

Chapter 1: RULE REGARDING ALLOPATHIC PHYSICIANS

SUMMARY: Chapter 1 pertains to the licensure, registration, notification and continuing medical education requirements for allopathic physicians. Chapter 1 also defines the duties of the Board Secretary.

SECTION 1. DEFINITIONS

1. "Accredited Medical School" means a school designated as accredited by the Liaison Committee on Medical Education.
2. "Active Status License" means the allopathic physician has an active license in Maine and can practice within the scope of the license issued.
3. "Administrative License" means a license limited to the practice of administrative medicine."
4. "Administrative Medicine" means: a) professional managerial or administrative activities related to the practice of medicine or to the delivery of health care services, but not including the practice of clinical medicine; and/or b) medical research, excluding clinical trials on humans.
5. "Administratively Complete Application" is an application for licensure as developed by the Board which when submitted 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, civil penalties or fines paid.
6. "Board" means the Board of Medicine.
7. "Clinical License" means a license that authorizes an allopathic physician to practice clinical medicine and/or surgery.
8. "Clinical Medicine" includes but is not limited to: a) direct involvement in patient evaluation, diagnosis and treatment; b) prescribing any medication; c)

- delegating medical acts, services or prescriptive authority; or d) the supervision of allopathic or osteopathic physicians who practice clinical medicine, physician associates who render medical services, or the clinical practice of advanced practice registered nurses.
9. "Educational Certificate" means a certificate issued by the Board to a medical school graduate who is enrolled in a post-graduate training program at a specific hospital for a period of not more than seven (7) years. The specific duration of the educational certificate will be based upon the request of the hospital and may be renewed every three years.
 10. "Emergency 100-day License" means a license issued to an allopathic physician for not more than 100 days and issued for declared emergencies in the State or for other appropriate reasons as determined by the Board.
 11. "Emeritus License" means a license issued to a qualified allopathic physician who is licensed in Maine and has retired from the active practice of medicine and does not practice medicine or prescribe any medications.
 12. "Fellowship" means advanced supervised postgraduate clinical education in a medical specialty.
 13. "Inactive Status License" means the allopathic physician has an inactive license and cannot practice medicine in Maine. An Inactive Status License is primarily designed for physicians who are still practicing in another state and may come back to practice in Maine in the future.
 14. "Jurisprudence Examination" means the examination regarding the Board's laws and rules and laws pertaining to the practice of medicine in Maine, which is required to be taken and passed upon initial active licensure and then every four (4) years thereafter upon application for re-licensure.
 15. "Pending Status License" means the allopathic physician has submitted an application for licensure or renewal of licensure upon which the Board has not made a final determination.
 16. "Postgraduate Medical Education" means a graduate educational program or combination of graduate educational programs, including but not limited to internships, residencies and fellowships, accredited by the Accreditation Council on Graduate Medical Education, the Canadian Medical Association, the Royal College of Physicians and Surgeons of Canada, or the Royal Colleges of England, Ireland and Scotland.

17. “Reentry License” means a license issued to a qualified allopathic physician who is otherwise qualified for clinical licensure but has not practiced clinically within the past 24 months. This license is contingent upon compliance with a reentry plan and Reentry to Practice Agreement and automatically ends upon successful completion of the reentry plan and conversion to a clinical license or if the terms of the reentry plan are not met at any time.
18. “SPEX” (Special Purpose Examination). The SPEX is a computerized, multiple-choice examination of current knowledge requisite for the general, undifferentiated practice of medicine owned and administered by the Federation of State Medical Boards. The examination is intended for allopathic physicians who currently hold, or who have previously held, a valid, unrestricted license to practice medicine in a U.S. or Canadian jurisdiction. Appropriate candidates for the SPEX include allopathic physicians seeking licensure reinstatement or reactivation after some period of professional inactivity or allopathic physicians involved in disciplinary proceedings in which the board determines the need for evaluation. The SPEX is also appropriate for allopathic physicians applying for licensure by endorsement who are several years beyond initial licensure.
19. “Temporary License” means a license issued by the Board to a qualified allopathic physician for a period not to exceed one year when the Board determines that this action is necessary in order to provide relief for local or national emergencies or for situations in which the number of physicians is insufficient to supply adequate medical services or for the purpose of permitting the allopathic physician to serve as locum tenens for another physician who is licensed to practice medicine in this State.
20. “Unaccredited Medical School” means a school that is not designated as accredited by the Liaison Committee on Medical Education.
21. “Volunteer License” means a license issued by the Board to a qualified allopathic physician who has retired or is retiring from the active practice of medicine and wishes to donate his or her expertise exclusively for the medical care and treatment of indigent and needy patients in the clinical setting of clinics organized, in whole or in part, for the delivery of health care services without charge.
22. “Youth Camp License” means a temporary license issued by the Board to a qualified allopathic physician authorizing the allopathic physician to practice medicine only for the patients in a particular youth camp.

SECTION 2. LICENSE REQUIRED

An individual must hold an active license issued by the Board in order to practice medicine or surgery or a branch of medicine or surgery or claim to be legally licensed to practice medicine or surgery or a branch of medicine or surgery within the State and practice within the scope of that license.

SECTION 3. REQUIREMENTS FOR MEDICAL LICENSURE

To qualify for licensure as an allopathic physician, an applicant must meet all of the following criteria:

1. Medical Education

- A. Graduate from a medical school designated as accredited by the Liaison Committee on Medical Education.
- B. Graduate from an unaccredited medical school and:
 - (1) Be evaluated by the Educational Commission for Foreign Medical Graduates and receive a permanent certificate from the Educational Commission for Foreign Graduates; or
 - (2) Achieve a passing score on the Visa Qualifying Examination (VQE) or another comprehensive examination determined by the Board to be substantially equivalent to the VQE.

2. Medical Examinations

A. U.S. National Examinations

- (1) An applicant must attain passing scores on each examination in ONE of the following examination sets separately or in a combination specified in the United States Medical Licensing Exam (USMLE) instructions:
 - (a) United States Medical Licensing Examination (USMLE), which includes step 1, step 2 and step 2C (clinical skills with standardized patients, if applicable at the time the test was taken), and step 3; or
 - (b) Federation Licensing Examination (FLEX); or

- (c) National Board of Medical Examiners Examination (NBME).

(2) **Time and Attempt Limits for Examinations**

The applicant must:

- (a) Complete the examination series (FLEX, NBME, USMLE) within seven (7) years of passing the first examination, with an automatic exception allowed for dual M.D./PhD. candidates.
- (b) Complete the first two steps of the USMLE examination (USMLE 1, USMLE 2 including USMLE 2C (if applicable at the time the test was taken)) or approved combinations with unlimited attempts. Steps 1, 2, and 2C may be retaken after successfully passing them ONLY for the purpose of accomplishing or maintaining the seven (7) year limitation named immediately above.
- (c) Complete the final examination in the series (i.e. FLEX 2, NBME 3, USMLE 3) in no more than three (3) attempts. Step 3 may not be retaken once passed with a minimum passing score.
- (d) Attain a minimum passing score of seventy-five (75) – on the two number scoring system – for each examination in the set. For FLEX examinations administered before December 1, 1985, the score must be a minimum of seventy-five (75) on the composite FLEX weighted average scoring system.
- (e) Request for Waiver

An applicant may apply to the Board for a waiver of the time and attempt limits. The Board may grant a waiver based upon unusual or extenuating circumstances as determined by the Board in its sole discretion.

B. Non-U.S. National Examinations

As an alternative to the U.S. National Examinations requirement above the Board may accept passing scores in one of the following examination sets:

- (1) A licensing examination administered by any medical board which is a member of the Federation of State Medical Boards;
- (2) Licentiate of Medical Council of Canada (LMCC);
- (3) British Isles Credentialing – General Medical Council of United Kingdom, or Republic of Ireland, or Scotland.

3. State of Maine Jurisprudence Examination

- A. Every applicant for licensure must attain a passing score of at least seventy-five (75) on the jurisprudence examination administered by the Board.
- B. If a candidate fails to attain a score of seventy-five (75) on the jurisprudence examination, the applicant may be required to appear for an interview before a committee of the Board.

4. Personal Interview

- A. In addition to all other qualifications, the Board may require a personal interview with the applicant to discuss issues identified in the application materials, including but not limited to:
 - (1) Clinical competence;
 - (2) Evidence of disruptive behavior which might negatively impact the practice of medicine or safety of patients;
 - (3) Any conduct that might be grounds for discipline or denial of licensure as provided by law or rule; or
 - (4) Communication skills.

5. Postgraduate Training

- A. Graduates after July 1, 2004

Applicants who graduated from a medical school after this date must satisfactorily complete at least thirty-six (36) months in a graduate educational program or combination of graduate educational programs accredited by the Accreditation Council on Graduate Medical Education, the Canadian Medical Association, the Royal College of Physicians and Surgeons of Canada, or the Royal Colleges of England, Ireland and Scotland.

B. Graduates before July 1, 2004 and after January 1, 1970

Applicants who graduated from an accredited medical school within this date range must have satisfactorily completed at least twenty-four (24) months in a graduate educational program or combination of graduate educational programs accredited by the Accreditation Council on Graduate Medical Education, the Canadian Medical Association, or the Royal College of Physicians and Surgeons of Canada.

C. Graduates before January 1, 1970

Applicants who graduated from an accredited medical school before January 1, 1970 must have satisfactorily completed at least twelve (12) months in a graduate educational program accredited by the Accreditation Council on Graduate Medical Education, the Canadian Medical Association, or the Royal College of Physicians and Surgeons of Canada.

D. Residents training in Maine

- (1) When the applicant for licensure is in an Accreditation Council on Graduate Medical Education accredited post-graduate training program in this State and has completed twenty-four (24) months of postgraduate training (in this State) and has received an unrestricted endorsement from the graduate educational program director, and it is confirmed that the applicant will continue in the program and complete thirty-six (36) months of postgraduate training, and if otherwise qualified, an active clinical license of normal duration may be issued.
- (2) If the applicant who is issued an active clinical license pursuant to subparagraph (D)(1) subsequently discontinues the graduate educational program or must postpone completing the last twelve (12) months of the graduate educational program, both the licensee and the graduate educational program director shall promptly notify the Board in writing, providing full details of the

issue(s) and plan for program completion, if any. The Board will review the information provided, and take any action permitted by law, including but not limited to revoking the license.

E. Waiver for Foreign Medical School Graduates

- (1) To be considered for a waiver of the postgraduate training requirement, an applicant must meet all of the following criteria:
 - (a) The applicant is a graduate of a foreign medical school, not including a medical school in Canada or Great Britain;
 - (b) The applicant holds an active, unrestricted license in another U.S. state that is not subject to discipline and authorizes the applicant to engage in the full scope of practice permitted by a Maine active clinical license; and
 - (c) The applicant has at least three (3) years of clinical experience in the area of expertise.
- (2) If the applicant meets the foregoing criteria, the Board may grant a waiver using the following qualifications:
 - (a) The applicant demonstrates completion of a three (3) year clinical fellowship in the United States in the area of expertise.
 - (b) The applicant demonstrates completion of a three (3) year clinical non- accredited fellowship that is equivalent to an Accreditation Council on Graduate Medical Education accredited fellowship and provides the Board with the following information:
 - (i) Detailed procedure/patient logs.
 - (i) Attestations from at least three (3) teaching physicians, senior residents, or other senior fellows, and nursing staff regarding the applicant's level of responsibility and supervision. The attestations shall include the name and contact address of the attester.

- (ii) Detailed list of conferences conducted and academic papers produced by applicant during the fellowship.
 - (iii) Monthly rotation schedule and the daily schedule detail for each, if available.
 - (iv) Fellowship conference schedule and list of those attended by the applicant.
 - (v) Attestation by the fellowship program director of how the following six core competencies are taught in the program: patient care; medical knowledge; interpersonal and communication skills; professionalism; practice-based learning and improvement; and systems-based practice.
 - (vi) Reference letters as to competency and character from the department chief and from the fellowship program director.
 - (vii) Proof that the fellowship is hospital-based and the hospital is accredited by The Joint Commission or the fellowship is medical school based and the school is accredited by the Liaison Committee on Medical Education (LCME).
- (c) The applicant has been appointed to a clinical academic position at a licensed medical school in the United States.
 - (d) The applicant has articles published in peer-reviewed clinical medical journals recognized by the Board.
 - (e) The number of years the applicant has been in clinical practice.
 - (f) Other criteria indicative of expertise such as awards or recognition for professional accomplishments.
 - (g) Not more than three (3) medical malpractice claims shall have been filed against the applicant in a ten (10) year period, nor shall there have been any one medical

malpractice settlement resulting in a settlement amount of greater than \$300,000.

- (3) The Board may assess an applicant for a waiver with the actual costs for investigating and determining the validity of information provided by the applicant for the waiver request.

6. Clinical Competence

Demonstrates continued clinical competency as required by this rule.

SECTION 4. CREDENTIAL VERIFICATION

1. Unless otherwise specified in this rule, all applicants for licensure must complete the process of verifying their core credentials with the Federation Credentials Verification Services (FCVS).

2. Federation Credentials Verification Services (FCVS) For Static Core Credentials

Unless otherwise specified in this rule, the Board requires that applicants for a medical license use the FCVS to verify qualifying credentials which are static or do not change, such as identity, education and post graduate training. This verification process is conducted separately and independently by FCVS.

Unless otherwise specified in this rule, applicants must submit an FCVS application directly to FCVS on an application supplied by the Board or requested directly from FCVS and pay any required fees directly to FCVS. FCVS will then provide the Board with a non-interpretive "Physician Information Profile" containing certified copies of the applicant's credentials.

3. **Exemptions to FCVS Credentials Verification.** The following applicants are exempt in whole or in part as specified from the requirement of FCVS credentials verification:
 - A. Licensees holding active clinical licenses issued by the Board who apply to convert their licenses to administrative, emeritus, volunteer, or inactive status do not have to complete the FCVS process;
 - B. Applicants who are recent medical school graduates and who apply for an Educational Certificate do not have to complete the FCVS process;

- C. Applicants for Youth Camp Licenses must show proof of completion of the FCVS application prior to being issued a license. Staff may issue a license prior to receiving the allopathic physician's credentialing report from the FCVS. Staff shall review the allopathic physician's credentialing report from the FCVS upon receipt, and notify the Board if any concerning information is discovered; and
- D. Applicants for Emergency 100-Day Licenses must show proof of completion of the FCVS application prior to being issued a license. Staff may issue a license prior to receiving the allopathic physician's credentialing report from the FCVS. Staff shall review the allopathic physician's credentialing report from the FCVS upon receipt and notify the Board if any concerning information is discovered.

SECTION 5. LICENSE APPLICATION PROCESS

1. The Board, or if delegated, Board staff may issue an active status clinical license to an applicant who:
 - A. Submits an administratively complete application on forms approved by the Board;
 - B. Pays the appropriate licensure fee or late fee (if any). The application fees cover the cost of processing the application and are not refundable;
 - C. Meets the education requirement;
 - D. Meets the post-graduate training requirement;
 - E. Meets the medical examination requirement;
 - F. Meets the jurisprudence examination requirement;
 - G. Meets the clinical practice requirement;
 - H. Worked and/or was licensed in a foreign country and that jurisdiction or licensing authority has provided verification of licensure directly to the Board;
 - I. Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and

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- J. Has personally completed the application, answered all application questions, and performed all steps of the application process not expressly required by law or Board rule to be performed by another person or entity.
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 may consult with the Board Secretary, Board Chair, or other Board designee who may approve the application or defer action on the application to an investigative committee of the Board.
3. **License Conversion Between Biennial Renewal Dates**
- Licensees may apply to convert their active status license to an inactive, emeritus, or volunteer license between scheduled biennial renewal dates by completing the appropriate renewal application and submitting it to the Board. No fee shall be assessed for this conversion. Board staff may convert the license to inactive status.
4. **Administratively Incomplete Application**
- A. Applicant fails to take action. Any application for a license that has been on file with the Board without action by the applicant for six (6) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process, including payment of new application fees, in order to be considered for licensure.
- B. Application incomplete after 12 months. Any application that is not complete within twelve (12) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process, including payment of new application fees, in order to be considered for licensure unless the applicant seeks, and the Board grants, a waiver of this time limit. Requests for waivers of this time limit may be granted for good cause shown.
- C. Current signed addendum required. Any applicant that has an application that has been submitted six months or longer before the application is complete must submit a new signed addendum prior to issuance of the license.
- D. Application fee required to process application. If the appropriate licensing fee has not been received within 90 days of the application

submission the application shall be voided and the applicant must restart the application process.

- E. Prior to the deadlines stated in this section, upon written statement by the applicant that they do not intend to complete their application, Board staff may close an application file as administratively incomplete upon Board staff's confirmation there are no open medical licensing complaints or investigations against the applicant in Maine or other U.S. jurisdictions.

SECTION 6. SPECIFIC TYPES OF MEDICAL LICENSES

1. Administrative License

- A. The Board, or if delegated, Board staff may issue an administrative license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;
- (3) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.

- B. Meets the same requirements for licensure as an applicant for an active clinical license with the exception that the applicant is not required to show that they have been engaged in the active clinical practice of medicine.

- C. **Renewal of Administrative License**

An allopathic physician applying to renew an administrative license must pay the same fees and meet the same requirements for renewing an active status license, including the requirement for continuing medical education (CME).

2. Educational Certificate

- A. The Board, or if delegated, Board staff may issue an educational certificate to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;
- (3) Meets the education requirement;
- (4) Provides documentation from the Maine educational/residency program demonstrating enrollment, including the dates of the program;
- (5) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.

B. Educational Certificate Limitation

Educational certificates may only be issued for a specific residency program at a specific Maine hospital.

C. Educational Certificate Duration

Educational certificates may be issued for the duration specified by the Maine hospital's residency director for a period of up to seven (7) years.

D. Educational Certificate Expiration

Educational certificates shall automatically expire:

- (1) On the date specified on the educational certificate, unless renewed; or
- (2) On the date that the Board receives written notification from the director of the residency program at the hospital or the resident that the resident is no longer enrolled in that specific hospital's residency program.
- (3) On the date that the Board receives written notification from the licensee that they are no longer employed or enrolled in that specific hospital's residency program.

3. Emergency 100-Day License

A. The Board, or if delegated, Board staff may issue an emergency 100-day license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;
- (3) Meets the education requirement;
- (4) Meets the post-graduate training requirement;
- (5) Meets the examination requirement;
- (6) Provides a Letter of Need which describes the circumstances that make the candidate eligible for the license. Such letter shall be transmitted directly from the organization where the allopathic physician will be practicing under the emergency 100-day license.
- (7) Holds a full and unrestricted license from another United States licensing jurisdiction at the time of the application, and maintains it for the duration of the emergency 100-day license.
- (8) Has had no other license restricted, limited or otherwise disciplined in any other jurisdiction.
- (9) Submits an application for an active clinical license simultaneously with the application for the 100-day license.
- (10) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
- (11) Demonstrates continuing clinical competency as required by this rule.

B. Emergency 100-Day License Limitations

- (1) Emergency licenses may only be issued once to the same applicant and for a period not to exceed 100 calendar days.

- (2) Emergency 100-day licenses may only be issued for a specific practice location.
- (3) Emergency 100-day licenses automatically expire:
 - (a) 100 days after the date of issuance; or
 - (b) On the date that the Board receives written notification from the licensee that they are no longer employed at the specific practice location.

4. Emeritus License

- A. The Board, or if delegated, Board staff may issue an emeritus license to an applicant who:

- (1) Currently holds an active or inactive clinical license to practice medicine in Maine;
- (2) Submits an administratively complete application on forms approved by the Board;
- (3) Meets the education requirement; and
- (4) Meets the post-graduate training requirement.

- B. Conversion to Emeritus License Between Scheduled Renewal Dates

An allopathic physician may convert an existing license to an emeritus license between scheduled renewal dates by filing an application with the Board. Upon receipt of an administratively complete application, the Board staff shall convert the existing license to an emeritus license. The biennial renewal date remains unchanged.

5. Inactive Status License

- A. Upon an application for inactive status, the Board, or if delegated, Board staff may issue an inactive status license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;

- (3) Meets the education requirement;
- (4) Meets the post-graduate training requirement;
- (5) Meets the examination requirement; and

B. Conversion to Inactive License Between Scheduled Renewal Dates

An allopathic physician may convert an existing license to an inactive license between scheduled renewal dates by filing appropriate documentation, ranging from written confirmation up to a full application for an inactive license, depending on the circumstances with the Board. Upon receipt of an administratively complete application, the Board staff shall convert the existing license to an inactive license. The biennial renewal date remains unchanged.

