;

(3) Call situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient;

(4) Cross-coverage situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient;

(5) Situations in which the patient has been examined in person by an advanced registered nurse practitioner or a physician assistant or other licensed practitioner with whom the licensee has a supervisory or collaborative relationship;

(6) Emergency situations in which the life or health of the patient is in imminent danger;

(7) Emergency situations that constitute an immediate threat to the public health including, but not limited to, empiric treatment or prophylaxis to prevent or control an infectious disease outbreak;

(8) Situations in which the licensee has diagnosed a sexually transmitted disease in a patient and the licensee prescribes or dispenses antibiotics to the patient's named sexual partner(s) for the treatment of the sexually transmitted disease as recommended by the U.S. Centers for Disease Control and Prevention;

(9) Situations where the patients are in a licensed or certified long term care facility, nursing facility, residential care facility, intermediate care facility, assisted living facility or hospice setting and doing so is within the practice standards for that setting; and

(10) Circumstances in which a patient's treating physician determines that a radiology or pathology consultation is warranted.

20. PRESCRIBING BASED SOLELY ON AN INTERNET REQUEST, INTERNET QUESTIONNAIRE OR A TELEPHONIC INTERVIEW PROHIBITED

Prescribing to a patient based solely on an Internet request or Internet questionnaire (i.e. static questionnaire provided to a patient, to which the patient responds with a static set of answers, in contrast to an adaptive, interactive and responsive online interview) is prohibited. Absent a valid physician-patient relationship, a licensee's prescribing to a patient based solely on a telephonic evaluation is prohibited, with the exception of the circumstances described in Section 19, subsection 3 of this rule.

Telemedicine technologies, where prescribing may be contemplated, must implement measures to uphold patient safety in the absence of traditional physical examination. Such measures should guarantee that the identity of the patient and provider is clearly established and that detailed documentation for the clinical evaluation and resulting prescription is required. Measures to assure informed, accurate and error prevention prescribing practices (e.g. integration with e-Prescription systems) are encouraged. All applicable law shall be complied with.

Prescribing medications, in-person or via telemedicine, is at the professional discretion of the physician. The physician prescribing via telemedicine must ensure that the clinical evaluation, indication, appropriateness, and safety consideration for the resulting prescription are appropriately documented and meet the applicable standard of care. Consequently, prescriptions via telemedicine carry the same accountability as prescriptions delivered during an encounter in person. However, where such measures are upheld, and the appropriate clinical consideration is carried out and documented, physicians may exercise their judgment and prescribe medications as part of telemedicine encounters.

STATUTORY AUTHORITY:

32 M.R.S. §§ 3269(3), 3269(7) (Board of Licensure in Medicine)
32 M.R.S. §2562 (Board of Osteopathic Licensure)

EFFECTIVE DATE:

December 10, 2016 – filings 2016-209, 210

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE

and

383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 10: SEXUAL MISCONDUCT

SUMMARY: This chapter defines sexual misconduct by physicians and physician assistants and sets forth the range of sanctions applicable to violations of this rule pursuant to Title 32 §3269 (7) and 3270-A, B, C., and 32 M.R.S.A. §2562, 2594-C.

§1 DEFINITIONS

1. "Physician" an individual who is qualified and licensed according to the provisions of 32 M.R.S.A. §3270 et seq. and 32 M.R.S.A. §2571 et seq.

2. "Physician Assistant" an individual who is qualified and licensed or certified according to the provisions of 32 M.R.S.A. § 3270-A and 3270-B and 32 M.R.S.A. § 2594-A and 2594-B.

3. "Physician/physician assistant sexual misconduct" is behavior that exploits the physician/physician assistant-patient relationship in a sexual way. This behavior is nondiagnostic and/or nontherapeutic, may be verbal or physical, and may include expressions or gestures that have a sexual connotation or that a reasonable person would construe as such. Sexual misconduct is considered incompetence and unprofessional conduct as defined by 32 M.R.S.A 2591-A (2) and 32 M.R.S.A. 3282 -A (2).

   There are two levels of sexual misconduct: sexual violation and sexual impropriety. Behavior listed in both levels may be the basis for disciplinary action.

   A. "Sexual violation" is any conduct by a physician/physician assistant with a patient that is sexual or may be reasonably interpreted as sexual, even when initiated by or consented to by a patient, including but not limited to:

      1. sexual intercourse, genital to genital contact;

      2. oral to genital contact;

3. oral to anal contact or genital to anal contact;

4. kissing in a sexual manner (e.g. - french kissing);

5. any touching of a body part for any purpose other than appropriate examination, treatment, or comfort, or where the patient has refused or has withdrawn consent;

6. encouraging the patient to masturbate in the presence of the physician/physician assistant or masturbation by the physician/physician assistant while the patient is present; and,

7. offering to provide practice-related services, such as drugs, in exchange for sexual favors.

B. "Sexual impropriety" is behavior, gestures, or expressions by the physician/physician assistant that are seductive, sexually suggestive, or sexually demeaning to a patient, including but not limited to:

1. kissing;

2. disrobing, draping practices or touching of the patient's clothing that reflect a lack of respect for the patient's privacy; deliberately watching a patient dress or undress, instead of providing privacy for disrobing;

3. subjecting a patient to an examination in the presence of another when the physician/physician assistant has not obtained the verbal or written consent of the patient or when consent has been withdrawn;

4. examination or touching of genitals without the use of gloves;

5. inappropriate comments about or to the patient, including but not limited to making sexual comments about a patient's body or underclothing; making sexualized or sexually demeaning comments to a patient, criticizing the patient's sexual orientation (homosexual, heterosexual, or bisexual); making comments about potential sexual performance during an examination or consultation (except when the examination or consultation is pertinent to the issue of sexual

function or dysfunction); requesting details of sexual history or sexual likes or dislikes when not clinically indicated;

6. using the physician/physician assistant-patient relationship to solicit a date or initiate romantic relationship;

7. initiation by the physician/physician assistant of conversation regarding the sexual problems, preferences, or fantasies of the physician/physician assistant; and,

8. examining the patient without verbal or written consent.

§2 SANCTIONS

If the Board finds that a licensee has engaged in sexual misconduct as defined in section 1 of these rules the licensee shall be disciplined in accordance with these rules.

1. All disciplinary sanctions under 32 M.R.S.A. § 2591-A, § 3282-A and 10 M.R.S.A. § 8003 are applicable.

2. Sexual Violations - Findings of sexual violations are egregious enough to warrant revocation of a physician/physician assistant's medical license. Boards may, at times, find that mitigating circumstances do exist and, may impose a lesser sanction.

3. Sexual Impropriety - Findings of sexual impropriety will result in harsh sanction, which may include revocation. Special consideration should be given to at least the following when determining an appropriate sanction:

   A. patient harm;

   B. severity of impropriety;

   C. culpability of licensee;

   D. psychotherapeutic relationship;

   E. inappropriate termination of physician/physician assistant-patient relationship;

   F. age of patient;

   G. physical /mental capacity of patient;

H. number of times behavior occurred;

I. number of patients involved;

J. period of time relationship existed; and,

K. evaluation/assessment results.

STATUTORY AUTHORITY: Title 32 M.R.S.A. §3269 (7) and 3270-A, B, C.
Title 32 M.R.S.A. §2562, 2594-C.

EFFECTIVE DATE: March 12, 1997

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE
380 STATE BOARD OF NURSING
383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 12 Joint Rule Regarding Office Based Treatment of Opioid Use Disorder

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Summary: Chapter 12 is a joint rule of the Board of Licensure in Medicine, the State Board of Nursing, and the Board of Osteopathic Licensure to ensure safe and adequate treatment of opioid use disorder with Approved Medications in an outpatient medical setting that is not a certified Opioid Treatment Program.

RULE INDEX

SECTION 1. DEFINITIONS

1. **Administrative Discharge** means the involuntary process of medically supervised withdrawal from medications for Opioid Use Disorder.

2. **Approved Medications** means medications that are FDA approved for the treatment of Opioid Use Disorder (OUD) in an office based setting that is not a certified Opioid Treatment Program (OTP).

3. **ASAM** means the American Society of Addiction Medicine.

4. **Board** means the Board of Licensure in Medicine, the State Board of Nursing, and the Board of Osteopathic Licensure.

5. **Clinical Discharge** means the voluntary process, agreed upon by both the patient and provider, of medically-supervised withdrawal by gradually tapering medication for ultimate cessation of therapy.

6. **Clinician** means a Maine-licensed physician, physician assistant, or advanced practice registered nurse.

7. **Co-occurring Disorder** means an individual who has a co-existing mental illness and a substance use disorder.

8. **DATA 2000** means the federal Drug Addiction Treatment Act of 2000, which permits clinicians who meet certain qualifications to treat individuals with OUD by prescribing FDA Approved Medications such as buprenorphine.

9. **DATA 2000 Waiver** means a DEA authorization for a licensed clinician who has met the training and credentialing registration requirements of DATA 2000 to prescribe Approved Medications to patients in settings other than OTPs.

10. **DEA** means the Drug Enforcement Administration in the U.S. Department of Justice.

11. **Drug Diversion** means the transfer of a controlled substance from authorized legal and medically necessary use or possession to illegal and unauthorized use or possession.

12. **FDA** means the U.S. Food and Drug Administration.

13. **Informed Consent** means written agreement by a patient to a medical procedure, or for participation in OBOT, after achieving an understanding of the relevant medical facts, risks and benefits, and alternative treatments.

