



The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Health Professions Licensure

Board of Registration in Pharmacy

239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

Tel: 617-973-0800
TTY : 617-973-0988
.mass.gov/dph/boards

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

NOTICE OF PUBLIC HEARING

Notice is hereby given pursuant to M.G.L. c. 30A, § 2, that the **Board of Registration in Pharmacy (Board)** within the Department of Public Health (Department), will hold a public hearing on proposed amendments to the Board's regulations at 247 CMR 3.00, 8.00, 10.00 and 16.00. These regulations set requirements and procedures for licensure as a pharmacist (3.00), and licensure as a pharmacy intern and pharmacy technician (8.00). They also set standards and requirements for pharmacists that enter into collaborative drug therapy management agreements (16.00). Lastly, they set forth provisions relating to the investigation of complaints, grounds for discipline, disciplinary actions and summary suspension proceedings (10.00).

The public hearing will be held on **Monday, September 19, 2016, at 1:00 pm in Room 417A/B (4th Floor), 239 Causeway Street, Boston, Massachusetts 02114**. Hearing testimony may be presented orally or in writing; a written copy of any oral testimony will be requested.

The Department encourages all interested parties to submit written testimony electronically to the following address: .Testimony@state.ma. Please submit electronic testimony as an attached Word document or as text within the body of an email, with "BOP: 247 CMR 3.00, 8.00, 10.00 and 16.00" in the subject line. All submissions must include the sender's full name and address. The Department will post all electronic testimony that complies with these instructions on its website. Parties who are unable to submit electronic testimony should mail submissions to: Catrice C. Williams, Office of the General Counsel, Department of Public Health, 250 Washington Street, Boston, Massachusetts 02108. All written testimony must be submitted by **5:00 pm on Monday, September 26, 2016**.

A copy of the Notice of Public Hearing and the proposed amendments to Board regulations may be viewed on the Department's website or obtained from Catrice C. Williams, Office of the General Counsel, at 617-624-5220.

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 3.00: PERSONAL REGISTRATION PHARMACIST LICENSURE REQUIREMENTS

Section

- 3.01: Examination for Personal Registration Licensure as a Pharmacist
- 3.02: Personal Registration Licensure by Reciprocity
- 3.03: Duplicate Certificate of Personal Registration Licensure
- 3.04: Licensure Retirement

- 3.01: Examination for Personal Registration Licensure as a Pharmacist

In order to be registered licensed as a pharmacist by examination by the Board, an applicant must meet the requirements set forth in 247 CMR 3.01~~(1) or (2)~~.

~~(1) of ACPE accredited and Board approved colleges/schools of pharmacy;~~

~~(a) graduate of an ACPE-accredited and Board-approved college/school of pharmacy An applicant shall be eligible for examination for personal registration licensure as a pharmacist provided the applicant:~~

~~(a)1. is 18 years old by the scheduled date of the examination applied for;~~

~~(b)2. has earned a qualifying doctor of pharmacy degree in pharmacy from a college/school of pharmacy accredited by the ACPE or approved by the Board;~~

~~(c)3. has completed a pharmacy internship in accordance with 247 CMR 8.01(1) acquired no less than 1500 hours of practical experience as a pharmacy intern under the supervision of a Board-approved pharmacist preceptor, of which at least 1000 hours must be completed in a pharmacy or pharmacy-related setting, as set forth in 247 CMR 8.01; and~~

~~(d)4. is of good moral character.~~

~~(2) A graduate of a non-approved college/school of pharmacy shall be eligible for examination for personal registration licensure as a pharmacist provided the applicant:~~

~~(a) is 18 years old by the scheduled date of the examination applied for;~~

~~(b) has received official Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP;~~

~~(c) has submitted an official copy of the applicant's FPGEC Certificate to the Board and the Board has received official notification from the NABP of the applicant's FPGEC Certification;~~

~~(d) has completed a pharmacy internship in accordance with 247 CMR 8.01(1); and~~

~~(e) is of good moral character.~~

~~(3)(b) An applicant shall properly apply to take NAPLEX and MPJE. A completed application for examination shall:~~

~~(a)1. be fully and correctly completed by the applicant;~~

~~(b)2. include a recent passport-size photograph of the applicant showing the applicant's likeness;~~

~~(c)3. include a certified birth certificate or other sufficient proof of place and date of birth;~~

~~(d)4. in the case of a name change, include a written notification to the Board or the Board's designee of such name change; and~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

~~(e)5. be accompanied by a check or money order in the proper amount made payable as directed on the examination application- payment of all required fees, unless waived in accordance with M.G.L. c. 112, § 1B;~~

(4)(e) An applicant for personal registration licensure as a pharmacist must pass both NAPLEX and MPJE.

(5)(d) To qualify for personal registration licensure, the applicant must achieve a NAPLEX score of not less than 75% and an MPJE score of not less than 75%.

(6)(e) An applicant who fails to achieve a passing score on either or both NAPLEX or MPJE may be re-examined on either or both examinations provided that the applicant submits a new application for examination to the Board or Board-approved testing service, accompanied by payment of all required fees, unless waived in accordance with M.G.L. c. 112, § ~~check or money order made payable, in the proper amount, to the Board's designee as appears on the examination application form.~~

(7)(f) An applicant who fails either NAPLEX or MPJE must reapply and to sit for the examination which the applicant failed within one year of the administration date of the original examination in order for both examination scores to be considered together. If the applicant does not pass both NAPLEX and MPJE within this one-year period, the applicant must apply to retake both NAPLEX and MPJE.

~~(2) Graduates of non-approved colleges/schools of pharmacy:~~

~~(a) In order for a graduate of a non-approved college/school of pharmacy to be eligible to apply for examination for personal registration as a pharmacist, the applicant shall must have received Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP.~~

~~(b) An applicant who has graduated from a non-approved college/school of pharmacy shall be eligible for examination for personal registration as a pharmacist provided the following requirements are met:~~

- ~~1. the applicant is 18 years old by the scheduled date of the examination applied for;~~
- ~~2. the applicant has received official FPGEC Certification from NABP;~~
- ~~3. the applicant has submitted an official copy of the applicant's FPGEC Certificate to the Board;~~
- ~~4. the Board has received official notification from the NABP of the applicant's FPGEC Certification;~~
- ~~5. the applicant has acquired no less than 1500 hours of practical experience as a pharmacy intern under the supervision of a Board-approved pharmacist preceptor, of which at least 1000 hours must be completed in a pharmacy or pharmacy related setting, as set forth in 247-CMR-8.01; and~~
- ~~6. is of good moral character.~~

~~(c) An applicant who has graduated from a non-approved college/school of pharmacy shall properly apply to take NAPLEX and MPJE. A completed application for examination shall:~~

- ~~1. be fully and correctly completed by the applicant;~~
- ~~2. include a recent passport-size photograph of the applicant showing the applicant's~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

likeness;

~~3.—include a certified birth certificate or other sufficient proof of place and date of birth;~~

~~4.—in the case of a name change, include a written notification to the Board or Board's designee of such name change; and~~

~~5.—be accompanied by required fee(s).~~

~~(d) An applicant for personal registration as a pharmacist who has graduated from a non-approved college/school of pharmacy must pass NAPLEX and MPJE in accordance with the requirements set forth in 247 CMR 3.01(1)(e) through (f).~~

~~(8)(3)~~ The Board may refuse to consider any application that has not been properly completed.

~~(9)(4)~~ All fees submitted to the Board in connection with an application for ~~personal registration licensure~~ as a pharmacist, reviewed and acted upon by the Board, are nonrefundable.

3.02: ~~Personal Registration Licensure~~ by Reciprocity

The Board may grant ~~personal registration licensure~~ as a pharmacist to an applicant who furnishes proof satisfactory to the Board that the applicant has been ~~registered licensed~~ by examination in another state or jurisdiction and that the applicant is in good standing in all states where the applicant holds a ~~registration license~~, provided that such other state or jurisdiction requires a degree of competency equal to that required of applicants in Massachusetts, and provided further that the Board recognizes the other state or jurisdiction for purposes of ~~personal registration licensure~~ by reciprocity.

An applicant who seeks ~~personal registration licensure~~ by reciprocity from the Board shall submit a preliminary application to NABP for license transfer. NABP, as agent of the Board, will conduct the preliminary evaluation of an applicant's qualifications for ~~personal registration licensure~~ by reciprocity.

(1) General Requirements:

(a) Whenever an applicant has been notified by NABP that the applicant does not meet the requirements for ~~personal registration licensure~~ by reciprocity, the applicant may in writing request the Board to review the basis of NABP's decision.

(b) The Board shall make the final determination of any applicant's eligibility to be registered as a pharmacist by reciprocity.

(c) A reciprocity application shall be valid for one year after the date of approval by NABP.

(d) All fees submitted to the Board in connection with an application for ~~personal registration licensure~~ by reciprocity, reviewed and acted upon by the Board, are nonrefundable.

(2) Specific Requirements for Graduates of ACPE-accredited or Board-approved Colleges/ Schools of Pharmacy.

(a) The requirements for the issuance by the Board of a ~~personal registration license~~ by reciprocity to an applicant who has graduated from an ACPE-accredited or Board-approved college/school of pharmacy shall include the following:

1. NABP approval;

2. documentation of experience ~~as required-~~ accordance with 247 CMR 8.01;

3. passing score (at least 75%) on MPJE; and

247 CMR: BOARD OF REGISTRATION IN PHARMACY

4. if requested, the applicant shall personally appear before the Board to discuss any matter related to the application.
 - (b) Upon receipt by the Board of evidence of an applicant's NABP approval and payment of all required fee(s), unless waived in accordance with M.G.L. c. 112, § ~~appropriate fee~~, the applicant may register with NABP to take MPJE.
- (3) Specific requirements for graduates of non-approved colleges/schools of pharmacy:
- (a) The requirements for the issuance of a personal registration licensure by reciprocity to an applicant who has graduated from a non-approved college/school of pharmacy shall include:
 1. Receipt by the Board of an official copy of the applicant's FPGEC Certificate from NABP;
 2. documentation satisfactory to the Board of ~~practical~~ internship experience in accordance with as required by 247 CMR 8.01;
 3. passing score (at least 75%) on MPJE; and
 4. if requested, the applicant shall personally appear before the Board to discuss any matter related to the application.
 - (b) Upon receipt by the Board of evidence of an applicant's NABP approval and payment of all required fee(s), unless waived in accordance with M.G.L. c. 112, § ~~appropriate fee(s)~~, the applicant must register with NABP to take MPJE.

