

DRAFT

243 CMR: BOARD OF REGISTRATION IN MEDICINE

243 CMR 2.12: COLLABORATIVE DRUG THERAPY MANAGEMENT

2.12: Collaborative Drug Therapy Management (CDTM) with Authorized Pharmacists

Chapter 528 of the Acts of 2008 (amending G.L. c. 94C, §§ 7 and 9 and G.L. c. 112, §§ 24B ½ and 24B ¾) 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 G.L. c. 112, §§ 24B ½ and 24B ¾. 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.

(1) 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 16.00.

As used in this section and defined in G.L. c. 112, § 24B ½, subsection (a), the following words shall have the following meanings:

Authorized pharmacist means a pharmacist who (1) is currently registered by the Board of Registration in Pharmacy and is 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.

Board means the Board of Registration in Medicine.

Collaborative 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.

Collaborative 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 practice. 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 written referral of an identified patient from the supervising physician to an authorized pharmacist, and shall include a written consent to the CDTM agreement by the named patient.

Community Pharmacy means a retail drug business setting, licensed pursuant to G.L. c. 112, § 38-39. When there is a collaborative drug therapy management agreement between an authorized pharmacist in a community pharmacy and a supervising physician, the physician must obtain the informed consent of the patient in writing prior to participating in CDTM.

License means a certificate of registration which the board issues to a person pursuant to the requirements of M.G.L. c. 112, §§ 2, 9 and 9B, and which authorizes the person to engage in the practice of medicine.

Patient 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 the community pharmacy setting, (1) the patient must be notified of, and provide written consent to, the collaborative drug therapy management services, and (2) 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.

Referral 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. The supervising physician shall execute a written CDTM referral which shall include, but is not 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.

Supervising physician means a physician who holds an active license to practice medicine in the Commonwealth of Massachusetts. A supervising physician in a CDTM agreement may only delegate to an authorized pharmacist pursuant to the written agreement and protocols with the pharmacist.

(2) Pharmacist Qualifications. In accordance with G.L. c. 112, § 24B ½, subsection (b), to qualify to enter into a collaborative practice agreement, 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 5 years of experience as a licensed pharmacist;
- (d) devote a portion of the 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 5 additional contact hours or 0.5 continuing education units (CEUs) of Board of Registration in Pharmacy-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 maintain a current controlled substance registration issued by the Department during the term of the agreement, pursuant to G.L. c. 94C, §§ 7 and 9 and 105 CMR 700.000.
- (g) Whenever an authorized pharmacist participating in a CDTM agreement is disciplined by the Board of Registration in Pharmacy, whether by consent agreement or by a final decision and 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.

(3) Physician Qualifications.

- (a) To be eligible to participate in a collaborative drug therapy management agreement, a physician must possess an active license to practice medicine issued by the board, and must be actively engaged in the clinical practice of medicine and the provision of patient care in the particular field of medicine in which the collaborative drug therapy management is to take place.
- (b) The physician is the supervisor in the CDTM agreement and retains the ultimate responsibility for the care of the patient. In a community pharmacy setting, a physician should enter into only as many CDTM agreements setting as he/she can reasonably and safely supervise at one time.
- (c) The supervising physician shall assess the patient and make a written referral of the identified patient to the authorized pharmacist. The supervising physician's written referral shall include a primary diagnosis and any co-morbid conditions that are included in the CDTM.

(d) A physician is ineligible to participate in a CDTM if he is in a Voluntary Agreement Not to Practice Medicine with the board, or has had his license to practice medicine temporarily suspended or revoked by the board. A physician shall be deemed ineligible to participate in CDTM if he has voluntarily surrendered or had suspended, revoked or restricted his/her controlled substances license, permit or registration, either state or federal. The board may revoke a physician's right to participate in a CDTM agreement for any of the grounds for discipline enumerated in 243 CMR 1.03(5).

(e) Whenever the board enters into a Voluntary Agreement Not to Practice with a licensee, or summarily suspends a physician's license, the board may require that the physician provide written notification to each authorized pharmacist with whom the physician is in a CDTM agreement. Whenever the board takes final disciplinary action against a licensee, either by a final decision and order or by consent agreement, the board may require that the physician provide written notification to each authorized pharmacist with whom he/she is in a CDTM agreement.

