The Sterile Compounding Permit Program was repealed during the 2015 Legislative Session by the passage of SB 69/HB 181 entitled “State Board of Pharmacy – Sterile Compounding – Compliance by Nonresident Pharmacies and Repeal of Permit Requirement,” effective April 14, 2015. Therefore, there is no separate permit required for a pharmacy performing sterile compounding pursuant to a patient specific prescription.

Non-resident pharmacies dispensing compounded sterile preparations into Maryland must submit a report of an inspection conducted by a Board approved entity that demonstrates compliance with USP 797 standards. The inspection must be conducted no more than 90 days prior to the date of application. Non-resident pharmacies engaged in sterile compounding must also comply with the Board’s regulations governing sterile compounding, COMAR 10.34.19.

For entities engaged in sterile compounding for office use, please register with the FDA as an Outsourcing Facility and obtain a Maryland wholesale distributor permit.

The Board will be proposing revisions to its current sterile compounding regulations that will include, among other things, specific adverse event reporting requirements. In the interim, the Board’s current regulations are still in effect.