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Drug Quality and Security Act *by James A. Hoover*

On Wednesday, Nov. 27, 2013, President Obama signed the Drug Quality and Security Act (the "Act"). The Act is an attempt by Congress to bring some compounding pharmacies that use certain bulk products under more federal oversight. Prior to the passage of the Act, jurisdiction over compounding pharmacies, particularly large scale compounders, has long been the subject of the "I got it, you take it" attitude between the federal Food and Drug Administration ("FDA") and the state boards of pharmacy. Generally, the FDA regulates drug manufacturers while the state boards of pharmacy regulate and license compounding pharmacies. The "gray area" typically occurs when a compounding pharmacy compounds medications in such large quantities the FDA has a colorable argument that the compounding pharmacy is acting more like a drug manufacturer than a compounding pharmacy. When this occurs, many times both the board of pharmacy and the FDA will exert oversight of the compounding pharmacy. Unfortunately, there are no bright line tests to determine when a compounding pharmacy is simply compounding or has crossed the threshold and become a drug manufacturer.

The Act attempts to clarify some of the legal gray between drug manufacturers and compounding pharmacies. The Act essentially creates a new class of compounding pharmacies called “outsourcing facilities.” Sterile compounding pharmacies can register with the FDA as an outsourcing facility but will have to submit to federal inspections and quality standards much like a drug manufacturer. Generally, the Act amends the Federal Food, Drug, and Cosmetic Act ("FFDCA") regarding the regulation of compounding drugs by exempting certain compounded drugs from the FDA's (i) new drug requirements, (ii) labeling requirements, (iii) track and trace requirements, and (iv) not requiring prescriptions for individually identifiable patients.

The term outsourcing facility is defined as a facility at one geographic location that engages in the compounding of sterile drugs, registers as an outsourcing facility and complies with all of the requirements of the Act. A sterile drug is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under federal or state law.

One of the benefits of registering as an outsourcing facility is that such a facility may compound sterile drugs without a prescription for an identified individual patient. Another potential benefit is an outsourcing facility is not required to be licensed as a pharmacy.

Registering as an outsourcing facility is completely voluntary. However, entities that do not register will be required to obtain prescriptions for individual patients.

The Act specifically prohibits the wholesaling of compounded drugs by prohibiting the drug from being sold or transferred by an entity other than the outsourcing facility. However, a drug may be administered in a healthcare setting or dispensed pursuant to a properly executed prescription.

The Act also requires that a compounded drug be labeled with the statement "This is a compounded drug" or a reasonable comparable alternative statement. The label must also contain various other information including but not limit to the lot or batch number, the date the drug was compounded, the expiration date and storage and handling instructions.

While it is too early to tell, the Act seems somewhat limited in its application to a large segment of the compound pharmacy industry. The Act only applies to those sterile compounders. Consequently, non-sterile pharmacies will continue to operate in the "gray area."

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