

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Sterile Compounding

Sections Affected: Title 16, Sections 1751 et seq.

Purpose of the Regulation

Section 1751 (Amend)

The changes to this section are needed to update standards for compounding areas and to delete obsolete language and to reflect changes in referenced code section numbers and to revise standards for certifying clean rooms and other compounding environments.

Section 1751.01 (Add)

This section establishes additional facility and procedure requirements for compounding sterile injectable drug products from non-sterile ingredients. These standards are based on standards adopted by the United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

Section 1751.02 (Add)

This section incorporates existing requirements for policies and procedures and adds new policy and procedure requirements for compounding from non-sterile ingredients. These policies and procedures are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

Section 1751.2 (Amend)

This section is amended to update the terminology and to conform with the usage in other portions of the regulation.

Section 1751.3 (Amend)

This section is amended to eliminate record keeping requirements that are duplicated in other board regulations and to establish additional recordkeeping requirements for pharmacies compounding sterile injectable products from non-sterile ingredients. These record keeping requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

Section 1751.4 (Amend)

This section amends existing requirements for protective clothing and establishes attire standards for pharmacy personnel compounding sterile injectable drugs from non-sterile ingredients. These requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

Section 1751.5 (Amend)

This section is amended to establish additional training standards for pharmacy staff involved in the compounding of sterile injectable drug products from non-sterile ingredients. These training standards are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

Section 1751.6 (Amend)

This section is amended to make the terminology consistent with other aspects of the regulation and to eliminate obsolete provisions.

Section 1751.7 (Amend)

This section updates existing quality assurance requirements and adds process validation requirements for pharmacies compounding sterile injectable drug products from non-sterile ingredients. The process validation requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

Section 1751.8 (Repeal)

This section is repealed and elements of its former provisions are incorporated in section 1751.02.

Section 1751.9 (Amend)

This section is amended to update the requirements for reference materials in pharmacies compounding sterile injectable drug products.

Factual Basis

The Board of Pharmacy is a consumer protection agency charged with ensuring public safety through licensure and education of practitioners and enforcement of the laws governing the distribution of prescription drugs. Over 70,000 licensees are regulated by the board in twelve major license categories. Among those regulated by the board are pharmacists and pharmacies. Pharmacists working in a licensed pharmacy are permitted by state law to compound drug products for patients pursuant to a prescription and are permitted to compound drugs that are furnished to prescribers for administration by those prescribers (Business and Professions Code 4051, 16CCR1716.1 & 1716.2). When compounding drugs pharmacists combine bulk ingredients (both active ingredients and inactive ingredients) and produce finished drugs in a

variety of forms. Prescribers and patients seek compounded drugs for a variety of reasons. Among those reasons are:

1. The drug required is not manufactured in the needed strength (common for children, seniors, pain control, and for veterinary purposes).
2. The prescriber requests a different form of the medication (flavored syrup, lollipops, etc.) to improve patient compliance with prescribed drug therapy.
3. The prescribed drugs need to be combined in forms not available from the manufacturer to improve patient response to prescribed drug therapy.
4. The patient is allergic to inactive ingredients (fillers, dyes, etc.) in the manufactured form of the drug.
5. The prescribed therapy requires tailoring to the individual patient (intravenous feeding solutions, chemotherapy, etc.)

Among the many drugs compounded by pharmacists, a number must be sterile (i.e., devoid of viable microorganisms such as bacteria) for safe use by patients. Among the more common sterile compounded drug products are intravenous solutions, drugs administered by intramuscular and subcutaneous injection, drugs administered by injection or implanted pump to the spinal cord (i.e., intrathecal administration), drugs administered by inhalation, and ophthalmic drugs. Existing law (16CCR1751 et seq.) establishes requirements for compounding drugs for parenteral administration (administered by injection) relating to facility, equipment, training, procedures, documentation, etc. Senate Bill 293 (Chapter 827, Statutes of 2001) requires the board to adopt standards for sterile injectable compounding pharmacies before July 21, 2003 and requires those standards to met prior to the issuance or renewal of a sterile injectable compounding pharmacy license.

Underlying Data

In drafting this proposed regulation the board relied on the following documents:

ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products, American Society of Health Systems Pharmacists, 2000

“<Chapter 1206> Sterile Drug Products for Home Use Preparations – Pharmacy Practices”, *United States Pharmacopeia*.

Federal Standard 209E – Airborne Particulate Cleanliness Classes In Cleanrooms and Clean Zones, Commissioner, Federal Supply Service, United States General Services Administration, as amended June 15, 1988.

“In Process Revisions <797> Pharmaceutical Compounding – Sterile Preparations”, *Pharmacopeial Forum*, Volume 28(2) [March-April 2002], pages 498-534.

Principles of Sterile Product Preparation, Revised 1st Edition, American Society of Health System Pharmacists, 2002.

Business Impact

Potential costs vary based on the number of pharmacies that perform sterile compounding activities, the existing facilities and equipment at those pharmacies, and the nature of the sterile compounding activities required at those pharmacies. Potential costs of approximately \$30,000 per sterile compounding pharmacy for facility upgrades may be incurred if the pharmacy elects to compound sterile injectable drug products from non-sterile ingredients.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

The board has not identified any equally effective alternatives that would lessen any adverse impact on small business.