(4) Practice Setting Requirements. In accordance with 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:

(a) Hospitals licensed pursuant to G.L. c. 111, § 51, subject to approval by the medical staff executive committee at a licensed hospital or designee;

(b) Long-Term Care Facilities licensed pursuant to G.L. c. 111, § 71, subject to approval by the long-term care facility medical director or designee;

(c) Inpatient or Outpatient Hospice Settings licensed pursuant to G.L. c. 111, § 57D, subject to approval by the hospice medical director or designee;

(d) Ambulatory Care Clinics licensed pursuant to G.L. c. 111, § 51, with on-site supervision by the attending physician and an authorized pharmacist, subject to approval by the ambulatory care clinic medical staff executive committee or designee, or medical director or designee;

(e) Community Pharmacies (retail drug business settings) licensed by the Board of Registration in Pharmacy pursuant to c. 112, § 39, subject to restrictions listed below and pursuant to a current collaborative practice agreement that includes the following requirements:

1. Patient Age. Patients must be 18 years of age or older;

2. Vaccine Administration. Pharmacists, as authorized pursuant to a collaborative practice agreement, may administer vaccines;

3. Patient Referral and Consent. The collaborative practice agreement must provide that the supervising physician will:

a. provide a written referral of the patient to the authorized pharmacist

b. specify the primary diagnosis for the patient and any secondary diagnoses in a written referral or a subsequent referral;

c. provide a copy of the written referral of the patient to the authorized pharmacist for CDTM services to the patient; and

- c. obtain the patient's written and informed consent to the collaboration and provide a copy of the consent to the patient.
4. The patient's written consent form shall include the following: "The pharmacist shall not supplant the physician as the principal medical decision maker;"
5. 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 record to be maintained by the authorized pharmacist and the supervising physician. 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.
6. Limited Prescribing Authority. A pharmacist currently registered by the Department, pursuant to G.L. c. 94C, §§ 7 and 9 and 105 CMR 700.00, 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 prescribed by the supervising physician by 30 days for one 30 day period only;
 - b. initiate, modify or discontinue dosages of medications prescribed by the supervising physician for:
 - i. asthma;
 - ii. chronic obstructive pulmonary disease;
 - iii. diabetes;
 - iv. hypertension;
 - v. hyperlipidemia;
 - vi. congestive heart failure;
 - vii. HIV or AIDS;
 - viii. osteoporosis; and
 - ix. co-morbidities, listed in (i-viii) above, and identified by the supervising physician along with the primary diagnosis on the physician's referral of the patient.
 - c. The authorized pharmacist must provide a copy of an initial prescription, a modification or a discontinuation of a prescription to the supervising physician within 24 hours of its issuance, unless more urgent notification is required under the circumstances. A copy of all prescriptions must be included in the patient's medical record in the custody of the supervising physician.
7. No authorized pharmacist in a community pharmacy may prescribe or be authorized to prescribe Schedule II through V controlled substances, as defined in G.L. c. 94C, § 3, subsections (2) through (5).
8. 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 G.L. c. 94C, § 3, subsection (6), for the diagnoses specified in the supervising physician's patient referral.

(5) Collaborative Practice Agreements

(a) 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 G.L. c. 112, § 24B ¾, all collaborative practice agreements must also include:

1. specific disease state(s) being co-managed, with each disease state identified as either primary or co-morbid;
2. specific pharmacist prescribing authority pursuant to the agreement;
3. detailed practice protocols;
4. description of risk management activities;
5. documentation of any initiation, modification or discontinuation of a patient's medication in the patient's medical record in the custody of the supervising physician;
6. description of outcome measurements;
7. detailed informed consent procedures;
8. 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 from the authorized pharmacist to the supervising physician, and a specific procedure for the pharmacist to identify and transmit any urgent communications; and 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 the supervising physician is unavailable or absent;
9. 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
10. the supervising physician's attestation of satisfaction of the qualifications listed in 243 CMR 2.12 for participating in collaborative drug therapy management.

(b) Duties. A collaborative practice agreement shall specify those duties of the authorized pharmacist that may be delegated to other staff and those duties under the agreement that shall not be delegated. A collaborative practice agreement shall specify when and how a supervising physician may delegate duties under the agreement, and the duration and scope of the delegation.

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

(d) Termination. Prior to terminating a CDTM agreement, the parties shall arrange for an uninterrupted continuation of the patient's drug therapy. When CDTM is terminated, the patient shall be informed in writing of the termination

and of the procedures in place for continuation of his or her drug therapy. The supervising physician has an ongoing responsibility for patient care unless and until the physician-patient relationship is terminated.

(e) Agreement to be Filed in Primary Practice Setting. An authorized pharmacist must maintain a copy of the current collaborative practice agreement in the primary practice setting, readily retrievable at the request of the Board of Registration in Medicine and the Board of Registration in Pharmacy. The supervising physician must maintain the original of the current collaborative practice agreement and the original of the patient's written consent in the patient's medical record in his/her custody. The supervising physician must maintain the patient's medical record in his/her custody and make it available upon request during an investigation by the Board of Registration in Medicine.

(f) Employment Relationships. In accordance with G.L. c. 112, § 24B ½, subsection (e):

1. 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 the patient of that physician or physician group;
2. 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
3. No community pharmacy may employ a physician for the purpose of maintaining, establishing or entering into an agreement.