C. Due to Investigation

In the event there is an active allegation or investigation about a licensee's fitness to practice, the licensee may agree to voluntarily convert to inactive status until the allegations are addressed.

6. Reentry License

A. The Board may issue a reentry license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;
- (3) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.
- (4) Meets the same requirements for licensure as an applicant for a clinical license with the exception that the applicant has not been engaged in the active clinical practice of medicine for the past 24 months and has provided a reentry plan approved by the Board.

B. A reentry plan must include the following:

- (1) Either (a) a statement of current medical knowledge or (b) an assessment of current medical knowledge and clinical skills, when required by the Board. The purpose of this assessment is to identify any gaps in medical knowledge and clinical skills, as well as to identify areas of strength. The assessment must be performed by an individual and/or entity approved by the Board. Examples of assessments for physicians include the Special Purpose Examination (SPEX) and the Post-Licensure Assessment System (PLAS);
- (2) **Refresher education.** This education is designed to fill the gaps in medical knowledge identified by the assessment. This may include completion of a mini-residency program;
- (3) **A clinical preceptorship or the equivalent.** This component is designed to provide mentoring and oversight of clinical care for a specified period by a practice mentor. The practice preceptor or equivalent must have sufficient time and experience, possess a full and unrestricted active clinical license, have no disciplinary history, and provide reports to the Board as required by a reentry to practice agreement;
- (4) **Final assessment of current competency to establish qualification for an active clinical license.** This component is designed to ensure that a physician or physician associate is ready and able to return to clinical practice without further oversight by the Board;
- (5) **Reentry to Practice Agreement.** This will be offered to the applicant after the Board has approved their reentry to practice plan. The applicant must execute and at all times comply with this agreement during the period of their licensure as a reentry licensee.
- (6) **End of Reentry to Practice Agreement.** The Reentry to Practice Agreement ends upon either successful completion of the reentry plan and conversion to a clinical license or if the terms of the reentry plan are not met at any time.
- (7) Reentry licensees must comply with their Board-approved reentry plan and practice agreement. Failure to do so may be grounds for imposing discipline on the reentry licensee's license for unprofessional conduct and as further permitted by Board law and rules, up to and including revocation of the license.

C. **Renewal of Reentry License**

An allopathic physician applying to renew a reentry license must pay the same fees and meet the same requirements for renewing a clinical status license, including the requirement for continuing medical education (CME) and be in compliance with the reentry plan.

7. Temporary License

A. The Board, or if delegated, Board staff may issue a temporary license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;
- (3) Meets the education requirement;
- (4) Meets the post-graduate training requirement;
- (5) Meets the examination requirement;
- (6) Provides a Letter of Need which describes the circumstances which make the candidate eligible for the license. Such letter shall be transmitted directly from the organization where the allopathic physician will be practicing under the temporary license.
- (7) Holds a full and unrestricted license in another state or Canadian province at the time of application and maintains it for the duration of the temporary license.
- (8) Has had no other license restricted, limited or otherwise disciplined in any other jurisdiction.
- (9) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
- (10) Demonstrates current clinical competency as required by this rule.

B. Temporary License Limitations

- (1) Temporary licenses may only be issued to the same applicant for a period not to exceed one (1) year. Once a licensee has held a temporary license or a combination of temporary licenses for one (1) year, they are no longer eligible for another temporary license.
- (2) Temporary licenses may only be issued for a specific practice location.
- (3) Temporary licenses automatically expire:
 - (a) On the date specified on the temporary license; or
 - (b) On the date that the Board receives written notification from the licensee that they are no longer employed at the specific practice location.
 - (c) If the Letter of Need is withdrawn during the application process the application shall be voided.

8. Youth Camp License

- A. The Board, or if delegated, Board staff may issue a youth camp license to an applicant who:
- (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure fee;
 - (3) Holds a full and unrestricted license in another state or Canadian province at the time of application, and maintains it for the duration of the temporary camp license;
 - (4) Has had no other license restricted, limited or otherwise disciplined in any other jurisdiction;
 - (5) Meets the examination requirement;
 - (6) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and

- (7) Demonstrates continuing clinical competency as required by this rule.

B. Youth Camp License Limitations

- (1) Youth Camp licenses are issued for a limited period.
- (2) Youth Camp licenses may only be issued for a specific youth camp (practice location).
- (3) Youth Camp licenses automatically expire:
 - (a) On the date specified on the Youth Camp license; or
 - (b) On the date that the Board receives written notification from the licensee that they are no longer employed at the specific youth camp (practice location).

9. Volunteer License

- A. The Board, or if delegated, Board staff may issue a volunteer license to an applicant who:
- (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate license conversion fee;
 - (3) Currently holds an active clinical license to practice medicine in a US State or Territory;
 - (4) The applicant must meet all the requirements for an active clinical Maine medical license, including CME requirements as defined in this rule;
 - (5) Must acknowledge or certify that the applicant's practice will be exclusively and totally devoted to providing medical care to needy and indigent persons in Maine. The treatment of family, friends or acquaintances is not permitted under a volunteer license;
 - (6) Must acknowledge or certify that the applicant will not receive any payment or compensation, either direct or indirect, or have

the expectation of any payment or compensation, for any medical services rendered;

- (7) Reports all locations where they will provide volunteer services; and
- (8) Provides to the Board a copy of a written agreement to provide volunteer services at every facility where services will be provided.
- (9) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.

B. Conversion to Volunteer License Between Scheduled Renewal Dates

When converting to a volunteer license between scheduled renewal dates, the allopathic physician shall follow the same procedure used to convert from an active clinical license to an inactive license. The biennial renewal cycle remains unchanged.

C. Renewal of Volunteer License

An allopathic physician applying to renew a volunteer license must meet all requirements for renewing an active clinical license, including CME.

10. Clinical License

This license authorizes an allopathic physician to practice clinical medicine and/or surgery and is generally renewable every two years.

A. Application Process

- (1) Applications for a clinical medical license will be reviewed by the Board Staff. After review, a clinical license may be issued to an applicant who:
 - (a) Submits an administratively complete application on forms approved by the Board;
 - (b) Pays the appropriate licensure and registration fee to the Board;

- (c) Meets the examination requirement;
 - (d) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
 - (e) Demonstrates continuing clinical competency as required by this rule.
- (2) Board staff may issue a clinical license to applicants who meet each criterion specified below and shall report such actions at the next regular meeting of the Board.
 - (a) A positive review by the Executive Director or the Assistant Executive Director of the application that includes the following criteria:
 - (i) Each qualification for licensure has been clearly met and verified, and all issues or questions have been fully explained and documented;
 - (ii) All personal data questions, with the exception of telemedicine, practice location and malpractice questions on the application have been answered "No"; and
 - (iii) The Board has received the names and contact information of three professional references regarding the applicant, and, if references are obtained, no issues have been identified by those references or contact with those references that reveals potentially disqualifying information
- (3) Applications that do not meet the foregoing criteria as determined by the Executive Director or Assistant Executive Director will be referred to the Board Secretary, Board Chair or other Board designee. The Board Secretary, Board Chair or other Board designee may approve the application or refer the application to an investigative committee of the Board.

SECTION 7. PROCESS FOR CONVERSION OF AN INACTIVE STATUS LICENSE OR ADMINISTRATIVE LICENSE TO AN ACTIVE CLINICAL LICENSE

1. The Board, or if delegated, Board staff may convert an administrative or inactive license to clinical license for an applicant who:
 - A. Submits an administratively complete application requesting an active status license on forms approved by the Board;
 - B. Pays the appropriate license conversion fee;
 - C. Provides evidence of having met the Board's requirements for CME;
 - D. Demonstrates continuing clinical competency as required by this rule;
 - E. Meets the examination requirement; and
 - F. Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.
2. In the event that there is any question regarding CME credits or active clinical practice, the application will be presented to an investigative committee of the Board.

SECTION 8. REQUIREMENTS FOR RENEWAL/REINSTATEMENT/WITHDRAWAL OF LICENSE

1. License Expiration and Renewal

With the exception of Emergency 100-day, Temporary, Youth Camp Licenses, and Temporary Educational Certificates, the license/registration of every allopathic physician born in an odd-numbered year expires at midnight on the last day of the month of the allopathic physician's birth every odd-numbered year. The license/registration of every allopathic physician born in an even-numbered year expires at midnight on the last day of the month of the allopathic physician's birth every even-numbered year. The allopathic physician must renew the license/registration every two (2) years prior to the expiration of the license/registration by submitting an administratively complete application to the Board on forms approved by the Board.

2. Renewal Notification

At least sixty (60) days prior to the expiration of a current license/registration, the Board shall notify each licensee of the requirement to renew the

license/registration. If an administratively complete re-licensure application has not been submitted prior to the expiration date of the existing license, the license immediately and automatically expires. A license may be reinstated up to 90 days after the date of expiration upon payment of the renewal fee and late fee. If an administratively complete renewal application is not submitted within 90 days of the date of the expiration of the license, the license immediately and automatically lapses. The Board may reinstate a license pursuant to law.

3. Criteria for Active License Renewal

- A. The Board, or if delegated, Board staff may renew the active license of an allopathic physician who meets all of the following requirements:
- (1) Submits an administratively complete license renewal application on forms approved by the Board;
 - (2) Pays the appropriate license renewal fee and/or late fee (if any);
 - (3) Affirms that the licensee has met the CME requirements. In the event that the required CME is not complete, the allopathic physician may request an extension of time for good cause to complete the CME. The Board Secretary, Board Chair, or other Board designee has the discretion to grant or deny a request for an extension of time to complete the required CME credits;
 - (4) Demonstrates continuing clinical competency as required by this rule;
 - (5) Successfully completes the Board's jurisprudence examination when directed by the Board;
 - (6) Successfully completes the minimum data set survey; and
 - (7) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of licensure as provided by law.
 - (8) 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 other Board designee who may approve the

application or defer action on the application to an investigative committee of the Board.

- (9) A new licensee who is scheduled to renew three (3) months or less from the date of original licensure will be issued a license through the next renewal cycle.

B. Timeliness of Application

If an application for renewal of license/registration is not administratively complete and postmarked or submitted electronically by the date of expiration of the license/registration, the late fee shall be assessed.

4. Criteria for all other License Renewals

- A. The Board, or if delegated, Board staff may renew the license/registration of an allopathic physician other than an active clinical license who meets all of the following requirements:
 - (1) Submits an administratively complete license/registration renewal application on forms approved by the Board;
 - (2) Pays the appropriate license renewal fee and/or late fee (if any);
 - (3) Affirms that the licensee has met the CME requirements. In the event that the required CME is not complete, the allopathic physician may request an extension of time for no more than six (6) months for prolonged illness, undue hardship, or other extenuating circumstances to complete the CME. The Board Secretary, Board Chair, or other Board designee has the discretion to grant or deny a request for an extension of time to complete the required CME credits; and
 - (4) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of licensure as provided by law.
 - (5) 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 other Board designee who may approve the application or defer action on the application to the full Board.

- (6) A new licensee who is scheduled to renew three (3) months or less from the date of original licensure will be issued a license through the next renewal cycle.

B. Timeliness of Application

If an application for renewal of license/registration is not administratively complete and postmarked or submitted electronically by the date of expiration of the license/registration, the late fee shall be assessed.

5. Process for Withdrawal of License or Withdrawal of an Application for License

- A. An allopathic physician may request to withdraw a license by submitting an administratively complete renewal application which states the reason for requesting the withdrawal of the license.
- B. An applicant may request to withdraw their application for a license by submitting a written request which states the reason for requesting to withdraw the application.
- C. The Board staff may approve an application to withdraw a license where the Board has no open investigation or complaint regarding the applicant, and the applicant is in compliance with any active consent agreement or decision and order.
- D. Withdrawal requests that occur while an investigation or complaint is pending in another jurisdiction will be reviewed by an investigative committee.
- E. The Board may grant or deny requests to withdraw a license or application for a license.

6. Requirements for License Reinstatement

- A. The Board, or if delegated, Board staff may reinstate a lapsed or withdrawn license of an allopathic physician who meets all of the following requirements:
 - (1) Submits an administratively complete reinstatement application on forms approved by the Board;

- (2) Pays the appropriate reinstatement fee(s) and/or late fees (if any);
 - (3) Provides a written statement explaining why they withdrew or allowed the license to lapse and a detailed listing of their activities since that time;
 - (4) Meets the examination requirement; and
 - (5) 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 other Board designee who may approve the application or defer action on the application to an investigative committee of the Board.
- C. An allopathic physician whose license has lapsed or been withdrawn for more than five (5) years shall apply for a new license.
- D. The applicant's license may not be reinstated if the applicant has not demonstrated current clinical competency as required by this rule.

SECTION 9. CONTINUING CLINICAL COMPETENCY REQUIREMENTS

1. Requirements

A. General

If an applicant has not engaged in the active practice of clinical medicine during the 24 months immediately preceding the filing of the application, the Board may determine on a case by case basis in its discretion whether the applicant has adequately demonstrated continued competency to practice clinical medicine.

B. Demonstrating Current Competency

The Board may require an applicant to submit to any competency assessment(s) or evaluation(s) conducted by a program approved by the Board. If the assessment/evaluation identifies gaps or deficiencies, the applicant must complete an educational/remedial program to

address them. The Board retains the discretion regarding the method of determining continued competency based upon the applicant's specific circumstances. The methodology may include but is not limited to successful passage of examination(s), completion of additional training, and successful completion of a formal reentry to practice program approved by the Board.

- C. If the Board determines that an applicant requires a period of supervised practice and/or the completion of an educational or training program, the Board may at its discretion issue the applicant a probationary license pursuant to a consent agreement or issue an applicant a reentry license in conjunction with a return to practice plan.
- D. All expenses resulting from the assessment and/or any training requirements are the sole responsibility of the applicant and not of the Board.

SECTION 10. FEES

1. License, Registration, Examination & Late Fees

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

(1)	Initial License Application	\$600
(2)	Initial Jurisprudence Examination	\$100
(3)	Temporary License Application.....	\$400
(4)	Emergency 100-Day License Application	\$400
(5)	Education Certificate (3 years)..... (Fee may be prorated for 2 nd or 3 rd year initial applicants)	\$300
(6)	Emeritus License	\$0
(7)	Volunteer License	\$50
(8)	Youth Camp License Application	\$100
(9)	License/Registration Renewal	\$500

(10)	License/Registration Renewal within 6 months of initial licensure	\$150
(11)	Inactive License Renewal	\$100
(12)	License Renewal Late Fee (Renewal application filed after license expiration date)	\$100
(13)	Emeritus License Renewal	\$0
(14)	Volunteer License Renewal	\$50
(15)	License Reinstatement after Withdrawal	\$550
(16)	License Reinstatement after Lapse	\$600
(17)	Protested check and/or returned checks	\$100

SECTION 11. CONTINUING MEDICAL EDUCATION (CME) REQUIREMENTS AND DEFINITIONS

1. Requirements

A. General

Each allopathic physician licensed by this Board with an active status license shall complete during each biennial licensing period, a minimum of forty (40) credit hours of Category 1 (as defined by this rule) continuing medical education (CME).

Current certification, including maintenance of certification, by the American Board of Medical Specialties (ABMS) is deemed equivalent to the requirements in section A. Lifetime certification is not deemed equivalent.

B. CME for Opioid Prescribing

Allopathic Physicians must complete 3 hours of Category 1 credit CME every two years on the prescribing of opioid medication as required by 32 M.R.S. § 20161(4) and Board Rule Chapter 21 "Use of Controlled Substances for Treatment of Pain."

- C. If an applicant for re-licensure/re-registration does not complete the required CME, then an Inactive license/registration will be issued unless the Secretary has granted an extension of time or deferment as described in subsection 4A below.

2. Definition of Category I CME

- A. Category 1 CME may include the following:

- (1) CME programs sponsored or co-sponsored by an organization or institution accredited by the American Medical Association Council on Medical Education (AMA), the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), the Committee on Continuing Medical Education of the Maine Medical Association or the Maine Osteopathic Association (MOA). Programs will be properly identified as such by the approved sponsoring or co-sponsoring organization. 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 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 a CME audit.
- (4) Teaching or presentation in activities designated for AMA 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 a 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 a CME audit.

- (6) Postgraduate training, i.e. internship, residency, fellowship.
VALUE: Fifty (50) credit hours per year. VERIFICATION: Certified copy of diploma or transcript, if requested by the Board as part of a CME audit.
- (7) The requirements of the following programs, if completed during the twenty-four (24) months preceding renewal may be considered as equivalent to Category 1. VALUE: Twenty-Five (25) credit hours per year. VERIFICATION: Certified copy of diploma or transcript, if requested by the Board as part of a CME audit.
 - (a) AMA Physicians Recognition Award.
 - (b) Membership in the American Academy of Family Physicians.
 - (c) Professional Development Program of the American College of Obstetricians and Gynecologists.
- (8) Other programs developed or approved from time to time by the Board. VALUE: Determined at the time of approval. VERIFICATION: Determined at the time of approval.

3. Evidence of Completion

Board staff shall perform random audits of CME.

4. Exceptions/Deferments to CME Requirements

- A. The Board Secretary, Board Chair, or other Board designee, at their discretion, may grant an extension of time or deferment not to exceed six (6) months to a licensee who because of prolonged illness, undue hardship, or other extenuating circumstances, has been unable to meet the requirements of CME.
- B. CME will be prorated during the first licensure period.
- C. CME requirements will be stayed for allopathic physicians called to active military duty.

- D. The Board may allow a full or partial exemption from CME requirements for a returning military veteran or the spouse of a returning military veteran; however, evidence of completion of CME may be required for a subsequent license/registration renewal.

SECTION 12. NOTIFICATION REQUIREMENTS FOR ALLOPATHIC PHYSICIANS

1. Change of Contact Information

An allopathic physician licensed with this Board shall notify the Board in writing within ten (10) calendar days of any change in work or home address, e-mail, phone, or other contact information.

2. Criminal Arrest/Summons/Indictment/Conviction

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

3. Changes in Status of Employment or Hospital Privileges

An allopathic physician licensed by the Board 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.

4. Change in Status of Employment of Allopathic Physicians Issued Emergency 100-Day, Temporary, Youth Camp License, or Educational Certificates

An allopathic physician issued an Emergency 100-Day license, Temporary License, Youth Camp License, or Educational Certificate shall notify the Board in writing within ten (10) calendar days of termination of employment with the specific practice location for which the license was issued.

5. Disciplinary Action

An allopathic physician licensed by the Board 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.

6. Material Change

An allopathic physician licensed by the Board 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 allopathic physician's most recent application submitted to the Board.

7. Change of Name

An allopathic physician licensed by the Board shall notify the Board in writing within thirty (30) calendar days regarding any legal change in their name and provide the Board with a copy of the pertinent legal document (e.g. marriage certificate or court order).

SECTION 13. CITATIONS

- 1.** In addition to the Chapter 4, Rules for the Issuance of Citations, the Board, or if delegated, Board staff may issue citations imposing administrative fines to allopathic physicians in lieu of taking disciplinary action for the failure to file a written notification with the Board as required by this rule as follows:

- A.** For each violation of the notification requirements in section 12 subparagraphs 1, 4, 6 and 7 of this chapter, a citation in the amount of \$100 may be issued.
- B.** For each violation of the notification requirements in section 12 subparagraphs 2, 3 and 5 of this chapter, a citation in the amount of \$200 may be issued.

2. Service of Citations

The citation may be served on the licensee by mail or email 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. §§ 20141-20144, 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. Citations 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 14. CONDUCT SUBJECT TO DISCIPLINE

Violation of this rule by an allopathic physician constitutes unprofessional conduct and is grounds for discipline of an allopathic physician's license.

Failure to personally complete all parts of initial or renewal applications and/or addendums that are not expressly required to be performed by another person or entity is a violation of this rule and is grounds for discipline of an allopathic physician's license.

SECTION 15. DUTIES OF THE SECRETARY OF THE BOARD

1. License/ Review and Action

A. The Secretary shall review all applications (initial/ renewal/conversion) for licensure with negative or questionable information. Following review, the Secretary may:

- (1) Approve an application for licensure conversion;
- (2) Require an applicant to submit additional information, including but not limited to professional references or reports, as part of

the application review process;

- (3) Refer an application to an investigative committee of the Board.

2. Other

- A. The Secretary shall provide final approval of special testing accommodations for the USMLE examinations, or may delegate those decisions to the contractor;
- B. All other duties as listed in statute or as from time to time delegated by the Board and recorded in the minutes of the Board.
- C. The Secretary shall review requests to withdraw applications and shall grant the requests or refer to an investigative committee of the Board for discussion.

