Senate Bill 294 – Sterile Compounding

Summary:

Senate Bill 294 gives the Board of Pharmacy greater regulatory oversight of both resident and non-resident pharmacies that compound sterile products.

Background:

In October of 2012, a fungal meningitis outbreak which affected hundreds across the country was traced back to the New England Compounding Center (NECC) located in Massachusetts. Although no California patients were affected, the California Board of Pharmacy was compelled to strengthen its regulatory oversight of both resident and non-resident pharmacies to avoid future tragedies of a similar nature. To this effect, the Board successfully ran and passed SB 294 which was signed into law in October of 2013.

What It Does:

SB 294 allows the Board to promulgate emergency regulations which are to be effective by July 1, 2014. Emergency regulations feature shorter comment periods to help expedite the process. Once completed, the Board will then conduct a full rule-making process to replace the emergency regulations with permanent regulations.

SB 294 Makes the Following Changes to Current Statute:

- SB 294 removes the word "injectable" from most of Article 7.5 which governs sterile drug products.
- New language requires pharmacies to obtain a sterile compounding pharmacy license if they compound "sterile drug products for injection, administration into the eye, or inhalation" – 4127(a).
- Current law requires both resident and non-resident pharmacies to obtain licensure to compound injectable sterile drug products with certain exceptions. Under SB 294, **both resident and non-resident pharmacies wishing to compound sterile drug products for California patients will be required to obtain a license to compound sterile drug products REGARDLESS of whether the pharmacy is accredited through the Joint Commission or another private accreditation**. A license is not necessary for a pharmacy reconstituting sterile powder obtained directly from the manufacturer. The license shall be renewed annually and is not transferable.

New Requirements for Both Resident and Non-Resident Pharmacies:

- The Board must review all of the following before issuing a license as of July 1, 2014:
  - A current copy of the pharmacy's policies and procedures for sterile compounding;

        - The pharmacy's completed self-assessment form.
        - Copies of all inspection reports conducted of the pharmacy's premises and any reports from private accrediting agencies conducted in the prior 12 months documenting the pharmacy's operations.
        - A list of all sterile medications compounded by the pharmacy since the last license renewal (resident pharmacies) or in the last 12 months (non-resident pharmacies). The Board has indicated that the list will only need to include type of products and quantity. This list will be used to ascertain whether the pharmacy is acting as a manufacturer.
    - Resident and non-resident pharmacies licensed to compound sterile products must do all of the following as of July 1, 2014:
        - Apply for licensure. Pharmacies with Joint Commission Accreditation or operating within facilities licensed by CDHP will no longer be exempted from the special licensure requirement for sterile compounding.
        - Provide to the Board a copy of any disciplinary or other action taken by another state within 10 days of the action.
        - Notify the Board within 10 days of the suspension of any accreditation held by the pharmacy.
        - Provide to the Board within 12 hours any recall notice issued by the pharmacy for sterile drug products it has compounded.
        - Submit adverse effects reported or potentially attributable to a pharmacy's sterile drug product to MedWatch within 12 hours.

New Requirements for Non-Resident Pharmacies Only:

- As of July 1, 2014, a non-resident license shall not be issued or renewed until the board completes the following:
    - Physically inspects the non-resident pharmacy. The non-resident pharmacy shall reimburse the Board for costs incurred related to conducting the inspection.
- Non-resident pharmacies licensed to compound sterile products must do all of the following as of July 1, 2014:
    - Advise the Board of any complaint it receives from a provider, pharmacy or patient in California.

Other Provisions:

SB 294 also requires the Board to provide a report to the Legislature by January 1, 2018 detailing activities related to the inspection and licensure of nonresident pharmacies, the Board's fiscal health related to the non-resident inspections, the status of any federal legislation which could affect compounding pharmacies and any recommendations from the Board for proposed statutory changes related to non-resident pharmacies.