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Board of Registration in Pharmacy Reporting Requirement Overview

This document outlines the most common reporting requirements and the method by which to report. Other requirements can be found in 247 CMR 20.00 *Reporting* and 247 CMR 21.00 *Registration of Outsourcing Facilities*.

Reporting Requirement	247 CMR	Timeframe for Reporting	Reporting Method
Serious Adverse Events			
Dispensing errors resulting in serious injury or death	20.02(1) 20.07(3)	7 business days from date of discovery	<i>Serious Adverse Drug Event form</i>
Any serious adverse drug event resulting from a compounded medication	20.02(2) 20.06(3)	7 business days from date of discovery	<i>Serious Adverse Drug Event form</i>
Change of Manager of Record (MOR) or Designated Pharmacist in Charge (PIC)			
Pharmacy must notify if MOR or PIC resigns, is terminated, or changes	20.05(1) 20.05(2)	14 calendar days	https://healthprofessionlicensing.mass.gov/login-register
<u>MA-located pharmacy only:</u> Manager of Record must also personally report when resigns, is terminated, or leaves an MOR position	20.05(3)	14 calendar days	Email: Pharmacy.Licensing@mass.gov
Individual Licensees <i>**There is no requirement to report employment changes.</i>			
Name, mailing address, phone number, email address changes	20.03(1) 20.03(2)	14 calendar days	https://healthprofessionlicensing.mass.gov/login-register
Arrests, pending criminal charges or convictions	20.03(3)	14 calendar days	<i>Mandatory Disclosure Form</i>
Any disciplinary action or loss of certification, including continuing education deficiencies	20.03(4)	14 calendar days	<i>Mandatory Disclosure Form</i>

Business Licensees/Registrants			
Prescription Monitoring Program (PMP)	105 CMR 700.012	within 24 hours or next business day	https://www.mass.gov/info-details/pharmacy-reporting-and-data-submission
Any disciplinary action or loss of certification	20.03(4)	14 calendar days	Mandatory Disclosure Form
Adverse change in status of pharmacy accreditation status	20.03(5)	14 calendar days	Mandatory Disclosure Form
Any inspection reports, investigation reports, or warning letters received from local, state, or federal agency (e.g., FDA, DEA, etc.)	20.03(6)	within 14 calendar days of receipt	Mandatory Disclosure Form
Change in corporate officers, management personnel	20.06(6)(e) 20.07(2)	30 calendar days	Email: Pharmacy.Licensing@mass.gov
DBA or name change	6.12	14 calendar days	https://healthprofessionlicensing.mass.gov/login-register
Ownership Changes defined as: - change in any direct owner(s) or parent company owner(s) of the current licensee; or - change in the IRS-issued FEIN number *Changes not meeting these criteria need not be reported.	6.11	at least 14 days prior	Outgoing licensee: use closing notice amendment application https://healthprofessionlicensing.mass.gov/login-register Proposed new licensee: apply for a new pharmacy license https://www.mass.gov/doc/pharmacy-application-checklist-pdf/download
<u>Non-resident pharmacy only:</u> List of drugs dispensed into MA	20.07	annually and within 30 days after any transfer of ownership, change in corporate officers, management personnel, or designated PIC	Use "List of Drugs Dispensed into Massachusetts" amendment application: https://healthprofessionlicensing.mass.gov/login-register

MA-located pharmacy only: Controlled Substance losses	20.03(7) 7.04(2)(g)	7 calendar days	<u>Report of Loss of Controlled Substances form</u>
Compounding Pharmacies			
List and volume of sterile and/or complex non-sterile prescriptions dispensed into, within, and from MA from October 1st through September 30th of the past year -consolidate compounds under the same name and route of administration/dosage form regardless of concentration/strength (e.g., ceftriaxone IV; TPN with lipids IV; progesterone suppositories; cyclobenzaprine gel; etc.)	20.06(1)	annually - embedded in renewal application	<u>https://healthprofessionlicensing.mass.gov/login-register</u>
MA-located pharmacy only: states/jurisdictions to which any sterile and/or complex non-sterile prescriptions were dispensed and the status of any non-resident licenses issued by those states/jurisdictions			
Defective sterile and complex non-sterile compounded preparations dispensed into, within, or from MA	20.06(2) 20.06(3)	7 calendar days from date of discovery	<u>Defective Drug Preparation form</u>
All sterile compounding pharmacies, including institutional and non-resident must report action level environmental monitoring results	20.06(4)	1 business day of receipt of the microbiology report	<u>Action Level Environmental Monitoring Results form</u>
All sterile compounding pharmacies, including institutional and non-resident must report any failed certification of primary or secondary engineering controls	20.06(5)	7 business days	<u>Failed Certification form</u>