3. Delegation by Secretary of Assigned Duties

- A. The Secretary may temporarily delegate any duties assigned under this rule to another member of the Board; and
- B. The Secretary may refer any assigned duty to an investigative committee of the Board for final decision.

STATUTORY AUTHORITY: 32 M.R.S. §§ 20112, 20113(1), 20127, 20129, 20130, 20131, 20133, & 20161

EFFECTIVE DATE:

Chapter 2: RULE REGARDING OSTEOPATHIC PHYSICIANS

SUMMARY: Chapter 2 pertains to the licensure, registration, notification and continuing medical education requirements for osteopathic physicians. Chapter 2 also defines the duties of the Board Secretary.

SECTION 1. DEFINITIONS

1. "Accredited Medical School" means a school designated as accredited by the American Osteopathic Association's Commission on Osteopathic College Accreditation.
2. "Active Status License" means the osteopathic physician has an active license in Maine and can practice within the scope of the license issued.
3. "Administrative License" means a license limited to the practice of administrative medicine."
4. "Administrative Medicine" means: a) professional managerial or administrative activities related to the practice of medicine or to the delivery of health care services, but not including the practice of clinical medicine; and/or b) medical research, excluding clinical trials on humans.
5. "Administratively Complete Application" is an application for licensure as developed by the Board which when submitted 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, civil penalties or fines paid.
6. "Board" means the Board of Medicine.
7. "Clinical License" means a license that authorizes a osteopathic physician to practice clinical medicine and/or surgery.

8. "Clinical Medicine" includes but is not limited to: a) direct involvement in patient evaluation, diagnosis and treatment; b) prescribing any medication; c) delegating medical acts, services or prescriptive authority; or d) the supervision of osteopathic or osteopathic physicians who practice clinical medicine, physician associates who render medical services, or the clinical practice of advanced practice registered nurses.
9. COMLEX means the National Board of Osteopathic Medical Examiners' Comprehensive Osteopathic Medical Licensing Examination.
10. "COMVEX" means the Comprehensive Osteopathic Medical Variable-Purpose Examination for the United States of America which was developed for osteopathic physicians who hold or have held a valid license to re-enter the practice of osteopathic medicine in the United States or where an assessment of an osteopathic physician's current medical knowledge is otherwise requested by a state medical board. Appropriate candidates for the COMVEX include osteopathic physicians seeking licensure reinstatement or reactivation after some period of professional inactivity or osteopathic physicians involved in disciplinary proceedings in which the board determines the need for evaluation. The COMVEX is also appropriate for osteopathic physicians applying for licensure by endorsement who are several years beyond initial licensure.
11. "Educational Certificate" means a certificate issued by the Board to a medical school graduate who is enrolled in a post-graduate training program at a specific hospital for a period of not more than seven (7) years. The specific duration of the educational certificate will be based upon the request of the hospital and may be renewed every three years.
12. "Emergency 100-day License" means a license issued to an osteopathic physician for not more than 100 days and issued for declared emergencies in the State or for other appropriate reasons as determined by the Board.
13. "Emeritus License" means a license issued to a qualified osteopathic physician who is licensed in Maine and has retired from the active practice of medicine and does not practice medicine or prescribe any medications.
14. "Fellowship" means advanced supervised postgraduate clinical education in a medical specialty.
15. "Inactive Status License" means the osteopathic physician has an inactive license and cannot practice medicine in Maine. An Inactive Status License is

- primarily designed for physicians who are still practicing in another state and may come back to practice in Maine in the future.
16. “Jurisprudence Examination” means the examination regarding the Board’s laws and rules and laws pertaining to the practice of medicine in Maine, which is required to be taken and passed upon initial active licensure and then every four (4) years thereafter upon application for re-licensure.
 17. “Pending Status License” means the osteopathic physician has submitted an application for licensure or renewal of licensure upon which the Board has not made a final determination.
 18. “Postgraduate Medical Education” means a graduate educational program or combination of graduate educational programs, including but not limited to internships, residencies and fellowships, accredited by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association.
 19. “Reentry License” means a license issued to a qualified osteopathic physician who is otherwise qualified for clinical licensure but has not practiced clinically within the past 24 months. This license is contingent upon compliance with a reentry plan and Reentry to Practice Agreement and automatically ends upon successful completion of the reentry plan and conversion to a clinical license or if the terms of the reentry plan are not met at any time.
 20. “Temporary License” means a license issued by the Board to a qualified osteopathic physician for a period not to exceed one year when the Board determines that this action is necessary in order to provide relief for local or national emergencies or for situations in which the number of physicians is insufficient to supply adequate medical services or for the purpose of permitting the osteopathic physician to serve as locum tenens for another physician who is licensed to practice medicine in this State.
 21. “Unaccredited Medical School” means a school that is not designated as accredited by the American Osteopathic Association’s Commission on Osteopathic College Accreditation.
 22. “Volunteer License” means a license issued by the Board to a qualified osteopathic physician who has retired or is retiring from the active practice of medicine and wishes to donate his or her expertise exclusively for the medical care and treatment of indigent and needy patients in the clinical setting of clinics organized, in whole or in part, for the delivery of health care services without charge.

23. “Youth Camp License” means a temporary license issued by the Board to a qualified osteopathic physician authorizing the osteopathic physician to practice medicine only for the patients in a particular youth camp.

SECTION 2. LICENSE REQUIRED

An individual must hold an active license issued by the Board in order to practice medicine or surgery or a branch of medicine or surgery or claim to be legally licensed to practice medicine or surgery or a branch of medicine or surgery within the State and practice within the scope of that license.

SECTION 3. REQUIREMENTS FOR MEDICAL LICENSURE

To qualify for licensure as an osteopathic physician, an applicant must meet all of the following criteria:

1. Medical Education

- A. Graduate from an osteopathic medical school designated as accredited by the American Osteopathic Association's Commission on Osteopathic College Accreditation.

2. Medical Examinations

A. U.S. National Examinations

- (1) An applicant must achieve a passing score on each component of the National Board of Osteopathic Medical Examiners' Comprehensive Osteopathic Medical Licensing Examination of the United States, known as the COMLEX-USA examination, or other examinations designated by the board as the qualifying examination or examinations for licensure.
- (2) Time and Attempt Limits for Examinations

The applicant must:

- (a) Complete the examination series (COMLEX-USA) within seven (7) years of passing the first examination, with an automatic exception allowed for dual D.O./PhD. candidates.

- (b) Complete the first two steps of the COMLEX-USA examination with unlimited attempts. Steps 1 and 2 may be retaken after successfully passing them ONLY for the purpose of accomplishing or maintaining the seven (7) year limitation named immediately above.
- (c) Complete the final examination in the series (COMLEX-USA) in no more than three (3) attempts. Step 3 may not be retaken once passed with a minimum passing score.
- (d) Request for Waiver

An applicant may apply to the Board for a waiver of the time and attempt limits. The Board may grant a waiver based upon unusual or extenuating circumstances as determined by the Board in its sole discretion.

3. State of Maine Jurisprudence Examination

- A. Every applicant for licensure must attain a passing score of at least seventy-five (75) on the jurisprudence examination administered by the Board.
- B. If a candidate fails to attain a score of seventy-five (75) on the jurisprudence examination, the applicant may be required to appear for an interview before a committee of the Board.

4. Personal Interview

- A. In addition to all other qualifications, the Board may require a personal interview with the applicant to discuss issues identified in the application materials, including but not limited to:
 - (1) Clinical competence;
 - (2) Evidence of disruptive behavior which might negatively impact the practice of medicine or safety of patients;
 - (3) Any conduct that might be grounds for discipline or denial of licensure as provided by law or rule; or
 - (4) Communication skills.

5. Postgraduate Training

A. Graduates on or after January 1, 2026

An applicant who has graduated from an accredited osteopathic medical school on or after January 1, 2026 must have satisfactorily completed at least 36 months in a graduate educational program accredited by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association.

B. Graduates before January 1, 2026

An applicant who has graduated from an accredited osteopathic medical school prior to January 1, 2026 must have satisfactorily completed at least 12 months in a medical graduate educational program accredited by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association.

C. Residents training in Maine

- (1) When the applicant for licensure is in a post-graduate training program in this State that is accredited by the Accreditation Council on Graduate Medical Education or American Osteopathic Association and has completed twenty-four (24) months of postgraduate training (in this State) and has received an unrestricted endorsement from the graduate educational program director, and it is confirmed that the applicant will continue in the program and complete thirty-six (36) months of postgraduate training, and if otherwise qualified, an active clinical license of normal duration may be issued.
- (2) If the applicant who is issued an active clinical license pursuant to subparagraph (D)(1) subsequently discontinues the graduate educational program or must postpone completing the last twelve (12) months of the graduate educational program, both the licensee and the graduate educational program director shall promptly notify the Board in writing, providing full details of the issue(s) and plan for program completion, if any. The Board will review the information provided, and take any action permitted by law, including but not limited to revoking the license.

6. Clinical Competence

Demonstrates continued clinical competency as required by this rule.

SECTION 4. CREDENTIAL VERIFICATION

1. Unless otherwise specified in this rule, all applicants for licensure must complete the process of verifying their core credentials with the Federation Credentials Verification Services (FCVS).

2. Federation Credentials Verification Services (FCVS) For Static Core Credentials

Unless otherwise specified in this rule, the Board requires that applicants for a medical license use the FCVS to verify qualifying credentials which are static or do not change, such as identity, education and post graduate training. This verification process is conducted separately and independently by FCVS.

Unless otherwise specified in this rule, applicants must submit an FCVS application directly to FCVS on an application supplied by the Board or requested directly from FCVS and pay any required fees directly to FCVS. FCVS will then provide the Board with a non-interpretive "Physician Information Profile" containing certified copies of the applicant's credentials.

3. Exemptions to FCVS Credentials Verification. The following applicants are exempt in whole or in part as specified from the requirement of FCVS credentials verification:
 - A. Licensees holding active clinical licenses issued by the Board who apply to convert their licenses to administrative, emeritus, volunteer, or inactive status do not have to complete the FCVS process;
 - B. Applicants who are recent medical school graduates and who apply for an Educational Certificate do not have to complete the FCVS process;
 - C. Applicants for Youth Camp Licenses must show proof of completion of the FCVS application prior to being issued a license. Staff may issue a license prior to receiving the osteopathic physician's credentialing report from the FCVS. Staff shall review the osteopathic physician's credentialing report from the FCVS upon receipt, and notify the Board if any concerning information is discovered; and

- D. Applicants for Emergency 100-Day Licenses must show proof of completion of the FCVS application prior to being issued a license. Staff may issue a license prior to receiving the osteopathic physician's credentialing report from the FCVS. Staff shall review the osteopathic physician's credentialing report from the FCVS upon receipt and notify the Board if any concerning information is discovered.

SECTION 5. LICENSE APPLICATION PROCESS

1. The Board, or if delegated, Board staff may issue an active status clinical license to an applicant who:
 - A. Submits an administratively complete application on forms approved by the Board;
 - B. Pays the appropriate licensure fee or late fee (if any). The application fees cover the cost of processing the application and are not refundable;
 - C. Meets the education requirement;
 - D. Meets the post-graduate training requirement;
 - E. Meets the medical examination requirement;
 - F. Meets the jurisprudence examination requirement;
 - G. Meets the clinical practice requirement;
 - H. Worked and/or was licensed in a foreign country and that jurisdiction or licensing authority has provided verification of licensure directly to the Board;
 - I. Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
 - J. Has personally completed the application, answered all application questions, and performed all steps of the application process not expressly required by law or Board rule to be performed by another person or entity.

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 may consult with the Board Secretary, Board Chair, or other Board designee who may approve the application or refer action on the application to an investigative committee of the Board.

3. License Conversion Between Biennial Renewal Dates

Licensees may apply to convert their active status license to an inactive, emeritus, or volunteer license between scheduled biennial renewal dates by completing the appropriate renewal application and submitting it to the Board. No fee shall be assessed for this conversion. Board staff may convert the license to inactive status.

4. Administratively Incomplete Application

- A. Applicant fails to take action. Any application for a license that has been on file with the Board without action by the applicant for six (6) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process, including payment of new application fees, in order to be considered for licensure.
- B. Application incomplete after 12 months. Any application that is not complete within twelve (12) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process, including payment of new application fees, in order to be considered for licensure unless the applicant seeks, and the Board grants, a waiver of this time limit. Requests for waivers of this time limit may be granted for good cause shown.
- C. Current signed addendum required. Any applicant that has an application that has been submitted six months or longer before the application is complete must submit a new signed addendum prior to issuance of the license.
- D. Application fee required to process application. If the appropriate licensing fee has not been received within 90 days of the application submission the application shall be voided and the applicant must restart the application process.
- E. Prior to the deadlines stated in this section, upon written statement by the applicant that they do not intend to complete their application,

Board staff may close an application file as administratively incomplete upon Board staff's confirmation there are no open medical licensing complaints or investigations against the applicant in Maine or other U.S. jurisdictions.

SECTION 6. SPECIFIC TYPES OF MEDICAL LICENSES

1. Administrative License

- A. The Board, or if delegated, Board staff may issue an administrative license to an applicant who:
 - (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure application fee;
 - (3) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.
- B. Meets the same requirements for licensure as an applicant for an active clinical license with the exception that the applicant is not required to show that he/she has been engaged in the active clinical practice of medicine.
- C. Renewal of Administrative License

An osteopathic physician applying to renew an administrative license must pay the same fees and meet the same requirements for renewing an active status license, including the requirement for continuing medical education (CME).

2. Educational Certificate

- A. The Board, or if delegated, Board staff may issue an educational certificate to an applicant who:
 - (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure application fee;

- (3) Meets the education requirement;
- (4) Provides documentation from the Maine educational/residency program demonstrating enrollment, including the dates of the program;
- (5) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.

B. Educational Certificate Limitation

Educational certificates may only be issued for a specific residency program at a specific Maine hospital.

C. Educational Certificate Duration

Educational certificates may be issued for the duration specified by the Maine hospital's residency director for a period of up to seven (7) years.

D. Educational Certificate Expiration

Educational certificates shall automatically expire:

- (1) On the date specified on the educational certificate, unless renewed; or
- (2) On the date that the Board receives written notification from the director of the residency program at the hospital or the resident that the resident is no longer enrolled in that specific hospital's residency program.
- (3) On the date that the Board receives written notification from the licensee that they are no longer employed or enrolled in that specific hospital's residency program.

3. Emergency 100-Day License

- A. The Board, or if delegated, Board staff may issue an emergency 100-day license to an applicant who:
 - (1) Submits an administratively complete application on forms approved by the Board;

- (2) Pays the appropriate licensure application fee;
- (3) Meets the education requirement;
- (4) Meets the post-graduate training requirement;
- (5) Meets the examination requirement;
- (6) Provides a Letter of Need which describes the circumstances that make the candidate eligible for the license. Such letter shall be transmitted directly from the organization where the osteopathic physician will be practicing under the emergency 100-day license.
- (7) Holds a full and unrestricted license from another United States licensing jurisdiction at the time of the application, and maintains it for the duration of the emergency 100-day license.
- (8) Has had no other license restricted, limited or otherwise disciplined in any other jurisdiction.
- (9) Submits an application for an active clinical license simultaneously with the application for the 100-day license.
- (10) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
- (11) Demonstrates continuing clinical competency as required by this rule.

B. Emergency 100-Day License Limitations

- (1) Emergency licenses may only be issued once to the same applicant and for a period not to exceed 100 calendar days.
- (2) Emergency 100-day licenses may only be issued for a specific practice location.
- (3) Emergency 100-day licenses automatically expire:
 - (a) 100 days after the date of issuance; or

- (b) On the date that the Board receives written notification from the licensee that they are no longer employed at the specific practice location.

4. Emeritus License

- A. The Board, or if delegated, Board staff may issue an emeritus license to an applicant who:

- (1) Currently holds an active or inactive clinical license to practice medicine in Maine;
- (2) Submits an administratively complete application on forms approved by the Board;
- (3) Meets the education requirement; and
- (4) Meets the post-graduate training requirement.

- B. Conversion to Emeritus License Between Scheduled Renewal Dates

An osteopathic physician may convert an existing license to an emeritus license between scheduled renewal dates by filing an application with the Board. Upon receipt of an administratively complete application, the Board staff shall convert the existing license to an emeritus license. The biennial renewal date remains unchanged.

5. Inactive Status License

- A. Upon application for an inactive status, the Board, or if delegated, Board staff may issue an inactive status license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;
- (3) Meets the education requirement;
- (4) Meets the post-graduate training requirement;
- (5) Meets the examination requirement; and

B. Conversion to Inactive License Between Scheduled Renewal Dates

An osteopathic physician may convert an existing license to an inactive license between scheduled renewal dates by filing appropriate documentation, ranging from written confirmation up to a full application for an inactive license, depending on the circumstances. with the Board. Upon receipt of an administratively complete application, the Board staff shall convert the existing license to an inactive license. The biennial renewal date remains unchanged.

C. Due to Investigation

In the event there is an active allegation or investigation about a licensee's fitness to practice, the licensee may agree to voluntarily convert to inactive status until the allegations are addressed.

6. Reentry License

A. The Board may issue a reentry license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;
- (3) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.
- (4) Meets the same requirements for licensure as an applicant for a clinical license with the exception that the applicant has not been engaged in the active clinical practice of medicine for the past 24 months and has provided a reentry plan approved by the Board.

B. A reentry plan must include the following:

- (1) Either (a) a statement of current medical knowledge or (b) an assessment of current medical knowledge and clinical skills, when required by the Board. The purpose of this assessment is to identify any gaps in medical knowledge and clinical skills, as well as to identify areas of strength. The assessment must be performed by an individual and/or entity approved by the Board.

Examples of assessments for physicians include the Comprehensive Osteopathic Medical Variable-Purpose Examination for the United States of America (COMVEX) and the Post-Licensure Assessment System (PLAS);

- (2) **Refresher education.** This education is designed to fill the gaps in medical knowledge identified by the assessment. This may include completion of a mini-residency program;
 - (3) **A clinical preceptorship or the equivalent.** This component is designed to provide mentoring and oversight of clinical care for a specified period by a practice mentor. The practice preceptor or equivalent must have sufficient time and experience, possess a full and unrestricted active clinical license, have no disciplinary history, and provide reports to the Board as required by a reentry to practice agreement;
 - (4) **Final assessment of current competency to establish qualification for an active clinical license.** This component is designed to ensure that a physician or physician associate is ready and able to return to clinical practice without further oversight by the Board;
 - (5) **Reentry to Practice Agreement.** This will be offered to the applicant after the Board has approved their reentry to practice plan. The applicant must execute and at all times comply with this agreement during the period of their licensure as a reentry licensee.
 - (6) **End of Reentry to Practice Agreement.** The Reentry to Practice Agreement ends upon either successful completion of the reentry plan and conversion to a clinical license or if the terms of the reentry plan are not met at any time.
- C. Reentry licensees must comply with their Board-approved reentry plan and practice agreement. Failure to do so may be grounds for imposing discipline on the reentry licensee's license for unprofessional conduct and as further permitted by Board law and rules, up to and including revocation of the license.
- D. Renewal of Reentry License

An osteopathic physician applying to renew a reentry license must pay the same fees and meet the same requirements for renewing a clinical

status license, including the requirement for continuing medical education (CME) and be in compliance with the reentry plan.

7. Temporary License

- A. The Board, or if delegated, Board staff may issue a temporary license to an applicant who:
- (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure application fee;
 - (3) Meets the education requirement;
 - (4) Meets the post-graduate training requirement;
 - (5) Meets the examination requirement;
 - (6) Provides a Letter of Need which describes the circumstances which make the candidate eligible for the license. Such letter shall be transmitted directly from the organization where the osteopathic physician will be practicing under the temporary license.
 - (7) Holds a full and unrestricted license in another state or Canadian province at the time of application, and maintains it for the duration of the temporary license.
 - (8) Has had no other license restricted, limited or otherwise disciplined in any other jurisdiction.
 - (9) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
 - (10) Demonstrates current clinical competency as required by this rule.
- B. Temporary License Limitations
- (1) Temporary licenses may only be issued to the same applicant for a period not to exceed one (1) year. Once a licensee has held a temporary license or a combination of temporary licenses

for one (1) year, they are no longer eligible for another temporary license.

- (2) Temporary licenses may only be issued for a specific practice location.
- (3) Temporary licenses automatically expire:
 - (a) On the date specified on the temporary license; or
 - (b) On the date that the Board receives written notification from the licensee that they are no longer employed at the specific practice location.
 - (c) If the Letter of Need is withdrawn during the application process the application shall be voided.

