GUIDANCE ON THE PERMITTING OF "OUTSOURCING FACILITIES"

On November 27, 2013, the President signed H.R. 3204, the Drug Quality and Security Act ("DQSA"). The DQSA makes a number of changes to the existing intersection of state and federal regulation of prescription drug compounding.

Among other things, the DQSA creates (in Section 503B) an entity called an "outsourcing facility." An outsourcing facility is "a facility at one geographic location or address that – (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of [Section 503B]." The DQSA exempts "a drug compounded [at an outsourcing facility] by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility" from the new drug approval and adequate directions for use labeling requirements of the FD&C Act (but not from cGMP requirements). Moreover an outsourcing facility "may or may not obtain prescriptions for identified individual patients." In other words, under the DQSA, an outsourcing facility may compound for so-called "office use."

From time to time, a question arises whether an outsourcing facility must obtain a pharmacy permit from the Board of Pharmacy. The answer depends on the services provided by the facility.

Scenario A – The "Dual Purpose" Facility

A facility that is located in North Carolina and dispenses compounded (and, likely, non-compounded) prescription drugs to individual patients pursuant to individual prescriptions decides also to become an outsourcing facility and produce and distribute compounded products not pursuant to prescriptions for identified individual patients. Alternatively, a facility that is located out of state and is permitted in its home state as a pharmacy decides also to become an outsourcing facility and produce and distribute compounded products not pursuant to prescriptions for identified individual patients.

Does the Dual Purpose Facility need a pharmacy permit? Yes. The Dual Purpose Facility is "dispensing" prescription drugs to individual patients and is "compounding" prescription drugs for individual patients. Under North Carolina law, a "pharmacy" is "any place where prescription drugs are dispensed or compounded."

Note further that a dual purpose facility would also need to be registered as a wholesaler with the North Carolina Department of Agriculture's Food and Drug Safety Division.

Scenario B – The "Outsourcing Only" Facility

A facility that will only produce outsourced compounded products; the facility will not engage in any dispensing of prescription drugs (compounded or not) to individual patients. Again, North Carolina law defines a pharmacy as "any place where prescription drugs are dispensed or compounded." The definition of "compounding," however, is "taking two or more ingredients and combining them into a dosage form of a drug, exclusive of compounding by a drug manufacturer, distributor, or packer." (emphasis added)

Does the Outsourcing Only Facility need a pharmacy permit? No. While in this scenario it is true that the Outsourcing Only Facility (which is not "dispensing") is engaged in "compounding" as that term is used in common parlance, is it not engaged in "compounding" as that term is defined in the North Carolina Pharmacy Practice Act.

An Outsourcing Only Facility (again, a facility that is not dispensing or compounding any prescription drug products to individual patients) is, however, at least one of (and possibly more than one of) a "drug manufacturer, distributor, or packer."

The North Carolina Food Drug and Cosmetic Act requires that "every person doing business in North Carolina and operating as a wholesaler, manufacturer, or repackager" of prescription drugs and devices must register with the North Carolina Department of Agriculture's Food and Drug Safety Division. Accordingly, an Outsourcing Only Facility must be properly permitted by that office (and, of course, with the federal Food and Drug Administration), but need not obtain a pharmacy permit from the North Carolina Board of Pharmacy.

7/2014