3.03: Duplicate Certificate of ~~Registration~~ Licensure

To request a duplicate certificate of personal registration licensure (wallet card), a registrant shall submit a Board-approved form and required documentation. In the event that an original certificate of registration licensure is recovered after a duplicate certificate has been issued, the duplicate shall be promptly returned to the Board.

3.04: Personal ~~Registration~~ Licensure Retirement

- (1) A licensee who meets the eligibility requirements in 247 CMR 3.04(2) may submit a petition to the Board to request that his or her license be placed on retired status. A retired status is a nondisciplinary status. The Board may decline to review any petition for reinstatement or return to current status from any licensee whose status has been changed to retired status.
- (2) A licensee will be eligible to submit a petition for retired status, if her or she:
 - (a) has a license that is not surrendered, suspended or revoked at the time of the petition;
 - (b) demonstrates, to the board's satisfaction, that he or she intends to permanently retire from active practice in the Commonwealth and in all other jurisdictions;
- (3) A licensee with a retired status may not practice.
- (4) Nothing in this section shall prevent the Board from initiating, pursuing or taking a disciplinary action against a licensee whose license is in retired status, including an action that imposes discipline or changes the status from retired to revoked or suspended, if the Board determines that such action is in the best interests of public health, safety or welfare.

REGULATORY AUTHORITY

247 CMR 3.00: M.G.L. c. 112, §§ 24 and 42A.

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 8.00: PHARMACY INTERNS AND TECHNICIANS

Section

- 8.01: Pharmacy Interns
- 8.02: Pharmacy Technicians
- 8.03: Pharmacy Technician Trainees
- 8.04: Certified Pharmacy Technicians
- 8.05: Requirements for the Handling of Schedule II Controlled Substances by Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians, and Pharmacy Technician Trainees
- 8.06: Duties of Pharmacist Utilizing Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians, and Pharmacy Technician Trainees
- 8.07: ~~Registration and~~ Renewal Procedures; ~~General Requirements~~

~~For the purposes of 247 CMR 8.00 "pharmacy" shall include retail, institutional, restricted and nuclear pharmacies and pharmacy departments.~~

8.01: Pharmacy Interns

(1) To be eligible for ~~registration~~ as a pharmacist, a candidate shall have completed a Board-approved pharmacy internship. ~~A Board-approved pharmacy shall have, which shall include:~~

~~(a) completed two years of education, or achieved standing as a student beyond the second year, in an approved college/school of pharmacy in which the candidate is currently enrolled; and~~

(c) completed at least 1500 hours of Board-approved pharmacy internship experience, of which:

1. at least 1000 hours has been acquired in a pharmacy or pharmacy-related setting approved by the Board; and
2. ~~no more than at least~~ 500 hours has been acquired in any one, or any combination of Board-approved internships(s) in the following areas:
 - a. clinical pharmacy;
 - b. demonstration project;
 - c. manufacturing; or
 - d. analytical or industrial pharmacy; or

(b) at least 1500 intern hours acquired through experiential pharmacy education, provided the student is a graduate of an ACPE accredited college or university.

(2) In order to be eligible for a pharmacy intern license, an individual shall:

(a) have achieved standing as a student in the first professional year in an approved college/school of pharmacy;

(b) be currently enrolled in a Doctor of Pharmacy ("PharmD") program; and

(c) be of good moral character.

247 CMR: BOARD OF REGISTRATION IN PHARMACY

() ~~The A~~ pharmacy shall ~~work be performed~~ under the direct supervision of a registered pharmacist preceptor.

() A pharmacy intern may ~~receive credit for up to~~ not receive more than 12 hours of pharmacy internship credit per day.

() Pharmacy internship hours may be acquired throughout a calendar year.

~~(5)(a) Before the commencement of a pharmacy internship in Massachusetts, persons who are enrolled, either full or part time, in an approved college/school of pharmacy shall record, on a form provided by the Board, certain information regarding the internship as the Board shall require. This form shall be fully completed and returned to the Board before commencement of any internship. This information shall include:-~~

(6) An application for a pharmacy intern license shall be made on forms prescribed by, and available from, the Board. The application shall include:

~~(a)1.~~ the applicant's name;

~~(b)2.~~ the applicant's address;

~~(c)3.~~ the applicant's date of birth;

~~(d)4. have attached thereto~~ a recent passport-size photo revealing the applicant's likeness; and

~~(e)5.~~ a certified statement by the approved college/school of pharmacy which indicates that the applicant has ~~completed two years of education or has achieved standing as a student beyond the second year~~ achieved standing as a student in the first professional year and is enrolled in a PharmD program.

~~(7)(b)~~ Graduates of -approved Colleges/Schools of Pharmacy. Before the commencement of a pharmacy internship in Massachusetts, a graduate of a non-approved college/school of pharmacy must have authorization, issued within the preceding year, from NABP to sit for the FPGEE (~~issued within the preceding year~~) and must provide a copy of the NABP FPGEE authorization to the Board, along with ~~and~~ any other documentation required by the Board.

(8) A PharmD graduate from an approved College/School of Pharmacy, who has accepted a residency in Massachusetts, shall apply for and obtain a pharmacy intern license until such time as he or she obtains a Massachusetts pharmacist license. A PharmD graduate enrolled in a residency in Massachusetts shall:

(a) hold a Massachusetts pharmacist license; or

(b) hold Massachusetts pharmacy intern license and be supervised by a pharmacist.

() During the course of the pharmacy internship, preceptors and pharmacy interns shall submit, in a timely manner, and on a form provided by the Board, any such information as the Board may require regarding the internship.

() A pharmacy intern who has graduated from an approved college/school of pharmacy may continue to act in the capacity of pharmacy intern until he or she becomes ~~registered~~ as a pharmacist.

247 CMR: BOARD OF REGISTRATION IN PHARMACY

- () The Board may grant credit for out-of-state pharmacy internship experience where an affidavit or certificate of approval issued by the jurisdiction the experience was acquired, is presented to the Board indicating that such internship experience has been duly approved in the jurisdiction.
- () Massachusetts approved Colleges/Schools of Pharmacy shall submit to the Board a written description of each demonstration project or clinical pharmacy program for which pharmacy internship credit is desired. The Board ~~shall review this information and~~ may determine whether or not student participation in such project(s) or program(s) may be credited to the internship requirement.
- () The Board shall issue a Summary of Objectives and Procedures for Pharmacy Internship and guidelines for registered pharmacist preceptors and pharmacy interns.
- () A pharmacy intern shall wear a name tag which indicates the intern's first name and the words "pharmacy intern."
- () A pharmacy intern acting under the direct supervision of an ~~approved~~-registered pharmacy preceptor may supervise pharmacy technicians.
- () A registered pharmacist preceptor shall not directly supervise more than two pharmacy interns at one time.
- () A pharmacy intern found to have engaged in conduct in violation of federal and/or state laws and/or regulations may be prohibited from taking the examination for ~~personal registration~~, in addition to other sanctions imposed by the Board.

(18) A pharmacy intern shall provide written notification to the Board within 14 days of his/her withdrawal from an approved College/School of Pharmacy or PharmD program.

8.02: Pharmacy Technicians

~~(1) Requirements for Registration as a Pharmacy Technician-~~

(1) No individual may serve as a pharmacy technician without holding a valid pharmacy technician license from the Board.

(2) An application for a pharmacy technician license shall be made on forms prescribed by, and available from, the Board. The application shall include:

- (a) the applicant's name;
- (b) the applicant's address;
- (c) the applicant's date of birth; and
- (d) a recent passport-size photo revealing the applicant's likeness.

() An applicant for ~~registration as a pharmacy technician~~ a pharmacy technician license shall ~~must meet the following requirements:~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

- ~~1.(a)~~ be at least 18 years of age;
- ~~2.(b)~~ be a high school graduate or the equivalent or currently enrolled in a program which awards such degree or certificate;
- ~~3.(c)~~ be of good moral character;
- ~~4.(d)~~ not have been convicted of a drug related felony or admitted to sufficient facts to warrant such findings;
- ~~5. Training/Experience Requirement. An applicant for registration as a pharmacy technician must meet the following training program or experience requirements:-~~
 - ~~a.(e)~~ have successfully completed a Board-approved pharmacy technician training program, which training program shall include coverage of the topics of job descriptions, pharmacy security, commonly used medical abbreviations, routes of administration, product selection, final check by pharmacists, guidelines for the use of pharmacy technicians, and any other requirements of the Board. Training programs which may be approved by the Board include:-
 - ~~i. a pharmacy technician training program accredited by the American Society of Health System Pharmacists;-~~
 - ~~ii. a pharmacy technician training program provided by a branch of the United States Armed Services or Public Health Service;~~
 - ~~iii. a Board-approved pharmacy technician training program which includes a minimum of 240 hours of theoretical and practical instruction; provided a minimum of 120 training hours are in theoretical instruction in a curriculum;-~~
 - ~~or~~
 - ~~iv. any other pharmacy technician training course approved by the Board; or~~
 - ~~b. have successfully completed a minimum of 500 hours of employment as a pharmacy technician trainee. Documentation of completion of the required 500 hours of experience shall be attested to by the applicant under the pains and penalties of perjury and witnessed by the employer; and~~
- (f) have successfully completed a minimum of 500 hours of employment as a pharmacy technician trainee. Documentation of completion of the required 500 hours of experience shall be attested to by the applicant under the pains and penalties of perjury and witnessed by the employer; and
- (g) achieve a Board-approved passing score on a Board-approved pharmacy technician assessment examination.

- (4) A Board-approved training program may include:
 - (a) a pharmacy technician training program accredited by the American Society of Health System Pharmacists;
 - (b) a pharmacy technician training program provided by a branch of the United States Armed Services or Public Health Service;
 - (c) a Board-approved pharmacy technician training program which includes a minimum of 240 hours of theoretical and practical instruction; provided a minimum of 120 training hours are in theoretical instruction in a curriculum; or
 - (d) any other pharmacy technician training course approved by the Board.