14. **Misuse** means all uses of a prescription medication other than those that are directed by a clinician in accordance with the plan of treatment.

15. **Office Based Opioid Treatment (OBOT)** means providing medication and other non-pharmacologic modalities to treat OUD in outpatient medical settings other than certified OTPs.

16. **Opioid Treatment Program (OTP)** - (sometimes referred to as a "methadone clinic" or "narcotic treatment program") means any treatment program certified by SAMHSA in conformance with 42 Code of Federal Regulations (CFR), Part 8, to provide supervised assessment and medication assisted treatment of patients with OUD. **Only federally certified and accredited OTPs may prescribe and or dispense methadone for the treatment of OUD.**

17. **Opioid Use Disorder (OUD)** means the criteria in the current edition of the Diagnostic and Statistical Manual of Mental Disorders for OUD. (See Appendix 1).

18. **Outpatient** means a medical setting where the patient is not admitted to a hospital, skilled nursing facility or long-term care facility.

19. **Psychosocial Assessment** means an evaluation of the psychological and social factors that are experienced by an individual or family as the result of addiction. The factors may complicate an individual's recovery or act as assets to recovery.

20. **Recovery** means a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.

21. **SAMHSA** means the federal Substance Abuse and Mental Health Services Administration.

22. **Toxicology Tests** means any laboratory analysis for the purpose of detecting the presence of alcohol and/or various scheduled or illicit drugs.

SECTION 2. PURPOSE

The Board is obligated under the laws of the State of Maine to protect the public health and safety. The Board recognizes that medical and advanced nursing practice dictate that the people of the State of Maine have access to appropriate, empathetic and effective treatment of opioid use disorder (OUD). This rule establishes minimum requirements for qualified Office Based Opioid Treatment (OBOT) clinicians to prescribe, and in limited circumstances, dispense approved medications to individuals requiring and seeking treatment for OUD.

The Board recognizes the body of evidence regarding the effectiveness of Approved Medications in the office based treatment of OUD, when such treatment is delivered in accordance with current standards of care, the requirements of the Drug Addiction Treatment Act of 2000 (DATA 2000), and this joint rule. Overdoses and deaths due to approved medications can occur and have been reported. Most overdoses, especially fatal ones, involve the concurrent use of another central nervous system (CNS) depressant such as benzodiazepines, other opioids, or alcohol. Approved Medications such as buprenorphine also pose a significant risk to non-tolerant individuals, especially children. The goal is to provide appropriate treatment of the patient's OUD (either directly or through referral), while adequately addressing other aspects of the patient's functioning, including co-occurring medical and psychiatric conditions and psychosocial issues.

The Board also recognizes the importance of appropriate training and education for clinicians providing OBOT. Clinicians providing OBOT are strongly encouraged to complete continuing education in OBOT and to review the published guidelines of SAMHSA and ASAM that are referenced in this rule, as the Board may use these guidelines, as well as other sources and outside expert reviews, as the standard of care when evaluating OBOT provided by clinicians.

SECTION 3. QUALIFICATIONS

1. Clinicians who wish to provide Approved Medications for OUD in an OBOT must:

   A. Hold a current license issued by the Board;

   B. Hold a current controlled substance registration issued by the DEA;

C. Obtain a DATA 2000 Waiver and complete buprenorphine training;

D. In the case of a physician assistant, be delegated the authority to provide OBOT pursuant to a written plan of supervision by a supervising physician who also meets the criteria for providing OBOT; and

E. Comply with this joint rule.

2. Patient limits. Clinicians must be aware of and comply with limits established by the DEA regarding the number of patients that can be treated with Approved Medications in OBOT.

SECTION 4. PRESCRIPTION REQUIREMENTS

Prescriptions for Approved Medications to treat OUD, must include:

1. The full identifying information for the patient, including his or her name and address;

2. The drug name, strength, dosage form, and quantity;

3. Directions for use;

4. The date on which the prescription is signed, which must be the same day it is issued;

5. If the date the medication is to be filled is different from the date it is written, it must be indicated on the prescription;

6. Both the clinician's regular DEA registration number and the clinician's DATA 2000 identification number (which begins with the prefix X);

7. The appropriate ICD code; and

8. The specific DHHS exemption code for dosage limits (if applicable).

SECTION 5. PRINCIPLES OF PROPER OBOT

1. Develop and Maintain Competency

A. The diagnosis and medical management of OUD should be based on current knowledge and research, and should encompass the use of both pharmacologic and nonpharmacologic treatment modalities. Thus, before

beginning to treat patients for opioid addiction, clinicians must be knowledgeable about OUD and its treatment, including the use of approved pharmacologic therapies and evidence-based nonpharmacologic therapies. Clinicians should consult the DEA regulations and the resources available on the DEA's website. Clinicians are encouraged to complete continuing education in OBOT and to access the following published guidelines on the use of medications for OUD:

1. SAMHSA - TIP 63 - Medication for Opioid Use Disorder (See Appendix 2); and

2. ASAM National Practice Guidelines For the Use of Medications in the Treatment of Addiction Involving Opioid Use (See Appendix 3).

2. OBOT Administration and Operations Requirements

OBOT clinicians shall ensure that all OBOT medical settings have and maintain all of the following in order to initiate and continue prescribing Approved Medications:

A. Sufficient space and adequate equipment to provide appropriate patient care and monitoring, including but not limited to ensuring:

1. Security and privacy for the collection of toxicology samples if samples are to be collected on site;

2. Clean and well maintained environment;

3. Areas where privacy and confidentiality can be maintained; and

4. Protection of all confidential medical information and records in hard copy or electronic formats.

B. Referral arrangements with other clinicians and practitioners to evaluate and treat medical comorbidities and co-occurring disorders to ensure that OBOT is provided in the context of other health issues the patient may have.

3. Clinician Absence and Closure Preparedness

A. Continuity of OBOT Services for Clinician Absence

Each OBOT clinician shall develop and maintain a written plan for the administration of Approved Medications to treat established OUD patients in the event of an absence. The plan should include:

1. Informing patients of alternate care; and

2. Emergency procedures for obtaining prescriptions/access to medications in case of temporary program/office closure. This should include an agreement with another clinician authorized to prescribe Approved Medications or with an OTP. It should also include the ability to transfer or provide access to patient records.

B. Permanent OBOT Program Closure

Each OBOT clinican shall have a written plan for ensuring continuity of care in the event that a future voluntary or involuntary program closure occurs. Clinicians shall have an operational plan for managing a program closure. The plan shall include:

1. Orderly and timely transfer of patients and records to another OBOT clinician; and
2. Notifying patients of transition plans.

4. Clinical Care and Management Requirements

A. Diagnosis of OUD and Acceptance for OBOT

Prior to commencing OBOT, and in addition to ensuring that any patient has a comprehensive medical evaluation as described below in this rule, the OBOT clinician shall assess the patient and diagnose and document an OUD as defined by the current edition of the Diagnostic and Statistical Manual of Mental Disorders.

B. Evaluation of the Patient's Health Status

1. Medical Evaluation

Prior to commencing OBOT, the OBOT clinician shall conduct an appropriate medical, social, and family history, physical examination and necessary laboratory tests (including pregnancy testing), or refer the patient to a medical professional who can perform such an evaluation. Identification of signs and symptoms of opioid use and/or withdrawal, comorbid medical and co-occurring psychological conditions, and how they will be addressed, should be a goal of the medical evaluation. Long-term management is effective for many chronic diseases, including OUD.

2. Psychosocial Assessment and Referral to Services

a. OBOT clinicians shall conduct a psychosocial assessment, or shall refer the patient for such an assessment to another clinician qualified by education, training or experience, or to a licensed mental health provider, before or as soon as possible after the initiation of the OBOT.

b. Based on the outcomes of the psychosocial assessment, the OBOT clinician may recommend to the patient that he or she should participate in ongoing counseling or other behavioral interventions such as recovery programs. Patients should be advised to receive counseling from OBOT clinicians or other qualified licensed providers.

c. An OBOT clinican should not deny or discontinue OBOT based solely on a patient's decision not to follow a recommendation to seek counseling or other behavioral interventions.

C. Developing an OBOT Plan

1. Individuals who are identified by OBOT clinicians as having higher needs for care (e.g. ASAM level 2 or higher), or needing more clinical oversight or structure than available through an OBOT, shall be referred to an appropriate OTP or other more intensive level of care (e.g. inpatient).

2. OBOT clinicians shall register with the Maine Prescription Monitoring Program (MPMP) and comply with Maine's laws and rules regarding reporting on dispensed controlled substances. OBOT clinicians shall check the MPMP prior to initiating OBOT and at least every ninety days thereafter or more frequently when clinically indicated.

3. OBOT clinicians shall adhere to all applicable standards of medical practice for providing treatment.

D. Informed Consent, Patient Treatment Agreement, Releases

Prior to providing OBOT, an OBOT clinician shall:

1. Obtain voluntary, written, Informed Consent to treatment from each patient, which shall include the known risks and benefits of the medication being prescribed.

2. Establish a written treatment agreement outlining the responsibilities and expectations of the OBOT clinician and the patient, which shall include possible reasons for discharge from the practice.

3. Provide OUD patients with education regarding the prevention of opioid overdose. In addition, OBOT clinicians should consider prescribing overdose rescue medications (e.g. naloxone) for all OUD patients.

