

Sterile Compounding Pharmacy Questions and Answers

Effective July 1, 2003, a pharmacy may not compound injectable sterile drug products in California unless:

1. The pharmacy is specially licensed with the board as a sterile compounding pharmacy, OR:
2. The pharmacy has a current accreditation from one of the following organizations:
 - Joint Commission on Accreditation of Healthcare Organizations
 - Accreditation Commission on Healthcare or
 - Community Health Accreditation Program

Nevertheless all pharmacies that compound injectable sterile drug products (whether separately licensed by the board as a compounding pharmacy) must follow board regulations for sterile compounding. These regulations are found in Title 16 California Code of Regulations as Article 8, beginning with section 1751. Additionally, the board is promulgating revised regulations for compounding injectable sterile drugs products. These regulations are expected to take effect sometime next year.

Note: If a nonresident pharmacy is shipping injectable drug products into California, this pharmacy must:

1. Be licensed as a nonresident pharmacy (form 17A-57)
2. Comply with board regulations for sterile compounding, AND
3. Be separately licensed with the board to compound injectable sterile drug products unless it is licensed as a hospital, home health agency or skilled nursing facility AND possesses current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Commission on Healthcare or the Community Health Accreditation Program. A separate application form for nonresident pharmacies compounding injectable sterile products is required. This application (form 17A-50) and the form described in item 1 may be downloaded from the board's Web site (www.pharmacy.ca.gov).

1. Q: When must pharmacies be separately licensed by the Board of Pharmacy if they will compound medication for patients in California?
A: July 1, 2003, unless they possess JCAHO, ACHC or CHAP accreditation. This requirement affects both California and specific non-resident pharmacies that will ship injectable compounded products into California. Nonresident pharmacies that are accredited by JCAHO, ACHC or CHAP and are licensed as a hospital, health agency or a skilled nursing facility are exempt from the specialty licensing provisions for sterile injectable drug compounding pharmacies.
2. Q: Who must possess a sterile compounding pharmacy license?
A: Pharmacies that combine/compound any products from sterile or non-sterile sources for injection. The pharmacy must be separately

licensed before performing these duties (unless it possesses current accreditation by the JCAHO, ACHC or CHAP).

3. Q: To whom will the sterile compounding license be issued?
A: To the owner of the pharmacy, which must be separately licensed as a pharmacy at the same location. This is required whether the pharmacy is located in California or elsewhere in the US.
4. Q: Does a hospital pharmacy have to possess a sterile compounding pharmacy license?
A: Yes, unless the hospital pharmacy is accredited by JCAHO, ACHC or CHAP. Hospital and community pharmacies that are accredited by these organizations do not have to be specially licensed with the board as a sterile compounding pharmacy; however, regardless of whether specially licensed or not, any hospital or community pharmacy compounding injectable sterile products must comply with board regulations for compounding.
5. Q: Can a pharmacy that only occasionally compounds injectable sterile medications pursuant to a prescriber's order do so without being separately licensed as a compounding pharmacy or meeting all the regulation requirements?
A: No. Even if only one injectable sterile drug for one patient is compounded in any year, the pharmacy must first either be licensed with the board as a compounding pharmacy or accredited by JCAHO, ACHC or CHAP, AND comply with regulation requirements in Article 8, beginning with section 1751 of Title 16 of California Code of Regulations.
6. Q: How long is the license issued for?
A: One year. However, the initial license will be issued so that it expires at the same time as does the regular pharmacy license at the same location, so the initial license may be issued for less than one year. After the first renewal, all licenses will expire in one year.
7. Q: Is an inspection required for renewal of the sterile compounding license?
A: Yes, an inspection is required before the issuance or renewal of any sterile compounding license for a pharmacy in California. For California pharmacies that are accredited by JCAHO, ACHC or CHAP, no separate inspection is required (because no separate compounding pharmacy license is mandated); however, the board will review compounding procedures and compliance during routine inspections.

For pharmacies located outside California, the board requires an inspection report from the accrediting agency for the nonresident

pharmacy or from the state pharmacy board in the state where the pharmacy is located to issue or renew the nonresident sterile compounding pharmacy license. This inspection report must document the pharmacy's compliance with board requirements as a condition for renewal of the nonresident sterile compounding pharmacy license.

8. Q: What will inspectors look for during inspections?

A: California Board of Pharmacy inspectors will determine compliance with California Code of Regulations Article 8, section 1751. This includes the maintenance of records, existence of current written policies and procedure that reflect operational practice, quality assurance/quality control, competencies and training of staff, equipment maintenance and calibration, sterilization process and associated records, biological sampling and qualitative/quantitative analysis of end products.

9. Q: Do out-of-state pharmacies have to obtain a pharmacy license to ship dangerous drugs into California?

A: Yes. A nonresident pharmacy may ship prescription drugs or devices into California only if licensed with the board as a nonresident pharmacy (California Business and Professions Code 4120).

10. Q: Do out-of-state pharmacies have to obtain the additional sterile compounding license to ship compounded injectable sterile product into California?

A: Yes, unless the nonresident pharmacy is licensed as a hospital, home health agency or a skilled nursing facility AND is accredited by JCAHO, ACHC or CHAP. If so, the nonresident pharmacy is exempt from specialty licensure as a nonresident sterile compounding pharmacy. (However, the nonresident pharmacy must still obtain the nonresident pharmacy permit described in questions 9.)

Again, regardless of whether the nonresident pharmacy is specially licensed with the board as a sterile compounding pharmacy or is JCAHO, ACHC or CHAP accredited and thus exempt from specialty licensure, all medications compounded for California must be prepared in accordance with board sterile compounding regulations (California Code of Regulations, Article 8, section 1751).

11. Q: How will the board determine compliance of nonresident pharmacies with board compounding requirements?

A: The board will use inspection reports from the board of pharmacy in the state where the pharmacy is located or from the accrediting agency when it last inspected the pharmacy.

12. Q: During an inspection, what will happen if an inspector identifies noncompliance or substandard practices?
- A: For violations of noncompliance that do not jeopardize the health and safety of patients, the inspector will request correction and proof of correction before a permit will be issued or renewed. Violations that pose an immediate threat to the health and safety of patients can result in the board's order to cease and desist compounding until the matter is resolved through administrative means or after correction of the problem. Specific procedures are established in California Business and Professions Code section 4127.3.
13. Q: Are there additional requirements for pharmacies that compound injectable sterile products from a non-sterile source?
- A: Pending board regulations that may take effect in January 2005 would require specialized equipment and procedures for pharmacies that perform this type of compounding. The proposed text of the regulations can be obtained from the board's Web site (www.pharmacy.ca.gov/pdfs/1751_exact.pdf).
14. Q: Question: Will the board accept policies and procedures from a source that sells written sterile compounding procedures?
- A: Whatever the source a pharmacy uses as the core of its policies and procedures, whether written by the pharmacy or obtained from another source, the procedures must be specific for the processes used by the pharmacy that compounds injectable sterile drug products. Many of the commercially available policies and procedures are written in a guideline format and need the pharmacy's modifications to reflect the specific processes that comply with California Code of Regulations section 1751.