~~6. Examination Requirement. An applicant for registration as a pharmacy technician must achieve a Board approved passing score on either:-~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

~~a. — a Board approved pharmacy technician assessment examination administered by the employer or the employer's agent. The examination must cover the following knowledge based areas:-~~

(5) A Board-approved examination shall cover the following knowledge based areas:

- i.(a) practice settings;
- ii.(b) duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel;
- iii.(c) laws and regulations regarding the practice of pharmacy and patient confidentiality;
- iv.(d) medical abbreviations and symbols;
- v.(e) common dosage calculations; and
- vi.(f) identification of drugs, dosages, routes of administration, and storage requirements; ~~or-~~

~~b. a Board approved national technician certification examination.~~

~~(b) GRANDPARENT PROVISION FOR EXPERIENCE PRIOR TO JULY 1, 2002- ONLY Application Expiration Date of July 1, 2003 for Experience Prior to July 1, 2002. An applicant for registration as a pharmacy technician based on at least 500 hours of employment as a pharmacy technician prior to July 1, 2002 shall be required to:-~~

- ~~1. apply to the Board for registration prior to July 1, 2003. Documentation of completion of the required 500 hours of experience must be attested to by the applicant under the pains and penalties of perjury and witnessed by the employer; and~~
- ~~2. meet the examination requirements of 247 CMR 8.02(1)(a)6. prior to July 1, 2003. Documentation of satisfaction of the examination requirements of 247-~~

(6) Licensure by - . A pharmacy technician currently ~~registered-~~ and in good standing in another state, or certified by a Board-approved certifying body, may be ~~registered-~~ by the Board; provided the requirements for ~~registration-~~ in the original state ~~of original and current registration~~ are substantially equivalent to the requirements of the Board.

(7) Pharmacy Technician Duties and Responsibilities

- (a) A pharmacy technician shall wear a name tag which indicates the individual's first name and the title "Pharmacy Technician."
- (b) A pharmacy technician may relay to the patient or responsible person the pharmacist's "offer to counsel," ~~as referenced in M.G.L. c. 94C, § 21A and 247 CMR 9.07(3): Patient Counseling.~~
- (c) With the approval of the pharmacist on duty, a pharmacy technician may request and accept authorizations for refills from ~~the a~~ prescriber or a prescriber's agent provided that no information has changed from the previous prescription.
- (d) A pharmacy technician may **not** administer ~~controlled substances;~~ medications or vaccines, perform drug utilization review; ~~conduct clinical conflict resolution;~~ contact prescribers concerning drug order- clarification or therapy modification; ~~provide patient counseling;~~ or perform final dispensing process validation; ~~receive new prescription drug orders; or conduct prescription-~~

~~transfers.~~

8.03: Pharmacy Technician Trainees

(1) No individual may serve as a pharmacy technician trainee without holding a valid Pharmacy Technician Trainee License from the Board.

- () A ~~shall must meet the following requirements:~~
- (a) be at least 16 years of age;
 - (b) be a high school graduate or the equivalent or currently enrolled in a program which awards such degree or certificate;
 - (c) be of good moral character; and
 - (d) not have been convicted of a drug related felony or admitted to sufficient facts to warrant such findings.

(3) An application for a pharmacy technician trainee License shall be made on forms prescribed by, and available from, the Board. The application shall include:

- (a) the applicant's name;
- (b) the applicant's address;
- (c) the applicant's date of birth; and
- (d) a recent passport-size photo revealing the applicant's likeness.

() Pharmacy Technician Trainee Duties and Responsibilities

- (a) A pharmacy technician trainee shall wear a name tag with the individual's first name and the title "Pharmacy Technician Trainee."
- (b) Except as set forth below, a ~~may~~ may be authorized to perform the duties of a ~~while receiving the training and supervision required by 247 CMR-8.02(1)(a)5. and~~ acting under the direct supervision of a pharmacist.
- (c) A pharmacy technician trainee ~~is not authorized to~~ may not take prescriptions over the telephone.

() Limitation on Period of Employment as a Pharmacy Technician Trainee. ~~An individual may act and be designated as a pharmacy technician trainee for not more than 1000 hours, unless an extension is granted by the Board. Pharmacy technician trainees under the age of 18 are not subject to the 1000 hour limitation. An individual may not work as a pharmacy technician trainee for more than 1250 hours or for more than one year, whichever period is shorter, unless:~~

- (a) the Board grants an extension;
- (b) the individual has not yet reached 18 years of age; or
- (c) the individual has not yet completed at least 500 hours of employment as a pharmacy technician trainee.

An individual who has worked as a pharmacy technician trainee for more than 1250 hours or for more than one year prior to / or her birthday shall submit an application for a pharmacy technician license within 30 days of his or her birthday.

8.04: Certified Pharmacy Technicians

247 CMR: BOARD OF REGISTRATION IN PHARMACY

~~(1) Qualifications.-~~

~~(a) A pharmacy technician currently:-~~

- ~~1. registered by the Board; and~~
- ~~2. certified by a Board approved certifying body may perform the duties as authorized to be performed by a certified pharmacy technician in 247 CMR 8.04(2).-~~

~~(b) At any time that certification lapses, the certified pharmacy technician:-~~

- ~~1. is limited to performing the functions of a pharmacy technician;~~
- ~~2. must use the title “pharmacy technician” and be limited to performing the duties authorized to be performed by pharmacy technicians, as set forth in 247 CMR 8.02; and~~
- ~~3. must be counted as a “pharmacy technician” in calculating supervisory ratios, as set forth in 247 CMR 8.06(3).-~~

(1) No individual may work as a certified pharmacy technician without holding a valid pharmacy technician license from the Board.

(2) Certified pharmacy technician means a pharmacy technician that is certified by a Board-approved certifying body.

(3) In the event that a certified pharmacy technician’s certification lapses, that technician shall:

- (a) be limited to performing the duties and responsibilities of a pharmacy technician, as set forth in 247 CMR 8.02;
- (b) use the title “pharmacy technician”; and
- (c) be counted as a “pharmacy technician” in calculating supervisory ratios, as set forth in 247 CMR 8.06(3).

(4) Certified Pharmacy Technician Duties and Responsibilities

(a) A ~~pharmacy technician eligible to function as a~~ certified pharmacy technician shall wear a name tag with the individual’s first name and the title “Certified Pharmacy Technician.”

(b) A certified pharmacy technician may relay to the patient or responsible person the pharmacist’s “offer to ~~eo~~ counsel,” ~~as referenced in M.G.L. c. 94C, § 21A and 247 CMR 9.07(3): Patient Counseling.~~

(c) A certified pharmacy technician, after identifying him~~self~~ or herself as such, may request refill authorizations from the prescriber or prescriber’s agent and, with the approval of the pharmacist on duty, receive new or omitted prescription information from the prescriber or agent, except where otherwise prohibited by federal or state laws and regulations.

(d) A certified pharmacy technician may, with the approval of the pharmacist on duty, perform prescription transfers between pharmacies for prescriptions issued for controlled substances in Schedule VI only and in accordance with the requirements of 247 CMR 9.13.

(e) A certified pharmacy technician may **not** administer ~~controlled substances;~~ medications or vaccines, perform drug utilization review; conduct clinical conflict resolution; ~~contact prescribers concerning drug order~~ clarification or

therapy modification~~;~~, provide patient counseling~~;~~, or perform final dispensing process validation.

8.05: Requirements for the Handling of Schedule II Controlled Substances by Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians, and Pharmacy Technician Trainees

- (1) Accountability for and security of Schedule II controlled substances shall be the direct responsibility of the pharmacist.
- (2) Under the supervision of a pharmacist:
 - (a) a pharmacy technician may assist in the transporting of Schedule II controlled substances; and
 - (b) a certified pharmacy technician may assist in the transporting and handling of Schedule II controlled substances; provided, the pharmacist has approved the certified pharmacy technician or pharmacy technician to assist the pharmacist in the handling or transporting of Schedule II controlled substances, in accordance with 247 CMR 8.05(2) and as evidenced by written policies and procedures to be followed in the pharmacy. ~~in the transporting and handling Schedule II controlled substances,~~ policies and procedures shall ~~to~~ be made available to the Board on request.
- (3) A certified pharmacy technician, pharmacy technician, or pharmacy technician trainee may not handle any hydrocodone-only extended release medication that is not in an abuse deterrent form. Pharmacy interns under the direct supervision of a registered pharmacist may handle hydrocodone-only extended release medication that is not in an abuse deterrent formulation.

8.06: Duties of a Pharmacist Utilizing Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians, and Pharmacy Technician Trainees

~~In addition to the requirements of 247 CMR 8.02 through 8.05, the following shall apply to a pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians and pharmacy technician trainees:~~

- (1) A pharmacist Manager of Record ~~of a pharmacy or pharmacy department~~ or the Director of Pharmacy in an institutional pharmacy which utilizes certified pharmacy technicians, pharmacy technicians, or pharmacy technician trainees shall make the following available to the Board upon request:
 - (a) a list of currently employed certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees;
 - (b) a written description of the duties delegated to certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees; and
 - (c) a written description of the scopes of responsibility for certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees.

247 CMR: BOARD OF REGISTRATION IN PHARMACY

- (2) A pharmacist may train a pharmacy technician or pharmacy technician trainee through an on-the-job training program, in accordance with 247 CMR ~~8.00 8.02(1)(a)5.a. and b.~~ All such training programs shall comply with written guidelines formulated by the pharmacy ~~or pharmacy department~~ in a manner consistent with professional, ethical, and legal standards of proper pharmacy practice. Copies of training program guidelines shall be provided to the Board on request.
- (3) Supervisory Ratios
- (a) A pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees to assist in filling prescriptions ~~may utilize such support personnel in accordance~~ comply with the following minimum supervisory ratios:
1. ~~1:4~~ One pharmacist for a maximum of four support personnel, provided:
 - a. at least one of the four support personnel is a certified pharmacy technician and one is a pharmacy intern; or
 - b. at least two of the support personnel are certified pharmacy technicians; or
 - c. two of the support personnel are pharmacy interns.
 2. ~~1:3~~ One pharmacist for a maximum of three support personnel, provided at least one of the three support personnel is a pharmacy intern or a certified pharmacy technician.
- (b) Sales clerks, messengers, delivery personnel, secretaries and any other persons who do not fall within the definitions of a pharmacy intern, certified pharmacy technician, pharmacy technician, or pharmacy technician trainee shall not be included for purposes of determining the ratios set forth in 247 CMR 8.06(3) as long as such persons are not supporting the pharmacist in any professional capacity.

