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Assembly Bill 1045 – Sterile Compounding

Summary:

In many ways, AB 1045 is essentially SB 294-lite: it creates a new notification requirement which foreshadows additional requirements as called for by SB 294, the Board of Pharmacy's sterile compounding legislation which goes into effect starting July 1, 2014.

Background:

The tragedy surrounding the New England Compounding Center (NECC) last year placed significant pressure on members of our State Legislature to respond in a meaningful manner. AB 1045 is a direct response to this impulse.

What It Does:

- **Notification Requirement –** AB 1045 requires a sterile compounding pharmacy that issues a recall notice for contaminated or flawed product to contact either the recipient pharmacy, prescriber, or patient within twelve hours of the recall if the recalled drug has the potential to cause serious adverse effects and if the drug was dispensed or intended for use in California. If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient by the pharmacy which compounded the drug. If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber who shall then ensure the patient is notified. **If the drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy who shall then have the responsibility of ensuring the patient is notified within twelve hours. All California pharmacies will need to be able to comply with the twelve hour requirement in the event of a recall of product compounded by a facility licensed by the Board as a sterile compounding pharmacy.**

- **Board Authority** – AB 1045 affirms the Board of Pharmacy's ability to cancel, deny, revoke or suspend a nonresident pharmacy license, as well as the Board's ability to issue a citation, letter of admonishment, or take other action as allowed for by law