8. Youth Camp License

- A. The Board, or if delegated, Board staff may issue a youth camp license to an applicant who:
 - (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure fee;
 - (3) Holds a full and unrestricted license in another state or Canadian province at the time of application, and maintains it for the duration of the temporary camp license;
 - (4) Has had no other license restricted, limited or otherwise disciplined in any other jurisdiction;
 - (5) Meets the examination requirement;
 - (6) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
 - (7) Demonstrates continuing clinical competency as required by this rule.

B. Youth Camp License Limitations

- (1) Youth Camp licenses are issued for a limited period.
- (2) Youth Camp licenses may only be issued for a specific youth camp (practice location).
- (3) Youth Camp licenses automatically expire:
 - (a) On the date specified on the Youth Camp license; or
 - (b) On the date that the Board receives written notification from the licensee that they are no longer employed at the specific youth camp (practice location).

9. Volunteer License

A. The Board, or if delegated, Board staff may issue a volunteer license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate license conversion fee;
- (3) Currently holds an active clinical license to practice medicine in a US State or territory;
- (4) The applicant must meet all the requirements for an active clinical Maine medical license, including CME requirements as defined in this rule;
- (5) Must acknowledge or certify that the applicant's practice will be exclusively and totally devoted to providing medical care to needy and indigent persons in Maine. The treatment of family, friends or acquaintances is not permitted under a volunteer license;
- (6) Must acknowledge or certify that the applicant will not receive any payment or compensation, either direct or indirect, or have the expectation of any payment or compensation, for any medical services rendered;

- (7) Reports all locations where they will provide volunteer services;
- (8) Provides to the Board a copy of a written agreement to provide volunteer services at every facility where services will be provided; and
- (9) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.

B. Conversion to Volunteer License Between Scheduled Renewal Dates

When converting to a volunteer license between scheduled renewal dates, the osteopathic physician shall follow the same procedure used to convert from an active clinical license to an inactive license. The biennial renewal cycle remains unchanged.

C. Renewal of Volunteer License

An osteopathic physician applying to renew a volunteer license must meet all requirements for renewing an active clinical license, including CME.

10. Clinical License

This license authorizes an osteopathic physician to practice clinical medicine and/or surgery and is generally renewable every two years.

A. Application Process

- (1) Applications for a clinical medical license will be reviewed by the Board Staff. After review, a clinical license may be issued to an applicant who:
 - (a) Submits an administratively complete application on forms approved by the Board;
 - (b) Pays the appropriate licensure and registration fee to the Board;
 - (c) Meets the examination requirement;

- (d) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
 - (e) Demonstrates continuing clinical competency as required by this rule.
- (2) Board staff may issue a clinical license to applicants who meet each criterion specified below and shall report such actions at the next regular meeting of the Board.
 - (a) A positive review by the Executive Director or the Assistant Executive Director of the application that includes the following criteria:
 - (i) Each qualification for licensure has been clearly met and verified, and all issues or questions have been fully explained and documented;
 - (ii) All personal data questions, with the exception of telemedicine, practice location and malpractice questions on the application have been answered “No”; and
 - (iii) The Board has received the names and contact information of three professional references regarding the applicant, and, if references are obtained, no issues have been identified by those references or contact with those references that reveals potentially disqualifying information
- (3) Applications that do not meet the foregoing criteria as determined by the Executive Director or Assistant Executive Director will be referred to the Board Secretary, Board Chair or other Board designee. The Board Secretary, Board Chair or other Board designee may approve the application or refer the application to an investigative committee of the Board.

SECTION 7. PROCESS FOR CONVERSION OF AN INACTIVE STATUS LICENSE OR ADMINISTRATIVE LICENSE TO AN ACTIVE CLINICAL LICENSE

1. The Board, or if delegated, Board staff may convert an administrative or inactive license to clinical license for an applicant who:
 - A. Submits an administratively complete application requesting an active status license on forms approved by the Board;
 - B. Pays the appropriate license conversion fee;
 - C. Provides evidence of having met the Board's requirements for CME;
 - D. Demonstrates continuing clinical competency as required by this rule;
 - E. Meets the examination requirement; and
 - F. Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.
2. In the event that there is any question regarding CME credits or active clinical practice, the application will be presented to an investigative committee of the Board.

SECTION 8. REQUIREMENTS FOR RENEWAL/REINSTATEMENT/WITHDRAWAL OF LICENSE

1. License Expiration and Renewal

With the exception of Emergency 100-day, Temporary, Youth Camp Licenses, and Temporary Educational Certificates, the license/registration of every osteopathic physician born in an odd-numbered year expires at midnight on the last day of the month of the osteopathic physician's birth every odd-numbered year. The license/registration of every osteopathic physician born in an even-numbered year expires at midnight on the last day of the month of the osteopathic physician's birth every even-numbered year. The osteopathic physician must renew the license/registration every two (2) years prior to the expiration of the license/registration by submitting an administratively complete application to the Board on forms approved by the Board.

2. Renewal Notification

At least sixty (60) days prior to the expiration of a current license/registration, the Board shall notify each licensee of the requirement to renew the license/registration. If an administratively complete re-licensure application has not been submitted prior to the expiration date of the existing license, the license immediately and automatically expires. A license may be reinstated up to 90 days after the date of expiration upon payment of the renewal fee and late fee. If an administratively complete renewal application is not submitted within 90 days of the date of the expiration of the license, the license immediately and automatically lapses. The Board may reinstate a license pursuant to law.

3. Criteria for Active License/ Renewal

- A. The Board, or if delegated, Board staff may renew the active license of an osteopathic physician who meets all of the following requirements:
- (1) Submits an administratively complete license renewal application on forms approved by the Board;
 - (2) Pays the appropriate license renewal fee and/or late fee (if any);
 - (3) Affirms that the licensee has met the CME requirements. In the event that the required CME is not complete, the osteopathic physician may request an extension of time for good cause to complete the CME. The Board Secretary, Board Chair, or other Board designee has the discretion to grant or deny a request for an extension of time to complete the required CME credits;
 - (4) Demonstrates continuing clinical competency as required by this rule;
 - (5) Successfully completes the Board's jurisprudence examination when directed by the Board;
 - (6) Successfully completes the minimum data set survey; and
 - (7) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of licensure as provided by law.

- (8) 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 other Board designee who may approve the application or defer action on the application to an investigative committee of the Board.
- (9) A new licensee who is scheduled to renew three (3) months or less from the date of original licensure will be issued a license through the next renewal cycle.

B. Timeliness of Application

If an application for renewal of license/registration is not administratively complete and postmarked or submitted electronically by the date of expiration of the license/registration, the late fee shall be assessed.

4. Criteria for all other License Renewals

- A. The Board, or if delegated, Board staff may renew the license of an osteopathic physician **other than an active clinical license** who meets all of the following requirements:
 - (1) Submits an administratively complete license renewal application on forms approved by the Board;
 - (2) Pays the appropriate license renewal fee and/or late fee (if any);
 - (3) Affirms that the licensee has met the CME requirements. In the event that the required CME is not complete, the osteopathic physician may request an extension of time for no more than six (6) months for prolonged illness, undue hardship, or other extenuating circumstances to complete the CME. The Board Secretary, Board Chair, or other Board designee has the discretion to grant or deny a request for an extension of time to complete the required CME credits; and
 - (4) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of licensure as provided by law.

- (5) 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 other Board designee who may approve the application or refer action on the application to an investigative committee of the Board.
- (6) A new licensee who is scheduled to renew three (3) months or less from the date of original licensure will be issued a license through the next renewal cycle.

B. Timeliness of Application

If an application for renewal of license is not administratively complete and postmarked or submitted electronically by the date of expiration of the license/registration, the late fee shall be assessed.

5. Process for Withdrawal of License or Withdrawal of an Application for License

- A. An osteopathic physician may request to withdraw a license by submitting an administratively complete renewal application which states the reason for requesting the withdrawal of the license.
- B. An applicant may request to withdraw their application for a license by submitting a written request which states the reason for requesting to withdraw the application.
- C. The Board staff may approve an application to withdraw a license where the Board has no open investigation or complaint regarding the applicant, and the applicant is in compliance with any active consent agreement or decision and order.
- D. Withdrawal requests that occur while an investigation or complaint is pending in another jurisdiction will be reviewed by an investigative committee.
- E. The Board may grant or deny requests to withdraw a license or application for a license.

6. Requirements for License Reinstatement

- A. The Board, or if delegated, Board staff may reinstate a lapsed or withdrawn license of an osteopathic physician who meets all of the following requirements:
 - (1) Submits an administratively complete reinstatement application on forms approved by the Board;
 - (2) Pays the appropriate reinstatement fee(s) and/or late fees (if any);
 - (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;
 - (4) Meets the examination requirement; and
 - (5) 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 other Board designee who may approve the application or refer action on the application to an investigative committee of the Board.
- C. An osteopathic physician whose license has lapsed or been withdrawn for more than five (5) years shall apply for a new license.
- D. The applicant's license may not be reinstated if the applicant has not demonstrated current clinical competency as required by this rule.

SECTION 9. CONTINUING CLINICAL COMPETENCY REQUIREMENTS

1. Requirements

A. General

If an applicant has not engaged in the active practice of clinical medicine during the 24 months immediately preceding the filing of the

application, the Board may determine on a case-by-case basis in its discretion whether the applicant has adequately demonstrated continued competency to practice clinical medicine.

B. Demonstrating Current Competency

The Board may require an applicant to submit to any competency assessment(s) or evaluation(s) conducted by a program approved by the Board. If the assessment/evaluation identifies gaps or deficiencies, the applicant must complete an educational/remedial program to address them. The Board retains the discretion regarding the method of determining continued competency based upon the applicant's specific circumstances. The methodology may include but is not limited to successful passage of examination(s), completion of additional training, and successful completion of a formal reentry to practice program approved by the Board.

C. If the Board determines that an applicant requires a period of supervised practice and/or the completion of an educational or training program, the Board may at its discretion issue the applicant a probationary license pursuant to a consent agreement or issue an applicant a reentry license in conjunction with a return to practice plan.

D. All expenses resulting from the assessment and/or any training requirements are the sole responsibility of the applicant and not of the Board.

SECTION 10. FEES

1. License, Registration, Examination & Late Fees

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

(1)	Initial License Application	\$600
(2)	Initial Jurisprudence Examination	\$100
(3)	Temporary License Application.....	\$400
(4)	Emergency 100-Day License Application	\$400

(5)	Education Certificate (3 years).....	\$300
	(Fee may be prorated for 2 nd or 3 rd year initial applicants)	
(6)	Emeritus License	\$0
(7)	Volunteer License	\$50
(8)	Youth Camp License Application	\$100
(9)	License/Registration Renewal	\$500
(10)	License/Registration Renewal within 6 months of initial Licensure	\$150
(11)	Inactive License Renewal	\$100
(12)	License Renewal Late Fee	\$100
	(Renewal application filed after license expiration date)	
(13)	Emeritus License Renewal	\$0
(14)	Volunteer License Renewal	\$50
(15)	License Reinstatement after Withdrawal	\$550
(16)	License Reinstatement after Lapse	\$600
(17)	Protested check and/or returned checks	\$100

SECTION 11. CONTINUING MEDICAL EDUCATION (CME) REQUIREMENTS AND DEFINITIONS

1. Requirements

A. General

- i. Each osteopathic physician licensed by this Board with an active status license shall complete during each biennial licensing period, a minimum of forty (40) credit hours of Category 1 (as defined by this rule) of continuing medical education (CME).
- ii. For the purposes of this section only, “Primary care physicians” means family or general practitioners, general internists and general

pediatricians and “Osteopathic specialists” means any doctor of osteopathy not considered a primary care physician.

- iii. For Primary care physicians at least twenty (20) of the forty (40) hours of CME obtained must be osteopathic medical education, "Osteopathic medical education" is CME designated by the American Osteopathic Association (AOA) as Category 1. This requirement does not apply to Osteopathic specialists.
 - iv. Current certification, including maintenance of certification, by the AOA for primary care physicians is deemed equivalent to the requirements in section A. Lifetime certification is not deemed equivalent.
 - v. Current certification, including maintenance of certification, by the AOA or the American Board of Medical Specialties (ABMS) for osteopathic specialists is deemed equivalent to the requirements in section A. Lifetime certification is not deemed equivalent.
- B. CME for Opioid Prescribing

Osteopathic Physicians must complete 3 hours of Category 1 credit CME every two years on the prescribing of opioid medication as required by 32 M.R.S. § 20161(4) and Board Rule Chapter 21 “Use of Controlled Substances for Treatment of Pain.”

- C. If an applicant for re-licensure/re-registration does not complete the required CME, then an Inactive license/registration will be issued unless the Secretary has granted an extension of time or deferment as described in subsection 4A below.

2. Definition of Category I CME

- A. Category 1 CME may include the following:

(1) CME programs sponsored or co-sponsored by an organization or institution accredited by the American Osteopathic Association (AOA), American Medical Association Council on Medical Education (AMA), the Accreditation Council for Continuing Medical Education (ACCME), the Maine Osteopathic Association (MOA), or the Committee on Continuing Medical Education of the Maine Medical Association. Programs will be properly identified as such by the approved sponsoring or co-sponsoring organization. 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 AOA or AMA 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 a CME audit.
- (4) Teaching or presentation in activities designated for AOA or AMA 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 a 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 a CME audit.
- (6) Postgraduate training, i.e. internship, residency, fellowship.
VALUE: Fifty (50) credit hours per year. VERIFICATION: Certified copy of diploma or transcript, if requested by the Board as part of a CME audit.
- (7) Other programs developed or approved from time to time by the Board. VALUE: Determined at the time of approval.
VERIFICATION: Determined at the time of approval.

3. Evidence of Completion

Board staff shall perform random audits of CME.

4. Exceptions/Deferments to CME Requirements

- A. The Board Secretary, Board Chair, or other Board designee, at their discretion, may grant an extension of time or deferment not to exceed six (6) months to a licensee who because of prolonged illness, undue hardship, or other extenuating circumstances has been unable to meet the requirements of CME.
- B. CME will be prorated during the first licensure period.
- C. CME requirements will be stayed for osteopathic physicians called to active military duty.
- D. The Board may allow a full or partial exemption from CME requirements for a returning military veteran or the spouse of a returning military veteran; however, evidence of completion of CME may be required for a subsequent license/registration renewal.

SECTION 12. NOTIFICATION REQUIREMENTS FOR OSTEOPATHIC PHYSICIANS

1. Change of Contact Information

An osteopathic physician licensed with this Board shall notify the Board in writing within ten (10) calendar days of any change in work or home address, e-mail, phone, or other contact information.

2. Criminal Arrest/Summons/Indictment/Conviction

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

3. Changes in Status of Employment or Hospital Privileges

An osteopathic physician licensed by the Board 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.

4. Change in Status of Employment of Osteopathic Physicians Issued Emergency 100-Day, Temporary, Youth Camp License, or Educational Certificates

An osteopathic physician issued an Emergency 100-Day license, Temporary License, Youth Camp License, or Educational Certificate shall notify the Board in writing within ten (10) calendar days of termination of employment with the specific practice location for which the license was issued.

5. Disciplinary Action

An osteopathic physician licensed by the Board 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.

6. Material Change

An osteopathic physician licensed by the Board 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 osteopathic physician's most recent application submitted to the Board.

7. Change of Name

An osteopathic physician licensed by the Board shall notify the Board in writing within thirty (30) calendar days regarding any legal change in their name and provide the Board with a copy of the pertinent legal document (e.g. marriage certificate or court order).

SECTION 13. CITATIONS

1. In addition to the Chapter 4, Rules for the Issuance of Citations, the Board, or if delegated, Board staff may issue citations imposing administrative fines to osteopathic physicians in lieu of taking disciplinary action for the failure to file a written notification with the Board as required by this rule as follows:
 - A. For each violation of the notification requirements in section 12 subparagraphs 1, 4, 6 and 7 of this chapter, a citation in the amount of \$100 may be issued.
 - B. For each violation of the notification requirements in section 12 subparagraphs 2, 3 and 5 of this chapter, a citation in the amount of \$200 may be issued.

2. Service of Citations

The citation may be served on the licensee by mail or email 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. §§ 20141-20144, 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. Citations 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 14. CONDUCT SUBJECT TO DISCIPLINE

Violation of this rule by an osteopathic physician constitutes unprofessional conduct and is grounds for discipline of an osteopathic physician's license.

Failure to personally complete all parts of initial or renewal applications and/or addendums that are not expressly required to be performed by another person or entity is a violation of this rule and is grounds for discipline of an osteopathic physician's license.

SECTION 15. DUTIES OF THE SECRETARY OF THE BOARD

1. License Review and Action

- A. The Secretary shall review all applications (initial/ renewal/conversion) for licensure with negative or questionable information. Following review, the Secretary may:
 - (1) Approve an application for licensure conversion;
 - (2) Require an applicant to submit additional information, including but not limited to professional references or reports, as part of the application review process;
 - (3) Present an application to the full Board.

2. Other

- A. The Secretary shall provide final approval of special testing accommodations for the USMLE examinations, or may delegate those decisions to the contractor;
- B. All other duties as listed in statute or as from time to time delegated by the Board and recorded in the minutes of the Board.
- C. The Secretary shall review requests to withdraw applications and shall grant the requests or refer to the full Board for discussion.

3. Delegation by Secretary of Assigned Duties

- A. The Secretary may temporarily delegate any duties assigned under this rule to another member of the Board; and
- B. The Secretary may refer any assigned duty to the full Board for final decision.

STATUTORY AUTHORITY: 32 M.R.S. §§ 20112, 20113(1), 20128, 20129, 20130, 20131, 20133, & 20161

EFFECTIVE DATE:

Chapter 3: RULE REGARDING PHYSICIAN ASSOCIATES

SUMMARY: Chapter 3 is a rule pertaining to the licensure, compact privileges, scope of practice, continuing clinical competency, consultation, notices of employment, collaborative agreements, notification, and continuing education requirements for physician associates who are licensed or hold privileges in Maine.

SECTION 1. DEFINITIONS

1. “AAPA” means the American Academy of Physician Associates.
2. “Active Unrestricted Physician License” means an active Maine physician license to practice medicine that does not include any restrictions or limitations on the scope of practice or ability to consult with or collaborate with physician associates.
3. “Administrative License” means a license limited to the practice of administrative medicine.”
4. “Administratively Complete Application” is an application for licensure 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.
5. “AMA” means the American Medical Association.
6. “AOA” means the American Osteopathic Association.
7. “Board” means the Board of Medicine.
8. “Collaborative Agreement” means a document agreed to by a physician associate and a physician that describes the scope of practice for the physician associate as determined by the practice setting and describes the

decision-making process for a health care team, including communication and consultation among health care team members. A collaborative agreement is subject to review and approval by the Board.

9. "Compact privilege" has the meaning set forth by the Legislature in 32 M.R.S. § 18532(3) and means the authorization granted by a remote state to allow a licensee from another participating state to practice as a physician associate to provide medical services and other licensed activity to a patient located in the remote state under the remote state's laws and regulations.
10. "Consultation" means engagement in a process in which members of a health care team use their complimentary training, skill, knowledge and experience to provide the best care for a patient.
11. "Emergency 100-day License" means a license issued to an physician associate for not more than 100 days and issued for declared emergencies in the State or for other appropriate reasons as determined by the Board.
12. "Emeritus License" means a license issued to a qualified physician associate who is licensed in Maine and has retired from the active practice of medicine and does not render medical services or prescribe any medications.
13. "Health care facility" means a facility, institution or entity licensed pursuant to State law or certified by the United States Department of Health and Human Services, Health Resources and Services Administration that offers healthcare to persons in this State, including hospitals and any clinics or offices affiliated with hospitals and any community health center, each of which has a system of credentialing and granting of privileges to perform health care services and that follows a written professional competence review process.
14. "Health care team" means 2 or more health care professionals working in a coordinated, complementary and agreed upon manner to provide quality, cost-effective, evidence-based care to a patient and may include a physician, physician associate, advance practice nurse, nurse, physical therapist, occupational therapist, speech therapist, social worker, nutritionist, psychotherapist, counselor or other licensed professional.
15. "Inactive status license" means the physician associate has an inactive license and cannot render medical services in Maine. An Inactive Status License is primarily designed for physician associates who are still practicing in another state and may come back to practice in Maine in the future.

