



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

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www.mass.gov/dph/boards/pharmacy

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Re: Registration of Non-Resident Outsourcing Facilities in Massachusetts

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 January 29, 2016, there are 59 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 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 establishes a grace period between now and September 30, 2016 to ease the transition.

Beginning October 1, 2016, 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 October 1, 2016 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 take steps to arrange for an inspection in order to meet the September 30, 2016 deadline.

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/>.

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