4. Make reasonable efforts to obtain releases of information for any health care providers or others important for the coordination of care to the extent allowed by the Health Insurance Portability and Accountability Act (HIPAA) and 42 CFR, Part 2.

E. Ongoing Patient Treatment and Monitoring

In addition to following standard clinical practices, OBOT clinicians must adhere to the following provisions:

1. Monitoring for Diversion

To ensure patient and public safety, each OBOT clinician shall develop a written policy outlining their clinical practices to minimize risk of diversion of medications to treat OUD. The frequency of monitoring procedures is based on the unique clinical treatment plan for each patient and his or her level of stability. At a minimum, this plan shall include the following practices:

a. Querying the MPMP;

b. Informing OBOT patients that diversion is a criminal offense;

c. Conducting toxicological tests;

d. Conducting medication counts;

e. For patients receiving services from multiple providers, the coordination of care and sharing of toxicology test results is encouraged;

f. Collecting all toxicological specimens with a standardized protocol and in a therapeutic context; and

g. Addressing and documenting the unexpected results of toxicological tests promptly with patients.

2. Education and Rescue Medications

OBOT clinicians shall provide OUD patients with education regarding the prevention of opioid overdose. In addition, OBOT clinicians should consider prescribing overdose rescue medications (e.g. naloxone) for all OUD patients.

5. Administrative Discharge from OBOT

A. Appropriate administrative discharge from OBOT does not constitute patient abandonment. OBOT clinicians may opt to discontinue prescribing medications for OUD and involuntarily discharge patients from their OBOT in the following situations:

1. Disruptive behavior that has an adverse effect on the OBOT practice, staff or other patients. These include, but are not limited to:

a. Violence;

b. Aggression;

c. Threats of violence;

d. Drug diversion;

e. Trafficking of illicit or prescription drugs;

f. Repeated loitering in or near the OBOT facility; and

g. Conduct resulting in an observable, negative impact on the patient, and/or staff and or other patients.

2. Incarceration or other relevant change of circumstance. However, if the incarceration follows criminal conduct that occurred prior to OBOT, then resumption of OBOT following incarceration is encouraged if clinically indicated.

3. Violation of or noncompliance with the treatment agreement.

4. Nonpayment of fees.

B. When an OBOT clinician or practice decides to administratively discharge an OBOT patient, the clinician must manage the appropriate tapering of buprenorphine or other medication, when it is clinically appropriate, and as long as it does not compromise the safety of patients, clinicians or program staff.

C. A patient who is involuntarily discharged from OBOT should be provided referral information for other OBOT clinicians, OTPs, or other OUD treatment programs. OBOT clinicians shall document referral efforts in the patient's medical record.

D. Factors contributing to the involuntary discharge from the program shall be documented in the patient's medical record.

6. Medical Records

OBOT clinicians shall keep accurate and complete medical records , with emphasis on documentation of and the patient's response to treatment. Information that shall be maintained in the medical record includes:

A. Copies of signed informed consent and treatment agreement;

B. The patient's medical history and any records from prior providers;

C. Documentation of MPMP queries and their effect on treatment;

D. Results of the physical examination, laboratory tests, and toxicological tests;

E. Treatment plan;

F. A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose, frequency and quantity);

G. Results of ongoing monitoring of patient progress (or lack of progress);

H. Notes on evaluations by and consultations with specialists; and

I. Other medical decision making to support the initiation, continuation, revision, or termination of treatment, and the steps taken in response to any abnormal toxicological test results or aberrant medication use behaviors.

7. Reportable Acts

Generally, information gained as part of the clinician/patient relationship remains confidential. However, the clinician has an obligation to deal with persons who use the clinician to perpetrate illegal acts, such as illegal acquisition or selling of drugs; this may include reporting to law enforcement. Information suggesting inappropriate or drug-seeking behavior should be addressed appropriately and documented. Use of the MPMP is mandatory in this situation.

8. Additional Requirements for Special Populations

A. Pregnant Patients

The decision to treat a pregnant patient with buprenorphine or to refer her to an OTP for methadone is one that should be made in conjunction with the patient. Due to the risks of opioid addiction to pregnant women and their fetuses, a pregnant woman seeking OBOT should be given priority for treatment, and every effort should be made for evaluation and treatment as soon as possible. Because of the high risk to the fetus, every effort should be made to maintain pregnant women on medications for OUD during pregnancy. If there is a compelling reason for involuntarily withdrawing a pregnant woman from OUD medications for reasons specified in this rule, the clinician shall refer the woman to the most appropriate obstetric care available and an alternative provider for OUD treatment as soon as possible.

B. Adolescent Patients

OBOT clinicians who do not specialize in the treatment of adolescent OUD should strongly consider consulting with or referring adolescent patients to a more qualified clinician, if available.

C. Patients with Co-occurring Disorders

OBOT clinicians should be aware of potential interactions between medications used to treat co-occurring psychiatric conditions and OUD. All patients with psychiatric disorders should be asked about suicidal ideation and/or attempts behavior. Patients with a history of suicidal ideation or attempts should have OUD and psychiatric medication use closely monitored. OBOT clinicians should consider referral to a mental health clinician, if available.

STATUTORY AUTHORITY:

32 M.R.S. §§ 3269(3),(7), 3300-F; (Board of Licensure in Medicine)
32 M.R.S. §§ 2102(2-A), 2153-A(1), 2210; (State Board of Nursing)
32 M.R.S. §§ 2562, 2600-C; (Board of Osteopathic Licensure)

Resources:

1) SAMHSA – TIP 63- Medication for Opioid Use Disorder
https://store.samhsa.gov/shin/content//SMA18-5063FULLDOC/SMA18-5063FULLDOC.pdf

2) The American Society of Addiction Medicine - National Practice Guidelines For the Use of Medications in the Treatment of Addiction Involving Opioid Use.
https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf

3) Federation of State Medical Boards Model Policy on DATA 2000 and Treatment of Opioid Addiction In the Medical Office. 2013
http://www.fsmb.org/globalassets/advocacy/policies/model-policy-on-data-2000-and-treatment-of-opioid-addiction-in-the-medical-office.pdf

4) Federal Guidelines for Opioid Treatment Programs
https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf

5) SAMHSA-_Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction.
https://www.ncbi.nlm.nih.gov/books/NBK64246/

6) SAMHSA – Maintains a list of all clinicians in Maine who are authorized to provide treatment with Buprenorphine:
https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator?field_bup_physician_us_state_value=ME

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 14: CONTINUING MEDICAL EDUCATION

SUMMARY: Title 32 M.R.S.A. § 2581 requires that every two years the osteopathic physician obtain 100 hours of continuing medical education, at least 40% of which must be osteopathic medical education as defined by the Board. This chapter defines what continuing medical education primary care physicians and osteopathic specialists must obtain in order to satisfy this statutory requirement and sets forth other provisions related to compliance with Section 2581.

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§ 1 DEFINITIONS

1. "AOA" is the American Osteopathic Association.

2. “ACGME” is the American College of Graduate Medical Education.

3. “AMA” is the American Medical Association.

4. “Board” is the Board of Osteopathic Licensure.

5. “CME” is continuing medical education.

6. “Continuing medical education” is any educational activity that is designated as Category 1 and 2 by the AOA or by the ACGME or the AMA.

7. "Osteopathic medical education" for primary care physicians is CME designated by the AOA as Category 1. For osteopathic specialists, osteopathic medical education is considered CME designated as Category 1 by the AOA or the ACGME or the AMA..

8. “Osteopathic specialists”, for the purpose of these rules, means any doctor of osteopathy not considered a primary care physician as defined below.

9. “Primary care physicians” means family or general practitioners, general internists, and general pediatricians.

10. “Satisfactory evidence” means a print out from the AOA, sponsor generated documentation evidencing attendance or completion of a CME program, completed and scored CME quiz, or other appropriate documentation acceptable to the Board.

§ 2 CONTINUING MEDICAL EDUCATION

1. Biennial Reports to the Board. As part of the renewal application, each physician licensed by the Board of Osteopathic Licensure pursuant to Title 32, chapter 36, must append satisfactory evidence or complete a form prescribed by the board certifying that the physician has obtained 100 hours of continuing medical education during the two years preceding the renewal of the physician's license. At least 40 of the 100 hours of continuing medical education obtained must be osteopathic medical education, as defined by the Board in Section 1, sub-section 6.

2. Failure to provide evidence. If the physician fails to report to the Board by January 1 of each even numbered year that the physician has obtained the number of hours of continuing medical education and osteopathic medical education required the Board will send notice of this deficiency to the physician by first class mail after January 1st of that year.

3. Lapse of license. The physicians license will lapse on the 31st day following the receipt of the notice letter from the Board, referred to in sub-section 2 unless the physician provides the Board with satisfactory evidence that he has obtained the required CME described in Section 2, sub-sections 1 or the physician has filed a petition in accordance with Section 2, sub-section 5, within 30 days of receipt of the notice letter.

   A physician whose license has lapsed in accordance with this sub-section, is not authorized to practice osteopathic medicine in Maine beginning on the 31st day after receipt of the notice letter described in the previous sub-section, until the Board reinstates the physician's license.

4. Reinstatement of license. Provided all other requirements for renewal have been met, the physicians license may be reinstated by the Board upon submission of satisfactory evidence that the physician has completed the number of continuing medical education hours required by these rules. Depending on the period of time before reinstatement is requested, the Board may require that the physician file a new application for renewal and pay a new renewal fee.