16. “License” means a document issued by the Board to a physician associate that identifies the physician associate as qualified by training and education to render medical services.
17. “NCCPA” means the National Commission on Certification of Physician Assistants.
18. “PA” means a physician associate in Maine, but other states, legal entities, or jurisdictions may use the alternate physician assistant. In this rule “PA” means either physician assistant or physician associate. An individual holding a Maine license or a compact privilege in Maine is a physician associate, regardless of the label they are given by other states, legal entities, or jurisdictions.
19. “PA Licensure Compact” means the licensure compact as enacted by the participating states which allows medical services to be rendered by PAs, via the mutual recognition of the licensee’s qualifying license by other compact participating states.
20. “Physician” means a person licensed as a physician by the Maine Board of Medicine.
21. “Physician associate” means a person who has graduated from a physician assistant or physician associate 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 issued by the Board. Only physician associates who are currently certified by the NCCPA may use the initials PA-C.
22. “Physician Group Practice” means an entity composed of 2 or more physicians that offers healthcare to persons in this State and that has a system of credentialing and granting of privileges to perform health care services and that follows a written professional competence review process.
23. “Qualifying License” means an unrestricted license to provide medical services as a PA that have been issued by a participating state under the PA Licensure Compact.

24. “Reentry License” means a license issued to a qualified physician associate who is otherwise qualified for clinical licensure but has not practiced clinically within the past 24 months. This license is contingent upon compliance with a reentry plan and Reentry to Practice Agreement and automatically ends upon successful completion of the reentry plan and conversion to a clinical license or if the terms of the reentry plan are not met at any time.
25. Rendering Medical Services includes but is not limited to: a) direct involvement in patient evaluation, diagnosis and treatment; b) prescribing any medication; or c) delegating medical acts, services or prescriptive authority.
26. “Volunteer License” means a license issued by the Board to a qualified physician associate who has retired or is retiring from the active rendering of medical services and wishes to donate their expertise exclusively for the medical care and treatment of indigent and needy patients in the clinical setting of clinics organized, in whole or in part, for the delivery of health care services without charge.
27. “Youth Camp License” means a temporary license issued by the Board to a qualified physician associate authorizing the physician associate to render medical services only for the patients in a particular youth camp.

SECTION 2. LICENSE OR COMPACT PRIVILEGE REQUIRED

All physician associates who render medical services to patients located in Maine shall hold either:

1. An active license issued by the Board, or
2. A valid compact privilege to provide medical services in Maine.

SECTION 3. QUALIFICATIONS FOR LICENSURE

1. Application for Licensure

- A. Applicants for physician associate licensure shall complete the Board-approved application forms and submit them to the Board together with all required fees and required documentation.

2. 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 associate to an applicant who:
- (1) Submits an administratively complete application;
 - (2) Pays the appropriate licensure fee;
 - (3) Has successfully completed an educational program for physician associate accredited by the American Medical Association Committee on Allied Health Education and Accreditation, the Commission for Accreditation of the Allied Health Education Programs, the Accreditation Review Commission on Education for the Physician Assistant or their successors;
 - (4) Has no license, certification or registration as a physician associate, 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 an investigative committee of the 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 associate 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. Administratively Incomplete Application

- (1) Applicant fails to take action. Any application for a license that has been on file with the Board without action by the applicant for six (6) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process, including payment of new application fees, in order to be considered for licensure.
- (2) Application incomplete after 12 months. Any application that is not complete within twelve (12) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process, including payment of new application fees, in order to be considered for licensure unless the applicant seeks, and the Board grants, a waiver of this time limit. Requests for waivers of this time limit may be granted for good cause shown.
- (3) Current signed addendum required. Any applicant that has an application that has been submitted six months or longer before the application is complete must submit a new signed addendum prior to issuance of the license.
- (4) Application fee required to process application. If the appropriate licensing fee has not been received within 90 days of the application submission it shall be voided and the applicant must restart the application process.
- (5) Prior to the deadlines stated in this section, upon written statement by the applicant that they do not intend to complete their application, Board staff may close an application file as administratively incomplete upon Board staff's confirmation

there are no open medical licensing complaints or investigations against the applicant in Maine or other U.S. jurisdictions.

3. Requirements for Full License

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

- (1) Submits an administratively complete application form;
- (2) Pays the appropriate licensure fee;
- (3) Has successfully completed an educational program for physician assistants/associates accredited by the American Medical Association Committee on Allied Health Education and Accreditation, or the Commission for Accreditation of the Allied Health Education Programs, the Accreditation Review Commission on Education for the Physician Assistant or their successors;
- (4) Has no license, certification or registration as a physician associate, 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.
- (8) Demonstrates current clinical competency as required by this rule.
- (9) A new licensee who is scheduled to renew three (3) months or less from the date of original licensure will be issued a license through the next renewal cycle.

- 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. Administratively Incomplete Application
- (1) Applicant fails to take action. Any application for a license that has been on file with the Board without action by the applicant for six (6) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process, including payment of new application fees, in order to be considered for licensure.
 - (2) Application incomplete after 12 months. Any application that is not complete within twelve (12) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process, including payment of new application fees, in order to be considered for licensure unless the applicant seeks, and the Board grants, a waiver of this time limit. Requests for waivers of this time limit may be granted for good cause shown.
 - (3) Current signed addendum required. Any applicant that has an application that has been submitted six months or longer before the application is complete must submit a new signed addendum prior to issuance of the license.
 - (4) Application fee required to process application. If the appropriate licensing fee has not been received within 90 days of the application submission it shall be voided and the applicant must restart the application process.
 - (5) Prior to the deadlines stated in this section, upon written statement by the applicant that they do not intend to complete their application, Board staff may close an application file as administratively incomplete upon Board staff's confirmation there are no open medical licensing complaints or investigations against the applicant in Maine or other U.S. jurisdictions.

SECTION 4: OTHER SPECIFIC TYPES OF LICENSES

1. Administrative License

- A. The Board, or if delegated, Board staff may issue an administrative license to an applicant who:
 - (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure application fee;
 - (3) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.
- B. Meets the same requirements for licensure as an applicant for an active full license with the exception that the applicant is not required to show that they have been engaged in the active rendering of medical services.
- C. Renewal of Administrative License

A physician associate applying to renew an administrative license must pay the same fees and meet the same requirements for renewing an active full license, including the requirement for continuing medical education (CME).

2. Emergency 100-Day License

- A. The Board, or if delegated, Board staff may issue an emergency 100-day license to an applicant who:
 - (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure application fee;
 - (3) Meets the education requirement;
 - (4) Meets the examination requirement;
 - (5) Provides a Letter of Need which describes the circumstances that make the candidate eligible for the license. Such letter shall be transmitted directly from the organization where the

physician associate will be practicing under the emergency 100-day license.

- (6) Holds a full and unrestricted license from another United States licensing jurisdiction at the time of the application and maintains it for the duration of the emergency 100-day license.
- (7) Has had no other license restricted, limited or otherwise disciplined in any other jurisdiction.
- (8) Submits an application for an active full license simultaneously with the application for the 100-day license.
- (9) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
- (10) Demonstrates continuing clinical competency as required by this rule.

B. Emergency 100-Day License Limitations

- (1) Emergency licenses may only be issued once to the same applicant and for a period not to exceed 100 calendar days.
- (2) Emergency 100-day licenses may only be issued for a specific practice location.
- (3) Emergency 100-day licenses automatically expire:
 - (a) On the date specified on the emergency 100-day license; or
 - (b) On the date that the Board receives written notification from the licensee that they are no longer employed at the specific practice location.

3. Emeritus License

A. The Board, or if delegated, Board staff may issue an emeritus license to an applicant who:

- (1) Currently holds an active or inactive full license to render medical services in Maine;

- (2) Submits an administratively complete application on forms approved by the Board; and
- (3) Meets the education requirement.

B. Conversion to Emeritus License Between Scheduled Renewal Dates

A physician associate may convert an existing license to an emeritus license between scheduled renewal dates by filing an application with the Board. Upon receipt of an administratively complete application, the Board staff shall convert the existing license to an emeritus license. The biennial renewal date remains unchanged.

4. Inactive Status License

A. The Board, or if delegated, Board staff may issue an inactive status license to an applicant who:

- (1) Submits an administratively complete application on forms approved by the Board;
- (2) Pays the appropriate licensure application fee;
- (3) Meets the education requirement; and
- (4) Meets the examination requirement.

B. Conversion to Inactive License Between Scheduled Renewal Dates

A physician associate may convert an existing license to an inactive license between scheduled renewal dates by filing appropriate documentation, ranging from written confirmation up to a full application for an inactive license, depending on the circumstances with the Board. Upon receipt of an administratively complete application, the Board staff shall convert the existing license to an inactive license. The biennial renewal date remains unchanged.

C. Due to Investigation

In the event there is an active allegation or investigation about a licensee's fitness to practice, the licensee may agree to voluntarily convert to inactive status until the allegations are addressed.

5. Reentry License

- A. The Board may issue a reentry license to an applicant who:
- (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure application fee;
 - (3) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.
 - (4) Meets the same requirements for licensure as an applicant for a full license with the exception that the applicant has not been engaged in the active rendering of medical services for the past 24 months and has provided a reentry plan approved by the Board.
- B. A reentry plan must include the following:
- (1) Either (a) a statement of current medical knowledge or (b) an assessment of current medical knowledge and clinical skills, when required by the Board. The purpose of this assessment is to identify any gaps in medical knowledge and clinical skills, as well as to identify areas of strength. The assessment must be performed by an individual and/or entity approved by the Board. Examples of assessments for physician associates include the Physician Assistant National Recertifying Exam® (PANRE), the Physician Assistant National Recertifying Exam-Longitudinal Assessment (PANRE-LA®), the Special Purpose Examination (SPEX) and the Post-Licensure Assessment System (PLAS);
 - (2) **Refresher education.** This education is designed to fill the gaps in medical knowledge identified by the assessment. This may include completion of a mini-residency program;
 - (3) **A clinical preceptorship or the equivalent.** This component is designed to provide mentoring and oversight of clinical care for a specified period by a practice mentor. The practice preceptor or equivalent must have sufficient time and experience, possess a full and unrestricted active clinical license, have no disciplinary

history, and provide reports to the Board as required by a reentry to practice agreement;

- (4) **Final assessment of current competency to establish qualification for an active clinical license.** This component is designed to ensure that a physician associate is ready and able to return to clinical practice without further oversight by the Board;
- (5) **Reentry to Practice Agreement.** This will be offered to the applicant after the Board has approved their reentry to practice plan. The applicant must execute and at all times comply with this agreement during the period of their licensure as a reentry licensee.
- (6) **End of Reentry to Practice Agreement.** The Reentry to Practice Agreement ends upon either successful completion of the reentry plan and conversion to a full license or if the terms of the reentry plan are not met at any time.

C. Reentry licensees must comply with their Board-approved reentry plan and practice agreement. Failure to do so may be grounds for imposing discipline on the reentry licensee's license for unprofessional conduct and as further permitted by Board law and rules, up to and including revocation of the license.

D. Renewal of Reentry License

A physician associate applying to renew a reentry license must pay the same fees and meet the same requirements for renewing a clinical full license, including the requirement for continuing medical education (CME) and be in compliance with the reentry plan.

6. Youth Camp License

- A. The Board, or if delegated, Board staff may issue a youth camp license to an applicant who:
 - (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate licensure fee;

- (3) Holds a full and unrestricted license in another state or Canadian province at the time of application, and maintains it for the duration of the temporary camp license;
- (4) Has had no other license restricted, limited or otherwise disciplined in any other jurisdiction;
- (5) Meets the examination requirement;
- (6) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law; and
- (7) Demonstrates continuing clinical competency as required by this rule.

B. Youth Camp License Limitations

- (1) Youth Camp licenses are issued for a limited period.
- (2) Youth Camp licenses may only be issued for a specific youth camp (practice location).
- (3) Youth Camp licenses automatically expire:
 - (a) On the date specified on the Youth Camp license; or
 - (b) On the date that the Board receives written notification from the licensee that they are no longer employed at the specific youth camp (practice location).

7. Volunteer License

- A. The Board, or if delegated, Board staff may issue a volunteer license to an applicant who:
- (1) Submits an administratively complete application on forms approved by the Board;
 - (2) Pays the appropriate license conversion fee;
 - (3) Currently holds an active full license to render medical services in a US State or Territory;

- (4) The applicant must meet all the requirements for an active full Maine license, including CME requirements as defined in this rule;
- (5) Must acknowledge or certify that the applicant's practice will be exclusively and totally devoted to providing medical care to needy and indigent persons in Maine. The treatment of family, friends or acquaintances is not permitted under a volunteer license;
- (6) Must acknowledge or certify that the applicant will not receive any payment or compensation, either direct or indirect, or have the expectation of any payment or compensation, for any medical services rendered;
- (7) Reports all locations where they will provide volunteer services; and
- (8) Provides to the Board a copy of a written agreement to provide volunteer services at every facility where services will be provided.
- (9) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.

B. Conversion to Volunteer License Between Scheduled Renewal Dates

When converting to a volunteer license between scheduled renewal dates, the physician associate shall follow the same procedure used to convert from an active full license to an inactive license. The biennial renewal cycle remains unchanged.

C. Renewal of Volunteer License

A physician associate applying to renew a volunteer license must meet all requirements for renewing an active full license, including CME.

SECTION 5: EXERCISE OF COMPACT PRIVILEGES

1. To exercise their compact privilege, an individual PA holding a qualifying license from a participating state must comply with the requirements of the PA Licensure Compact and the Compact Rules.

2. All PAs holding compact privileges to provide medical services in Maine are subject to Maine's disciplinary statutes and rules applicable to the rendering or providing of medical services.
3. Compact privileges are effective for the term defined by the PA Licensure Compact and Compact Rules.

SECTION 6. PROCESS FOR CONVERSION OF AN INACTIVE STATUS LICENSE OR ADMINISTRATIVE LICENSE TO AN ACTIVE CLINICAL LICENSE

1. The Board, or if delegated, Board staff may convert an administrative or inactive license to full license for an applicant who:
 - A. Submits an administratively complete application requesting an active status license on forms approved by the Board;
 - B. Pays the appropriate license conversion fee;
 - C. Provides evidence of having met the Board's requirements for CME;
 - D. Demonstrates continuing clinical competency as required by this rule;
 - E. Meets the examination requirement; and
 - F. Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.
2. In the event that there is any question regarding CME credits or active clinical practice, the application will be presented to an investigative committee of the Board.

SECTION 7. REQUIREMENTS FOR RENEWAL / INACTIVE STATUS / REINSTATEMENT / WITHDRAWAL OF LICENSE

1. License Expiration and Renewal

Except for temporary licenses and compact privileges, the license of every physician associate born in an odd-numbered year expires at midnight on the last day of the month of the physician associate's birth every odd-numbered year. The license of every physician associate born in an even-numbered year expires at midnight on the last day of the month of the physician

associate's birth every even-numbered year. The physician associate must renew the license every two (2) years prior to the expiration of the license by submitting an administratively complete application to the Board on forms approved by the Board.

Compact privileges are valid until the expiration or revocation of the qualifying license unless terminated pursuant to an Adverse Action. Compact privileges must be renewed at the time the qualifying license is renewed.

2. Renewal Notification

At least sixty (60) days prior to the expiration of a current license, the Board shall notify each licensee of the requirement to renew the license. If an administratively complete re-licensure application has not been submitted prior to the expiration date of the existing license, the license immediately and automatically expires. A license may be reinstated up to 90 days after the date of expiration upon payment of the renewal fee and late fee. If an administratively complete renewal application is not submitted within 90 days of the date of the expiration of the license, the license immediately and automatically lapses. The Board may reinstate a license pursuant to law.

3. Criteria for Active License Renewal

- A. The Board, or if delegated, Board staff may renew the active license of a physician associate who meets the following requirements:
- (1) Submits an administratively complete license renewal application form;
 - (2) Pays the appropriate license renewal fee and/or late fee (if any);
 - (3) Affirms that the licensee has met the CME requirements. In the event that the required CME is not complete, the physician associate 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;
 - (4) Demonstrates continuing clinical competency as required by this rule;
 - (5) Successfully completes the Board's jurisprudence examination when directed by the Board; and

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

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 refer action on the application to an investigative committee of the Board.

C. Timeliness of Application

If an application for renewal of license is not administratively complete and postmarked or received electronically by the date of expiration of the license, the late fee shall be assessed.

4. Criteria for Inactive License Renewals

A. The Board, or if delegated, Board staff may renew the inactive license of a physician associate who meets all of the following requirements:

- (1) Submits an administratively complete license application form;
- (2) Pays the appropriate license renewal fee and/or late fee (if any); and
- (3) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of licensure as provided by law.

B. Timeliness of Application

If an application for renewal of license is not administratively complete and postmarked or received electronically by the date of expiration of the license, the late fee shall be assessed.

5. License Status Conversions Between Scheduled Renewal Dates

A. Process for Conversion from Active to Inactive License

A physician associate may convert an active license to an inactive license between scheduled renewal dates by filing a written request

with the Board. Upon receipt of a written request, the Board staff shall convert the active license to an inactive license. The biennial renewal date remains unchanged.

6. Process for Withdrawal of License or Withdrawal of an Application for License

- A. A physician associate may request to withdraw a license by submitting an administratively complete renewal application which states the reason for requesting the withdrawal of the license.
- B. An applicant may request to withdraw their application for a license by submitting a written request which states the reason for requesting to withdraw the application.
- C. The Board staff may approve an application to withdraw a license where the Board has no open investigation or complaint regarding the applicant, and the applicant is in compliance with any active consent agreement or decision and order.
- D. Withdrawal requests that occur while an investigation or complaint is pending in another jurisdiction will be reviewed by an investigative committee.
- E. The Board may grant or deny requests to withdraw a license or application for a license.

7. Requirements for License Reinstatement

- A. The Board, or if delegated, Board staff may reinstate a lapsed or withdrawn license of a physician associate who meets all of the following requirements:
 - (1) Submits an administratively complete reinstatement application;
 - (2) Pays the appropriate reinstatement fee(s);
 - (3) Provides a written statement explaining why they withdrew or allowed the license to lapse and a detailed listing of their activities since that time;

- (4) Held a Maine physician associate license or was deemed to have held a valid Maine physician associate license prior to filing an application for reinstatement;
 - (5) Passes, at the time of license application, a jurisprudence examination administered by the Board;
 - (6) 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;
 - (7) Demonstrates current clinical competency as required by this rule; and
 - (8) 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 refer action on the application to an investigative committee of the Board.
- C. A physician associate whose license has lapsed or been withdrawn for more than five (5) years shall apply for a new license.
- D. The applicant's license may not be reinstated if the applicant has not provided evidence satisfactory to the Board of having actively engaged in active rendering of medical services continuously for at least the past 12 months under the license of another jurisdiction of the United States or Canada unless the applicant has first satisfied the Board of the applicant's current competency by passage of written examinations or practical demonstrations as the Board may prescribe, including but not limited to meeting the continued clinical competency requirements of this rule.

SECTION 8. CONTINUING CLINICAL COMPETENCY REQUIREMENTS

1. Requirements

A. General

If an applicant has not engaged in the active rendering of medical services during the 24 months immediately preceding the filing of the application, the Board may determine on a case-by-case basis in its discretion whether the applicant has adequately demonstrated continued competency to render medical services.

B. Demonstrating Current Competency

The Board may require an applicant to submit to any competency assessment(s) or evaluation(s) conducted by a program approved by the Board. If the assessment/evaluation identifies gaps or deficiencies, the applicant must complete an educational/remedial program to address them or engage in supervised practice as required by the Board. The Board retains the discretion regarding the method of determining continued competency based upon the applicant's specific circumstances. The methodology may include but is not limited to successful passage of examination(s), completion of additional training, and successful completion of a formal reentry to practice plan approved by the Board.

C. If the Board determines that an applicant requires a period of supervised practice and/or the completion of an educational or training program, the Board may at its discretion issue the applicant a probationary license pursuant to a consent agreement or issue an applicant a reentry license in conjunction with a reentry to practice plan.

D. All expenses, including but not limited to, expenses associated with the assessment, evaluation, test, supervision and/or training requirements are the sole responsibility of the applicant.

