



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
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Bureau of Health Professions Licensure
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Board of Registration in Pharmacy

Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Telepharmacy

I. Policy Statement

The Massachusetts Board of Registration in Pharmacy (“Board”) adopts this policy regarding the use of Shared Pharmacy Service models. The purpose of this policy is to provide minimum standards for the establishment of various Shared Pharmacy Service models.

Shared Pharmacy Service models conducted pursuant to this policy are intended to improve the delivery of pharmacy services, optimize the provision of pharmaceutical care to patients, and establish safeguards to protect public safety.

Unless otherwise noted, any other Shared Pharmacy Service models that have not been addressed in this policy will require a petition to the Board for approval.

II. Definition

Shared Pharmacy Services are defined by the National Association of Boards of Pharmacy (“NABP”) as a system that allows a participating pharmacist or pharmacy, pursuant to a request from another participating pharmacist or pharmacy, to process or fill a prescription drug order, which may include preparing, packaging, labeling, compounding for specific patients, dispensing, performing Drug Utilization Reviews (“DUR”), conducting claims adjudication, obtaining refill authorizations, reviewing therapeutic interventions, and/or reviewing institutional facility orders.

III. General Requirements for All Shared Pharmacy Service Models

- a. All licensees must maintain full compliance with all federal and state laws and regulations while implementing and utilizing Shared Pharmacy Service models.
- b. Pharmacies engaged in Shared Pharmacy Services must comply with Massachusetts laws and regulations with respect to requirements for supervision of pharmacy technicians (or state equivalent).

- c. Pharmacies dispensing medication into or from Massachusetts must possess a license issued by the Board.
- d. Pharmacies engaged in Shared Service models must:
 - i. have the same owner; or
 - ii. have a written contract or agreement that outlines the services provided and the shared responsibilities of each party.
- e. Pharmacies must share a common electronic file or technology that allows secure access to required information.
- f. Pharmacies must assure data security and establish controls to protect the confidentiality and integrity of Protected Health Information (“PHI”).
- g. Pharmacies must maintain data security and ensure that no part of the database is duplicated, downloaded, or removed from the pharmacy’s electronic database.
- h. Shared Pharmacy Services must occur within the United States.
- i. Dispensed medications must be pursuant to valid, patient-specific prescriptions or standing orders.
- j. Pharmacy systems must have the ability to track and produce an audit trail of the prescription during each step in the pharmacy process to include at a minimum: date/time and individuals involved.
- k. Each Board licensee engaging in Shared Pharmacy Services is jointly responsible for properly processed and filled prescriptions.
- l. Shared Pharmacy Service models must not compromise initiation or continuation of patient therapy, quality, or safety.
- m. Retail pharmacies must notify patients that their prescription drug orders may be processed or filled by another pharmacy.
- n. Retail pharmacies must provide a mechanism for patients to “opt out” of the Shared Pharmacy Service.
- o. All personnel engaged in Shared Pharmacy Services must have documented training.
- p. Each participant in Shared Pharmacy Services must jointly develop, implement, review, revise, and comply with joint policies and procedures for Shared Pharmacy Services. Each participant is required to maintain the portion of the joint policies and procedures that relate to that participant’s operations. The policies and procedures must include, at a minimum, those outlined in the “Shared Pharmacy Services” section in most recent version of the NABP Model Act:
<https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/>
- q. Pharmacies must conduct a review of the written policies and procedures at least annually and document such review.
- r. Pharmacies must establish and maintain a continuity of care plan outlining how patients’ prescription needs will be met in the event that any Shared Pharmacy Services participant is unable to process or fill patient prescriptions.
- s. Any other requirements deemed necessary by the Board to protect the health and safety of the public.

IV. Central Fill Pharmacy

a. Scope and Definition

Retail pharmacies licensed by the Board may serve as central fill pharmacies for other Board licensed retail pharmacies to fulfill patient prescription needs. A central fill pharmacy may provide central filling for one or more pharmacies. When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the filled prescription to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a "central fill" activity.

