247 CMR 16.00: COLLABORATIVE DRUG THERAPY MANAGEMENT

Section

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16.01: Purpose

247 CMR 16.00 sets 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.

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) 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 completed five years of experience as a licensed pharmacist or have satisfied one of the requirements in 247 CMR 16.02(1)(c)1. through 2.:

1. have earned a doctor of pharmacy degree and have entered into a collaborative practice agreement on or before June 30, 2017; 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) devote a portion of practice to the defined drug therapy area that the pharmacist shall co-manage;

(e) complete, in each year of the term of the agreement, at least five additional contact hours 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:

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: *Implementation of M.G.L. c. 94C*.

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. 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, § 24B½.

(2) An authorized pharmacist participating in CDTM must maintain evidence of completion of required continuing education 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(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 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: *Implementation of M.G.L. c. 94C*, 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;
iv. hypertension;

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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:

(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 super-vision 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;

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(i) the authorized pharmacist's attestation of satisfaction of the qualifications listed in 247 CMR16.02(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.

(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: *Collaborative Drug Therapy Management (CDTM) with Authorized Pharmacists*, 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):
(a) 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;
(b) 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
(c) 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: *Licensing and the Practice of Medicine*.

REGULATORY AUTHORITY

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

(PAGES 79 AND 80 ARE RESERVED FOR FUTURE USE.)