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Possible Legislative Changes to Compounding Pharmacies

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Often times it seems that compounding pharmacies operate in a "gray area" between state legislative oversight and federal legislative oversight. However, due to the attention created by several sterile compounding pharmacies, the federal government is once again proposing ways to regulate the compounding pharmacy industry.

The U.S. Senate recently drafted proposed legislation ("Senate Proposal") targeting compounding pharmacies. The Senate Proposal contains some fundamental changes to compounding pharmacies. For example, the proposed legislation includes compounded drugs within the definition of a "new drug" under the Federal Food, Drug and Cosmetic Act ("FDCA"). This inclusion would create a presumption that compounded drugs have to comply with the burdensome requirements of the FDCA for registration of a new drug and complying with certain manufacturing processes.

The Senate Proposal also creates two categories of compound pharmacies, "traditional compounders" and "compounding manufacturers." While the definition of "traditional compounder" is very similar to the historical use of the term "compounding pharmacy" and would continue to be licensed by state boards of pharmacy, a "traditional compounder" would be subject to additional federal requirements. On the other hand, "compounding manufacturer" is a new category. "Compounding manufacturer" would mean an entity that compounds any sterile drug without receiving a prescription order prior to beginning compounding and introduces the compounded drug into interstate commerce or that repackages a drug using sterile preservative-free, single-dose vials or by pooling sterile drugs. Under the Senate Proposal, "compounding manufacturers" cannot be licensed as pharmacies under state laws. It is interesting that the definition of "compounding manufacturer" is specifically limited to the compounding of sterile drugs.

On September 12, 2013 Reps. Morgan Griffith (R-VA), Gene Greene (D-TX), and Diana DeGette (D-CO) introduced a compounding pharmacy bill named the Compounding Clarity Act ("CCA") that is intended to clarify FDA authority over compounding in the wake of the recent issues involving sterile compounding pharmacies. The CCA attempts to distinguish between small-scale and large-scale compounders by clarifying the roles that individual states and the FDA have in regulating such compounders. According to the CCA, traditional pharmacies will remain under the jurisdiction of state boards of pharmacy and remain exempt from the FDA's manufacturing authority. The FDA, on the other hand, will have authority over "compounding manufacturers" that provide over 5% of their compounded medications for use in a facility, such as a hospital, as well as "outsourcing facilities" that ship medications across state lines. The CCA seeks to preserve the current physician-patient-pharmacist relationship by allowing all compounding to be done pursuant to a patient-specific

prescription, and allowing for anticipatory compounding based on a pre-existing relationship with a patient or doctor. The CCA also proposes to establish a safety standard for all compounded drugs to follow. Additionally, the practice of office use where drugs are dispensed in a healthcare setting will be permitted, provided a prescription or patient name is reconciled back to the pharmacy within seven days.

The Senate Bill seems to have a more significant impact on compounding pharmacies than the CCA, especially the provision that treats all "compounded drugs" as "new drugs" under the FDCA. Although as of the publishing of this article, no new legislation has been passed with the increased legislative activity, it is only a matter of time before the federal government issues new legislation applicable to compounding pharmacies.

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