SECTION 9. FEES

1. License, Registration, Examination & Late Fees

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

- (1) Initial License Application\$300
- (2) Initial Jurisprudence Examination\$50

(3)	Emergency 100-Day License Application	\$200
(4)	Emeritus License	\$0
(5)	Volunteer License	\$50
(6)	Youth Camp License Application	\$100
(7)	Late Fee	\$50
(8)	Inactive License Renewal	\$50
(9)	License Renewal	\$250
(10)	Emeritus License Renewal	\$0
(11)	Volunteer License Renewal	\$50
(12)	License Reinstatement after Withdrawal	\$200
(13)	License Reinstatement after Lapse	\$400
(14)	Compact Privilege Initial	\$300
(15)	Compact Privilege Renewal.....	\$250

2. Board staff may prorate the fees for any license that will expire less than six (6) months after its issuance.

SECTION 10. SCOPE OF PRACTICE FOR PHYSICIAN ASSOCIATES

1. General

A licensed physician associate or one holding a compact privilege may provide any medical service for which the physician associate has been prepared by education, training and experience and is competent to perform. The scope of practice of a physician associate is determined by the practice setting. Physician associate scope of practice delineated in collaborative agreements are subject to review and approval by the Board.

2. Practice Setting

A physician associate may render medical services in the following settings including, but not limited to a physician employer setting, physician group practice setting or independent private practice setting, or in a health care facility setting, by a system of credentialing and granting of privileges.

3. Consultation

Physician associates shall, as indicated by a patient's condition, the education, competencies and experience of the physician associate and the standards of care, consult with, collaborate with or refer the patient to an appropriate physician or other health care professional. The level of consultation required is determined by the practice setting, including a

physician employer, physician group practice, or private practice, or by the system of credentialing and granting of privileges of a health care facility.. Consultation may occur electronically or through telecommunication and includes communication, task sharing and education among all members of a health care team. Upon request of the Board, a physician associate shall identify the physician who is currently available or was available for consultation with the physician associate.

4. Delegation by Physician Associates

A physician associate may delegate to the physician associate's employees or support staff or members of a health care team, including medical assistants, certain activities relating to medical care and treatment carried out by custom and usage when the activities are under the control of the physician associate. The physician associate who delegates an activity is legally liable for the activity performed by the employee, medical assistant, support staff or a member of a health care team.

5. Dispensing Drugs

Except for distributing a professional sample of a prescription or legend drug, a physician associate who dispenses a prescription or legend drug:

- A. Shall do so consistent with the standard of care, appropriate prescribing based on the patient's presentation and appropriate medical decision making, and solely within their appropriate scope of practice
- B. Shall comply with all relevant federal and state laws and federal regulations and state rules; and
- C. May dispense the prescription or legend drug only when:
 - (1) A pharmacy service is not reasonably available; or
 - (2) An emergency exists or the physician associate acts entirely consistently with a facility's written dispensing protocol.

6. Legal Liability

A physician associate is legally liable for any medical service rendered by the physician associate.

7. Collaborative Agreements

Physician associates who are required to have a collaborative agreement with an actively licensed Maine physician shall conform their scope of practice to that which has been reviewed and approved by the Board. Such agreements must be kept on file at the physician associate's main location of practice and be made available to the Board or the Board's representative upon request. Upon any change to the parties in a collaborative agreement or other substantive change to the collaborative agreement, the physician associate shall submit the revised collaborative agreement to the Board for review and approval.

8. Criteria for Requiring Collaborative Agreements

A. **Collaborative Agreement.** Physician associates with less than 4,000 hours of documented clinical practice must have one (1) of the following in order to render medical services under their Maine license:

- (1) A Board-approved collaborative practice agreement with a Maine physician holding an active, unrestricted physician license; or
- (2) A scope of practice agreement through employment with a health care system or physician group practice as defined by this rule that has a system of credentialing and granting of privileges.

B. **Exception.** Physician associates with more than 4,000 hours of documented clinical practice as determined by the Board are not required to have a collaborative agreement.

C. **Documentation.** Acceptable documentation of clinical practice includes, but is not limited to the following:

- (1) Copies of previous plans of supervision, together with physician reviews;
- (2) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;
- (3) Attestation of completion of 4,000 hours of clinical practice from an employer(s).

9. Criteria for Reviewing Scope of Practice for Physician Associates in Collaborative Agreements

- A. In reviewing a proposed scope of practice delineated in a collaborative agreement, the Board may request any of the following from the physician associate:
- (1) Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;
 - (2) Copies of previous plans of supervision, together with physician reviews;
 - (3) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;
 - (4) Letter(s) from a physician(s) attesting to the physician associate's competency to render the medical services proposed;
 - (5) Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the NCCPA or its successor organization;
 - (6) Preparation of a plan for rendering medical services for a period of time under the supervision of a physician;
 - (7) Successful completion of an educational and/or training program approved by the Board.
- B. Physician associates who work outside of a health care facility or physician group practice may not render medical services until their scope of practice is reviewed and approved by the Board.

SECTION 11. ELEMENTS OF WRITTEN COLLABORATIVE AGREEMENTS

1. All written collaborative agreements shall include at a minimum:
 - A. A detailed description of the physician associate'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 associate in the practice setting, and the tasks that the physician associate may be delegating to medical assistants.

- B. The name and license number of any and all active Maine physician(s) who are signatories to a collaborative agreement that describes the physician associates' scope of practice;
- C. A detailed description of the method(s) of consultation with the active Maine physicians who are signatories to a collaborative agreement, and any limitations regarding the ability of the physician(s) to provide consultation, including limitations as to scope of practice or availability. The physician(s) who are signatories to a collaborative or practice agreement shall provide consultation only within their scope of practice and must be available for consultation with the physician associate at all times and for all medical services rendered by the physician associate.

2. Maintenance and production of collaborative agreements.

- A. Physician associates licensed to practice in accordance with these rules must prepare and have on file in the main administrative office of the practice or practice location a written, dated collaborative agreement that is signed by both the physician(s) and the physician associate and contains the elements as required by this rule.
- B. Failure to have a current written collaborative agreement on file and/or failure to produce a current collaborative or practice agreement upon request of the Board or Board staff shall result in a citation and/or possible disciplinary action.

SECTION 12. NOTIFICATION REQUIREMENTS FOR PHYSICIAN ASSOCIATES

1. Change of Collaborative Agreement

A physician associate licensed by the Board or holding a compact privilege shall notify the Board in writing within ten (10) calendar days of any change to a collaborative agreement by submitting a revised collaborative agreement to the Board for review and approval.

2. Termination of Collaborative Agreement

A physician associate shall notify the Board in writing within ten (10) calendar days regarding the termination of any collaborative agreement. Such notification shall include the reason for the termination.

3. Change of Contact Information

A physician associate 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 Collaborating Physician

A physician associate shall notify the Board in writing within ten (10) calendar days of the death or permanent or long-term departure of a collaborating physician who is a signatory to a collaborative agreement.

5. Failure to Pass NCCPA Examination

A physician associate 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 associate 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 associate 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 associate 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 associate 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 associate's most recent application.

10. Name Change

A physician associate shall notify the Board in writing within thirty (30) calendar days regarding any legal change in their name and provide the Board with a copy of the pertinent legal document (e.g. marriage certificate or court order).

SECTION 13. CITATION

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

- A. The failure to have a current written collaborative agreement that conforms to the requirements of this rule on file at the location specified. The administrative fine for each violation is \$200; or
- B. The failure to file a written notification with the 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 or email sent from the Board office.

3. Right to Hearing

The citation shall inform the physician associate that the physician associate may pay the administrative fine or request in writing a hearing before the Board regarding the violation. If the physician associate requests a hearing, the citation shall be processed in the same manner as a complaint pursuant to 32 M.R.S. §§ 20141-20144 except that the physician associate'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 physician associate 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 physician associate to further disciplinary action by the Board for unprofessional conduct, including but not limited to an additional fine and action against the license or compact privilege.

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 14. CONDUCT SUBJECT TO DISCIPLINE

1. Violation of this Chapter by a physician associate constitutes unprofessional conduct and is grounds for discipline of a physician associate's license or compact privilege.
2. A physician associate who is certified by the National Commission on Certification of Physician Assistants ("NCCPA") shall comport their conduct to the NCCPA Code of Conduct, and failure to do so constitutes unprofessional conduct and is a ground for discipline of a physician associate's license or compact privilege.

SECTION 15. CONTINUING MEDICAL EDUCATION (CME) REQUIREMENTS AND DEFINITIONS

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

1. **Requirements**

- A. **Required CME.** Each physician associate 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 fifty (50) hours must be in Category 1 (as defined by this rule);
 - (2) The total one hundred (100) hours may be in Category 1.
 - (3) Fifty (50) credit hours may be in Category 2 (as defined by this rule); and
 - (4) Maine-required opioid CME.
- B. **Failure to complete CME results in inactive status.** 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. **Current NCCPA Certification.** Proof of current NCCPA certification at the time an application for renewal is submitted satisfies CME requirements.
- D. **CME for Opioid Prescribing.** All physician associates must complete 3 hours of Category 1 credit CME every two years on the prescribing of opioid medication as required by Board Rule Chapter 21 “Use of Controlled Substances for Treatment of Pain.”

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 Associates (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 Secretary, at their discretion, may grant an extension of time not to exceed six (6) months 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 associates called to active military duty.

D. Evidence of completion

Board staff shall perform random audits of CME.

SECTION 16. IDENTIFICATION REQUIREMENTS

- 1. Physician associates licensed or holding compact privileges from the Board shall:

- A. Keep their licenses or compact privileges available for inspection at the location where they render medical services;
- B. Wear a name tag identifying themselves as physician associates when rendering medical services; and
- C. Verbally identify themselves as physician associates whenever greeting patients during initial patient encounters and whenever patients incorrectly refer to them as “doctors.”

STATUTORY AUTHORITY: 32 M.R.S. §§ 20112, 20113(1), 20125, 20126, 20129, 20130, 20131, 20133, & 20161

EFFECTIVE DATE:

SUMMARY: Chapter 4 lists the violations for which a citation and administrative fine may be issued, describes the licensee's right to request a hearing, and describes the time and manner in which the fine must be paid. Section 2 specifies the Board may issue a complaint charging unprofessional conduct and states that administrative fines are not reportable to any databanks.

SECTION 1

1. List of Violations

Board staff may issue citations for:

- A. Failure to report the existence of an outstanding complaint before the Maine Board of Medicine against the applicant on a license application, license renewal application, or other document provided to the Board.
- B. Failure to provide a response to the notice of a complaint within the statutorily specified 30 days from notice or within the timeframe specified by issuance of an extension of response as granted by Board staff.
- C. Failure to answer accurately any question on any Board of Medicine application.
- D. Failure to submit a complete application for licensure within 14 days from issuance of an emergency license, unless a waiver has been granted.
- E. Failure to meet Continuing Medical Education (CME) requirements at license renewal as confirmed by random audit.
- F. Failure to complete the jurisprudence exam within 14 days of issuance of initial license or privilege for compact participants.
- G. Failure to provide a response to any Board request within the timeframe specified in the request or of an extension of response as granted by Board staff.

2. Fine Amount

The administrative fine for each violation is \$200.00.

3. Service of Citation

The citation may be served on the licensee/applicant by email sent from the Board office.

4. Right to Hearing

The citation shall inform the licensee/applicant that the licensee/applicant may pay the administrative fine or may request a hearing before the Board regarding the violation. If

the licensee/applicant requests a hearing, the citation shall be processed in the same manner as a complaint pursuant to 32 M.R.S. §20142, except that the licensee/applicant's written response to the citation must be filed at the same time as the written request for hearing.

5. Time for Payment or Request for Hearing

The licensee/applicant shall either pay the administrative fine within 30 days or request a hearing in writing within 30 days following issuance of the citation. Failure to take either action within this 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.

6. Administrative Process

- A. If a citation is issued, any pending applications will not be processed further until the administrative fine is received by the Board or the Board takes final action regarding the citation following an adjudicatory hearing. After receipt of the administrative fine the application will be re-placed in processing order. The application will be processed further, subject to all regular reviews and processes.
- B. If a citation is issued relating to a complaint investigation, any pending investigative process will continue unabated, including presenting the complaint information at the next Board meeting, absent the complainant's response, for adjudication.

SECTION 2

1. Filing a Complaint

Nothing in this chapter shall prohibit the Board from issuing a complaint pursuant to 32 M.R.S. §20142 in addition to a citation for a violation listed in this chapter. In case of failure to file a permanent application for licensure after the issuance of a citation, a complaint may be filed charging unprofessional conduct in addition to the citation.

2. Citation Violations Not Reportable

Administrative fines paid solely in response to citations issued pursuant to this chapter do not constitute discipline or negative action or finding and shall not be reported to the Federation of State Medical Boards, the National Practitioner Databank, or to any other person, organization, or regulatory body except as allowed by law. Citation violations and administrative fines paid 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.

STATUTORY AUTHORITY: 10 M.R.S. §8003-E; 32 M.R.S. §20113

EFFECTIVE DATE:

COLLABORATIVE DRUG THERAPY MANAGEMENT

Summary: This is a joint rule of the Board of ~~Licensure in~~ Medicine and the Board of Pharmacy for purposes of establishing safe and effective collaborative practice agreements, treatment protocols, and documentation and reporting requirements between a pharmacist and a practitioner.

Acknowledgment. The Boards recognize that the Maine Legislature enacted 2013 Public Law Chapter 308 to allow collaborative practice agreements between authorized practitioners and pharmacists and to expand access to healthcare while ensuring that all patients receive the most appropriate healthcare possible and to provide safe and efficient care to the citizens of Maine.

1. Definitions

1. **Board.** For purposes of this chapter, “Board” means the Maine Board of Pharmacy.
2. **Collaborative drug therapy management.** “Collaborative drug therapy management” is defined in 32 MRS §13702-A(2-A). The statutory requirements for collaborative drug therapy management are set forth in 32 MRS §§ 13841-13847.
3. **Collaborative practice agreement.** “Collaborative practice agreement” is defined in 32 MRS §13702-A(2-B).
4. **Practitioner.** “Practitioner” is defined in 32 MRS §13702-A(29).
5. **Qualifying condition.** “Qualifying condition” means a condition or disease with generally accepted standards of care, which may include, but is not limited to, the following examples:
 - A. Anticoagulation
 - B. Asthma
 - C. Diabetes
 - D. Dyslipidemia
 - E. Hyperlipidemia
 - F. Hypertension
 - G. Infectious Disease

H. Cancer

I. Thyroid Disorder

6. **Treatment protocol.** “Treatment protocol,” as referenced in 32 MRS §13845, means the written document by which the practitioner describes the activities of drug therapy management in which the pharmacist is authorized to engage under a collaborative practice agreement and specifies the procedures and parameters of that practice authority.
7. **Unrestricted pharmacist license.** “Unrestricted pharmacist license” means a pharmacist license, the holder of which is not subject to any conditions of licensure affecting the scope of practice.

2. Application

1. Pharmacist Qualifications

In order to enter into a collaborative practice agreement with a practitioner, a pharmacist must meet the qualifications set forth in 32 MRS §13842. The pharmacist must complete the 15 hours of continuing education referred to in 32 MRS §13842(2)(A), (B), and (C) within the two-year period preceding the date of application.

[**Note:** A pharmacist who enters into a collaborative practice agreement must agree to complete, in each year of the agreement, continuing education hours as set forth in 32 MRS §13735.]

2. Application Submission

The pharmacist shall submit to the Board an application form supplied by the Board and such other information as the Board may require. Incomplete applications will not be considered and will be returned to the applicant.

3. Collaborative Practice Agreement Submission

Prior to commencement of the collaborative practice, the pharmacist shall submit to both the Board and the licensing board that licenses the practitioner a copy of the collaborative practice agreement. A copy of the treatment protocol, as established by the practitioner, must be included in the submission.

3. Collaborative Practice Agreement Content

A collaborative practice agreement may authorize collaborative drug therapy management only for qualifying conditions. A collaborative practice agreement must:

1. Require that activity in the initial 3 months of a collaborative practice agreement be limited to monitoring drug therapy, after which, the practitioner and pharmacist shall meet to review the collaborative practice agreement and determine the scope of the agreement, which, only after this meeting, may be expanded to include a pharmacist’s

initiating, monitoring, modifying, and discontinuing a patient's drug therapy, which actions the pharmacist must report to the practitioner in a timely manner;

2. Identify the parties to the agreement and their dates of execution of the agreement, and specify the effective date and expiration date of the agreement;
3. Permit either party to cancel the collaborative practice agreement by written notification;
4. Specify the site and setting at which the collaborative practice will occur;
5. Specify the qualifications of the participants in the collaborative practice agreement;
6. Describe in detail the types of diseases, drugs or drug categories involved and collaborative drug therapy management allowed in each patient's case;
7. Include a procedure for the referral of each patient to the practitioner that expressly states:
 - A. No party to the collaborative practice agreement may receive remuneration of any kind for a referral made pursuant to the agreement; and
 - B. The practitioner is under no obligation to refer patients to the contracting pharmacist;
8. Include a plan for measuring and assessing patient outcomes;
9. Require that all parties to the agreement maintain professional liability insurance covering the scope of the collaborative practice, which proof of insurance shall be attached to the agreement;
10. Include the treatment protocol(s) that will be utilized under the agreement;
11. Contain a provision that states that the agreement will terminate immediately in the event that the pharmacist no longer holds an unrestricted pharmacist license and immediately when the pharmacist knows or should know that the practitioner no longer holds an unrestricted license;
12. Contain a provision that states that the agreement will terminate upon the death of a party to the agreement; and
13. Specify how the continuity of care for patients will be handled in the event that the agreement suddenly terminates.

Subsections 1 - 9 above are the minimum requirements set forth in 32 MRS §13843(5) and (6).

4. Treatment Protocol Content

A treatment protocol shall describe the activities that the pharmacist is authorized to engage in and must, at a minimum, include the requirements set forth below.

1. **Informed Consent Procedures.** The protocol shall specify the procedures for obtaining informed consent from each patient involved in the drug therapy management, which

consent shall include the patients' consent to release all relevant medical information to both the practitioner and the pharmacist.

2. **Scope of Activities.** A description of the activities the pharmacist is authorized to engage in, including the procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management pursuant to a medical order from the practitioner.
3. **Documentation.** A description of the manner in which the pharmacist shall document all activities involved in providing drug therapy management in collaboration with a practitioner.
4. **Communication.** A description of the procedures the pharmacist shall follow for reporting activities and results to the practitioner, including but not limited to:
 - A. A description of the timeframe in which the pharmacist must relay normal test results to the practitioner, not to exceed one week for routine results and twenty-four hours for abnormal results; and
 - B. A description of the timeframe in which the pharmacist must relay adverse drug events, not to exceed twenty-four hours.
5. **Supervision**
 - A. A provision that allows the practitioner to override a collaborative practice decision made by the pharmacist when appropriate; and
 - B. A provision that provides for periodic review and revision of the drug therapy management by the practitioner and pharmacist.

5. Notifications

A pharmacist shall notify both the Board and the board that licenses the practitioner of the occurrence of any of the following changes no later than 10 days after the change:

1. Any modification to a collaborative practice agreement, which notification must include a copy of the amended collaborative practice agreement, which must be signed and dated in accordance with section 3(2) of this rule;
2. Any modification to a treatment protocol, which notification must include a copy of the amended treatment protocol; and
3. Any change in liability insurance, which notification must include proof of existing liability insurance, i.e., a liability insurance policy certificate.

6. Recordkeeping Requirements

Records received or created by a pharmacist pursuant to this chapter are subject to the record retention and production requirements of Chapter 24 of the Board's rules.

7. Complaints

In the event that the Board or the licensing board that licenses the practitioner receives a complaint related to a collaborative practice agreement, the boards may share the complaint and any investigative information obtained during an investigation of the complaint, as permitted under 10 MRS §8003-B(2).

8. Duty to Report Disciplinary Action

1. Any party to a collaborative practice agreement who has had disciplinary action taken against any professional license held by that party shall report such disciplinary action to all other parties to the agreement and to the licensing boards of those parties within 10 days of the disciplinary action.
2. The Board and the Board of ~~Licensure in~~ Medicine shall notify each other of any disciplinary action against the professional licensees who are party to a collaborative practice agreement as soon as practicable.

STATUTORY AUTHORITY:

32 MRS §§ 13720, 13846 (Board of Pharmacy)

32 MRS §~~3269(3), (7)~~20113 (Board of ~~Licensure in~~ Medicine)

EFFECTIVE DATE:

March 14, 2016 – filings 2016-040, 041

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373500 BOARD OF LICENSURE IN MEDICINE

a joint rule with

383 BOARD OF OSTEOPATHIC LICENSURE

380 STATE BOARD OF NURSING

Chapter 11: JOINT RULE REGARDING TELEHEALTH STANDARDS OF PRACTICE

SUMMARY: Chapter 11 establishes standards for using telehealth in providing health care.