5. Illness, hardship or military service. If the physician has been unable to obtain the number of hours of continuing medical education required for renewal due to illness, hardship or military service, or other good cause, the physician may petition the Board in writing to either waive the requirement or to enter into a consent agreement which will allow the physician additional time to obtain the required CME hours.

   A. The petition must be supported by appropriate documentation to demonstrate the reason for the CME deficiency and, if an extension is requested, must be accompanied by a proposal for when and how the physician proposes to make up the deficiency.

B. The Board will review the petition and notify the physician of its decision to grant or deny the petition or it may offer the physician the opportunity to attend an informal conference prior to acting upon the petition.

C. If the physician is aggrieved by the Board's decision regarding the petition, the physician may request, within 30 days of receipt of the Board's decision regarding the petition, that the Board hold an adjudicatory hearing regarding the physician's petition, in accordance with the Maine Administrative Procedure Act.

D. If the physician fails to appeal the notice of denial or, if the Board denies the petition after hearing, the physician's license will lapse and must be reinstated in accordance with subsection 4.

§ 3 RANDOM AUDITS.

1. In each odd numbered year, the Board will conduct a random audit of 10% of the licensed physicians to verify the information regarding continuing medical education contained on the reporting form submitted pursuant to Section 2, sub-section 1, of these rules.

2. When the renewal application is sent to the physician, the Board will inform physicians of the requirement of the random audit and the necessity of retaining satisfactory evidence to verify the information reported to the Board regarding continuing medical education.

3. Within 30 days of the receipt of the request from the Board, each physician selected to participate in the random audit is required to produce satisfactory evidence of having obtained the hours reported to the Board at the time of the previous renewal.

4. If the physician is not able to produce satisfactory evidence of compliance with 32 M.R.S.A. § 2581, the Board will notify the physician of the deficiency. The procedures in Section 2, sub-sections 3 through 5, are applicable, except that a new application and a new renewal fee will be required prior to any reinstatement.

5. The Board may also take any other disciplinary action authorized by law, as appropriate.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 2562 & 2581.

EFFECTIVE DATE:
July 27, 1998

AMENDED:
November 8, 1999

02 DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION

383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 16: PRESCRIBING AND TREATMENT FOR SELF AND FAMILY MEMBERS

SUMMARY: The purpose of these rules is to identify under what circumstances it is appropriate for a physician or physician assistant to treat self and family members.

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§1 DEFINITIONS

1. "Acute problem" is one expected to persist no longer than one month but which requires intervention on an immediate basis.

2. "Board" is the Board of Osteopathic Licensure.

3. "Chronic problem" is one previously diagnosed and treated by another which by circumstance requires interim adjustment or continuation of treatment.

4. "Emergency" is a condition threatening a person's life or limb when left untreated.

5. "Immediate family members" are spouse, significant other(s), child(ren), parent(s), person(s) living in the home of the physician or physician assistant, or others for whom the physician or physician assistant is legally responsible.

6. "Isolated setting" is one removed from access to routine or alternate sources of care due to the unreasonable distance or time needed to obtain these services.

7. "Physician", for the purposes of these rules, means any physician licensed by the Board to practice osteopathic medicine.

8. "Physician Assistant" means any physician assistant licensed by the Board to perform delegated medical activities under the supervision of a physician licensed to practice osteopathic medicine.

9. "Treat" or "Treatment" includes, but is not limited to:

   A. diagnosis of a physical or psychological condition;

   B. prescribing various therapies to resolve, ameliorate or rehabilitate a diagnosed condition;

C. dispensing of non-controlled or controlled substances;

D. writing a prescription for controlled or non-controlled substances;

E. radiological procedures;

F. surgical therapies, and

G. psychotherapy.

§2 PRESCRIBING AND TREATMENT FOR SELF AND FAMILY MEMBERS

Physicians may treat themselves or immediate family members, under the following circumstances:

A. Physicians may treat themselves or immediate family members in emergency situations when there are no other qualified physicians that are reasonably available to address the emergency.

B. Physicians may treat themselves and immediate family members for acute problems.

C. Physicians may treat their own chronic problems or those of immediate family members for a period no longer than two months when in an isolated setting or when regular care is not otherwise reasonably available and the delay involved in obtaining treatment from a routine or alternate source of medical care may result in an emergency or acute exacerbation of the chronic problem.

D. Physicians may also treat themselves and family members for seasonal problems.

E. Following the provision of care under A., B., C., the physician must promptly seek treatment from another physician or promptly refer the immediate family member to another qualified physician for follow-up.

F. Under the circumstances described in A., B. & C., the physician is held to the same standard of care applicable to physicians providing treatment for patients who are not immediate family members, and the physician must only treat within the physician’s expertise and training.

§3 PHYSICIAN ASSISTANTS

Physician assistants must not treat themselves or immediate family members, except in an emergency situation, unless under the direction of the supervising physician.

§4 RECORD KEEPING

When physicians or physician assistants treat themselves or immediate family members pursuant to these rules, the physician and physician assistant must maintain the same standard of record-keeping applicable to a patient who is a non-family member under the same circumstances.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 2562 & 2581

EFFECTIVE DATE:
June 27, 2001

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 17: PHYSICIAN/PHYSICIAN ASSISTANT - PATIENT BOUNDARIES - GIFTS

SUMMARY: The purpose of this rule is to identify under what circumstances the giving or receiving of gifts by a physician or physician assistant is considered as unprofessional conduct.

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§ 1 DEFINITIONS

1. "Board" is the Board of Osteopathic Licensure.

2. "Immediate family members" are spouse/partner, dependent children, persons living in the home of the physician or physician assistant, or persons for whom the physician or physician assistant is legally responsible.

3. "Physician" is an individual who is qualified and licensed according to the provisions of 32 M.R.S.A. § 2571 *et seq*.

4. "Physician assistant' is an individual who is qualified and licensed or certified according to the provisions of 32 M.R.S.A. §§ 2594-A and 2594-B.

5. "Significant monetary value" means a value of Fifty Dollars ($50.00) or over.

6. "Slight monetary value" means a value under Fifty Dollars ($50.00).

§ 2 GIFTS

1. It is considered unprofessional conduct as defined by 32 M.R.S.A. § 2591-A(2)(F) if a physician or physician assistant:

   A. accepts from a patient a gift of significant monetary value, frequent gifts of any monetary value, or a gift of a highly personal or intimate nature when the receipt of such gifts interferes with or has a reasonable likelihood of interfering with an appropriate patient-physician relationship;

   B. gives a patient a gift of significant monetary value, frequent gifts of any value, a gift of a highly personal or intimate nature, or refrains from charging a fee when this is not necessitated by the patient's financial condition;

C. permits immediate family members to accept or to give gifts to patients when this interferes with or has the reasonable likelihood of interfering with an appropriate patient-physician relationship;

D. encourages a patient to bequeath or otherwise give money or anything of significant monetary value to the physician or physician assistant after the patient's death, or does not actively discourage the patient when the physician or physician assistant is informed of the patient's intent to do so, or

E. encourages a patient to donate money or anything of significant monetary value or does not actively discourage the patient when the physician or physician assistant is informed of the patient's intent to do so and the donation has the potential for creating a conflict of interest which interferes with or has a reasonable likelihood of interfering with appropriate care of the patient.

2. This rule is not intended to prohibit the physician or physician assistant from accepting certain gifts, such as homemade baked goods and crafts, garden vegetables, photographs and cards that are frequently given by patients around holidays, or to prevent a one time gift of a slight monetary value that has sentimental value for the patient and is given to express gratitude to the physician or physician assistant.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 2562 & 2581.

EFFECTIVE DATE:

December 23, 2002 - filing 2002-475

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 19: PHYSICIAN – SCHEDULE FOR LICENSE RENEWALS

SUMMARY: The purpose of this rule is to describe the schedule for renewal of an osteopathic physician's license.

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§ 1. DEFINITIONS

1. **Board.** "Board" is the Board of Osteopathic Licensure.

2. **Physician**. "Physician" is an individual who is qualified and licensed according to the provisions of 32 M.R.S.A. § 2571 *et seq.*

§ 2. EXPIRATION OF PREVIOUS LICENSE.

Beginning with licenses expiring after December 31, 2003, regardless of the date of initial licensure or last license renewal,

1. the license of every physician born in an even-numbered year expires at midnight in 2004 on the last day of the month of the physician birth; and

2. the license of every physician born in an odd-numbered year expires at midnight in 2005 on the last day of the month of the physician birth.

§ 3. SCHEDULE FOR RENEWAL

1. Upon expiration of the license as stated in Section 2, a physician must file a timely and sufficient application with the Board to renew the license issued pursuant to 32 M.R.S.A. § 2581 every two years by the last day of the month of birth of the physician seeking license renewal, on forms prescribed and supplied by the Board.

   Example A: Physician A's birth date is February 29, 1966. After December 31, 2003, Physician A must submit a signed and completed application, on forms prescribed and supplied by the Board, by midnight on February 29, 2004 and must be renewed again by February 28, 2006 and each and every even- numbered year thereafter by the last day of Physician A's birth month.

   Example B: Physician B's birth date is July 5, 1957. After December 31, 2003, Physician B must submit a signed and completed application, on forms prescribed and supplied by the Board, by midnight on July 31, 2005 and must be renewed again by July 31, 2007 and every odd numbered year thereafter by the last day of Physician B's birth month.

