

## 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*.

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	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.ma ss.qov/login-register				
MA-located pharmacy only: Pharmacist Manager of Record must also personally report when resigns, is terminated, or leaves an MOR position	20.05(3)	14 calendar days	Email: Pharmacy.Admin@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.g ov/login-register				
Arrests, pending criminal charges or convictions	20.03(3)	14 calendar days	Mandatory Disclosure Form				

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Any disciplinary action or loss of certification, including continuing education deficiencies	20.03(4)	14 calendar days	Mandatory Disclosure Form
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, etc.)	20.03(6)	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.Admin@mass.gov
MA-located pharmacy only: Controlled Substance losses	20.03(7) 7.04(2)(g)	7 calendar days	Report of Loss of Controlled Substances form
<b>Compounding Pharmacies</b>		I	
List and volume of sterile and complex non-sterile prescriptions dispensed into, within, and from MA  MA-located pharmacy only: the states to which any sterile and	20.06(1)	Annually with renewal	https://healthprofessionlicensing.ma ss.qov/login-register
complex non-sterile prescriptions were dispensed and the status of any non-resident licenses issued by other states			
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

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All sterile compounding pharmacies,	20.06(4)	1 business day	Action Level Environmental
including institutional and non-		of receipt of	Monitoring Results form
resident must report action level		the	
environmental monitoring results		microbiology	
		report	
All sterile compounding pharmacies,	20.06(5)	7 business	Failed Certification form
including institutional and non-		days	
resident must report any failed			
certification of primary or secondary			
engineering controls			

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