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Frequently Asked Questions about Federal and State Sterile Compounding Regulations

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In response to the 2012 New England Compounding Center tragedy, where contaminated injections led to 64 deaths and hundreds of illnesses nationwide, federal and state laws have been revised to provide increased oversight and better safeguards for sterile compounded pharmaceuticals.

These FAQs are intended for hospital and health care providers as they attempt to comply with changing federal sterile compounding standards and new state regulations that take effect beginning January 1, 2017.

Why were the California Board of Pharmacy sterile compounding regulations changed?

The Board of Pharmacy changed its regulations to ensure they reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565). The regulations also address the problem of ensuring that board regulations are aligned with compounding standards in United States Pharmacopeia (USP) 797 and USP 800, which further ensures the safety of consumers receiving compounded drugs in California.
(See www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_leg.pdf.)

What are USP 797 and USP 800?

The professional compounding standards used nationally are known as the United States Pharmacopeia and The National Formulary (USP–NF). The USP specifically features monographs for drug substances, dosage forms, and compounded preparations. Its widely recognized quality standards for pharmacy compounding of sterile and nonsterile preparations, USP 797 and USP 800, reference the handling and administration of drugs that present physical or health hazards. Many states, including California, incorporate USP standards into pharmacy laws and regulations.
(See www.pharmacy.ca.gov/laws_regs/1735_nopa.pdf.)

What do pharmacies need to know about USP 797 and 800?

- **USP 800, finalized this year**: USP 800 focuses entirely on employee safety when handling hazardous drugs; facilities will have two years to comply (July 2018). There is no waiver or mechanism to delay compliance with USP 800.
- **USP 797, undergoing revisions**: USP 797 is due to be finalized in January 2018, when the California Department of Public Health will use it for survey purposes.

To what facilities do these regulations and standards apply?

- USP 797 and 800 apply to any practice site that compounds sterile products or administers hazardous drugs (e.g., doctors' offices, licensed pharmacies and clinic-based infusion centers).
- The California Board of Pharmacy regulations apply to any licensed pharmacy in California that compounds sterile products.

What about compounding facilities that ship their products to California?

Included as part of the federal Drug Quality and Security Act, which became effective on Nov. 27, 2013, are provisions that establish federal regulation and oversight of large-scale drug compounding by "outsourcing facilities." The law sets forth voluntary requirements for licensure and enforcement of these entities. However, California's law is more restrictive than the federal law in several areas. California will continue to require any pharmacy that compounds sterile products for California residents or practitioners to possess licensure with the Board of Pharmacy and comply with California requirements as sterile compounding pharmacies.

Under the current federal regulatory system, drug manufacturers are regulated by the Food and Drug Administration (FDA). Prior to the enactment of the Drug Quality and Security Act, compounding pharmacies were regulated by their respective states of residence.

What is included in the Board of Pharmacy's recent sterile compounding regulatory changes?

Changes were made to lab testing requirements, temperature requirements, cleaning requirements, quality assurance requirements, frequency of documentation, policies and procedures, competency assessments and physical plant and facilities requirements.

The regulations amend Sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8,1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, 1751.8, and 1751.10, as well as adds Article 7.5 and Sections 1751.9, 1752, 1753, and 1754 of Division 17 of Title 16 of the California Code of Regulations.

When do the new Board of Pharmacy sterile compounding regulations go into effect?

Jan. 1, 2017. (See www.pharmacy.ca.gov.)

When do the USP revised standards go into effect?

- USP 800 goes into effect in July 2018.
- It is presumed that the draft USP 797 standards will go into effect in July 2018 along with USP 800, but that has not been confirmed by the FDA.

What if our facility won't be ready to meet the deadline?

Where compliance with the state Board of Pharmacy's Jan. 1, 2017 amendments requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical changes. (See www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_leg.pdf page 231- section 1735.6 [f])

What is the process for requesting a waiver from the Board of Pharmacy?

Waiver applications must be submitted by the licensee in writing, and the request must identify the provisions requiring physical construction or alteration, as well as the timeline for such changes. The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver. (See www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_leg.pdf).