STATUTORY AUTHORITY: 32 M.R.S.A. § 2581

EFFECTIVE DATE:
April 14, 2003

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE
380 STATE BOARD OF NURSING
383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 21: USE OF CONTROLLED SUBSTANCES FOR TREATMENT OF PAIN

SUMMARY: Chapter 21 is a joint rule of the Board of Licensure in Medicine, the State Board of Nursing, and the Board of Osteopathic Licensure to ensure safe and adequate pain management for the citizens of Maine.

RULE INDEX

SECTION 1. PURPOSE

The Boards are obligated under the laws of the State of Maine to protect the public health and safety. The Boards recognize that medical and advanced nursing practice dictate that the people of the State of Maine have access to appropriate, empathetic and effective pain management. The application of up-to-date knowledge and treatment modalities can help restore function and thus improve the quality of life of patients who suffer from pain, especially chronic pain.

The Boards recognize that controlled substances, including opioid analgesics, may be essential in the treatment of acute and chronic pain, whether due to cancer or non-cancer origins. However, the Boards are also aware that the inappropriate prescribing of controlled substances poses a threat to the patient and society, and may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical uses. Controlled substance abuse and overdoses have become very serious public health problems in the United States and Maine. In October 2015, the Maine State Epidemiological Outcomes Workgroup (SEOW) issued a special report on heroin, opioids, and other drugs in Maine.[1] The executive summary of that report included:

- Prescription drugs continue to represent a serious public health concern.
- Prescription drug misuse continues to have a large impact on treatment, mortality/morbidity, and crime in Maine.
- Pharmaceutical drugs contribute to the majority of drug overdose deaths.
- As the availability of prescription narcotics has leveled off, heroin use and the consequences thereof have been on the rise.
- Availability and accessibility of opioids continues to be a problem.

[1] Maine Department of Health and Human Services, Office of Substance Abuse. SEOW Special Report: Heroin, Opioids, and Other Drugs in Maine. October 2015.
http://www.maine.gov/dhhs/samhs/osa/data/cesn/Mental_Health_in_Maine_SEOW.pdf .

According to the SEOW report, from 2009 to 2014 drug-related overdose deaths went up each year. In 2014, there were 208 drug-related overdose deaths compared to 131 motor vehicle related deaths. Of the 208 drug-related deaths, 186 (89%) involved pharmaceutical drugs. According to the Maine Attorney General's Office, in 2015 there were 272 drug-related overdose deaths in Maine – an increase of 31% over 2014.[2] The increase was attributed to heroin or fentanyl or a combination of the two drugs. In addition, overdose deaths (157) caused by illegal drugs like heroin exceeded overdose deaths (111) caused by pharmaceutical opioids. In December 2015, the CDC issued a new report[3] on opioid overdose deaths in the U.S., which included the following observations:

- There is an epidemic of drug overdose (poisoning) deaths in the United States.
- Since 2000, the rate of deaths from drug overdoses has increased 137%, including a 200% increase in the rate of overdose deaths involving opioids (opioid pain relievers and heroin).
- In 2014 there were 47,055 drug overdose deaths in the United States.
- The opioid epidemic is worsening.
- Maine was one of 14 states with statistically significant increases in the rate of drug overdose deaths from 2013-2014.
- Opioids – primarily prescription pain relievers and heroin - are the main drugs associated with overdose deaths.
- Natural and semisynthetic opioids – which include the most commonly prescribed opioid pain relievers oxycodone and hydrocodone – continue to be involved in more overdose deaths than any other opioid type.
- Heroin drug overdoses tripled in 4 years – and are closely tied to opioid pain reliever misuse and dependence**.**
- Reversing this epidemic of opioid drug overdose deaths requires intensive efforts to improve safer prescribing of opioids.

In 2016, on a national level prescriptions for narcotic medications were down 16% from their peak in 2011.[4] However, in 2016, there were 376 opiate-related overdoses in Maine (representing a 38% increase over 2015). The vast majority (84%) were caused by at least one opioid, including pharmaceutical and illicit opioid drugs. Pharmaceutical opioid deaths (33%) remained mostly stable; however, the number of deaths caused by hydrocodone increased substantially from 2 in 2015 to 18 in 2016.[5] Accordingly, the purpose of this rule is to require that clinicians, consistent with the "CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016,"[6] first consider the use of non-pharmacologic modalities and non-controlled drugs in the treatment of pain prior to prescribing controlled substances. Clinicians shall also be required to use and document Universal Precautions when prescribing controlled substances for the treatment of pain, including conducting a risk assessment to minimize the potential for adverse effects, abuse, misuse, diversion, addiction and overdose from controlled substances. Diversion and "doctor

[2] Gagnon, Dawn. "Overdose Deaths Hit Record High in Maine." *Bangor Daily News*. Mar. 8, 2016, p. A1.
[3] "Increases in Drug and Opioid Overdose Deaths – United States 2000-2014." U.S. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 64, December 18, 2015.
[4] Doug Long (IMS Health), "The U.S. Pharmaceutical Market: Trends and Outlook," August 7, 2016.
[5] Marcella H. Sorg, PhD (2016) "Expanded Maine Drug Death Report for 2016," Margaret Chase Smith Policy Center, University of Maine.
[6] "CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016," U.S. Department of Health and Human Services Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 65, March 15, 2016. http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

shopping" account for 40% of drug overdose deaths in the United States.[7] To address this issue, clinicians have an obligation to utilize the PMP. While appropriate pain management is the clinician's responsibility, inappropriate treatment of pain may result from a clinician's lack of knowledge about pain management. Therefore, clinicians who prescribe controlled substances are required to maintain current clinical knowledge by complying with continuing education requirements set forth in this rule. In addition, clinicians shall comply with all applicable state and/or federal laws regarding prescribing of controlled substances.

The Boards also recognize that tolerance and physical and psychological dependence are normal consequences of the sustained use of opioid analgesics and are not the same as addiction, but addiction is a definite risk of such treatment. Clinicians shall offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

The Boards will evaluate allegations of inappropriate prescribing of controlled substances by referring to current clinical practice guidelines, including the "CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016." In addition, the Boards will review compliance with this rule, and when necessary, employ expert review in evaluating clinician prescribing of controlled substances. Clinicians should not fear disciplinary action from the Boards for prescribing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice if they are following standards of care, established guidelines and the requirements of this rule. Judgement regarding the propriety of any specific course of action must be made based on all of the circumstances presented, and thoroughly documented in the patient's medical record.

SECTION 2. DEFINITIONS

1. **Abuse** – A maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence, addiction, or that is other than the purpose for which the medication was prescribed.

2. **Acute pain** – The normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically associated with invasive procedures, trauma and disease. Acute pain is generally time limited, often lasting less than 90 days.

3. **Addiction** – A primary, chronic, neurobiologic disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. Addiction is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

4. **CDC** – U.S. Department of Health and Human Services Centers for Disease Control and Prevention.

[7] Paulozzi, L. Baldwin, G., Franklin, G., Ghiya, N., & Popovic, T. (2012). CDC Grand Rounds: Prescription Drug Overdoses – a U.S. epidemic. Center for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), 61(01), 10-13. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm.

5. **Chronic Pain** – A state in which pain persists beyond the usual course of an acute disease or healing of an injury that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain for more than 90 days and may last months or years.

6. **Clinician** – An allopathic (MD) or osteopathic (DO) physician, physician assistant (PA), advanced practice registered nurse (APRN), or podiatrist (DPM).

7. **Controlled Substance** – A drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA), as amended; see 21 U.S.C. §801, et seq. Most opioid analgesics are classified as Schedule II or III under the CSA, indicating that they have a significant potential for abuse, a current acceptable medical use, and that abuse of the drug may lead to severe psychological or physical dependence.

8. **Drug Diversion**- The transfer of a controlled substance from authorized legal and medically necessary use or possession to illegal and unauthorized use or possession.

9. **Functional Assessment**- An objective review of an individual's ability to perform key activities of daily living including mobility, self-care, ability to do household chores, work and engage in social interactions. It is used to establish or determine appropriate therapeutic interventions.

10. **Medical Emergency –** Means an acute injury or illness that poses an immediate risk to a person's life or long-term health.

11. **Misuse** – All uses of a prescription medication other than those that are directed by a clinician, used by a patient within the law, and within the plan of treatment.

12. **Morphine Milligram Equivalent (MME)** - A conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

13. **Opioid** – Any compound that binds to an opioid receptor in the central nervous system (CNS), including naturally occurring, synthetic or semi-synthetic, and endogenous opioid peptides.

14. **Opioid Agonists** – Drugs that bind to the opioid receptors and provide pain relief. Examples include morphine, oxycodone, hydromorphone, fentanyl, codeine, and hydrocodone. Buprenorphine is a partial agonist, meaning it activates the opioid receptors in the brain, but to a much lesser degree than a true opioid.

15. **Opioid Antagonists** – Drugs that cause no opioid effect and block full agonist opioids such as morphine. Examples are naltrexone and naloxone. Naloxone is sometimes used to reverse a heroin overdose.

16. **Opioid Use Disorder** – See Diagnostic and Statistical Manual of Mental Disorders (DSM) DSM-5 criteria. https://www.buppractice.com/node/1514.

17. **Pain** – An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

18. **Palliative Care** – Is defined in Title 22 M.R.S., section 1726, subsection 1, paragraph A, and means patient-centered and family-focused medical care that optimizes quality of life by anticipating, preventing and treating suffering caused by a medical illness or a physical injury or condition that substantially affects a patient's quality of life, including, but not limited to, addressing physical, emotional, social and spiritual needs; facilitating patient autonomy and choice of care; providing access to information; discussing the patient's goals for treatment and treatment options, including, when appropriate, hospice care; and managing pain and symptoms comprehensively. Palliative care does not always include a requirement for hospice care or attention to spiritual needs.