SECTION 1. STATEMENT REGARDING TELEHEALTH

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. Telehealth 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 telehealth 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 telehealth in providing health care may subject the licensee to potential discipline by the Board.

SECTION 2. DEFINITIONS

1. "Asynchronous encounter" means an interaction between an individual and a licensee through a system that has the ability to store digital information, including but not limited to still images, video files, audio files, text files and other relevant data, and to transmit such information without requiring the simultaneous presence of the individual and licensee.
2. "Board" means the Maine Board of ~~Licensure in Medicine, the Board of Osteopathic Licensure~~ or the State Board of Nursing.
3. "Health care services" means services provided by a licensed or registered physician, physician ~~assistant~~ associate, or nurse according to the applicable scope of practice and standard of care.

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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 clinician-patient encounter.
5. "Licensee" means a physician, physician ~~assistant~~associate, licensed practical nurse, registered professional nurse, or advanced practice registered nurse licensed or registered by the Board.
6. "Licensee-patient relationship" means the relationship established between a licensee and a patient according to this rule and the laws, rules, and standards of practice applicable to a licensee.
7. "Nurse compact state" means a state that has enacted the Nurse Licensure Compact as revised by the National Council of State Boards of Nursing.
8. "Nursing assessment" means a pertinent assessment of a patient conducted by a registered professional nurse in accordance with the laws and rules of the Board and nursing standards of care for the purpose of the patient visit.
9. "Physical examination" means a pertinent physical examination of a patient conducted by a licensed physician, physician ~~assistant~~associate, or advanced practice registered nurse in accordance with the standard of care for the purpose of the patient visit.
10. "Store and forward transfer" means the transmission of an individual's records through a secure electronic system to a licensee.
11. "Synchronous encounter" means a real-time interaction conducted with an interactive audio or video connection between an individual and a licensee or between a licensee and another health care provider.
12. "Telehealth" means the provision 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. Telehealth includes asynchronous store-and-forward technologies, telemonitoring, and real-time interactive services, including teleradiology and telepathology. When necessary and appropriate under the circumstances and if in compliance with the applicable standard of care, telehealth includes the use of audio-only technology. Telehealth shall not include the provision of health care services only through e-mail, instant messaging, facsimile transmission, or U.S. mail or other parcel service, or any combination thereof between a licensee in one location and a patient in another location with or without an intervening health care provider.
13. "Telehealth 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.
14. "Telemonitoring" means the use of information technology to remotely monitor a patient's health status via electronic means, allowing the licensee to track the patient's health data over time. Telemonitoring may be synchronous or asynchronous.

SECTION 3. PRACTICE GUIDELINES

1. A licensee who uses telehealth shall utilize evidence-based telehealth 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 and nursing specialty organizations have established comprehensive telehealth practice guidelines that address the clinical and technological aspects of telehealth for many health care specialties.
2. MAINE LICENSE REQUIRED
 - A. Physicians, physician ~~assistant~~associates and advanced practice registered nurses who use telehealth in the examination, diagnosis, consultation or treatment of a patient located in Maine shall hold an active Maine license, ~~or shall hold an active registration in Maine to provide interstate consultative telemedicine services.~~
 - B. Licensed practical nurses and registered professional nurses who use telehealth to provide nursing care services to a patient located in Maine shall hold an active Maine nursing license or an active multistate license in a nurse compact state.
3. STANDARDS OF CARE AND PROFESSIONAL ETHICS

A licensee who uses telehealth 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 telehealth 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. Neither this rule nor telehealth as a delivery model expands the scope of practice of any licensee or changes the scope and process regarding delegation of health care services by physicians, physician ~~assistant~~associates or nurses. A licensee must comply with applicable Board laws and rules related to the coordination, supervision, collaboration, direction, oversight of and delegation to other licensed or certified personnel and unlicensed health care assistive personnel.
 - B. A licensee who uses telehealth 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, registration and certification.
 - C. A licensee providing telehealth services must comply with all State and federal laws, rules and regulations as well as applicable standards of practice.
5. IDENTIFICATION OF PATIENT AND LICENSEE

A licensee who uses synchronous telehealth 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, registration, certification, and credentials of all health care providers who provide telehealth services prior to the provision of care.

6. LICENSEE-PATIENT RELATIONSHIP

- A. A licensee who uses telehealth in providing health care shall establish a valid licensee-patient relationship with the person who receives telehealth services. The licensee-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, nursing assessment, 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 licensee-patient relationship may be established between a licensee who uses telehealth in providing health care and a patient who receives telehealth 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) **Telehealth encounter.** Through telehealth, if the standard of care does not require an in-person encounter, and in accordance with evidence-based standards of practice and telehealth practice guidelines that address the clinical and technological aspects of telehealth.

7. MEDICAL HISTORY AND PHYSICAL EXAMINATION

Generally a physician, physician [assistant/associate](#), and advanced practice registered nurse shall perform an in-person clinical interview and physical examination for each patient. However, the clinical interview and physical examination may not be in-person if the technology utilized in a telehealth encounter is sufficient to establish an informed diagnosis as though the clinical interview and clinician examination had been performed in-person. Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telehealth in providing health care shall interview the patient to collect the relevant medical history and perform a pertinent physical examination as defined by the standard of care for the purpose of the visit, when clinically 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 clinical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by the licensee.

8. NURSING ASSESSMENT

Generally a registered professional nurse shall perform an in-person clinical interview and pertinent nursing assessment for each patient. However, the clinical interview and nursing assessment may not be in-person if the technology utilized in a telehealth encounter is sufficient to establish an informed nursing assessment as though the clinical interview and nursing assessment had been performed in-person. Prior to providing treatment, a licensee who uses telehealth in providing health care shall interview the patient to collect the relevant medical history and perform a pertinent nursing assessment as defined by the standard of care for the purpose of the visit, when clinically necessary, sufficient for the nursing assessment 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 clinical interview and nursing assessment for the provision of treatment by the licensee.

9. NON-CLINICIAN HEALTH CARE PERSONNEL

- A. If a licensee who uses telehealth in providing health care relies upon or delegates the provision of telehealth services to non-clinician health care personnel, the licensee shall:
- (1) Ensure that systems are in place to ensure that the non-clinician health care personnel are 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-clinician health care personnel, particularly in the case of injury or an emergency.

10. INFORMED CONSENT

A licensee who uses telehealth 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 telehealth to conduct a nursing assessment or physical examination, consultation, and diagnosis and treatment, and that such informed consent is timely documented in the patient's telehealth record.

11. COORDINATION OF CARE

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

12. FOLLOW-UP CARE

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

13. EMERGENCY SERVICES

A licensee who uses telehealth 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.

14. PATIENT TELEHEALTH RECORDS

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

15. PRIVACY AND SECURITY

- A. A licensee who uses telehealth in providing health care shall ensure that all telehealth 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.

16. TECHNOLOGY AND EQUIPMENT

- A. The Board recognizes that three broad categories of telehealth technologies currently exist, including asynchronous store-and-forward technologies, telemonitoring, and real-time interactive services. While some telehealth programs are multispecialty in nature, others are tailored to specific diseases and medical specialties. The technology and equipment utilized for telehealth shall comply with the following requirements:
- (1) The technology and equipment utilized in the provision of telehealth 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 telehealth services must be of sufficient quality, size, resolution and clarity such that the licensee can safely and effectively provide the telehealth services;
 - (3) The technology and equipment utilized in the provision of telehealth 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 telehealth services must be able to verify the identity and location of the patient; and
 - (5) The technology and equipment utilized in the provision of telehealth services must be able to specify and disclose the identity and credentials of the health care provider(s).

17. DISCLOSURE AND FUNCTIONALITY OF TELEHEALTH SERVICES

- A. Except for health care provider to health care provider direct consultation, a licensee who uses telehealth 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, registration, credentials and qualifications of all health care providers who are providing the telehealth services;
- (4) Limitations in the drugs and services that can be provided via telehealth;
- (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 and equipment, including in emergency situations;
- (8) Privacy and security risks of the technologies and equipment;
- (9) Uses of and response times for e-mails, electronic messages and other communications transmitted via telehealth technologies;
- (10) To whom patient health information may be disclosed and for what purpose;
- (11) Rights of patients with respect to patient health information; and
- (12) Information collected and passive tracking mechanisms utilized.

18. PATIENT ACCESS AND FEEDBACK

- A. A licensee who uses telehealth 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 telehealth services provided; and
 - (3) To register complaints. The mechanism shall include information regarding the filing of complaints with the Board.

19. 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.

20. CIRCUMSTANCES WHERE THE STANDARD OF CARE MAY NOT REQUIRE A LICENSEE TO PERSONALLY INTERVIEW OR CONDUCT A NURSING ASSESSMENT OR PHYSICAL EXAMINATION OF A PATIENT

A. Under the following circumstances, whether or not such circumstances involve the use of telehealth in providing health care, a licensee may treat a patient who has not been personally interviewed, examined, assessed 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 licensee-patient relationship with the patient;
- (4) Cross-coverage situations in which a licensee is taking call for another licensee who has an established licensee-patient relationship with the patient;
- (5) Situations in which the patient has been examined in person by an advanced practice registered nurse or a physician [assistant/associate](#) 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 clinician determines that a radiology or pathology consultation is warranted.

21. **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 licensee-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 3, subsection 20, subparagraph A(3) of this rule.

Telehealth 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 telehealth, is at the professional discretion of the licensee. The licensee prescribing via telehealth 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 telehealth 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, licensees may exercise their judgment and prescribe medications as part of telehealth encounters.

STATUTORY AUTHORITY:

32 M.R.S. §§ ~~3269(3), 3269(7), 3300AA-3300EE~~20113 (Board of ~~Licensure in~~ Medicine)
~~32 M.R.S. §§ 2562, 2600AA-2600EE (Board of Osteopathic Licensure)~~
 32 M.R.S. §§ 2102(2-A), 2153-A(1), 2266 - 2270 (State Board of Nursing)

Commented [ML1]: 32 M.R.S. §§ 3300AA and 3300EE relate to telehealth services and I think we need to include the new statutory references § 20181 and § 20185

EFFECTIVE DATE:

December 10, 2016 – filings 2016-209, 210 (Chapter 6)

AMENDED:

July 24, 2022 – filings 2022-139, 140, 141

APAO WORD VERSION CONVERSION (IF NEEDED) AND ACCESSIBILITY CHECK: July 18, 2025

ADOPTED RULE

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

~~373~~500 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

Summary: Chapter 12 is a joint rule of the Board of ~~Licensure in~~ Medicine, ~~and~~ 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

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SECTION 2. Purpose
SECTION 3. Qualifications
SECTION 4. Prescription Requirements
SECTION 5. Principles of Proper OBOT
SECTION 6. Telemedicine Practice
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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, ~~and~~ 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~~associate, 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. **DEA** means the Drug Enforcement Administration in the U.S. Department of Justice.
9. **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.
10. **FDA** means the U.S. Food and Drug Administration.
11. **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.
12. **Medical Emergency** means an acute injury or illness that poses an immediate risk to a person's life or long-term health.
13. **Misuse** means all uses of a prescription medication other than those that are directed by a clinician in accordance with the plan of treatment.
14. **Office Based Opioid Treatment (OBOT)** means providing medication and other non-pharmacologic modalities to treat OUD in outpatient medical settings other than certified OTPs.
15. **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.**
16. **Opioid Use Disorder (OUD)** means the criteria in the current edition of the Diagnostic and Statistical Manual of Mental Disorders for OUD.
17. **Outpatient** means a health care setting where the patient is not admitted to a hospital, skilled nursing facility or long-term care facility.
18. **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.
19. **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.
20. **SAMHSA** means the federal Substance Abuse and Mental Health Services Administration.
21. **Telehealth** means the provision 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 clinician in one location and a patient in another location with or without an intervening health care provider. Telehealth includes asynchronous store-and-forward technologies, telemonitoring, and

real-time interactive services, including teleradiology and telepathology. When necessary and appropriate under the circumstances and if in compliance with the applicable standard of care, telehealth includes the use of audio-only technology. Telehealth shall not include the provision of health care services between a licensee in one location and a patient in another location with or without an intervening health care provider only through e-mail, instant messaging, facsimile transmission, or U.S. mail or other parcel service, or any combination thereof.

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 federal laws and regulations, 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.

The Board will evaluate allegations of inappropriate OBOT by referring to the rules, current clinical practice guidelines, and standards of care. Clinicians should not fear disciplinary action by the Board for providing OBOT if they are following standards of care, established guidelines and the requirements of this rule. Judgment regarding the propriety of any specific course of action must be based on all of the circumstances presented, and thoroughly documented in the patient's medical record.

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. Complete buprenorphine training in accordance with applicable State and federal laws, rules, and regulations;
 - D. When required by State law, physician ~~assistant~~ associates must work in collaboration with a licensed physician when prescribing medications for the treatment of opioid use disorder; and
 - E. Comply with this joint rule.
2. Patient limits. Clinicians must be aware of and comply with limits, if any, 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 the patient's 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. The clinician's DEA registration number;
- 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; and
2. ASAM National Practice Guidelines For the Use of Medications in the Treatment of Addiction Involving Opioid Use.

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 clinician 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**

When commencing OBOT, and in addition to ensuring that any patient has an appropriate 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**

When commencing OBOT, the OBOT clinician shall conduct an appropriate medical, social, and family history, physical examination and necessary laboratory tests (including pregnancy testing when appropriate), 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 psychologic 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 the patient 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 clinician should employ appropriate clinical judgment in deciding whether to 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

Unless unable to do so as a result of a genuine "medical emergency" as defined in Section 1 of this rule, prior to providing OBOT, an OBOT clinician shall:

1. Obtain and document voluntary 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 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 the patient's 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. This includes, but is 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. **Patient Records**

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

SECTION 6. Telehealth Practice

1. Telehealth 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.
2. Clinicians using telehealth in providing health care will be held to the same standards of care and professional ethics as clinicians providing traditional in-person health care.
3. Failure to conform to the appropriate standards of care or professional ethics while using telehealth in providing health care may subject the clinician to potential discipline by the Board.
4. Clinicians shall follow all applicable rules regarding Telehealth, including the Chapter 11 Joint Rule Regarding Telehealth Standards of Practice.

STATUTORY AUTHORITY:

32 M.R.S. §§ ~~3269(3),(7), 3300-EE, 3300-F20113~~; (Board of ~~Licensure in~~ Medicine)

32 M.R.S. §§ 2102(2-A), 2153-A(1), 2210, 2270; (State Board of Nursing)

~~32 M.R.S. §§ 2562, 2600-C, 2600-EE; (Board of Osteopathic Licensure)~~

EFFECTIVE DATE:

April 29, 2020 – filings 2020-107, 108, 109

AMENDED:

July 24, 2022 – filings 2022-142, 143, 144

February 26, 2024 – filings 2024-036, -037, -038

Commented [ML1]: 32 M.R.S. § 3300EE relates to telehealth service. I think we need to include the new statutory reference - § 20185. § 3300-F relates to requirements for prescribing opioid medications. I think we need to include the new statutory reference - § 20161.

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

~~373500~~ BOARD OF ~~LICENSURE IN~~ MEDICINE

A joint rule with

380 STATE BOARD OF NURSING

~~383~~ BOARD OF ~~OSTEOPATHIC LICENSURE~~

**Chapter 15: JOINT RULE REGARDING STANDARDS OF PRACTICE FOR
INTRAVENOUS (IV) THERAPY BUSINESSES, MEDICAL SPAS AND MEDICAL
AESTHETIC BUSINESSES**

SUMMARY: Chapter 15 clarifies standards of practice for providing health care services in intravenous (IV) therapy businesses, medical spas and medical aesthetic businesses.

RULE INDEX

SECTION 1. Statement Regarding IV Therapy and Medical Spas/Aesthetic Services

SECTION 2. Definitions

SECTION 3. Scope of Practice and Practice Standards

SECTION 4. Practice Standards for Compounding Medications

SECTION 5. Drug Shortages

SECTION 6. Conduct Subject to Discipline

**SECTION 1. STATEMENT REGARDING IV THERAPY AND
MEDICAL SPAS/AESTHETIC SERVICES**

1. The Board is charged by the Legislature with implementing and enforcing laws for the protection of the public health and welfare, including by setting minimum standards of professional practice. The Board has the authority to adopt rules setting minimum standards.
2. Nationally, and here in Maine, there has been a proliferation of new health care business types – medical spas, intravenous (IV) therapy businesses and medical aesthetic businesses.
3. Medical spas, sometimes referred to as med spas or medispas, offer an array of services from traditional aesthetic services (e.g., hairdressing, manicures) to health care services and procedures (e.g., neurotoxin treatment, dermal fillers, laser treatment, IV injections). This commingling of aesthetic and medical services can confuse licensees, employees and the public about what services require a licensed health care professional, and which do not. This rule is

intended to delineate the minimum standards of practice for authorized licensees working in medical spas who authorize, oversee, or provide medical services to patients and to clarify which individuals may be authorized to provide which services.

4. Generally, the intravenous (IV) therapy business model involves a walk-in (sometimes within medical spas) or mobile clinic that offers the public a “menu” of “cocktails” consisting of saline solution for administration intravenously (or parenterally) alone or in combination with additives (e.g. vitamins, minerals, amino acids, nutrients, or prescription drugs, including, e.g. antiemetics, etc.). The IV or parenteral preparations are offered for choice by the client and purport to improve hydration, treat hangovers, assist in athletic recovery, prevent aging, etc. The public may be offered a “menu” of different types of IV treatments from which to choose. These scenarios pose a risk to the public because the diagnosis of a patient’s condition and subsequent recommendation to administer IV therapy constitutes the practice of medicine and/or advanced practice nursing and can be performed only by licensed physicians, physician associates, and advanced practice registered nurses. To be clear: IV fluids are medications with the potential to help or harm patients. Similar to medical spas, the general business model and setting of the IV therapy business can confuse the public about whether IV hydration is even a medical service and, if so, what the standards are to deliver it safely. This rule is intended to delineate the standards expected of authorized licensees in IV hydration businesses and to mitigate any confusion by the public who receive those services.
5. Preparations that are administered intravenously, including saline, are almost universally required to be prepared in sterile conditions consistent with federal and state laws and regulations. Intravenous preparations are sometimes referred to as parenteral, meaning not administered via the alimentary or digestive system. Parenteral administration directly into a patient’s bloodstream creates significant risk to the patient if the administered preparation was not compounded under sterile conditions. Under federal laws and regulations there are only very limited circumstances, identified in United States Pharmacopeia standard <797>, where an appropriately licensed health care practitioner can prepare a solution for parenteral administration where they use less than sterile technique, and instead use “aseptic technique,” as defined in USP <797>, to combine an IV bag of saline with an additive, including a prescription drug, for administration to a patient in need and for immediate use, defined as within four hours. These federal limitations and conditions reduce the very serious risks to patients of administration of non-sterile preparations directly into the patient’s bloodstream.
6. In addition, the menu option, where clients choose an option from the menu for a condition the patient perceives they have or need, may create serious risks to a patient if they have a medical condition that, within a normal licensee-patient relationship, would be known or discovered and would preclude the administration of the IV cocktail or saline.

7. Furthermore, some individuals within these settings may be performing procedures or administering IV preparations that are not within their scope of practice nor adhering to the proper standards of care. Thus, patients receiving health care services in these settings are at a higher risk for complications, including inadequate results (requiring additional procedures), infections, burns, and in extreme cases, death. IV treatments and medications need to be individualized for patients and prescribed in the same manner as they would be in an urgent care center, emergency department, practitioner's medical office, or hospital.
8. Persons with no professional license are prohibited from performing any medical procedures. Authorizing the administration of parenteral and/or IV preparations, or administering parenteral and/or IV preparations, requires proper professional licensure or proper supervision by a legally authorized licensed professional. **A course certificate of completion does not constitute a license.** Performing any medical procedures, including authorizing or administering parenteral and/or IV preparations, without a license or proper supervision may subject an individual to fines and/or civil or criminal penalties.
9. Only physicians, physician associates, and advanced practice registered nurses with prescriptive authority can evaluate the patient, make a diagnosis, and prescribe a treatment. This authority cannot be delegated to any person without prescriptive authority, including a registered nurse. Use of a simple questionnaire without an appropriate clinical assessment (i.e., a history and physical examination) does not meet the standard of care and places the patient at risk of misdiagnoses, mistreatment, and harm. A physician, physician associate, or advanced practice nurse may be an owner, a co-owner, investor, associate, or designated as the medical director of a medical spa, IV therapy or medical aesthetic business, however, any of those levels of participation is insufficient to establish a valid licensee-patient relationship that is required prior to the prescription and administration of drugs including IV therapies, aesthetic treatments and medications requiring prescriptions.
10. An authorized licensee must create a medical record of the patient examination, medical history, diagnoses, and treatment in any health care setting, including medical spas, IV therapy and medical aesthetic businesses. The medical record is essential for the licensee, the patient, and any subsequent health care practitioners who may evaluate and treat the patient.
11. Based upon the foregoing, the Board created this rule to provide clarity to both the public and licensees regarding the licensure, standard of care, and standards of practice for authorized licensees providing health care services in medical spas and IV therapy businesses.