8.07: - Renewal ; General Requirements

~~(1) Application for Registration. Upon meeting the requirements for registration as a pharmacy technician, an applicant may apply for registration on forms provided by the Board.~~

~~(2) Renewal of Registration.~~

~~(1)(a) A pharmacy technician registrations license shall expire every two years on the birthdate of the .~~

~~(2)(b) A pharmacy technician registration license must be timely renewed to continue practice as a pharmacy technician. Any practice as a pharmacy technician after the expiration date of a pharmacy technician registration license shall constitute unlicensed practice as a pharmacy technician subjecting the individual to any and all penalties established for unlicensed practice.~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

~~(3)(e)~~ A pharmacy technician whose registration license has lapsed may renew such registration upon filing of a renewal application and payment of an annual license, applicable back fees, and a late fee, as established by the Commissioner of Administration and Finance, pursuant to M.G.L. c. 7, § 3B.

~~(4)(d)~~ A pharmacy technician whose registration license has lapsed for more than two years may be required to meet other conditions as determined by the Board as a prerequisite to registration license renewal.

~~(3) General Requirements-~~

~~(a) A pharmacy technician who changes his or her mailing address or name shall notify the Board of such change(s) in writing within ten working days of such changes(s) (M.G.L. c. 112, § 24F). In the case of a change of name, the pharmacy technician shall submit a sworn statement indicating that the pharmacy technician has changed his or her name with a photocopy of a valid picture identification card.~~

~~(b) A pharmacy technician shall carry, or have readily available, at all times where the pharmacy technician is employed, evidence of current registration with the Board.~~

REGULATORY AUTHORITY

247 CMR 8.00: M.G.L. c. 94C, § 6 and M.G.L. c. 112, §§ ~~30~~, 24D, 24E, 24F, 24G and 42A.

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 10.00: INVESTIGATIONS, COMPLAINTS AND BOARD ACTIONS DISCIPLINARY PROCEEDINGS

Section

10.01: Purpose

10.02: Investigations, Formal Docketed Complaints and Licensee's Responsibility to Respond Prior to the Issuance of an Order to Show Cause Definitions

10.03: Grounds for Board Action Discipline

10.04: Board Actions on Formal, Docketed Complaints Investigative Conference

10.05: Summary Actions Disposition by the Board

10.06: Additional provisions applicable to Investigations, Complaints and Board Actions Disciplinary Action

10.07: (Reserved) Suspension Prior to Hearing

10.08: (Reserved) Summary Cease and Desist and Quarantine Notice

10.01: Purpose

247 CMR 10.00 authorizes Board staff to conduct investigations and initiate formal docketed complaints on behalf of the Board. It also establishes the grounds for discipline and the actions that may be taken in resolution of such complaints, by the Board and on behalf of the Board, in accordance with M.G.L. c. 30A and Standard Adjudicatory Rules of Practice and Procedure at 801 CMR 1.01 *et seq.* It also establishes the standards and procedures for summary suspensions.

~~The purpose of 247 CMR 10.00 is to outline the procedures used by the Board in order to handle complaints received against Board registrants or licensees. The Board may take disciplinary action against a registered pharmacist, pharmacy technician, pharmacy, pharmacy department, wholesale license, and/or controlled substance registration issued by the Board.~~

10.02: Investigations, Formal Docketed Complaints and Licensee's Responsibility to Respond Prior to the Issuance of an Order to Show Cause Definitions

(1) Investigations Generally. Any person or organization may submit information, in any form, alleging misconduct by a licensee to the offices of the Board. The Board may direct or authorize that one or more of following actions be taken on its behalf:

(a) Review all information that they receive alleging or indicating acts or omissions by a licensee and to identify whether such acts or omissions, if true constitute grounds for Board action pursuant to 247 CMR 10.03;

(b) Request the licensee who is alleged to have engaged in the alleged acts or omissions to submit a written response to the allegations and any documents or other evidence in the licensee's possession and control that may be relevant to the allegations;

(c) Gather additional information as necessary to determine if the alleged acts or omissions are supported by evidence; and

247 CMR: BOARD OF REGISTRATION IN PHARMACY

(d) Initiate a formal, docketed complaint against a licensee based on evidence that the licensee has engaged in specific acts or omissions that constitute grounds for Board action.

(2) Licensee's Response. Except as otherwise provided by law, a licensee who is asked for a written response to a pending investigation or docketed complaint pursuant to 247 CMR 10.02(1) shall provide such response within 21 days of the licensee's receipt of the request. The licensee's written response shall be signed by the licensee. A licensee who claims that he or she is exempt by law from either responding to the Board or from producing requested documents or evidence to the Board shall provide a written statement setting forth the legal authority on which he or she relies.

(3) Closure of Investigation. If a formal, docketed complaint has not been initiated, the Board may direct or authorize that that one or more of the following actions be taken on its behalf:

(a) Close the investigation for any of the reasons set forth in 247 CMR 10.04(1)(a)(1)- (3);

(b) Send an advisory letter in accordance with 247 CMR 10.06(1) to the licensee who is the subject of an investigation.

(c) Reopen a closed investigation on the receipt of new or previously unavailable evidence

~~-Hearing means a formal administrative hearing held by the Board conducted to determine the truth and validity of complaints filed against a registrant or licensee. Such hearing is held pursuant to M.G.L. c. 30A and 801 CMR 1.01: Formal Rules.~~

~~-means a communication filed with the Board or the Division of Health Professions Licensure which the Board determines, after investigation, merits further consideration or action.~~

~~-shall include any guilty verdict or finding of guilt and any admission to or finding of sufficient facts to warrant a finding of guilt, regardless of adjudication, a continuance without a finding, and any plea of guilty or nolo contendere, of or to a crime in any jurisdiction, which has been accepted by the court, whether or not a sentence has been imposed. A conviction of any person licensed or registered by the Board shall be conclusive evidence of the commission of that crime in any disciplinary proceeding against such person based upon the conviction.~~

~~-Conference means an informal discussion relating to a complaint held with the Board.~~

~~-to Show Cause means a document served by the Board upon a registrant ordering the registrant or licensee to appear before the Board for a formal adjudicatory hearing.~~

10.03: Grounds for Board Action Discipline

247 CMR: BOARD OF REGISTRATION IN PHARMACY

(1) The Board may ~~impose disciplinary take~~ action against ~~an individual or entity licensed or registered by the Board,~~ license of a licensee based on one or more of the following grounds ~~for discipline listed in M.G.L. c. 112, § 61 or one or more of the following grounds:~~

- (a) The licensee fails to comply with any provision of M.G.L. c. 112, §§ 24 through 42A, or any provision of M.G.L. c. 94C;
- (b) The licensee fails to comply with any provision of 247 CMR, or any rule, advisory ruling or policy adopted by the Board;
- (c) The licensee fails to comply with an Order of the Commissioner of the Department of Public Health pursuant to a Declaration of Emergency Detrimental to Public Health made in accordance with M.G.L. c. 17, § 2A or pursuant to such other authority as may be vested in the Commissioner;
- (d) The licensee fails to comply with any provision of 105 CMR 700.000, 720.000, 721.000, 722.000 or 724.000, or any rule, advisory ruling or policy adopted by the Department of Public Health, Drug Control Program;
- (e) The licensee fails to comply with any order of the Board;
- (f) The licensee fails to comply with the terms of any Consent Agreement entered into with the Board;
- (g) The licensee engages in conduct outside the licensee's scope of practice, except as may be otherwise authorized by law or licensing authority;
- (h) The licensee continues to practice after the expiration, revocation, suspension, surrender or retirement of his or her license, or after the licensee has entered into a Consent Agreement in which he or she agreed to refrain from engaging in practice;
- (i) The licensee knowingly permits, aids or abets an unlicensed person to perform activities that requires a license issued by the Board;
- (j) The licensee fraudulently procures a license or its renewal;
- (k) In connection with any examination related to license, the licensee
 1. impersonates or acts as proxy for another individual;
 2. discloses the contents of any examination;
 3. compromises the integrity of any such examination; or
 4. cheats, or assists another person to cheat, on any such examination;
- (l) The licensee knowingly provides false information to the Board, either directly or through another person acting on the licensee's behalf;
- (m) The licensee fails, without cause, to appear before the Board when so requested as part of the Board's review of a matter concerning the licensee, including but not limited to an investigation, complaint, report required pursuant to 247 CMR 20.00, plan of correction or application;
- (n) The licensee fails, without cause, to provide a written response to a pending investigation or complaint or to provide documents or other evidence in the licensee's possession or control that may be relevant to the allegations, in accordance with 247 CMR 10.02(2) and 247 CMR 10.06(2);
- (o) Another government licensing or authorizing agency, within or outside the Commonwealth, imposes discipline against any professional certificate, registration, license or authorization held by the licensee for reasons that are substantially the same as grounds for Board action in this section;

247 CMR: BOARD OF REGISTRATION IN PHARMACY

- (p) The licensee has been convicted of a crime;
 - (q) The licensee engages in conduct that demonstrates a lack of good moral character;
 - (r) The licensee engages in practice while his or her ability to practice is impaired by alcohol, drug, physical disability or mental instability;
 - (s) The licensee obtains or uses any drug in an unlawful manner;
 - (t) The licensee engages in behavior that is likely to have an adverse effect upon the health, safety or welfare of the public; or
 - (u) The licensee engages in conduct that undermines public confidence in the integrity of the profession.
- ~~(a) — Violating any of the duties and standards set out in Board regulations (247 CMR 2.00: Definitions) or any rule or written policy adopted by the Board;~~
 - ~~(b) — Violating any provision of M.G.L. c. 112, §§ 24 through 42A or any provision of state or federal statutes or rules or regulations promulgated thereunder related to the practice of the profession;~~
 - ~~(c) — Failing to submit an acceptable plan of correction pursuant to 247 CMR 6.13: Plans of Correction;~~
 - ~~(d) — Failing to remedy or correct a violation cited in a deficiency statement by the date specified in the plan of correction submitted in accordance with 247 CMR 6.13: Plans of Correction, as accepted or modified by the Board, unless the pharmacy or pharmacy department demonstrates to the satisfaction of the Board that such failure was not due to any neglect of duty and occurred despite his/her good faith attempt to remedy or correct the violations(s) by the specified time;~~
 - ~~(e) — Engaging in misconduct in the practice of the profession;~~
 - ~~(f) — Engaging in conduct beyond the authorized scope of a pharmacist, pharmacy intern or pharmacy technician;~~
 - ~~(g) — Practicing the profession while the ability to practice is impaired by illness, use of alcohol, drugs, chemicals, or any other type of substance, or as a result of any mental or physical condition;~~
 - ~~(h) — Engaging in abuse or illegal use of prescription drugs or controlled substances;~~
 - ~~(i) — Continuing to practice the profession after a registration is lapsed, suspended or revoked;~~
 - ~~(j) — Violating the terms of a Consent Agreement, Final Decision and Order, Surrender Agreement or any other order issued by or agreement entered into with the Board;~~
 - ~~(k) — Engaging in conduct that has the capacity or potential to place the public health, safety or welfare at risk;~~
 - ~~(l) — Engaging in conduct that has the capacity or potential to deceive or defraud;~~
 - ~~(m) Knowingly permitting, aiding or abetting an unlicensed person to perform activities requiring a license or registration;~~
 - ~~(n) — Being convicted of any crime, entering a plea of guilty to any crime, entering a plea of nolo contendere to any crime, or admitting to sufficient facts to warrant a finding of guilty of any crime;~~
 - ~~(o) — Fraudulently procuring a license or registration or its renewal;~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

