SMITH & ASSOCIATES

Offices:

3301 Thomasville Road,
Suite 201
Tallahassee, Florida 32308

1499 S. Harbor City Blvd.,
Suite 202
Melbourne, Florida 32901

Phone:

(321) 676-5555

(850) 297-2006

Website:

www.smithlawtlh.com

Corinne T. Porcher **October 10, 2014**

NEW STERILE COMPOUNDING LAW TO TIGHTEN FLORIDA'S BORDERS

Beginning October 1, 2014, nonresident pharmacies and outsourcing facilities that wish to ship, mail, deliver or dispense any compounded sterile pharmaceutical drug or product into Florida will need a Nonresident Sterile Compounding Permit (NSCP) from the Florida Board of Pharmacy in addition to a Nonresident Pharmacy Permit. Previously, such nonresident pharmacies shipping compounded sterile pharmaceuticals were only required to have a Nonresident Pharmacy Permit.

A "compounded sterile product" is defined by statute as a drug that is intended for parenteral administration (e.g., intravenous), an ophthalmic or oral inhalation drug in aqueous format, or a drug or product that is required to be sterile under federal or state law or rule, which is produced through compounding, but is not approved by the U.S. Food and Drug Administration. Section 465.003(20), Florida Statutes. "Compounding" means the combining, mixing, or altering of ingredients of one or more drugs or products to create another drug or product. Section 465.003(18), Florida Statutes.

The new law, codified as section 465.0158, Florida Statutes, was enacted during the last legislative session in response to a national outbreak of fungal meningitis in 2012 that killed 64 people. Seven of the victims were in Florida. According to the Centers for Disease and Control, eight clinics in Florida received contaminated medications from unregulated, nonresident pharmacies. A bill to create tighter controls was first drafted in 2013, but was not passed into law by the Florida Legislature until the last legislative session.

The new law provides additional time to previously licensed nonresident pharmacies so they can continue doing business with Florida until a NSCP is issued. If a nonresident pharmacy was registered pursuant to section 465.0156, Florida Statutes, *before* October 1, 2014, then the pharmacy may continue to ship, mail, deliver or dispense a compounded sterile product into Florida without a NSCP until February 28, 2015, provided the pharmacy meets the following conditions outlined in section 465. 0158 (6), F. S.:

1. The compounded sterile product meets or exceeds the standards for sterile compounding in Florida;
2. The product is not compounded in violation of any law or rule of the state, territory or district where the pharmacy is located; *and*
3. The pharmacy is issued the new NSCP permit on or before February 28, 2015.

According to the Florida Board of Pharmacy website, NSCP applications must be received by January 15, 2015, to ensure a NSCP is issued prior to the February 28, 2015 deadline. Please note that nonresident pharmacies that became registered per section 465.0156, F. S., on or after October 1, 2014, may not enjoy the benefits of continued shipments to Florida through February 28, 2015, without a NSCP.

NSCP Licensure Requirements

To obtain a NSCP, a completed Nonresident Sterile Compounding Application (Form DH5003-MQA-9/14) and initial filing fee of $255 must be submitted to the Florida Board of Pharmacy along with the following documentation:

1. Proof of registration as an "outsourcing facility" with the U.S. Department of Health and Human Services, if applicant meets the definition of an outsourcing

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facility as defined below;

2. Proof of registration as a Nonresident Pharmacy pursuant to 465.0156, if applicant is a pharmacy;
3. Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager or pharmacist in charge that:
    a. The attestor has read and understands the laws and rules for sterile compounding in Florida;
    b. The compounded sterile product being shipped, mailed or delivered into Florida meets or exceeds Florida's standards for sterile compounding; and
    c. The compounded sterile product being shipped, mailed or delivered into Florida is not compounded in violation of the laws and rules of the state, territory or district in which the applicant is located.
4. The applicant's policies and procedures, which must comply with all pharmaceutical standards in Chapter 797 of the U.S. Pharmacopoeia and either the Florida Board of Pharmacy rules for sterile compounding or good manufacturing practices for an outsourcing facility.
5. An inspection report from the regulatory or licensing agency in the state where applicant is located or, if such a report cannot be obtained, then an inspection report from a board-approved entity.

The new law will also require all nonresident outsourcing facilities to obtain a Nonresident Sterile Compounding Permit. Outsourcing facilities must obtain this new permit in addition to being registered with the Food and Drug Administration. According to section 465.003(19), Florida Statutes, an "Outsourcing facility" means a single physical location registered as an outsourcing facility under the federal Drug Quality and Security Act, Pub. L. No. 113-54, at which sterile compounding of a drug or product is conducted.

The Board of Pharmacy is authorized to discipline any pharmacy or outsourcing facility for failure to comply with the new NSCP law. Discipline may include any of the following: permit denial, revocation or suspension, fine and reprimand.

Please contact our office in Tallahassee at 850-297-2006, or Melbourne at 321-676-5555 if you have any questions about the new Nonresident Sterile Compounding Permit or for assistance with any matter before the Florida Board of Pharmacy.

Corinne T. Porcher is a shareholder in the law firm of Smith & Associates, and has practiced in the area of health care law for over 7 years.