19. **Serious illness** - Is defined in Title 22 M.R.S., section 1726, subsection 1, paragraph B, and means a medical illness or physical injury or condition that substantially affects quality of life for more than a short period of time. "Serious illness" includes, but is not limited to, Alzheimer's disease and related dementias, lung disease, cancer, heart, renal or liver failure, and chronic, unremitting or intractable pain such as neuropathic pain.

20. **Physical Dependence** – A state of adaptation manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

21. **Substance Abuse** – The use of any substance(s) for non-therapeutic purposes or for purposes other than those for which it is prescribed.

22. **Substance Misuse** - The use of a medication (with therapeutic intent) other than as directed or as indicated, and whether harm results or not.

23. **Tolerance** – A state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction.

24. **Universal Precautions** - A standardized approach to the assessment and ongoing management of all pain patients who are prescribed controlled substances.

SECTION 3. PRINCIPLES OF PROPER PAIN MANAGEMENT

1. Develop and Maintain Competence

Clinicians must achieve and maintain competence to assess and treat pain to improve function. This includes understanding current, evidence-based practices and using other resources and tools related to opioid prescribing. In some situations, consultation with a specialist is appropriate. Not all pain requires opioid treatment, and clinicians should not prescribe opioids when non-opioid medication is both effective and appropriate for the level of pain and function of the patient.

2. Universal Precautions

Because of the potential harmful effects of controlled substances, all clinicians prescribing them must employ Universal Precautions unless unable to do so as a result of a genuine "medical emergency" as defined in Section 2 of this rule. Universal

Precautions is a standardized approach to the assessment and ongoing management of all patients whose pain is being treated with controlled substances. The Boards recognize the fact that prescribing controlled substances carries with it the risk of physical and/or psychological dependency in patients, regardless of a pre-existing substance use disorder and that certain combinations of controlled substances and certain drug dosages further increase the risk of patient overdoses. The use of Universal Precautions is designed to mitigate the risk posed by prescribing controlled substances while simultaneously managing patient pain and any possible co-occurring medical issues. The elements of Universal Precautions are detailed below.

A. **Evaluation of the Patient**

(1) **Medical History and Physical**

Before prescribing any controlled substances to a patient for acute or chronic pain, a clinician shall perform an initial medical history and appropriate physical examination and evaluation of the patient, which must be documented in the patient's medical record. The documentation shall include:

(a) Duration, location, nature and intensity of pain.

(b) The effect of pain on physical and psychological function, such as work, relationships, sleep, mood.

(c) Coexisting diseases or conditions.

(d) Allergies or intolerances.

(e) Current substance use.

(f) Any available diagnostic, therapeutic or laboratory results.

(g) Current and past treatments of pain including consultation reports.

(h) Documentation of the presence of at least one recognized medical indication for the use of controlled substances if one is to be prescribed.

(i) All medications with date, dosage and quantity.

(2) **Risk Assessment**

Before prescribing or increasing the dose of any controlled substances to a patient for acute or chronic pain, a clinician shall perform and document a risk assessment of the patient. The risk assessment is meant to determine whether the potential benefits of prescribing controlled substances outweighs the risks, and includes factors involved in a patient's overall level of risk of developing adverse effects, abuse,

addiction or overdose. For acute pain, a basic consideration of short term risk shall be assessed.

For the treatment of chronic pain, the use of an appropriate risk screening tool is encouraged. The following factors should be considered as part of the risk assessment:

(a) Personal or family history of addiction or substance abuse/misuse.

(b) History of physical or sexual abuse.

(c) Current use of substances including tobacco.

(d) Psychiatric conditions; especially poorly controlled depression or anxiety. Use of a depression screening tool may be helpful.

(e) Regular use of benzodiazepines, alcohol, or other central nervous system medications.

(f) Receipt of opioids from more than one prescribing practitioner or practitioner group.

(g) Aberrant behavior regarding opioid use, such as repeated visits to an emergency department ("ED") seeking opioids.

(h) Evidence or risk of significant adverse events, including falls or fractures.

(i) History of sleep apnea or other respiratory risk factors.

(j) Comorbidities that may affect clearance and metabolism of the opioid medication.

(k) Possible pregnancy. Assess pregnant women taking opioids for opioid use disorder. If present, refer to a qualified specialist.

The clinician shall document in the patient's medical record a statement that the risks and benefits have been assessed.

B. **Treatment with Controlled Substances**

(1) **Treatment Plan**

The written treatment plan shall be documented in the patient's medical record. It shall state objectives, beyond subjective reports of pain, that will be used to determine treatment success, such as pain reduction and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. Specific functional goals shall be identified. Understanding that some pain cannot be fully relieved, realistic outcomes and expectations of treatment shall

be discussed with the patient. Regular physical activity should be considered as part of the treatment plan unless contraindicated.

Opioids should be prescribed only if the clinician reasonably concludes that other treatment modalities including non-pharmacological treatments, and non-opioid alternatives up to a maximum recommended by the CDC or dictated by patient safety, have been inadequate to address the patient's pain and functionality. Other treatment modalities, referrals, or rehabilitation programs should be discussed with the patient and documented in the patient's medical record. This does not mean that all patients should expect to fail non-pharmacologic therapy before proceeding to opioids, but the benefits must outweigh the risks.

If a clinician is continuing treatment of chronic pain on a patient who was previously treated with long term controlled substances by another clinician, that patient requires re-assessment of the prior work up, non-pharmacologic treatment and appropriateness of the controlled substance dosing.

(2) **Initiating or Continuing Prior Opioid Therapy**

When prescribing controlled substances, clinicians shall:

(a) Prescribe the lowest possible dosage to a controlled substance naïve patient and titrated to effect based on a documented functional assessment.

(b) Prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) when first initiating pain treatment. Long acting forms are more appropriate for chronic pain patients when immediate release forms are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

(c) When prescribing controlled substances for the treatment of chronic pain, clinicians shall present it as a therapeutic trial for a defined period of time, and for no more than 30 days. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.

(d) **Dosage Limits**

(i) The dosage of the combination of opioid medication in an aggregate amount must not exceed 100 MME per day unless the patient meets one of the exemptions to dosage limits identified below.

(ii) Any patients who have been prescribed more than 100 MME per day prior to January 1, 2017, their aggregate dosage cannot exceed 300 MME per day, and those

patients who do not meet any exemptions to the dosage limits must be weaned below 100 MME per day by July 1, 2017.

(e) **Exemptions to Dosage Limits**

(i) Pain due to active cancer or cancer treatment or aftercare cancer treatment post-remission (Exemption Code A).

(ii) Palliative care in conjunction with a serious illness (Exemption Code B).

(iii) Hospice/end of life care (Exemption Code C).

(iv) Medically assisted treatment of substance use disorder (Exemption Code D).

(v) Medication is being directly ordered or administered in an emergency department setting, an inpatient hospital setting, a long-term care facility or a residential care facility or in connection with a surgical procedure (in or out patient).

(vi) A pregnant individual with a pre-existing prescription for opioids in excess of the 100 MME aggregate daily limit. This exemption applies only during the duration of the pregnancy (Exemption Code E).

(vii) Acute pain for an individual with an existing opioid prescription for chronic pain. In such situations, the acute pain must be post-operative or new onset. The seven day prescription limit applies (Exemption Code F).

(viii) Individuals pursuing an active taper of opioid medications, with a maximum taper period of six months, after which time the opioid limitations will apply, unless one of the other exceptions applies (Exemption Code G).

(ix) Individuals who are prescribed a second opioid after proving unable to tolerate a first opioid, thereby causing the individual to exceed the 100MME limit for active prescriptions. For this exemption to apply, each individual prescription must not exceed 100 MME (Exemption Code H).

(x) Any exception identified in any rule promulgated by the Maine Department of Health and Human Services.

(f) **Prescription Requirements/Restrictions**

(i) Electronic Prescriptions: Effective July 1, 2017, prescriptions for controlled substances must be submitted electronically to the dispensing pharmacy unless the clinician's practice has obtained a waiver from the Commissioner of Health and Human Services.

(ii) Prescriptions for opioids that are prescribed for "palliative care" which will cause the patient to exceed the 100 MME aggregate daily limit must contain a diagnosis code (ICD-10) and an exemption code identified by any rule promulgated by the Maine Department of Health and Human Services.

(iii) Prescriptions for chronic pain shall be limited to a 30 day supply within a 30 day period. Although it is recommended that prescriptions for chronic pain be filled in multiples of 7 to reduce risk of weekend refill requests, with a maximum 28 day supply in a 28 day period.

(iv) Prescriptions for acute pain shall be limited to a 7 day supply within a 7 day period, unless the opioid product is labeled by the federal Food and Drug Administration to be dispensed only in a stock bottle that exceeds a 7-day supply as prescribed, in which case the amount dispensed may not exceed a 14-day supply.

(g) For high risk patients, consider equipping the patient, or others designated by the patient, with opioid antagonists (e.g. Naloxone) for the possible event of overdose.

