

## The Commonwealth of Massachusetts

Executive Office of Health and Human Services
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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.* 

		Timeframe for				
Reporting Requirement	247 CMR	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	Serious Adverse Drug Event form			
Any serious adverse drug event resulting from a compounded medication	20.02(2) 20.06(3)	7 business days from date of discovery	Serious Adverse Drug Event form			
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			
MA-located pharmacy only: 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 **There is no requirement to report employment changes.						
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	<u>Mandatory Disclosure Form</u>			
Any disciplinary action or loss of certification, including continuing education deficiencies	20.03(4)	14 calendar days	Mandatory Disclosure Form			

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<b>Business Licensees/Registrants</b>			
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://healthprofessionlicensin g.mass.gov/login-register
Transfer of Ownership  - change to a person or entity other than who is listed on license (i.e., owner); or -change in the IRS-issued FEIN number	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
MA-located pharmacy only: Controlled Substance losses	20.03(7) 7.04(2)(g)	7 calendar days	Report of Loss of Controlled Substances form
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	20.06(1)	annually - embedded in renewal application	https://healthprofessionlicensin g.mass.gov/login-register

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name and route of administration/dosage form regardless of concentration/strength (e.g., ceftriaxone IV; TPN with lipids IV; progesterone suppositories; cyclobenzaprine gel; etc.)  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	Defective Drug Preparation form
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	Action Level Environmental Monitoring Results form
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	Failed Certification form

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