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MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

newsletter to promote pharmacy and drug law compliance

Drug Control Program or Board of Pharmacy?

In Massachusetts, the Board of Registration in Pharmacy is not responsible for prescribing practices, the prescription monitoring program (PMP), or for registering prescribers, manufacturers, or distributors. The Board's sister agency, the Drug Control Program (DCP), handles these services and many more.

DCP was established by Massachusetts General Laws (MGL) c.94C, §7 and sets the standards for prescribing and administering controlled substances (CS) by health care professionals. Practitioners must obtain a Massachusetts Controlled Substances Registration (MCSR) from DCP to prescribe or obtain any CS, including Schedule VI drugs.

In addition to prescribers, DCP also issues MCSR registrations to entities that handle, deliver, and dispense CS, including manufacturers, distributors, clinics (and their pharmacies), and hospitals (and their inpatient pharmacies).

The PMP also falls under DCP's purview. The PMP tracks dispensed prescriptions for Schedule II-V medications and gabapentin so that prescribers and pharmacists can make informed decisions to better care for their patients. Prescribers and patients can request copies of their prescribing history and personal prescription history, respectively.

Many DCP regulations and circular letters apply to pharmacists and pharmacies. Circular letters provide enforceable guidance and are essentially the equivalent of Board policies. The circular letters that are most applicable to pharmacy may be found on the Board's website

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as well as applicable DCP regulations at 105 Code of Massachusetts Regulations (CMR) 700.000 Implementation of MGL c. 94C and 105 CMR 721.000 Standards for Prescription Format and Security in Massachusetts.

In contrast, the Board licenses pharmacies and pharmacy personnel and sets standards for pharmacy practice. Its regulations are located at 247 CMR. The Board has jurisdiction over pharmacists, interns, technicians, and pharmacies. It also issues policies (which are required to be followed) and advisories that provide general guidance.

Although the Board and DCP have separate jurisdictions, do not worry if you reach out to the wrong entity. The Board will send your question along to DCP if it does not have the answer.

Interchange Mandate

State law requires that all prescriptions are interchanged with a less expensive generic version unless the prescriber has indicated "no substitution." For prescriptions written for a brand-name drug, this means that a generic must be dispensed, if available. When "no substitution" is indicated on the prescription, the exact product as written by the prescriber must be dispensed.

Without an indication of "no substitution" from the prescriber, the pharmacist must dispense the least expensive product as long as the substitution is AB rated in Food and Drug Administration's (FDA's) *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). In most cases, this will be an available generic product. The patient must be made aware of the substitution by labeling the product with the term "interchange" or other recognizable language.

Interchange of certain biosimilars is also permitted. Biologic products do not have true generics and may have appreciable differences between manufacturers. However, a biosimilar, as authorized by FDA's Database of Licensed Biological Products ("Purple Book"), bears no clinically meaningful distinction from its reference product in regard to safety, purity, and potency. Prescriptions for biologic products lacking a "no substitution" indication must be dispensed with the least expensive biosimilar product, if available.

State law requires an additional step when interchanging biosimilars. Within a reasonable time following the substitution, the prescriber must be notified of the substitution by the pharmacist making a note in the patient's electronic health record. If this is not feasible, notification may be made by fax, electronic transmission, or by making a note in the patient's pharmacy record that is accessible to the prescriber upon request.

Licensing System Update

The Bureau of Health Professions Licensure has transitioned the Board and corresponding collaborative drug therapy management (CDTM) pharmacist MCSRs to a new online licensing system. The online licensing system will improve your licensing experience.

Everyone must create a new account by clicking the "Create Account" button found below the "Sign In" button on the new eLicensing System web page.

Once your account is created, you may apply for a new license or use your license type, license number, date of birth, and Social Security number to link your license to your account. After linking your license, you may renew your license online up to 90 days in advance of the license expiration date.

Video tutorials with step-by-step instructions on creating your account, applying for a new license, linking your license, and renewing your license are available via the online Licensing System User Guide. If you need additional assistance, please contact the Help Desk at 617/973-0935 or elicensing.helpdesk@mass.gov.

Transfer of Unfilled Prescriptions

New Drug Enforcement Administration (DEA) regulations have been released regarding the transfer of unfilled electronic prescriptions for controlled substances (EPCS). On a one-time basis, unfilled EPCS for **Schedules II-V** may be electronically transmitted from one pharmacy to another without any alteration of the prescription contents in accordance with 21 Code of Federal Regulations 1306.08.

DEA **does not** permit the transfer of any original unfilled paper, fax, or oral prescriptions for federally scheduled CS. Entering such prescriptions into an electronic database does not transform them into EPCS. They remain subject to all the regulations applicable to paper, fax, and oral prescriptions.

However, Massachusetts allows unfilled electronic, paper, fax, and oral **Schedule VI** prescriptions to be either electronically transmitted or transferred to another pharmacy in accordance with 247 CMR 9.00. See the Board's policy for more information.

Vaccine Administration

Board policy changes now allow qualified pharmacy personnel to administer FDA-approved or -authorized vaccines that have been recommended for routine use by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC). This includes those that are not yet on the CDC's recommended immunization schedules, such as the new respiratory syncytial virus vaccine.

CDTM pharmacists are now also authorized to administer travel vaccines and other nonroutine vaccines in accordance with their CDTM agreement. Review the policy for all vaccination requirements.

Did You Know?

- **Veterinarians** do not have National Provider Identifier numbers because they do not provide care to humans. Schedule VI prescriptions do not require DEA numbers as long as the prescriber's MCSR number is provided. If you have difficulty with the data entry process using the MCSR number, contact your pharmacy's IT Department/Help Desk to walk you through it.

- **MassHealth** has recently published information regarding co-pay changes and the end of the public health emergency. You can see all of their documents and sign up for MassHealth Pharmacy Facts on the MassHealth website.
- All interns, technicians, and pharmacists must have a **valid Massachusetts license** whenever they work or intern in a Massachusetts-located pharmacy. Out-of-state registrations or licenses are not sufficient.
- The statewide emergency contraception standing order and frequently asked questions are available on the Massachusetts Department of Public Health website.
- Most Massachusetts insurance plans, including MassHealth, Group Insurance Commission, and private insurers, are required to cover a **12-month supply of birth control** pills to be dispensed all at once. Check with the insurer for any questions. Be aware that pharmacists are permitted to make quantity changes for drugs that do not require PMP reporting in accordance with Board policy.
- Please review the updated Data Submission Guide for Dispensers for **acceptable identification,** as well as the dispensing procedures for when identification is not available. Although not specifically listed, firearms licenses are acceptable for identification since they are a state-issued form of identification.

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