SECTION 2. DEFINITIONS

For the purposes of these rules, the following definitions apply.

1. **“Authorized licensee”** means a physician, physician associate, licensed practical nurse, registered professional nurse, or advanced practice registered nurse licensed or registered by the Board that oversees their practice area, which licensee may be authorized to provide healthcare services in a medical spa, IV therapy or medical aesthetic business because of their legally permitted scope of practice.
2. **“Board”** means the Board of ~~Licensure in Medicine, the Board of Osteopathic Licensure~~ and the State Board of Nursing.
3. **“Compounding”** means the preparation, mixing, assembling, packaging or labeling of a drug, drug-delivery device, or device in accordance with a physician’s, physician associate’s, or advanced practice registered nurse’s prescription, medication order, or other legal authorization based on the practitioner/pharmacist/compounder relationship with the patient in the usual course of professional practice.
4. **“Health care services”** means services of a medical nature that are required by law to be provided by a licensed or registered physician, physician associate, licensed practical nurse, registered professional nurse, or advanced practice registered nurse according to the applicable scope of practice and standard of care.
5. **“Informed consent”** means an educational process between a patient and a licensee involving the patient in shared decision making and during which process the licensee determines the patient’s ability to understand medical information, treatment alternatives, and decision about what, if any, treatment to accept.
6. **“Intravenous”** means a method of administration of saline, or saline with additives, performed parenterally via injection into the patient’s bloodstream.
7. **“Intravenous (IV) preparation”** means a saline solution, with or without additives, including but not limited to prescription drugs, vitamins, nutrients, minerals and/or amino acids, that is administered to the client/patient via the patient’s bloodstream.
8. **“Intravenous (IV) therapy business”** means a walk-in or mobile business that provides patients with IV fluids with or without additives, including but not limited to prescription drugs, vitamins, nutrients, minerals and/or amino acids.

9. **“Licensee-patient relationship”** means a legitimate and valid relationship established between a licensee and a patient according to this rule and the laws, rules, and standards of practice applicable to a licensee.
10. **“Medical aesthetic business”** means a business that provides patients with medical aesthetic services including but not limited to neurotoxin treatment, dermal fillers and laser treatments, and medical weight loss treatment.
11. **“Medical spa”** means an entity that offers or performs aesthetic procedures that (a) do not require sedation; (b) are directed at improving the person's appearance; and (c) do not meaningfully promote the proper function of the body or prevent or treat illness or disease. These entities are sometimes referred to as med spas or medispas.
12. **“Menu”** means a list of IV preparations or treatments available to consumers at an IV therapy business, a medical spa, or a medical aesthetic business.
13. **“Nursing assessment”** means a pertinent assessment of a patient conducted by a registered professional nurse in accordance with the laws and rules of the State Board of Nursing and nursing standards of care for the purpose of the patient visit.
14. **“Nurse compact state”** means a state that has enacted the Nurse Licensure Compact as revised by the National Council of State Boards of Nursing.
15. **“Parenteral”** means a route of administration other than via the alimentary or digestive system, including intravenous (IV) administration into the patient's bloodstream.
16. **“Physical examination”** means a pertinent physical examination of a patient conducted by a licensed physician, physician associate, or advanced practice registered nurse in accordance with the standards of care for the purpose of the patient visit.

SECTION 3. LICENSE REQUIRED, PRACTICE STANDARDS, AND SCOPE OF PRACTICE

1. A licensee who provides health care services in IV therapy businesses, medical spas, and medical aesthetic businesses shall utilize evidence-based national standards of practice, to the degree they are available, and the practice standards established by this rule to ensure patient safety and understanding, quality of care, and positive outcomes.

2. MAINE LICENSE REQUIRED

- A. Parenteral and IV preparations, including saline, shall be administered to a person or patient only following an appropriate examination and diagnosis by a licensed physician, physician associate, or advanced practice registered nurse pursuant to a legitimate and valid licensee-patient relationship.
- B. A determination of whether to authorize and administer parenteral and IV preparations to a patient, and determination of what should be included in those parenteral or IV preparations, requires a physician, physician associate, or advanced practice registered nurse license, an appropriate licensee-patient relationship, as well as the appropriate supervision of the administration to the patient by a licensed physician, physician associate, or advanced practice registered nurse.
- C. Physicians, physician associates and advanced practice registered nurses who examine, diagnose, consult with, treat, or authorize the administration of parenteral or IV preparations to any person or patient located in Maine shall hold an active Maine license or shall otherwise be legally authorized to provide medical or nursing services in Maine.
- D. Licensed practical nurses and registered professional nurses who provide nursing care services to a patient located in Maine shall hold an active Maine nursing license or an active multistate license in a nurse compact state.

3. STANDARDS OF CARE AND PROFESSIONAL ETHICS

A licensee providing health care services in a medical spa, intravenous (IV) therapy business, or medical aesthetic business shall be held to the same standards of care and professional ethics as a licensee providing health care services in traditional health care environments with patients. Failure to conform to the appropriate standards of care or professional ethics while providing health care services in a medical spa, IV therapy business, or medical aesthetic business will constitute a violation of this rule and may subject the licensee to potential discipline by the Board.

4. SCOPE OF PRACTICE

- A. Neither this rule nor providing health care services in a medical spa, IV therapy and/or medical aesthetic business expands the scope of practice of any licensee or changes the scope and process regarding delegation of health care services by licensees.

A licensee must comply with applicable Board laws and rules related to the supervision, collaboration, direction, and delegation to other licensed or certified personnel and unlicensed health care personnel.

- B. A licensee providing health care services in a medical spa, IV therapy business and/or medical aesthetic business shall ensure that the services provided are consistent with the licensee's scope of practice, including the licensee's education, training, experience, ability, licensure, registration and certification.
- C. A licensee providing health care services in a medical spa, IV therapy business and/or medical aesthetic business must comply with all State and federal laws, rules and regulations, including but not limited to laws and rules related to compounding, as well as applicable standards of practice.

5. LEGITIMATE LICENSEE-PATIENT RELATIONSHIP

- A. A licensee who provides health care services in a medical spa, IV therapy and/or medical aesthetic business shall establish a legitimate and valid Licensee-patient relationship with the person who receives health care services. The licensee-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, nursing assessment, consultation or treatment of the person; and
 - (3) The person agrees to receive health care services from the licensee.

6. MEDICAL HISTORY AND EXAMINATION

Generally, a physician, physician associate, and advanced practice registered nurse shall perform an in-person clinical interview and physical examination for each patient. However, the clinical interview and physical examination may not be in-person if the technology utilized in a telehealth encounter is sufficient to establish an informed diagnosis as though the clinical interview and physical examination had been performed in-person. For example, if a patient has signs of heart failure, listening to the heart and lungs with a stethoscope and looking for pitting edema in the lower extremities is critical, as such evidence would be a contraindication for additional fluids. Prior to providing treatment, including issuing prescriptions, electronically or

otherwise, a licensee who uses telehealth in providing health care shall interview the patient to collect the relevant medical history and perform a pertinent physical examination as defined by the standard of care for the purpose of the visit, when clinically 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 clinical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by the licensee.

7. NURSING ASSESSMENT

Generally, a registered professional nurse shall perform an in-person clinical interview and pertinent nursing assessment for each patient. However, the clinical interview and nursing assessment may not be in-person if the technology utilized in a telehealth encounter is sufficient to establish an informed nursing assessment as though the clinical interview and nursing assessment had been performed in-person. Prior to providing treatment, a licensee who uses telehealth in providing health care shall interview the patient to collect the relevant medical history and perform a pertinent nursing assessment as defined by the standard of care for the purpose of the visit, when clinically necessary, sufficient for the nursing assessment 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 clinical interview and nursing assessment for the provision of treatment by the licensee.

8. UNLICENSED HEALTH CARE PERSONNEL

- A. If an authorized licensee who provides health care services in a medical spa, IV therapy or medical aesthetic business relies upon or delegates the provision of health care services to unlicensed health care personnel, the authorized licensee shall:
 - (1) Verify that systems are in place to ensure that the unlicensed health care personnel are qualified, trained, and authorized to provide that service; and
 - (2) Ensure that the licensee is available in person or electronically to consult with the unlicensed health care personnel, particularly in the case of injury or an emergency.
- B. Under no circumstances may a licensee delegate to unlicensed health care personnel the examination, nursing assessment, diagnosis,

prescription, or administration of medications to patients in IV hydration businesses, medical spas or medical aesthetic businesses.

9. INFORMED CONSENT

A licensee who provides health care services in a medical spa, IV therapy business and/or medical aesthetic business shall ensure that the patient provides appropriate informed consent for the health care services provided and that such informed consent is timely documented in the patient's medical record.

10. PATIENT MEDICAL RECORDS

A licensee who provides health care services in a medical spa, IV therapy or medical aesthetic business shall ensure that complete, accurate and timely patient records are maintained and comply with the standards of care. The medical records must include, to the extent required by the standard of care, the following:

1. Patient history, to include all current medical issues and medications;
2. Physical examination results;
3. Nursing assessment;
4. Diagnosis;
5. Laboratory and other diagnostic test results;
6. The nature and purpose of recommended interventions;
7. The burden, risks, and expected benefits of all options, including foregoing treatment;
8. Records of drugs (including intravenous fluids) prescribed, dispensed, and/or administered;
9. Patient's decision; and
10. The need for follow-up care or emergency services.

11. STANDING ORDERS

The use of standing orders in medical spas, IV therapy businesses and medical aesthetic businesses for an individualized assessment, diagnosis and treatment of patients is considered unprofessional conduct and may result in disciplinary action.

SECTION 4. PRACTICE STANDARDS FOR COMPOUNDING MEDICATION AND OBTAINING COMPOUNDED PREPARATIONS

1. Compounding of prescription drugs may only be undertaken by those who are authorized by law to compound drugs.

2. Compounding of prescription drugs, including mixing saline with one or more additives, must be performed consistent with all federal and state laws and regulations.
3. Licensees shall be responsible for knowing and complying with all state and federal laws and regulations, including those imposed under the United States Food Drug and Cosmetic Act related to obtaining, storing, and compounding prescription drugs, including IV saline with or without additives.
4. Licensees shall be responsible for knowing and complying with all state and federal laws and regulations related to obtaining, storing, and administering compounded prescription drugs, including IV saline solution with or without additives, prepared by someone else.
5. Licensees shall be responsible for knowing and complying with recipients' responsibilities for using only authorized sterile compounding facilities and legally authorized distribution channels for prescription drugs under federal and state laws and regulations.
6. Administration of compounded prescription drugs, or IV saline with or without additives, must result from a valid physician, physician associate, or advanced practice registered nurse order in the usual course of professional practice and not from a patient-driven menu.
7. When compounding is performed in a clinic or office setting where patients or clients are administered the compounded solutions, a licensed physician must perform the compounding, and must do so for valid and recognized reasons under federal and state laws and regulations, and not in response to a patient's selection from a menu of available compounded preparations, including IV saline with or without additives or prescription drugs.
8. Federal law imposes significant legal and regulatory limitations on compounding practices, including United States Pharmacopeia standard USP <797>, governing sterile compounding, which applies to IV preparations. The U.S. Food and Drug Administration (FDA) recognizes and enforces USP <797>. For sterile compounding performed by a pharmacist in Maine, the Maine Board of Pharmacy has incorporated USP <797> by reference in its Board rules.
9. USP <797> applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other health care institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarians' practice sites.
10. USP <797> contains an "immediate use" exception that allows for the preparation of a drug product that usually must be prepared in sterile conditions to be prepared and immediately administered to a patient in emergent or urgent situations. In some cases, IV therapy businesses have been misinterpreting the concept of "immediate use" to justify their deviation from sterile preparation requirements. This is not consistent with federal law or how FDA interprets the "immediate use" provision. Walk-in, mobile or concierge IV therapy services do not fall under the USP <797> "immediate use" exception.

SECTION 5. DRUG SHORTAGES

1. The FDA maintains a database of drug shortages and discontinuations. When any licensee who is authorized by law to prescribe drugs prescribes a drug that is in the FDA drug shortage database at the time of the prescription, the legally authorized prescriber must document in the patient's medical record sufficient information to support the use of the drug for elective/nonmedical use during the shortage.

SECTION 6. CONDUCT SUBJECT TO DISCIPLINE

1. Violation of this rule by a licensee constitutes unprofessional conduct and is grounds for discipline.

STATUTORY AUTHORITY:

32 M.R.S. §§ ~~3269(3) and (7), 3270, 3270-A, and 3270-20113~~E (Board of ~~Licensure in Medicine~~)

~~32 M.R.S. § 2562 (Board of Osteopathic Licensure)~~

32 M.R.S. § 2102(2-A), 2153-1(A), 2270 (State Board of Nursing)

EFFECTIVE DATE (NEW): July 14, 2026 – filings 2026-167, 2026-168, 2026-169

Commented [ML1]: 32 M.R.S. §§ 3270, 3270-A and 3270-E relate to licensure and delegation. Should we include the new statutory references?

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

§1 DEFINITIONS

1. “Board” is the Board of Medicine.
2. “Chronic problem” is one previously diagnosed and treated by another which by circumstance requires interim adjustment or continuation of treatment.
3. “Close Personal Contact” is a friend, colleague, acquaintance, or extended family member.
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 associate, or others for whom the physician or physician associate 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 medicine.
8. “Physician Associate” means any physician associate licensed or privileged by the Board to render medical services.
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, FAMILY MEMBERS AND CLOSE PERSONAL CONTACTS

Physicians/physician associates may only treat themselves, immediate family members or close personal contacts, under the following circumstances:

- A. In emergency situations when there are no other qualified providers that are reasonably available to address the emergency.
- B. In an isolated setting 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.
- C. The physician/physician associate must promptly seek treatment from another provider or promptly refer the immediate family member or close personal contact to another qualified provider for follow-up.
- D. The physician/physician associate is held to the same standard of care applicable to providing treatment for patients and the physician/physician associate must only treat within their expertise and training.

§3 RECORD KEEPING

A medical record must be created and forwarded to the patient's primary care provider or regular treating provider, if any, or directly to the patient if none, within a reasonable time.

For the purposes of this rule, the medical records must include, to the extent required by the standard of care, the following:

1. Patient history, to include all current medical issues and medications;
2. Physical examination results;
3. Diagnosis;
4. Laboratory and other diagnostic test results;
5. The nature and purpose of recommended interventions;

6. The burden, risks, and expected benefits of all options, including foregoing treatment;
 7. Records of drugs prescribed, dispensed, and/or administered;
 8. Patient's decision; and
 9. The need for follow-up care or emergency services.
-

STATUTORY AUTHORITY: 32 M.R.S.A. §20113

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

383500 BOARD OF ~~OSTEOPATHIC LICENSURE~~MEDICINE

Chapter 17: PHYSICIAN/PHYSICIAN ~~ASSISTANT~~ASSOCIATE - 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~~associate is considered as unprofessional conduct.

§ 1 DEFINITIONS

1. "Board" is the Board of ~~Osteopathic Licensure~~Medicine.
2. "Immediate family members" are spouse/partner, dependent children, persons living in the home of the physician or physician ~~assistant~~associate, or persons for whom the physician or physician ~~assistant~~associate 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~~Chapter 153.
4. "Physician ~~assistant~~associate" is an individual who is qualified and licensed or ~~certified-privileged~~ according to the provisions of 32 M.R.S.A. ~~§§ 2594-A and 2594-B~~Chapter 153.
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)~~20144 (F) if a physician or physician ~~assistant~~associate:
 - 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~~licensee 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~~ licensee relationship;
 - D. encourages a patient to bequeath or otherwise give money or anything of significant monetary value to the physician or physician ~~assistant~~ associate after the patient's death, or does not actively discourage the patient when the physician or physician ~~assistant~~ associate 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~~ associate 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~~ associate 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~~ associate.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ ~~2562 & 2581~~ 20113.

EFFECTIVE DATE:

December 23, 2002 - filing 2002-475

ADOPTED RULE

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

~~373~~500 BOARD OF ~~LICENSURE IN~~ MEDICINE
380 STATE BOARD OF NURSING
~~383~~ BOARD OF ~~OSTEOPATHIC LICENSURE~~
396 BOARD OF LICENSURE OF PODIATRIC MEDICINE

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, ~~the Board of Osteopathic Licensure~~, and the Board of Licensure of Podiatric Medicine to ensure safe and adequate pain management for the citizens of Maine.

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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.

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 report³ 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.

¹ Maine Department of Health and Human Services, Office of Substance Abuse. SEOW Special Report: Heroin, Opioids, and Other Drugs in Maine. October 2015.

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.

- 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 Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95⁶ first consider the use of nonopioid therapies in the treatment of acute pain, subacute pain, and chronic 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 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 Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. 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

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.

Copies of the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain can be obtained at: <http://dx.doi.org/10.15585/mmwr.rr7103a1>.

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>.

medical purpose and in the course of professional practice if they are following standards of care, established guidelines and the requirements of this rule. Judgment 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.
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~~ associate (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. **Hospice Services** – Is defined in Title 22 M.R.S., section 8621, subsection 11 and means a range of interdisciplinary services provided on a 24-hours-a-day, 7-days-a-week basis to a person who is terminally ill and that person's family. Hospice services must be delivered in accordance with hospice philosophy.
11. **Medical Emergency** – Means an acute injury or illness that poses an immediate risk to a person's life or long-term health.
12. **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.
13. **Morphine Milligram Equivalent (MME)** - A conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.
14. **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.
15. **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.
16. **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.
17. **Opioid Use Disorder** – See Diagnostic and Statistical Manual of Mental Disorders (DSM) DSM-5 criteria.
18. **Pain** – An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
19. **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.
20. **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.
21. **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.

22. **Substance Abuse** – The use of any substance(s) for non-therapeutic purposes or for purposes other than those for which it is prescribed.
23. **Substance Misuse** - The use of a medication (with therapeutic intent) other than as directed or as indicated, and whether harm results or not.
24. **Terminally Ill** – Is defined in Title 22 M.R.S., section 8621, subsection 17 and means that a person has a limited life expectancy in the opinion of the person’s primary physician, physician ~~assistant~~associate, advanced practice registered nurse, or medical director.
25. **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.
26. **Universal Precautions** - A standardized approach to the assessment and ongoing management of all pain patients who are prescribed controlled substances.

SECTION 3. APPLICABILITY OF RULE

1. **Custodial Care Facilities**

This rule does not apply to the treatment of patients who are in-patients of any medical facility or to the treatment of patients in any custodial care facilities (including nursing homes, rehabilitation facilities, and assisted living facilities) where the patients do not have possession or control of their medications and where the medications are dispensed or administered by a licensed, certified or registered health care provider.

2. **Hospice Care**

This rule does not apply to the treatment of patients who are terminally ill and who are receiving hospice services as defined by this rule.

SECTION 4. 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) **Prescription Requirements/Limits**
 - (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.
- (f) **Exemptions to Dosage and Days' Supply Prescribing 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 100 MME 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.
- (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 indicators, 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 performing 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 governed by federal laws and regulations and Board Rule Chapter 12, “Joint Rule Regarding Office Based Treatment of Opioid Use Disorder.”

5. Use of the CDC Guideline for Prescribing Opioids for Chronic Pain

Clinicians are responsible for being familiar with the CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No.

RR-3):1–95. Copies of the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain can be obtained at: <http://dx.doi.org/10.15585/mmwr.rr7103a1>.

SECTION 5. CONTINUING EDUCATION

1. Board of ~~Licensure in~~ Medicine

~~By December 31, 2017 and thereafter, c~~linicians 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 ~~Assistant~~Associates (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).~~

4. Board of Licensure of Podiatric Medicine

By December 31, 2017 and thereafter, clinicians 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.

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STATUTORY AUTHORITY:

32 M.R.S. §§ ~~3269(3),(7), 3300-F20113~~; (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)~~
32 M.R.S. §§ 3605-B, 3657; (Board of Licensure of Podiatric Medicine)

EFFECTIVE DATE FOR THIS FILING:

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