(h) Avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

(3) **Periodic Review of Treatment Efficacy**

The clinician shall periodically review and document in the patient's medical record the course of pain treatment and any new information about the etiology of the pain or the patient's state of health and level of function. The frequency of review shall be determined by the patient's risk factors, the medication dose and other clinical indictors, and shall comply with the following:

Level of Risk	**Recommended Frequency**
Low risk and doses < 30 mg daily MME	Every 6-12 months
Low risk	Every 6 months
Moderate risk	Every 3 months
High risk or Opioid doses > 90 mg/day daily MME	Every 1-3 months

During the periodic review, the clinician shall determine and/or perform the following actions, which shall be documented in the patient's medical record:

(a) If pain, function, or quality of life have improved or diminished using patient history and collateral information from family members or other caregivers. Collateral information of the patient's condition may include an ongoing assessment of the patient's functional status, such as the ability to engage in work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Clinicians should also use measuring tools to assess the patient's level of pain, function and quality of life.

(b) If continuation or modification of medications for pain management treatment is necessary based on the clinician's evaluation of progress towards treatment objectives.

(c) If there are any new or ongoing comorbidities (such as COPD, liver or renal failure, sleep apnea) or medications that may increase the risk for adverse effects such as overdose.

(d) Patient adherence to the treatment plan.

(e) Review the patient's Prescription Monitoring Program profile if not done within the last 90 days.

(f) Calculate the patient's daily MME if there has been a dosage change.

If the patient's progress or compliance with the current treatment plan is unsatisfactory, the clinician shall consider tapering, changing or discontinuing treatment with controlled substances.

(4) **Consultation or Referral**

The clinician shall consult or refer, as necessary, for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients who:

(a) May benefit from psychoactive medications, such as benzodiazepines, because they may be at higher risk.

(b) Have a high risk for medication abuse, diversion, such as those on greater than daily 90 MME.

(c) Are at high risk for adverse effects from multiple co-morbidities or polypharmacy, especially the elderly.

Customary referrals may include: Physical, Occupational, Osteopathic or Chiropractic Therapy; Physiatry; Surgery; Chronic Pain Clinic; Geriatric consult; Psychiatric evaluation or counseling; and Methadone or Suboxone treatment for opioid addiction. Clinicians shall consider behavioral interventions to improve patient self-efficacy and address psychosocial barriers to recovery, such as Cognitive Behavioral Therapy, Mindfulness-Based Stress Reduction, yoga, acupuncture, etc.

(5) **Patients with Opioid Use Disorder**

Patients being treated for opioid use disorder with Suboxone, Methadone, Naloxone or any other medication who develop conditions causing acute pain may find it difficult to get the care they need because clinicians may feel wary of prescribing opioids to these patients. Yet they deserve a full evaluation and treatment of their pain. Prompt consultation with a pain or addiction specialist should be considered.

(6) **Coordination of Care**

Clinicians prescribing opioids to patients who have signed a narcotic contract with another clinician, shall contact that clinician to coordinate care if there are questions about treatment or concern for adverse effects of additional treatment or concerns of misuse.

(7) **Discontinuing Opioid Therapy**

If opioid therapy is discontinued, be it for treatment agreement violations, recurrent drug seeking behavior, lack of efficacy or adverse effects, the patient who has become physically dependent should be provided with a safely structured tapering regimen when appropriate. Withdrawal can be managed either by the prescribing clinician or by referring the patient to an addiction specialist. For patients with addiction/opioid use disorder, clinicians should offer or arrange for evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies). The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists.

C. **Informed Consent**

Before prescribing any controlled substances to a patient for 90 days or more for chronic pain, the clinician shall discuss and obtain a written signed consent on the risks and benefits of the use of controlled substances with the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative. The informed consent form shall at a minimum include the following benefits and risks:

(1) **Benefits**

(a) Reduction in pain.

(b) Improved physical and psychological functioning.

(2) **Risks**

(a) Side effects of the specific medication being used. These may include nausea, vomiting, constipation, drowsiness and impaired motor skills, cognitive impairment, falls, sexual dysfunction, and the potential for life-threatening respiratory depression.

(b) Ability to safely operate a vehicle in any mode of transportation.

(c) Allergic reactions.

(d) Interactions with other medications.

(e) The likelihood that tolerance to and physical and/or psychological dependence on the medication will develop with prolonged use.

(f) The risk of opioid misuse, addiction and potentially fatal overdose (especially when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates), and the fact that this risk rises as the dose increases.

(g) In the case of physical dependence or addiction, patient awareness that sudden decreases or discontinuation of the medication may result in withdrawal symptoms, which may include abdominal pain and cramping, vomiting, diarrhea, irritability, shakiness, insomnia, body aches and increased pain.

(h) The risk of potentially fatal overdose as a result of accidental exposure, especially by children.

(i) Women who are or may become pregnant should be counseled that opioid use during pregnancy is associated with adverse pregnancy outcomes such as preterm delivery, poor fetal growth, and stillbirth. Their child may also be born addicted to opioids and at risk for neonatal abstinence syndrome.

D. **Prescription Monitoring Program (PMP)**

(1) Querying and Assessing Requirements on or after January 1, 2017. Prescribers must check the PMP:

(a) Before initially prescribing any benzodiazepine for any diagnosis.

(b) Before initially prescribing any controlled substance to a patient for the treatment of acute or chronic pain, a clinician or his/her

designee shall request patient prescribing information from the PMP that covers at least the previous 12 months and document the PMP check in the patient's medical record. The PMP must be queried at intervals not to exceed 90 days for as long as that prescription is renewed. More frequent queries are encouraged for high risk patients, at the discretion of the clinician.

(c) Under any of the circumstances described above, the clinician is responsible for reviewing and assessing the PMP information, which shall include:

(i) Checking the aggregate daily MME (to include any new prescription) for the person for whom medication may be prescribed;

(ii) Checking the number of clinicians currently prescribing controlled substances to the person for whom medication may be prescribed; and

(iii) Checking the number of pharmacies currently filling prescriptions for controlled substances to the person for whom medication may be prescribed.

(2) **Exceptions**

Clinicians are not required to query and assess patient prescribing information from the PMP when:

(a) The controlled substance is directly ordered for administration in an emergency department, inpatient hospital setting, a long-term care facility or a residential care facility; or

(b) The controlled substance is directly ordered, prescribed or administered to a person suffering from pain associated with end-of-life or hospice care.

E. **Treatment Agreement**

(1) **Requirements**

Before prescribing any controlled substances to a patient for 90 days or more for chronic non-cancer/non-hospice/non-end-of-life pain, the prescriber and patient shall execute a written agreement for treatment that includes policies and expectations for the patient. The executed treatment agreement shall be documented in the patient's medical record and a copy given to the patient. Treatment agreements shall include the following:

(a) The patient agrees to tell their clinician about all of their medical conditions and all medication they are taking.

(b) The responsibility of the patient to be discreet about possessing narcotics and keeping them in an inaccessible place so they may not be stolen.

(c) The patient agrees to take their medications only as prescribed, not to use any illegal substances or use alcohol in excess.

(d) The clinician's prescribing policies and expectations, including:

(i) The patient will only obtain prescription opioids from one clinician or practice, except in the case of emergency for a new and severe pain.

(ii) The use of a single designated pharmacy.

(iii) The clinician's policy on early refills, after hour refills, replacement of lost or stolen pills.

(e) The patient's responsibility to inform the clinician if they do receive opioids from another clinician, and likewise to inform those clinicians that they have an opioid treatment agreement in place.

(f) An agreement that the patient will keep scheduled appointments and will comply with random pill counts and or random urine/blood testing to determine compliance.

(g) A statement that if the clinician becomes concerned that there has been illegal activity, the clinician may notify proper authorities, and it may specify that local episodic care facilities, other health care providers and pharmacies can be made aware of the treatment agreement.

(h) A statement that violation of the contract may result in opioids being reduced or discontinued, and that the patient may risk discharge from the practice.

(2) **Violation of Treatment Agreements**

If the agreement is violated, the violation and the clinician's response to the violation will be documented in the patient's medical record. In addition, the clinician shall document the rationale for changes in the treatment plan such as weaning the patient off medication, reporting to legal authorities etc.

F. **Toxicological Drug Screens and Random Pill Counts**

(1) **Toxicological Drug Screens**

Clinicians who prescribe controlled substances to a patient for 90 days or more for chronic non-cancer/non-hospice/non-end-of-life pain shall

ensure that the patient undergoes a toxicological (e.g. urine or serum) drug screen prior to the initiation of treatment and then periodic random screening during the course of treatment to ensure that the patient is adhering to the prescribed treatment regimen. Clinicians may use clinical judgment in deciding whether or not to initiate a trial course of treatment prior to receipt of the results of the toxicological drug screen. **These toxicological drug screens shall be done at least annually, but frequency should be based on the patient's level of risk.** Clinicians shall be responsible for documenting in the patient's medical record the time, date and results of the toxicological drug screens. In addition, clinicians shall document the response to any abnormal toxicological drug screens, the discussion of the abnormal results with the patient, and the rationale for any changes to the treatment plan. Clinicians should be aware of the limitations of available testing and take care to order tests appropriately. Consultation with a laboratory toxicologist or clinical pathologist to confirm significant or unexpected results is advisable.

(2) **Pill Counts**

Random pill counts are an additional tool to ensure patient adherence to the prescribed treatment regimen. Clinicians should be confident that they are counting the actual medication that was prescribed and that it has not been replaced with a similarly appearing pill. Pharmacists may be helpful in pill identification or in preforming a random count. Results of pill counts should be documented in the patient's medical record.