- ~~(p) — Providing false information on an application for a license or registration or its renewal;~~
- ~~(q) — Failing without cause, to cooperate with any request by the Board to appear before it or to provide requested information; failing to respond to a Board subpoena or failing to furnish the Board, its investigators or representatives with records, documents, information or testimony to which the Board is legally entitled;~~
- ~~(r) — Engaging in conduct that demonstrates a lack of good moral character;~~
- ~~(s) — Cheating on or attempting to compromise the integrity of any licensing or registration examination;~~
- ~~(t) — Having been disciplined in another jurisdiction in any way for reasons substantially the same as those set forth in 247 CMR 10.03;~~
- ~~(u) — Engaging in conduct which undermines public confidence in the integrity of the profession;~~
- ~~(v) — Committing an act that violates recognized standards of pharmacy practice;~~
- ~~(w) — Failing to comply with recognized ethical standards of the profession, including, but not limited to, the standards of practice of pharmacists, pharmacy interns, pharmacies and pharmacy departments set forth in 247 CMR 9.01: Code of Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments;~~
- ~~(x) — Violation of M.G.L. c. 94C or any rules or regulations promulgated thereunder;~~
- ~~(y) — Failing to report or failing to accurately report to the Board within seven business days, in a manner and format determined by the Board, discipline (247 CMR 10.06) on the basis of actions listed in 247 CMR 10.03(1);~~
- ~~(z) — Failing to report to the Board, in a manner and format determined by the Board, within seven business days, any final action (including license surrender or resignation) regarding a registrant or licensee, including any against any other health care related professional registration or license held by a registrant or licensee, by any other governmental authority in this state or another jurisdiction;~~
- ~~(aa) — Failing to report to the Board, in writing, within 30 days, any pending criminal charge or conviction, as defined in 247 CMR 10.02, of a registrant or licensee, in Massachusetts or any other jurisdiction; and~~
- ~~(bb) — Failure to comply with reporting requirements described in 247 CMR 6.15: Duty to Report Certain Factors of Pharmacy Operations(2) through (7) or to cooperate fully in the Board's investigation of any such report.~~
- ~~(cc) — Violation of, or failure to comply with, an Order issued by the Commissioner of the Department of Public Health pursuant to a Declaration of Emergency Detrimental to Public Health made in accordance with M.G.L. c. 17, § 2A or pursuant to such other authority as may be vested in the Commissioner.~~

(2) Nothing in ~~247 CMR 10.03~~ this section shall limit the Board's adoption of ~~policies and~~ grounds for discipline through adjudication ~~as well as through~~ rulemaking.

10.04: Board Actions on Formal, Docketed Complaints Investigative Conference

247 CMR: BOARD OF REGISTRATION IN PHARMACY

(1) Dismissal

(a) The Board may direct or authorize the dismissal of a complaint for the following reasons:

1. The Board lacks jurisdiction;
2. There is insufficient evidence to support a finding that the licensee engaged in acts or omissions that constitute grounds for Board action; or
3. There may be sufficient evidence to support a finding that the licensee engaged in acts or omissions that constitute grounds for Board action; however the Board concludes that even if true, the alleged acts or omissions in the specific circumstances presented, do not warrant action against the license.

(b) The Board may direct or authorize the reopening of any dismissed complaint upon receipt of new or previously unavailable evidence except when the dismissal follows a formal adjudicatory hearing conducted in accordance with Standard Adjudicatory Rules of Practice and Procedure at 801 CMR 1.01 *et seq.*

(c) When dismissing a complaint, the Board may direct or authorize the Executive Director to send, on the Board's behalf, an advisory letter in accordance with 247 CMR 10.06(a) to the licensee.

(2) Orders

(a) Order to Show Cause. The Board may authorize prosecuting counsel to initiate and prosecute formal disciplinary proceedings by issuing, on the Board's behalf, an order for the licensee to appear and show cause why the Board should not take action against his or her license. Both the issuance of an Order to Show Cause and the subsequent adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and Standard Adjudicatory Rules of Practice and Procedure at 801 CMR 1.01 *et seq.* The Board may designate an administrative hearings counsel as the Presiding Officer to conduct the adjudicatory proceeding. The Board may authorize prosecuting counsel to file and amend pleadings on the Board's behalf to promote the efficient and expeditious resolution of the adjudicatory proceeding.

(b) Final Orders. If, after an adjudicatory hearing conducted in accordance with M.G.L. c. 30A and Standard Adjudicatory Rules of Practice and Procedure at 801 CMR 1.01 *et seq.*, the Board makes or adopts findings that one or more of the grounds for board action specified in 247 CMR 10.03 exist, the Board may direct the Executive Director to issue an order on the Board's behalf taking one or more of the following actions:

1. Stayed Probation. The Board may place a license on stayed probation, which does not constitute discipline and allows the licensee to engage in practice subject to temporary conditions set by the Board and specified in the order;
2. Reprimand. The Board may reprimand the license. A reprimand is a formal, public rebuke that constitutes discipline but does not prohibit practice or subject practice to conditions;
3. Probation. The Board may place a license on probation, which constitutes discipline and allows the licensee to engage in practice subject to temporary conditions set by the Board and specified in the order;

247 CMR: BOARD OF REGISTRATION IN PHARMACY

4. Suspension. The Board may suspend a license, which constitutes discipline and prohibits the licensee from engaging in practice for a specific period, or until specific conditions have been met, or both.

5. Revocation. The Board may revoke a license, which constitutes discipline and prohibits the licensee from engaging in practice.

(c) Further Action.

1. The Board order may set conditions or requirements that must be met before the Board will consider a petition to modify or remove any conditions on the license or a petition for reinstatement of the license.

2. The Board order may authorize the Executive Director to take additional actions against a license as a consequence of failing to comply with the terms of the order.

(3) Permanent Surrender. The Board may accept the permanent surrender of a license by a licensee who is the subject of a complaint. A licensee may offer to permanently surrender their license by submitting to the Board a signed, written statement that asserts his or her intent to permanently relinquish the right to hold or renew his or her license. The Board's acceptance of a licensee's permanent surrender constitutes discipline and resolution of the complaint. The Board may deem the complaint allegations to be true and to constitute grounds for discipline.

(4) Consent Agreements. The Board may enter into a Consent Agreement with a licensee for the purpose of resolving the complaint. In a Consent Agreement, the Board and the licensee may agree that the Board will take one or more of the Board actions specified in this section, or may agree that the licensee shall refrain from engaging in practice. Consent Agreements may also include other terms as permitted by law.

(5) Except as the Board may otherwise specify in an Order or a Consent Agreement, any action taken against a license shall apply to the right to renew such license.

(6) Except as otherwise provided by law, all Order and Consent Agreements, whether disciplinary or non-disciplinary in nature, constitute a public record.

(7) Nothing in this section shall limit the Board's ability to resolve a pending complaint by any other action, including but not limited to the imposition of a fine, permitted by law.

~~To facilitate disposition of any complaint, the Board may schedule an investigative conference at any time prior to the commencement of a formal adjudicatory proceeding. The Board shall give timely notice of the conference, and this notice shall include a general statement of the nature of the issues to be discussed.~~

10.05: Summary Actions Disposition by the Board

(1) Purpose. 247 CMR 10.05 establishes parameters for summary actions against a license, in advance of a hearing, by either the full Board or by the Board President acting

on the Board's behalf, in order to prevent an immediate and serious threat to the public health, safety or welfare presented by a licensee's practice.

(2) Summary Suspension

(a) Authorization for Order of Summary Suspension.

1. Request. The Executive Director, may present a request for an Order of Summary Suspension to the Board or, if the next scheduled meeting of the Board is more than 48 hours into the future, to the Board President. The Board President may either defer to the full Board or act on the Board's behalf. All members of the Board shall receive a copy of the request for an Order of Summary Suspension presented to the Board President. The request for an Order of Summary Suspension must be supported by affidavits, or documentary evidence, or both.

2. Immediate and Serious Threat. If, upon review of the information presented in the request for an Order of Summary Suspension, the Board, or Board President, determines that licensee's continued practice presents an immediate and serious threat to the public health, safety or welfare, and that summary suspension is necessary to prevent that threat, the Board, or the Board President acting on the Board's behalf, may authorize the Executive Director to issue an order summarily suspending the license of a licensee.

3. Serious Threat. If, upon review of the information presented in the request for an Order of Summary Suspension, the Board, or Board President, determines that licensee's continued practice presents a serious threat to the public health, safety or welfare, and that summary suspension is necessary to prevent that threat, the Board, or the Board President acting on the Board's behalf, may authorize the Executive Director to issue an order commanding the licensee to file opposing affidavits or other evidence within three business days. If, upon review of the information presented in both the request for an Order of Summary Suspension and the evidence submitted by the licensee, the Board, or Board President, again determines that licensee's continued practice presents a serious threat to the public health, safety or welfare, and that summary suspension is necessary to prevent that threat, the Board, or the Board President acting on the Board's behalf, may authorize the Executive Director to issue an order summarily suspending the license of a licensee.

(b) Order of Summary Suspension: Content, Notice and Enclosures.

1. An Order of Summary Suspension shall notify the licensee that his or her license has been suspended and that he or she is prohibited from engaging in practice until further notice by the Board, effective upon the licensee's receipt of the order.

2. An Order of Summary Suspension shall include notice of the date, time and location of the post-suspension hearing.

3. An Order of Summary Suspension shall be mailed to the licensee by United States Postal Service, first class mail and by either United States

Postal Service or a comparable private mail service that delivers within 24 hours.

4. An Order of Summary Suspension shall be accompanied by a copy of the Executive Director's request for an Order of Summary Suspension and its supporting affidavits and documentary evidence.