Refer to the full DEA definition and requirements for "central fill pharmacy":

https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_content.htm#12

b. Requirements

- i. A pharmacy licensed by the Board planning to serve as a central fill pharmacy for other pharmacies must file a petition to the Board and receive the Board's approval prior to engaging in any central filling activities.
- ii. Any central fill pharmacy dispensing medications into or from Massachusetts to participating pharmacies must be licensed in Massachusetts.
- iii. Participating pharmacies must follow DEA regulations for "Central Fill Pharmacies", be registered with the DEA, and authorized to dispense federally controlled substances (Schedules II-V). Except as noted below, participating pharmacies must handle the central filling of Massachusetts Schedule VI controlled substances in the same manner as outlined in DEA regulations for Schedule II-V controlled substances:
https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_15.htm
- iv. Centrally filled Schedule II-V controlled substances must be delivered to the pharmacy where the prescription originated for final dispensing to the patient.
- v. Centrally filled Schedule VI controlled substances (non-federally controlled substances), with the exception of drugs requiring reporting to MassPAT ("PMP"), may be delivered or shipped directly to the patient from the central fill pharmacy.
- vi. Unless otherwise approved by the Board, the central filling of compounded sterile preparations or complex non-sterile preparations to be dispensed into or from Massachusetts is not permitted.

- vii. Participating pharmacies must maintain a policy and procedure regarding the handling of medications that have not been dispensed to patients.

V. Central and Remote Processing

a. Scope and Definition

Central and remote processing services are defined as a system that allows the processing of patient-specific prescriptions for a Massachusetts licensed pharmacy without final product verification or dispensing responsibilities.

b. Requirements

- i. Prescriptions may be processed outside the premises of a licensed Massachusetts pharmacy provided that the processes are verified by a Massachusetts licensed pharmacist or performed in a pharmacy licensed by the Board.

NOTE: Pharmacy technicians may perform remote processing of prescriptions on behalf of a retail or institutional pharmacy that is located in Massachusetts without the on-site supervision by a Board-licensed pharmacist provided they hold a Massachusetts pharmacy technician license.

VI. Telepharmacy

a. Scope and Definitions

- i. Telepharmacy means the utilization of telecommunications technology to oversee aspects of pharmacy operations or provide patient care services¹.

“Telepharmacy Technologies” means secure electronic communications, information exchange, or other methods that meet applicable state and federal requirements for security and confidentiality. These technologies include, but are not limited to, computer, video and audio communication systems².

- ii. The scope of telepharmacy allowed by this policy is limited to:
 - 1. Remote pharmacist verification of the final patient-specific product utilizing telepharmacy technologies.

¹ This definition was adapted from the American Society of Health-System Pharmacists (ASHP)

² This definition was adapted from the NABP Model Act

2. Clinical activities conducted by a pharmacist such as patient counseling, drug utilization review, and drug therapy monitoring utilizing telepharmacy technologies.

b. Requirements

- i. Telepharmacy activities allowed by this policy must be conducted by a Massachusetts licensed pharmacist or performed in a pharmacy licensed by the Board.
- ii. The Massachusetts Board licensed pharmacy dispensing the final patient specific product must have at least one licensed pharmacist on the premises.
- iii. Technologies utilized for remote verification of medications must be in good working order and have, at a minimum, high definition image resolution with variable viewing options to accurately and safely verify the final dispensed product, and sufficient data retention capabilities to investigate any quality-related events.

Supersedes Policy 2019-01

Please direct any questions to: Pharmacy.Admin@MassMail.State.MA.US



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MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD,
MPH Commissioner

MEMORANDUM

TO: Pharmacies and Pharmacists Participating in Shared Services

FROM: Massachusetts Board of Registration in Pharmacy

DATE: May 2, 2019

SUBJECT: Implementation of Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Telepharmacy

The Massachusetts Board of Registration in Pharmacy ("Board") would like to advise all pharmacies of the intended implementation timeline in relation to Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Telepharmacy.

The Board expects Massachusetts pharmacies and non-resident pharmacies to be fully compliant with Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Telepharmacy by August 2, 2019 or at the time of final promulgation 247 CMR 6.00, whichever is later. The Board does not intend to take enforcement action with respect to the shared services policy prior to the final promulgation of 247 CMR 6.00.

Please be advised that a pharmacy utilizing shared services is ultimately responsible for accurately processing prescriptions and dispensing medications.

As you should already be aware, the Board is preparing to implement M.G.L. c. 112, § 39J, which requires the Board to license non-resident pharmacies. On or about February 1, 2018, the Board approved the final draft of 247 CMR 6.00: Licensure of Pharmacies and the regulation is undergoing a final review by the administration. At this time, the Board does not have an estimate as to when final promulgation of 247 CMR 6.00 will occur.