OKLAHOMA
State Board of Pharmacy

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To: All Pharmacies with Parenteral Permits Compounding Sterile Drugs

Date: June 22, 2015

Subject: Oklahoma licensed PIC requirement

Effective August 27, 2015 important changes to Title 535, Chapter 15, Subchapter 10, Part 3, may affect pharmacies with parenteral permits.

Board of Pharmacy rule 535:15-10-64, which allowed retail and non-resident pharmacies with a parenteral (sterile) permit to compound non-patient specific sterile drugs for sale to physician offices or hospitals, has been revoked.

- Pharmacies may no longer compound non-patient specific sterile drugs for sale to physician offices or hospitals to administer.

The Board took this action to align Board rules with new federal law in response to provisions in the Drug Quality and Security Act of 2013 (DQSA2013) which updated the Food Drug and Cosmetic Act (Act) Sections 503A and 503B.

Section 503A of the Act provides for specific exemptions from the Food and Drug Administration's (FDA) new and amended new drug application (NDA and ANDA) process for compounded drugs which are dispensed by a pharmacy only upon a valid prescription for a specific patient. (See the websites listed below for more detailed information.) Sterile drugs compounded under Section 503A must comply with <USP797> standards.

Section 503B created a new business entity called an "outsourcing facility" which are required to be licensed by the FDA and by the Oklahoma State Board of Pharmacy if they ship drugs into or out of Oklahoma. Under Section 503B, outsourcing facilities ARE allowed to compound non-patient specific sterile drugs for sale to practitioner offices or hospitals for administration in the physician office or the hospital. The drugs must be marked "NOT FOR RESALE." The physician or hospital is NOT allowed to dispense these drugs on a prescription for the patient to take home. They must be administered in the practitioner office or the hospital. In addition to being registered by FDA, outsourcing facilities which compound sterile drugs are inspected by FDA officers under the FDA's current Good Manufacturing Practices standards which are significantly more stringent than <USP797> requirements.

- If an Oklahoma licensed pharmacy with a parenteral permit is currently licensed by the FDA as an "Outsourcing Facility" they may continue to provide compounded sterile drugs to practitioner offices and hospitals under that license only until November 1, 2015. Effective November 1, 2015, they must apply to the Board for an Outsourcing Facility License to continue operations.

If an Outsourcing Facility also plans to fill patient specific prescriptions they must also have an Oklahoma pharmacy license, but they are not required to have the parenteral (sterile drug) permit if they have an FDA Outsourcing Facility license. All outsourcing facilities must have an Oklahoma licensed pharmacist-in-charge (PIC).

Section 503A:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376733.htm

Section 503B:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm393571.htm