G. **Medical Records**

The clinician shall keep accurate and complete medical records on the above criteria, with emphasis on documentation of and the patient's response to controlled substances. Records should remain current and be maintained in an accessible manner, readily available for review. Information that should be maintained in the medical record includes:

(1) Copies of signed informed consent and treatment agreement.

(2) The patient's medical history.

(3) Documentation that a PMP query was performed.

(4) Results of the physical examination and laboratory tests.

(5) Results of the risk assessment, including results of any screening instruments or tools used.

(6) A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).

(7) Instructions to the patient, including discussions of risks and benefits.

(8) Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.

(9) Notes on evaluations by and consultations with specialists.

(10) Any other information used to support the initiation, continuation, revision, or termination of treatment, and the steps taken in response to any aberrant medication use behaviors.

3. Reportable Acts

Generally, information gained as part of the clinician/patient relationship remains confidential. However, the clinician has an obligation to deal with persons who use the clinician to perpetrate illegal acts, such as illegal acquisition or selling of drugs; this may include reporting to law enforcement. Information suggesting inappropriate or drug-seeking behavior should be addressed appropriately and documented. Use of the PMP is mandatory in this situation.

4. Compliance With Controlled Substances Laws and Regulations

A. **State and Federal Laws and Regulations**

To prescribe, dispense or administer controlled substances, a clinician must possess an active license to practice in the State of Maine, a current United States Department of Justice, Drug Enforcement Administration ("DEA") registration, and comply with applicable federal and state regulations. Clinicians are referred to the *Practitioners Manual of the U.S. DOJ Drug Enforcement Administration* and any relevant documents issued by the appropriate board or agency for specific rules governing controlled substances as well as other applicable state regulations.

B. **Methadone and Buprenorphine**

Clinicians shall not prescribe methadone for treatment of opioid use disorder or for the treatment of chronic pain unless knowledgeable of methadone's non-linear pharmacokinetics, unpredictable clearance, multiple drug-to-drug interactions, and additional monitoring requirements. Office based prescribing of Suboxone for treatment of opioid use disorder is restricted to clinicians who have training in addiction and are registered with the DEA as a Narcotic Treatment Program (NTP). In order to prescribe buprenorphine for opioid use disorder/addiction, clinicians must apply for a DATA 2000 waiver and be granted an "X" number by the DEA.

5. Compliance with CDC guideline for prescribing opioids for chronic pain

Clinicians shall be aware of and follow the "CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016" as published in the U.S. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 65, March 15, 2016. Copies of the CDC guideline may be obtained at:

http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

SECTION 4. CONTINUING EDUCATION

1. **Board of Licensure in Medicine**

By December 31, 2017 and thereafter, clinicians must complete 3 hours of Category 1 credit Continuing Medical Education (CME) every two years on the prescribing of opioid medication as a condition of prescribing opioid medication. By December 31, 2018 and thereafter, all clinicians must complete 3 hours of Category 1 credit Continuing Medical Education every two years on the prescribing of opioid medication regardless of whether or not they prescribe opioid medication. Category 1 credits will be accepted for CME regarding opioid prescribing from any of the following: the American Academy of Physician Assistants (AAPA); the American Medical Association Council on Medical Education (AMA); the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the Committee on Continuing Medical Education of the Maine Medical Association (MMA); the American Osteopathic Association (AOA); or the Maine Osteopathic Association (MOA).

2. State Board of Nursing

By December 31, 2017 and thereafter, advanced practice registered nurses with prescriptive authority must complete 3 contact hours of Category 1 continuing education every two (2) years on the prescribing of opioid medication as a condition of prescribing opioid medication.

3. Board of Osteopathic Licensure

By December 31, 2017 and thereafter, clinicians must complete 3 hours of Category 1 credit Continuing Medical Education (CME) every two years on the prescribing of opioid medication as a condition of prescribing opioid medication. Category 1 credits will be accepted for CME regarding opioid prescribing from any of the following: the American Academy of Physician Assistants (AAPA); the American Medical Association Council on Medical Education (AMA); the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the Committee on Continuing Medical Education of the Maine Medical Association (MMA); the American Osteopathic Association (AOA); or the Maine Osteopathic Association (MOA).

STATUTORY AUTHORITY:

32 M.R.S. §§ 3269(3),(7), 3300-F; (Board of Licensure in Medicine)
32 M.R.S. §§ 2102(2-A), 2153-A(1), 2210; (State Board of Nursing)
32 M.R.S. §§ 2562, 2600-C; (Board of Osteopathic Licensure)

EFFECTIVE DATE:
March 24, 2018 – filings 2018-043, 044, 045

APPENDIX:

RESOURCES

(a) Chronic pain management resources such as tools for Risk Assessment, Functional Assessment, Depression Screening, Treatment agreements, Informed Consent Forms, MME calculator, Opioid Taper Plan, Pain Tool Kit and much more are all available at: https://www.mainequalitycounts.org/page/2-1224/chronic-pain-collaborative-2

(b) Interagency Guideline on Prescribing Opioids for Pain, 2015. A comprehensive resource for opioid prescribing. Includes opioid taper guide: http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

(c) CDC Guideline for Prescribing Opioids for Chronic Pain: http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

(d) Withdrawal Symptoms Assessment: "Clinical Opiate Withdrawal Scale." The national Alliance for Advocates for Buprenorphine Treatment: www.naabt.org

(f) Drug Abuse resources. Substance Abuse and Mental Health Services Administration: www.samhsa.gov

(g) Maine Prescription Monitoring Program: http://www.maine.gov/dhhs/samhs/osa/data/pmp/index.htm

(h) A Data Resource for Medical Professionals and Law Enforcement: www.diversionalert.org

(i) FSMB Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain: http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf

(j) Responsible Opioid Prescribing: A Clinician's Guide. Scott M. Fishman, M.D. 2014 http://www.fsmb.org/books

(k) ER/LA Opioids: Assessing Risks, Safe Prescribing Free Online CME from the Federation of State Medical Boards (FSMB Provider's Clinical Support System for Opioid Therapies): http://www.fsmb.org/policy/education-meetings/er-la-opioids

Organizational Chart

Governor Janet Mills

Commissioner Anne Head

Scott Thomas, D.O. – Board Chair

Susan E. Strout, Executive Secretary

Savannah Okoronkwo, Consumer Assistant

PROGRAM: **BOARD OF OSTEOPATHIC LICENSURE (0383)**
FUNDING SOURCE: **Dedicated Revenue**

	FISCAL YEAR	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
ALLOCATED	PERSONAL SERVICES	$71,621	$72,834	$67,359	$69,231	$75,324	$73,425	$77,124	$75,780	$84,192	$94,129
	ALL OTHER	$125,658	$154,572	$195,884	$137,639	$143,408	$134,182	$157,480	$151,624	$176,315	$168,764
	TOTAL	**$197,279**	**$227,406**	**$263,243**	**$206,870**	**$218,732**	**$207,607**	**$234,604**	**$227,404**	**$260,507**	**$262,893**
EXPENDED											
	PERSONAL SERVICES	$68,424	$66,853	$67,111	$68,446	$73,012	$72,238	$76,425	$74,257	$83,111	$94,016
	ALL OTHER	$124,667	$154,189	$195,734	$127,310	$142,492	$133,665	$155,239	$144,062	$150,349	$152,567
	TOTAL	**$193,090**	**$221,043**	**$262,846**	**$195,756**	**$215,504**	**$205,903**	**$231,665**	**$218,319**	**$233,459**	**$246,584**

**Allocated includes funds allotted by Financial Order*

COMPLIANCE

Review Summary | Attestation | Missing Actions | Messages

Your compliance officer:
ANDY JORDAN
(301) 594-0197
ajordan@hrsa.gov

Send a Secure Message

Compliance Review Summary

The National Practitioner Data Bank (NPDB) periodically reviews adverse actions taken by state licensing and certification boards for selected health care professions. The NPDB reviewed adverse actions published on your organization's website that were taken from January 1, 2016, to August 31, 2017.

The NPDB reviewed the actions for selected professions to determine if they are reportable. We compared the reportable actions to NPDB reports submitted by your board to match them together. **Each profession is assigned a compliance status based on the percentage of actions taken by your board from January 1, 2016, to August 31, 2017 that match with a submitted NPDB report**.

Professions with 100% Compliance

Thank you for achieving 100% compliance. All actions for the listed profession(s) matched with a submitted report. Please continue to report all actions within 30 days of the date they are taken.

✔ **100% COMPLIANT**

Profession Name	Match%	Action Required
Osteopathic Physician (DO)	100%	None
Physician Assistant	100%	None

Resources

- Data Request Worksheet
- Your Compliance Officer
- Compliance Overview
- State Licensing Boards
- The NPDB Guidebook - State Licensure and Certification Actions
- Reporting to the NPDB

Return to Options

List of Reports and Applications

Reports

Annual Report to Secretary of State

Annual Report of Complaints Received/Disciplinary Actions Taken

Report of Disciplinary Actions to National Practitioners Data Bank

Report of Disciplinary Actions to Federation of State Medical Boards

Applications

Application to Practice Permanent Osteopathic Physician

Application to Practice Permanent Physician Assistant

Registration of Supervisory Relationship (w/Physician Assistant)

Termination of Supervisory Relationship (w/Physician Assistant)

Application to Practice as a Locum Tenens Physician

Application for Temporary Educational Permit

Application to Practice as a Camp Physician