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MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

Reporting Requirement for All Nonresident Pharmacies

As a reminder, a list of all drugs dispensed into Massachusetts must be submitted to the Massachusetts Board of Registration in Pharmacy annually and within 30 days of any change in ownership, corporate officers, management personnel, or designated pharmacists-in-charge.

To complete this requirement, use the "List of Drugs Dispensed into Massachusetts" amendment application under your pharmacy's profile.

Details and other reporting requirements may be found on the Board's Reporting Requirement Overview.

Compounded Defective Drugs

Any compounded drug preparation dispensed into, within, or from Massachusetts that is or may be defective in any way must be recalled by the dispensing pharmacy. Additionally, the pharmacy must maintain a defective drug preparation log that includes the details of the recall for at least 10 years, as outlined in the Board's policy.

How is "defective" defined?

This refers to a compounded drug preparation that has any out of specification result, such as the potency, pyrogenicity, stability, improper composition, contamination, mislabeling, or sterility of a compounded sterile preparation, or the potency, purity, quality, mislabeling, or stability of any compounded nonsterile preparation.

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Compounded Defective Drugs *(cont)*

What is the definition of "dispense"?

In addition to the definition outlined in Massachusetts General Laws Chapter 94C, §1, "dispense" in a hospital setting also includes any medication or compound that has left the pharmacy, is ready for administration, and will not be subjected to further pharmacy or pharmacist verification before its use upon receipt of a patient-specific prescription or order.

Along with recalls, any dispensed **sterile** or **complex nonsterile** defective drug preparations must also be reported to the Board.

If a pharmacy discovers the defect prior to dispensing, the pharmacy should document it in its continuous quality improvement program. These events do not need to be reported to the Board.

If the defective drug preparation has also caused or may have potentially caused a serious adverse drug event (SADE), the pharmacy must also submit a SADE form.

Prescription Filling Requirements

105 Code of Massachusetts Regulations 721.000 outlines requirements for all prescriptions generated in Massachusetts that have either been issued by prescribers or reduced to writing by pharmacists.

The chart below illustrates the minimum required elements of a prescription that allow it to be filled by a resident pharmacy. Please note that the regulations do require prescribers to add certain items, but the lack of them does not necessarily prevent the pharmacy from filling the prescription (eg, name of supervising physician for mid-level prescribers).

Sometimes pharmacy systems require additional common data items that are not legally necessary to fill a prescription. For instance, National Provider Identifier numbers are not required to fill a prescription and are not even issued to veterinarians. If your computer system has this as a mandatory field, contact your IT department to find out how to add veterinarians to the system.

Also, many prescribers provide their Drug Enforcement Administration (DEA) numbers for Schedule VI prescriptions, and this is acceptable. However, only their Massachusetts Controlled Substances Registration (MCSR) number is needed. The MCSR is a registration that every Massachusetts prescriber must have. If a prescriber only wants to provide their MCSR for a Schedule VI prescription, it can be verified on the MCSR page. You may need to contact your IT department for guidance if the computer system requires a DEA number.

	Schedule II	Schedules III-V	Schedule VI
Permitted Formats[1]	Paper[2],Verbal[3],Electronic[4], Faxed[5]		
Refills	Not permitted (However, multiple prescriptions are permitted up to a 90-day supply.)	No more than 5 refills within 6 months; no fills/refills after 6 months from date of issuance	No fills/refills after 12 months from date of issuance
Required Information to Fill	Prescriber's DEA number	Prescriber's DEA number	Prescriber's DEA or MCSR[6] number
	Prescriber name and address		
	Date issued and "do not fill before date"[7] (as applicable)		

Prescription Filling Requirements *(cont)*

	Schedule II	Schedules III-V	Schedule VI
Required Information to Fill	Drug name, dosage, strength, quantity		
	Patient name and address (unless a veterinary prescription)		
			For expedited partner therapy, use "Expedited Partner Therapy," "EPT," or "E.P.T." in place of name and address; for naloxone, use "Naloxone Rescue Kit" in place of name and address
	Directions for use and any cautionary statements		
	Signature[8]		
	"Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law" language		
	"No substitution" language and area to indicate if the prescriber does not want substitution		
	For Schedule II opioids, "partial fill upon patient request" language		

1 Although prescribers are required to submit Schedule II-V prescriptions electronically, regulations specifically allow pharmacists to fill them if received on paper, verbally, or by fax.

2 Paper prescriptions must be issued on a tamper-resistant form consistent with federal requirements for Medicaid. To be considered tamper resistant, the prescription must contain the following three characteristics:

1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form (such as a high security watermark on the reverse side of the blank, the use of thermochromic ink, etc)
2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber (such as tamper-resistant background ink showing erasures or attempts to change written information)
3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms (sequentially numbered blanks, duplicate or triplicate blanks, etc)

3 Verbal prescriptions for Schedule II may be accepted in an emergency only, while verbal prescriptions for Schedule III-V drugs may be accepted at any time. However, follow-up electronic or written prescriptions for all verbal Schedule II-V prescriptions must be sent to the pharmacy within seven business days. Follow up and document if the prescriber fails to provide it.

4 Electronic prescriptions must be generated on a federally compliant electronic prescribing system with an electronic signature and sent by electronic transmission to a pharmacy without alteration of the prescription information. A faxed prescription is not an electronic prescription.

5 Faxed prescriptions should not be sent on tamper-resistant paper. Faxed Schedule II-V prescriptions for residents of long-term care facilities or hospice patients do not need follow-up electronic or paper prescriptions. A faxed Schedule II prescription for an ambulatory patient may be filled, but a paper or electronic prescription must be provided before the medication can be dispensed.

6 MCSR is the registration that **every Massachusetts prescriber** must have. Verify it on the MCSR page.

7 If a "do not fill before" date is present, it should be used as "Day 1" instead of using the date issued for the purpose of calculating the expiration of the prescription. This may be done in scenarios such as counting the five-day validity for a Schedule II prescription issued by a nonresident prescriber or the 30-day expiration of a Schedule II prescription issued by a Massachusetts prescriber.

8 A handwritten signature is required on all paper and faxed prescriptions.

Did You Know?

- You can ask a pharmacy practice question at pharmacy.admin@mass.gov.
- You can be notified of changes to Massachusetts regulations and other updates by emailing the Board at pharmacy.admin@mass.gov and asking to be added to the Board's email distribution list.

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