PRESIDENT SIGNS COMPOUNDING PHARMACY BILL – FIRST RELATED FDA GUIDANCE PUBLISHED

EXECUTIVE SUMMARY

On November 27, 2013, President Obama signed the Drug Quality and Security Act ("Act") into law. The Act was introduced primarily in response to longstanding issues highlighted by a deadly fungal meningitis outbreak that occurred last year. The Act, which is aimed at ensuring providers and patients have access to safe compounded drugs, will have a wide-ranging effect on the compounding pharmacy industry.

At a high level, the Act is designed to: (i) clarify the Food and Drug Administration's ("FDA's") oversight responsibilities for both small- and large-volume compounders; and (ii) require higher quality standards for these same facilities, in particular for large-volume compounders. These goals are facilitated through a variety of mechanisms, including the removal of certain Federal Food, Drug and Cosmetic Act compounding provisions that some federal courts had deemed unenforceable.

The Act also creates a new category of compounder known as an "Outsourcing Facility" and contains "track-and-trace" provisions designed to implement a uniform national process for documenting drug transfers from manufacturing through dispensing. For more information about the provisions of Act, please see our previous alert.

Finally, the FDA has already made available the first related implementation guidance, as discussed further below.

ACTION ITEMS

Compounding pharmacies, and providers that rely on compounding pharmacies, will want to familiarize themselves with the Act's requirements and consider how it will affect their operations and compliance activities. Among other steps, they should analyze the track-and-trace provisions that will take effect beginning January 1, 2015 and begin developing internal processes and procedures to comply with the various labeling, reporting and documentation requirements.

Going forward, interested parties will want to monitor issuance of various compliance guidance documents that will be published as required by the Act, the first of which have been proposed and are noted below. Additionally, in response to the Act, compounding pharmacies will want to:

- Determine whether Outsourcing Facility status is the right choice for their organizations;
- If Outsourcing Facility status is the right choice, register with the FDA as an Outsourcing Facility either through an interim email process or Structured Product Labeling ("SPL") format described in new draft guidance, which can be found here. Outsourcing Facilities will be required to register using the SPL format by September 30, 2014;
- Register annually between October 1 and December 31 of each year after initial Outsourcing Facility registration;
- Upon initial registration and in the months of June and December of each year, submit electronically to the FDA a report identifying all drugs compounded by the Outsourcing Facility in the previous six-month period, as described in draft guidance, which can be found here; and
- Revise internal processes, policies and procedures to address changes required or necessitated by the Act.

Similarly, providers that rely on compounding pharmacies will want to:

- Ensure that the compounding pharmacies they deal with are compliant with the requirements of the Act; and
- Revise internal processes, policies and procedures to address changes required or necessitated by the Act.

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NEXT STEPS/PRACTICAL TAKEAWAYS

Both compounding pharmacies and the providers that rely on them will want to pay close attention in the near and intermediate term as regulations are implemented and further guidance is issued. This will afford interested parties the opportunity to comment on regulations and guidance documents that will have a substantial impact on the compounding pharmacy supply chain.

If you have questions regarding how this new law could affect your practice or would like additional information, please contact:

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