



Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
Bureau of Health Professions Licensure  
Board of Registration in Pharmacy

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MARYLOU SUDDERS  
Secretary

MONICA BHAREL, MD, MPH  
Commissioner

**Re: Registration of Non-Resident Outsourcing Facilities in Massachusetts - UPDATED**

Please be advised that effective July 1, 2015, Massachusetts law requires § 503B Outsourcing Facilities located outside Massachusetts to obtain a registration from the Massachusetts Board of Registration in Pharmacy ("Board") in order to distribute any sterile compounded product in Massachusetts. M.G.L. c. 112, §§ 36E & 39F.

Regulations implementing Outsourcing Facility registration were promulgated on January 29, 2016. The Board is currently accepting applications for both resident and non-resident Outsourcing Facility registration. The application form can be found here:

<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/pharmacy-outsourcing-application.pdf>

As of September 7, 2016, there are 63 existing 503B Outsourcing Facilities, located outside of Massachusetts. In order for these entities to obtain a Non-Resident Outsourcing Facility registration, they must meet requirements set forth at M.G.L. c. 112, § 36E(c) and 247 CMR 21.04. These requirements include an inspection conducted by the FDA in connection with section 503B of the FDCA *within two years immediately preceding the application*. The Board has issued registration to 21 Non-Resident Outsourcing Facilities.

The Board recognizes that healthcare providers and facilities may rely on existing 503B Outsourcing Facilities to supply customized sterile compounded medications on a larger scale than is possible at traditional pharmacies and that disruption of this supply during the transition into the new registration requirement may have adverse consequences for patients. The Board also recognizes that some existing 503B Outsourcing Facilities have not been inspected by the FDA within the past two years. For these reasons, the Board previously established a grace period until September 30, 2016 to ease the transition. **The Board now extends this grace period until January 29, 2017, but limits this extension to Non-Resident Outsourcing Facilities that have a pending application for registration received by the Board on or before September 30, 2016.**

**Beginning October 1, 2016, all 503B Outsourcing Facilities located outside of Massachusetts must either hold a Non-Resident Outsourcing Facility registration in order to distribute sterile drug products into Massachusetts or have a pending application for Non-Resident Outsourcing Facility registration received by the Board on or before September 30, 2016.** All other 503B Outsourcing Facilities that ship sterile drug products into

Massachusetts on or after October 1, 2016 will be subject to prosecution and penalties for unlawful distribution as provided by law.

**Beginning January 30, 2017, all 503B Outsourcing Facilities located outside of Massachusetts must hold a Non-Resident Outsourcing Facility registration in order to distribute sterile drug products into Massachusetts.** Unregistered 503B Outsourcing Facilities that ship sterile drug products into Massachusetts on or after January 30, 2017 will be subject to prosecution and penalties for unlawful distribution as provided by law.

The Board urges all 503B Outsourcing Facilities that are located outside of Massachusetts, that have not been inspected by the FDA within the past two years and that are shipping sterile drug products into Massachusetts to immediately submit an application for Non-Resident Outsourcing Facility registration and take steps to arrange for an FDA inspection.

Healthcare providers and facilities seeking to purchase sterile drug products can determine if a 503B Outsourcing Facility has registered with the Board through the Massachusetts Health Care Safety & Quality, License Verification Site, located at <https://checklicense.hhs.state.ma.us/MyLicenseVerification/><sup>1</sup>.

Please contact the Board at 617-937-0960 with questions concerning registration of Non-Resident Outsourcing Facilities.

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<sup>1</sup> In the search form, first click the link “Click here to search for a Business,” then select “Pharmacy” for Profession and “Non-Resident Outsourcing Facility” for License Type, then click “Search” to generate the list.