(c) Post-Suspension Hearing.

1. The Board shall hold a post-suspension hearing in order to determine whether to continue or rescind the Order of Summary Suspension based on findings with respect to whether the licensee's continued practice presents an immediate and serious threat to the public health, safety or welfare, and that summary suspension is necessary to prevent that threat. The post-suspension hearing will be conducted in accordance with M.G.L. c. 30A and Standard Adjudicatory Rules of Practice and Procedure at 801 CMR 1.01. The Board may designate an administrative hearings counsel as the Presiding Officer to conduct the post-suspension hearing.

2. The post-suspension hearing shall take place within seven business days of the issuance of the Order of Summary Suspension. The licensee may submit a written request for a continuance to the administrative hearing counsel assigned with notice to the prosecuting counsel assigned to the summary suspension hearing. The administrative hearings counsel may continue the post-suspension hearing to a date and time mutually agreeable to the licensee and prosecuting counsel. The summary suspension shall remain in effect during the time that the post-suspension hearing is continued at the licensee's request.

3. Administrative hearings counsel may admit into evidence:

(i) the Executive Director's request for an Order of Summary Suspension and its supporting affidavits and documentary evidence;

(ii) relevant evidence presented by the licensee; and

(iii) relevant evidence presented by prosecuting counsel that was unknown, or unavailable, or both, at the time the Order of Summary Suspension issued, provided that prosecuting counsel disclosed such evidence to the licensee prior to the hearing.

4. Administrative hearings counsel shall, within 30 days of the conclusion of the post-suspension hearing, either issue a tentative decision or provide a status report to the Board.

(d) Final Decision and Order of Summary Suspension.

1. Final Decision. Upon review of the tentative decision and any objections and responses to objections that may be filed, the Board shall issue a Final Decision and Order of Summary Decision, which shall include findings of fact on the allegations that the licensee's practice presents an immediate and serious threat, or serious threat, to the public health, safety or welfare, and that summary suspension is necessary to prevent that threat.

2. Default. If the licensee fails to appear and defend at the hearing, the administrative hearings counsel shall issue a notice of default to the licensee, the prosecuting counsel and the Board. The Board shall adopt the facts as alleged in the Request for Summary Suspension as its findings.

3. Rescission of Order of Summary Suspension. If the Board's Final Decision concludes either that the licensee's practice does not present an immediate and serious threat to the public health, safety or welfare, or that summary suspension is not necessary to prevent that threat, the Board shall rescind the Order of Summary Suspension and restore the license to the status that was in effect immediately before the Order of Summary Suspension issued.

4. Continuation of Order of Summary Suspension. If the Board's findings include both that the licensee's practice presents an immediate and serious threat to the public health, safety and welfare, and that summary suspension is necessary to prevent that threat, the Board shall order the continuation of the Order of Summary Suspension. An Order of Summary Suspension that has been continued shall remain in effect until resolution of the underlying complaint.

(3) Cease and Desist or Quarantine Notices

(a) Authorization for Cease and Desist or Quarantine Notice.

1. Request. The Executive Director or Board Counsel may request authorization from the Board or the Board President to issue a cease and desist notice or quarantine notice, or both. The request must be supported by evidence, which may include the verbal description of conditions observed by investigators or inspectors during the course of an inspection.

2. Immediate threat. If, upon review of the information presented in the request for authorization, the Board, or Board President, determines that a licensee, or the drug preparations prepared by a licensee, are an immediate threat to the public health, safety or welfare, the Board, or the Board President may authorize the Executive Director or Board Counsel to:

(i) issue a cease and desist notice or quarantine notice that requires cessation or restriction of any and all pharmacy operations or outsourcing facility operations and prohibiting the use of medications prepared by or in possession of a pharmacy or outsourcing facility; or

(ii) issue a cease and desist notice that places non-disciplinary restrictions on a licensee to the extent necessary to avert a continued threat, pending final investigation results.

(b) Cease and Desist or Quarantine Notice: Content, Notice and Enclosures.

1. A Cease and Desist or Quarantine notice shall notify the licensee of the extent to which the licensee must cease or restrict operations or must quarantine and refrain from using or dispensing prepared medications.

2. A Cease and Desist or Quarantine notice shall include notice of the date, time and location of the post-suspension hearing.

3. A Cease and Desist or Quarantine notice shall be mailed to the licensee by United States Postal Service, first class mail and by either United States Postal Service or a comparable private mail service that delivers within 24 hours.

4. A Cease and Desist or Quarantine notice shall identify the nature of the conditions or practices on which the determination that the licensee, or the drug preparations prepared by a licensee are an immediate threat to the public health, safety or welfare;

(c) Hearing following Cease and Desist or Quarantine notice

1. The Board shall hold a hearing in order to determine, with the licensee's participation, the necessity for the cease and desist notice or quarantine notice. The hearing will be conducted in accordance with M.G.L. ch. 30A and Standard Adjudicatory Rules of Practice and Procedure at 801 CMR 1.01, et seq.. The Board may designate an administrative hearings counsel as the Presiding Officer to conduct the post-suspension hearing.

2. The hearing shall take place within 15 business days of the issuance of the Cease and Desist or Quarantine notice. The licensee may submit a written request for a continuance to the administrative hearing counsel assigned with notice to the prosecuting counsel assigned to the hearing. The administrative hearings counsel may continue the hearing to a date and time mutually agreeable to the licensee and prosecuting counsel. The Cease and Desist or Quarantine notice shall remain in effect during the time that the hearing is continued at the licensee's request.

3. Administrative hearings counsel may admit all relevant evidence into evidence at the hearing.

4. Administrative hearings counsel shall, within 30 days of the conclusion of the hearing, either issue a tentative decision or provide a status report to the Board.

(d) Final Decision and Order on the Necessity of the Cease and Desist or Quarantine Notice.

1. Final Decision. Upon review of the tentative decision and any objections and responses to objections that may be filed, the Board shall issue a Final Decision and order on the necessity of the Cease and Desist or Quarantine notice, which shall include findings of fact on the allegations that the licensee, or the drug preparations prepared by a licensee, are an immediate threat to the public health, safety or welfare.

2. Default. If the licensee fails to appear and defend at the hearing, the administrative hearings counsel shall issue a notice of default to the licensee, the prosecuting counsel and the Board. The Board shall adopt the facts as alleged in the Cease and Desist or Quarantine notice as its findings.

3. Rescission of Cease and Desist or Quarantine notice. If the Board's final decision concludes either that the licensee, or the drug

preparations prepared by a licensee, do not pose, or no longer pose an immediate threat to the public health, safety or welfare, the Board shall rescind the Order of Summary Suspension and restore the license to the status that was in effect immediately before the Cease and Desist or Quarantine notice issued. Nothing in this section shall prevent the Board or the Board President from authorizing the rescission of the Cease and Desist or Quarantine notice in the event that the Board or the Board President is satisfied that licensee, or the drug preparations prepared by a licensee, no longer pose an immediate threat to the public health, safety or welfare.

4. Continuation of Order of Summary Suspension. If the Board's final decision concludes that the licensee, or the drug preparations prepared by a licensee, are an immediate threat to the public health, safety or welfare, the Cease and Desist or Quarantine notice shall remain in effect until the Board or the Board President is satisfied that licensee, or the drug preparations prepared by a licensee, no longer pose an immediate threat to the public health, safety or welfare.

~~After receipt of a complaint and all related investigative materials, the Board may schedule an investigative conference or may schedule a formal adjudicatory hearing pursuant to M.G.L. c. 30A and 801 CMR 1.01: Formal Rules if it determines that one is required.~~

10.06 Additional provisions applicable to Investigations, Complaints and Board Actions Disciplinary Action

(1) Advisory letters. An advisory letter is not a formal Board action against a license and makes no determination or finding on whether the recipient engaged in alleged acts or omissions. It constitutes a public record of notice to the recipient that:

- (a) identifies the reason for closure of an investigation or dismissal of a complaint;
- (b) identifies any applicable statute(s), regulation(s), rules, advisories or policies that are relevant to the alleged acts or omissions that form the subject matter of an investigation or complaint; and
- (c) includes a reminder of the general requirement to comply with the identified provisions.

(2) Receipt by a licensee. The Board may deem a licensee to have received a request, notice, order or other correspondence on the date that such item has been delivered to the address of record provided by the licensee. In the event that delivery is not possible at such address because the licensee has moved and left no forwarding address or because the address is otherwise invalid, the Board may deem receipt by the licensee to have occurred on the date that delivery was attempted but failed.

(3) Authority.

247 CMR: BOARD OF REGISTRATION IN PHARMACY

(a) The Board may direct or authorize the Board President, the Executive Director, investigators, Board staff, Board counsel, prosecuting counsel, or any combination of the same, to act on the Board's behalf by a Board vote specific to a particular licensee, or a general policy that sets parameters for action on the Board's behalf, or a combination of both.

(b) In the event that the Board President has a conflict of interest, an appearance of a conflict of interest, or that the Board President is incapacitated or inaccessible for a period of time that exceeds the reasonable time frame in which the Board President would be expected to act pursuant to this section or as otherwise authorized by the Board, the authority conferred upon the Board President may be exercised by the next most senior member of the Board, in the Board President's stead.

(c) In the event that the Executive Director has a conflict of interest, an appearance of a conflict of interest, or that the Executive Director is incapacitated or inaccessible for a period of time that exceeds the reasonable time frame in which the Executive Director would be expected to act pursuant to this section or as otherwise authorized by the Board, the next most senior member of Board staff, shall be authorized to act in the Executive Director's stead.

