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Board of Registration in Pharmacy

Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, 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 involving Massachusetts licensees. 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.

Until the final promulgation of 247 CMR 6.00 (*Licensure of Pharmacies*) that will require non-resident pharmacy licensure, the Board does not intend to take enforcement action with respect to shared pharmacy services occurring in a non-resident pharmacy on behalf of a Massachusetts-located pharmacy. Please be advised that the Massachusetts-licensed pharmacy is ultimately responsible for the accurate processing and dispensing of prescriptions.

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 including Massachusetts' requirements for pharmacy technician supervision (or state equivalent).
- b. Shared Pharmacy Services must occur within the United States.
- c. 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.
- d. Pharmacies must share a common electronic file or technology that allows secure access to required information.
- e. Pharmacies must assure data security and establish controls to protect the confidentiality and integrity of Protected Health Information ("PHI").
- f. Pharmacies must ensure that no part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.
- g. Dispensed medications must be pursuant to valid, patient-specific prescriptions or standing orders.
- h. 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.
- i. Each licensee is jointly responsible for properly processed and filled prescriptions.
- j. The initiation or continuation of patient therapy, quality, or safety must not be compromised.
- k. Retail pharmacies must notify patients that their prescriptions may be processed or filled by another pharmacy.
- l. Retail pharmacies must provide a mechanism for patients to "opt out".
- m. All licensees must have documented training.
- n. Each participant 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/>

- o. Participants must conduct a review of the written policies and procedures at least annually and document such review.
- p. 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.
- q. Licensees must comply with 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 a "central fill pharmacy": [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-046\)\(EO-DEA154\) Pharmacist Manual.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046)(EO-DEA154) Pharmacist Manual.pdf)

b. Requirements

- i. A pharmacy 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, within, or from Massachusetts to participating pharmacies must be licensed in Massachusetts.
- iii. Participating pharmacies that dispense federally controlled substances (Schedules II-V) must follow DEA regulations for "Central Fill Pharmacies" and be registered with the DEA. 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.ecfr.gov/current/title-21/chapter-II/part-1306?toc=1>

- 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 Massachusetts 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, within, 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. Remote Processing

a. Scope and Definition

Remote processing services are defined as a system that allows the processing of patient-specific prescriptions outside the licensed pharmacy premises of a Massachusetts-licensed pharmacy without final product verification or dispensing responsibilities.

b. Requirements

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

NOTE: In accordance with the Board’s *Licensee Scope of Practice* policy, 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 Massachusetts-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. Utilizing telepharmacy technologies, the scope of telepharmacy allowed by this policy is limited to:
 1. remote pharmacist verification of final patient-specific products; and
 2. clinical activities conducted by a pharmacist such as patient counseling, drug utilization review, and drug therapy monitoring.

b. Requirements

- i. Telepharmacy activities allowed by this policy must be conducted by a Massachusetts-licensed pharmacist or performed in a Board-licensed pharmacy.
- ii. The Massachusetts-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 product to be dispensed, and sufficient data retention capabilities to investigate any quality-related events.

Please direct any questions to: Pharmacy.Admin@mass.gov

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

² This definition was adapted from the NABP Model Act