~~Actions which may be taken by the Board are:~~

~~(1) Dismissal of the complaint.~~

~~(2) Advisory Letter. An official written document retained in the Board's files delineating the Board's concerns with the registrant's or licensee's professional practice. An advisory letter does not constitute formal disciplinary action.~~

~~(3) Reprimand or Censure of the Registrant or Licensee. A reprimand constitutes formal disciplinary action. A censure is a severe reprimand.~~

~~(4) Probation. Probation constitutes disciplinary action against the registrant or licensee and consists of a period of time during which the registrant or licensee may practice under conditions imposed by the Board pursuant to a formal adjudicatory hearing or consent agreement.~~

~~(5) Suspension/Revocation of Personal Registration, Pharmacy Permit, License or Controlled Substances Registration. Suspension or revocation of a personal registration, pharmacy permit, license or controlled substance registration may be imposed pursuant to a decision and order of the Board following a formal adjudicatory hearing or following the execution of a consent agreement.~~

~~(6) Consent Agreement. A resolution of a complaint agreed upon by the Board and the registrant or licensee which may contain conditions placed by the Board on the registrant's or licensee's professional conduct and practice and which may include the voluntary suspension or surrender of a personal registration, pharmacy permit, license or controlled substance registration. The voluntary surrender of a personal registration,~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

~~pharmacy permit, license, or controlled substance registration, may be permanent or for a fixed period of time. The voluntary surrender agreement shall:~~

- ~~(a) — be in writing and be signed by the registrant or the licensee and the Board;~~
- ~~(b) — recite the facts upon which the agreement is based and shall include, but not be limited to provisions addressing reinstatement and any conditions the Board may elect to impose;~~
- ~~(c) — state that the registrant or licensee realizes that the voluntary surrender of his or her personal registration, pharmacy permit, license or controlled substance registration, is an act which deprives him or her of all privileges of registration and is not subject to judicial review; and~~
- ~~(d) — be placed in the registrant's or licensee's Board file as part of the registrant's or licensee's permanent Board records.~~

~~(7) — Disciplinary Action Against a Massachusetts Registrant or Licensee Taken in Another State. Disciplinary action taken against a Massachusetts registrant or licensee by another state or jurisdiction in which that person is also registered or licensed may be the basis for initiation by the Board of disciplinary action against the Massachusetts registrant or licensee provided that the conduct disciplined in another state or jurisdiction constitutes a violation of Massachusetts law.~~

~~(8) — Summary Cease and Desist Notice. A summary cease and desist notice may be imposed by the Board or Board President prior to hearing in order to stop or restrict operations by a registrant or licensee to immediately protect the public health, safety or welfare. The Board or Board President may rescind or amend a summary cease and desist notice.~~

~~(9) — Summary Quarantine Notice. A summary quarantine notice may be imposed by the Board or Board President prior to hearing in order to prevent the use of medications prepared by or in possession of a registrant or licensee to immediately protect the public health, safety or welfare. The Board or Board President may rescind or amend a summary quarantine notice.~~

10.07: (Reserved) Suspension Prior to Hearing

~~If, based upon affidavits or other documentary evidence, the Board determines that a licensee is an immediate or serious threat to the public health, safety, or welfare, the Board may suspend or refuse to renew a license pending a final hearing on the merits of the allegations regarding the licensee. A hearing limited to the determination of the necessity of the summary action shall be afforded the licensee within seven days of the Board's action.~~

10.08: (Reserved) Summary Cease and Desist and Quarantine Notice

~~(1) — If, based upon affidavits or other evidence, the Board or Board President determines that a registrant or licensee or the products prepared by a registrant or licensee~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

~~are an immediate or serious threat to the public health, safety, or welfare, the Board or Board President may:~~

- ~~(a) — issue a Cease and Desist Notice and/or Quarantine Notice, requiring non-disciplinary cessation or restriction of any and all pharmacy operations, and prohibiting the use of medications prepared by or in possession of a pharmacy; or~~
- ~~(b) — issue a Cease and Desist Notice placing non-disciplinary restrictions on a Board registrant or licensee, to the extent necessary, to avert a continued threat, pending final investigation results.~~

~~(2) — Requirements of the Cease and Desist Notice and/or Quarantine Notice shall remain in effect until the Board or Board President rescinds or amends such requirements or until such time as the Board takes final action on any related pending complaint and the Board issues a final decision.~~

~~(3) — A hearing limited to the determination of the necessity of Notices issued pursuant to 247 CMR 10.06(8) and (9), or 247 CMR 10.08(1) shall be afforded the registrant or licensee within 15 business days of the Board or Board President's action.~~

REGULATORY AUTHORITY

247 CMR 10.00: ~~801 CMR 1.01~~; M.G.L. c. 112, § 24 and 42A; c. 30A

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 16.00: COLLABORATIVE DRUG THERAPY MANAGEMENT

Section

16.:

~~16.01: Definitions~~

16.02: Pharmacist Qualifications

16.03: Practice Setting Requirements

16.04: Collaborative Practice Agreements - Required Agreement Terms for All Practice Settings; Duties; Biennial Renewal; Termination; Agreement to be Filed in Primary Practice Setting; Employment Relationships

16.05: Authority of Board of Registration in Medicine

16.:

~~St. 2008, c. 528 (amending M.G.L. c. 94C, §§ 7 and 9 and M.G.L. c. 112, §§ 24B½ and 24B¾) authorized pharmacists and physicians to engage in collaborative drug therapy management (CDTM) in the Commonwealth pursuant to collaborative practice agreements meeting the requirements of regulations adopted by the Boards of Registration in Pharmacy and Medicine. The Board of Registration in Pharmacy has promulgated 247 CMR 16.00 in accordance with M.G.L. c. 112, §§ 24B½ and 24B¾. Board of Registration in Medicine regulations (243 CMR 2.12) include additional definitions and requirements applicable to pharmacists and physicians entering into collaborative practice agreements to practice CDTM in the Commonwealth. purpose of 247 CMR 16.00 is to set forth criteria applicable to pharmacists and pharmacies that engage in collaborative drug therapy management with physicians in accordance with M.G.L. c. 112, §§ 24½ and 24¾, including pharmacist qualifications, and requirements for practice settings and collaborative practice agreements.~~

~~.01: Definitions~~

~~Additional definitions applicable to the practice of CDTM in the Commonwealth appear in Board of Registration in Medicine regulations at 243 CMR 2.12 and Board of Registration in Pharmacy regulations at 247 CMR 2.00.~~

~~As used in 247 CMR 16.00, all references to “written” regarding collaborative practice agreement referrals, consents and any other documents related to a collaborative practice agreement shall be:~~

- ~~(1) if paper based, written in ink, indelible pencil or any other means; or~~
- ~~(2) transmitted electronically in a format that maintains patient confidentiality and can be read and stored in a retrievable and readable form. Collaborative practice agreements and related referrals, consents and other documentation may be transmitted electronically with the electronic signature(s) without alteration of the information, provided the~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

~~electronic transmission is in accordance with the requirements of M.G.L. c. 94C, § 23, subsection (g); 105 CMR 721.00, and 247 CMR 5.00, 9.01(19) and 9.07(1)(a).~~

~~As used in 247 CMR 16.01 and defined in M.G.L. c. 112, § 24B½, subsection (a), the following words shall have the following meanings:~~

~~Pharmacist means a pharmacist who:~~

- ~~(1) is currently registered by the Board and in good standing;~~
- ~~(2) meets the requirements of 247 CMR 16.02; and~~
- ~~(3) is participating in drug therapy management with a supervising physician pursuant to a written CDTM agreement with written protocols.~~

~~_____ means the Board of Registration in Pharmacy.~~

~~Drug Therapy Management or CDTM means the initiating, monitoring, modifying and discontinuing of a patient's drug therapy by an authorized pharmacist under the supervision of a physician in accordance with a collaborative practice agreement. Collaborative drug therapy management may include: collecting and reviewing patient histories; obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration; and, under the supervision of, or in direct consultation with, a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation shall not include a diagnostic component.~~

~~Practice Agreement or CDTM Agreement means a written and signed agreement between an authorized pharmacist with training and experience relevant to the scope of the collaborative practice and a supervising physician that defines the collaborative practice in which the authorized pharmacist and supervising physician propose to engage. The collaborative practice must be within the scope of the supervising physician's practice. In the community pharmacy setting, the CDTM agreement shall include:~~

- ~~(1) a written referral of a specific patient from the supervising physician to an authorized pharmacist; and~~
- ~~(2) the written consent of the patient to the CDTM agreement.~~

~~Pharmacy means a pharmacy or pharmacy department, as defined in 247 CMR 2.00, in a "retail drug business" setting, as referenced in M.G.L. c. 112, § 24B½, currently licensed by the Board pursuant to M.G.L. c. 112, §§ 38 and 39.~~

~~_____ means a person who is referred to an authorized pharmacist by a supervising physician for the purpose of receiving collaborative drug therapy management services from the pharmacist. In a community pharmacy setting:~~

- ~~(1) the patient must be notified of, and provide written consent to, the collaborative drug therapy management services; and~~
- ~~(2) in accordance with 243 CMR 2.12, the supervising physician must provide the patient with a copy of the referral to the authorized pharmacist and the written consent to the~~

~~referral provided by the patient.~~

~~_means the individual patient referral by a supervising physician to an authorized pharmacist for the purpose of receiving CDTM services in a community pharmacy setting. In other practice settings, “referral” means the consultation of a supervising physician and an authorized pharmacist about a patient for the purpose of receiving CDTM services. In accordance with 243 CMR 2.12, the supervising physician shall execute a written CDTM referral which shall include, but not be limited to, the patient's name and address, the primary diagnosis for which CDTM services are authorized, the diagnosis of any co-morbid conditions for which CDTM services are authorized, any known patient drug allergies, a statement that the patient has executed a written consent to CDTM services and any other specific instructions to the authorized pharmacist.~~

~~Physician, as defined in 243 CMR 2.12(1), means a physician who:~~

- ~~(1) holds an active license in good standing to practice medicine in the Commonwealth of Massachusetts; and~~
- ~~(2) may delegate specific CDTM services to an authorized pharmacist pursuant to the terms of the CDTM agreement with the authorized pharmacist.~~

16.02: Pharmacist Qualifications

(1) In accordance with M.G.L. c. 112, § 24B½, subsection (b), to qualify to enter into a collaborative practice agreement and engage in collaborative practice, a pharmacist must:

- (a) hold a current unrestricted license in good standing to practice pharmacy in the Commonwealth and currently be engaged in pharmacy practice in the Commonwealth;
- (b) ~~agree to~~ maintain at least \$1,000,000 (per occurrence) of professional liability insurance during the term of the agreement which specifically covers drug therapy management;
- (c) ~~have earned a doctor of pharmacy degree or~~ have completed five years of experience as a licensed pharmacist or have satisfied this requirement with one of the following:
 - 1. have earned a doctor of pharmacy degree and have entered into a collaborative practice agreement on or before January 1, 2016, or
 - 2. have completed such other education or residency criteria that the Board determines to be the equivalent of five years experience as a licensed pharmacist;
- (d) ~~agree to~~ devote a portion of practice to the defined drug therapy area that the pharmacist shall co-manage;
- (e) ~~agree to~~ complete, in each year of the term of the agreement, at least five additional contact hours ~~or 0.5 continuing education units~~ of Board-approved continuing education that address areas of practice generally related to the particular collaborative practice agreement; and
- (f) if prescriptive practices are included in the collaborative practice agreement, ~~agree to~~:-

247 CMR: BOARD OF REGISTRATION IN PHARMACY

1. _____ maintain a current controlled substance registration issued by the Department during the term of the agreement, pursuant to M.G.L. c. 94C, §§ 7 and 9 and 105 CMR 700.000;
 2. complete training required pursuant to M.G.L. c. 94C, §18(e) prior to initially obtaining a controlled substance registration and at least biennially thereafter as a condition precedent to renewing his or her pharmacist license;
 3. effective _____, submit an attestation, signed under the pains and penalties of perjury, that the pharmacist participates in, or had applied to participate in, MassHealth as either a provider of services or for the limited purpose of ordering and referring services covered by MassHealth, in accordance with M.G.L. c. 112, § 24B1/2.
- (2) An authorized pharmacist participating in CDTM must maintain evidence of completion of required continuing education ~~units~~ for at least two years after the date of the current collaborative practice agreement.
- (3) Whenever an authorized pharmacist participating in CDTM is disciplined by the Board, whether by agreement or Board order, or otherwise subject to any practice restrictions, the authorized pharmacist must provide written notification of such discipline or practice restriction to each supervising physician.

16.03: Practice Setting Requirements

In accordance with M.G.L. c. 112, § 24B½, ~~subsection~~(c), collaborative drug therapy management may be performed in the following settings by pharmacists meeting the requirements of 247 CMR 16.02(1) and authorized by a supervising physician pursuant to a current collaborative practice agreement:

- (1) Hospitals licensed pursuant to M.G.L. c. 111, § 51, subject to approval by the hospital medical staff executive committee or designee;
- (2) Long-term Care Facilities licensed pursuant to M.G.L. c. 111, § 71, subject to approval by the long-term care facility medical director or designee;
- (3) Inpatient or Outpatient Hospice Settings licensed pursuant to M.G.L. c. 111, § 57D, subject to approval by the hospice medical director or designee;
- (4) Ambulatory Care Clinics licensed pursuant to M.G.L. c. 111, § 51, with on-site supervision by an attending physician affiliated with the ambulatory clinic and an authorized pharmacist, subject to approval by the ambulatory care clinic medical staff executive committee or designee, or medical director or designee;
- (5) Community Pharmacies (retail drug business settings) licensed by the Board pursuant to M.G.L. c. 112, § 39, subject to the restrictions listed below and pursuant to a

247 CMR: BOARD OF REGISTRATION IN PHARMACY

current collaborative practice agreement that includes the following requirements:

- (a) Patient Age. Patients must be 18 years of age or older.
- (b) Vaccine Administration. Pharmacists, as authorized pursuant to a collaborative practice agreement, may administer vaccines.
- (c) Patient Referral and Consent. In accordance with 243 CMR 2.12, the collaborative practice agreement must provide that the supervising physician will:
 1. provide a written referral of the patient to the authorized pharmacist;
 2. specify the primary diagnosis for the patient and any secondary diagnoses in the written referral or a subsequent referral;
 3. provide a copy of the written referral of the patient to the authorized pharmacist for CDTM services to the patient; and
 4. obtain the patient's written informed consent to the collaboration in the collaborative practice agreement and provide a copy of the consent to the patient.
- (d) Record of Referral and Consent. The authorized pharmacist and supervising physician must maintain a written record of both the individual patient referral and the patient's written informed consent to the collaboration in the patient's records which are maintained by the authorized pharmacist and the supervising physician. In accordance with 243 CMR 2.12, the supervising physician shall:
 1. maintain the original patient consent to the referral in the record in the custody of the supervising physician;
 2. transmit a copy of the patient's consent to the authorized pharmacist within 24 hours;and
 3. provide copies of the referral and consent to the patient in a timely manner.
- (e) Limited Prescribing Authority.
 1. An authorized pharmacist currently registered by the Department, pursuant to M.G.L. c. 94C, §§ 7 and 9 and 105 CMR 700.000, to prescribe and possess controlled substances, who practices in a community pharmacy pursuant to a collaborative practice agreement that includes individually developed prescriptive practice guidelines pursuant to which the supervising physician has authorized the pharmacist to prescribe, may:
 - a. extend current drug therapy by 30 days for not more than two 30 day periods or as may otherwise be specifically authorized by the supervising physician in the referral of the patient and as provided in the CDTM agreement;
 - b. initiate, modify or discontinue dosages of medications prescribed by the supervising physician for:
 - i. asthma;
 - ii. chronic obstructive pulmonary disease;
 - iii. diabetes;

247 CMR: BOARD OF REGISTRATION IN PHARMACY

- iv. hypertension;
- v. hyperlipidemia;
- vi. congestive heart failure;
- vii. HIV or AIDS;
- viii. osteoporosis; and
- ix. co-morbidities listed in 247 CMR 16.03(5)(e)1.b.i. through viii. and identified by the supervising physician along with the primary diagnosis in the supervising physician's referral of the patient.

2. The authorized pharmacist must provide a copy of an initial prescription or a modification or discontinuation of a prescription to the supervising physician within 24 hours of issuance, unless more urgent notification is required under the circumstances, and must note the action taken in the patient's medical record. A copy of all prescriptions must be included in the patient's medical record in the custody of the supervising physician.

3. No authorized pharmacist in a community pharmacy may prescribe or be authorized to prescribe Schedule II through V controlled substances, as defined in M.G.L. c. 94C, § 3, subsections (2) through (5).

4. An authorized pharmacist in a community pharmacy may be authorized by a supervising physician to issue prescriptions for Schedule VI controlled substances, as defined in M.G.L. c. 94C, § 3, subsection (6), for the diagnoses specified in the supervising physician's patient referral.

16.04: Collaborative Practice Agreements - Required Agreement Terms for All Practice Settings; Duties; Biennial Renewal; Termination; Agreement to be Filed in Primary Practice Setting; and Employment Relationships

(1) A collaborative practice agreement must be a written and signed agreement between an authorized pharmacist with training and experience relevant to the scope of the collaborative practice and a supervising physician that defines the collaborative practice in which the authorized pharmacist and supervising physician propose to engage. The collaborative practice must be within the scope of the supervising physician's practice. In the community pharmacy setting, the CDTM agreement shall include:

- (a) a written referral of a specific patient from the supervising physician to an authorized pharmacist; and
- (b) the written consent of the patient to the CDTM agreement.

(2) Required Agreement Terms for All Practice Settings. In addition to specific practice setting collaborative practice agreement requirements, pursuant to 247 CMR 16.03, and in accordance with M.G.L. c. 112, § 24B¾ and 243 CMR 2.12, all collaborative practice agreements must also include:

247 CMR: BOARD OF REGISTRATION IN PHARMACY

- (a) specific disease state(s) being co-managed, with each disease state identified as either primary or co-morbid;
- (b) specific pharmacist prescribing authority pursuant to the CDTM agreement;
- (c) detailed practice protocols;
- (d) description of risk management activities;
- (e) documentation of any initiation, modification or discontinuation of a patient's medication in the patient's permanent medical record;
- (f) description of outcome measurements;
- (g) detailed informed consent procedures appropriate to the practice setting;
- (h) detailed procedures and periods by which time any test results, copies of initial prescriptions, modifications or discontinuances, copies of the patient consent and the CDTM agreement, and other patient information will be forwarded by the authorized pharmacist to the supervising physician, and a specific procedure for the authorized pharmacist to identify and transmit any urgent communications; description of the nature and form of the supervision of the authorized pharmacist by the supervising physician, and a description of the procedure to follow when either the authorized pharmacist or supervising physician is unavailable or absent;
- (i) the authorized pharmacist's attestation of satisfaction of the qualifications listed in 247 CMR 16.02(1) for participating in collaborative drug therapy management; and
- (j) the supervising physician's attestation of satisfaction of the qualifications listed in 243 CMR 2.12 for participating in collaborative drug therapy management.

(3) Duties. A collaborative practice agreement shall specify those duties of the authorized pharmacist that may be delegated to other appropriately trained and authorized staff and those duties under the agreement that shall not be delegated. A collaborative practice agreement shall specify when and how an authorized pharmacist may delegate duties under the agreement, and the duration and scope of the delegation. Pharmacy interns and pharmacy technician duties providing support to an authorized pharmacist acting pursuant to a collaborative practice agreement must perform services in accordance with 247 CMR 8.01 (pharmacy interns) and 8.02 through 8.06 (pharmacy technicians).

(4) Biennial Renewal. A collaborative practice agreement must be reviewed and renewed by the authorized pharmacist and supervising physician(s) at least every two years.

(5) Termination. Prior to termination or non-renewal of a CDTM agreement, an authorized pharmacist and supervising physician shall arrange for an uninterrupted continuation of the patient's drug therapy, in accordance with the terms of the CDTM agreement. When a CDTM agreement is not renewed or CDTM is otherwise terminated, an authorized pharmacist and supervising physician shall inform the patient in writing of the termination and of the procedures in place for the continuation of the patient's drug therapy, in accordance with the terms of the CDTM agreement.

247 CMR: BOARD OF REGISTRATION IN PHARMACY

(6) Agreement to be Filed in Primary Practice Setting. An authorized pharmacist must maintain a copy of the current CDTM agreement, including copies of current patient referral and patient consent, in the primary practice setting, readily retrievable at the request of the Board of Registration in Pharmacy and Board of Registration in Medicine. In accordance with 243 CMR 2.12, the supervising physician must maintain the original of the current CDTM agreement, including the original current patient referral and patient consent, in the patient's medical record in the custody of the supervising physician.

- (7) Employment Relationships. In accordance with M.G.L. c. 112, § 24B½, subsection (e):
- (i) A qualified pharmacist may be hired by a physician or group of physicians for the purpose of practicing collaborative drug therapy management under an agreement for the benefit of a patient of that physician or physician group;
 - (j) A community pharmacy may hire a physician or licensed medical practitioner to conduct quality assurance reviews of pharmacists engaged in collaborative drug therapy management; and
 - (k) No community pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement.

16.05: Authority of Board of Registration in Medicine

Nothing in 247 CMR 16.00 shall limit the Board of Registration in Medicine's review, monitoring and investigation of its licensees' activities pursuant to 243 CMR 2.00.

REGULATORY AUTHORITY

247 CMR 16.00: M.G.L. c. 112, § 24B½ and 24B¾.