Compounding Regulations Frequently Asked Questions (FAQs)

Title 16, California Code of Regulations (CCR),
Sections 1735 et seq., 1736 et seq., 1737 et seq., and 1738 et seq.

Regulations Effective October 1, 2025

This document is intended solely to assist pharmacists and pharmacies with understanding the California regulations governing nonsterile compounding, sterile compounding, hazardous drugs, and radiopharmaceuticals that took effect on October 1, 2025. It is not nor is it a substitute for legal advice. References to specific sections of the regulations are provided to aid the users of this document. Licensees are strongly encouraged to read the regulations in their entirety to have full understanding of the requirements. Licensees are also reminded that the regulations are in addition to (not in replacement of) applicable state and federal law and USP standards, and are advised that this document only addresses the additional requirements that apply under the regulations. All references in this document to California Business and Professions Code (BPC) sections are in Division 2, Chapter 9. All references in this document to California Code of Regulations (CCR) sections are in Title 16. Licensees are also advised that this is a dynamic document, which may be updated periodically.

General Compounding FAQs:

1) **Question: How do the previous California regulations addressing compounding correspond to the current compounding regulations that took effect on October 1, 2025?**

   Answer:

Type of Compounding	Previous CCR	Current CCR	USP Related Chapters
Nonsterile compounding	1735 - 1735.8	1735 – 1735.15	USP 795
Sterile compounding	1735 – 1735.8 and 1751 – 1751.10	1736 – 1736.21	USP 797
Handling of hazardous drugs	1735 – 1735.8 and 1751 – 1751.10	1737 – 1737.17	USP 800

Radiopharmaceutical-preparation, compounding, dispensing and repackaging	1708.3 - 1708.5, 1735 – 1735.8, and 1751 -1751.10	1738 – 1738.14	USP 825

2) Question: Can a facility have more than one designated person (DP) and does the DP need to be a pharmacist?

Answer:
For nonsterile and sterile compounding, "designated person(s)" means one or more individuals assigned by the pharmacist-in-charge (PIC) to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded nonsterile preparations (CNSPs)/ compounded sterile preparations (CSPs), as applicable. Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. Nothing in this definition prohibits the PIC from also serving as the designated person.

For hazardous drugs (HDs), in a pharmacy, the "designated person(s)" must be approved by the PIC to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of HDs. The designated person(s) shall not exceed the scope of their issued license. When a designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist.

For radiopharmaceuticals, "designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals. Nothing in this definition prohibits the PIC from also serving as the designated person.

[Reference: CCR 1735(b), 1736(c), 1737.2(a)(1), 1738(c)]

3) Question: When can a facility compound a drug in shortage?

Answer:
For nonsterile compounding: A facility may compound a drug in shortage

when the drug product appears in an American Society of Health-System Pharmacists (ASHP) Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding or within 60 days of the end of the shortage, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained.

For sterile compounding: A facility may compound a drug in shortage when that drug product appears in an ASHP Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding and at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained.

[Reference: CCR 1735.1(e)(1)(A), 1736.1(e)(1)(A)]

4) **Question: Is an audit trail required if I make a change on any of my compounding records?**

Answer: For nonsterile compounding, sterile compounding, and the processing of radiopharmaceuticals, the regulations require that records be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained for at least three years from the date the record was created, modified, or relied on, in a readily retrievable format and include the changes to the document, identification of the individual who made each change, and the date of each change.

[Reference: CCR 1735.14(b), 1736.20(b), 1738.9(d)]

5) **Question: Where can I submit licensing questions to the Board?**

Answer: Questions regarding your compounding license, license renewal, or general licensing questions can be submitted to Compounding.Pharmacy@dca.ca.gov.

6) **Question: How do the regulations define "essentially a copy" of a commercially available drug product for purposes of nonsterile or sterile compounding?**

Answer:

Under the regulations, "essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product.

[Reference: CCR 1735(d), 1736(e)]

7) **Question: What is required before a trainer is allowed to provide training to other pharmacy staff performing nonsterile or sterile compounding duties?**

Answer:
Any person assigned to provide the training specified in section 1735.2 (applicable to nonsterile compounding) or section 1736.2 (applicable to sterile compounding) shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's standard operating procedures (SOPs).

[Reference: CCR 1735.2(c), 1736.2(e)]

8) **Question: As the designated person, how do I document a garbing accommodation?**

Answer: For nonsterile or sterile compounding, any garbing accommodations provided by the designated person shall be documented, and the documentation shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation.

[Reference: CCR 1735.3(f), 1736.3(e)]

9) **Question: Does the compounding record (CR) need to be one document?**

Answer:
For nonsterile or sterile compounding, a CR shall, upon request, be produced as a single document.

[Reference: CCR 1735.7(c), 1736.11(c)]

10) **Question: Are a facility's SOPs required to address the handling of temperature sensitive Compounded Non-sterile Preparations (CNSPs)/ Compounded Sterile Preparations (CSPs)?**

Answer: The facility's SOPs for nonsterile compounding must describe the validated processes for storage, for shipping containers (as applicable), and for transportation of temperature sensitive CNSPs (as applicable) to preserve quality standards for integrity, quality and labeled strength. For sterile compounding, there must be written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality, and labeled strength.

[Reference: CCR 1735.11(a)(2)(D), 1736.17(g)]

Nonsterile Compounding FAQs

11) **Question: If the pharmacist does not follow the manufacturer's instructions when reconstituting a commercially available drug product, is this considered compounding?**

Answer:
Yes, reconstitution of a conventionally manufactured drug product that is not done in accordance with the FDA approved directions is considered compounding.

[Reference: CCR 1735.1(b)]

12) **Question: How much CNSP can a pharmacy compound in advance and store in the pharmacy prior to receiving a patient-specific prescription for the CNSP?**

Answer:
A limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.

[Reference: CCR 1735.1(c)]

13) Question: How much CNSP can a pharmacy furnish to a veterinary office for use by the veterinarian?

Answer:
A reasonable quantity of CNSP may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office.

(2) for furnishing of no more than a 14-day supply, for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing.

[Reference: CCR 1735.1(d)]

14) Question: Do gloves need to be wiped or changed when performing nonsterile compounding?

Answer:
Gloves must be wiped or replaced before beginning a CNSP that contains different components.

[Reference: CCR 1735.3(d)]

15) Question: How long is the pharmacy required to maintain the source referenced to support the assigned beyond-use date (BUD)?

Answer:
If a source is referenced to support an assigned BUD, the source referenced must be readily retrievable at the time of compounding and must be maintained for three (3) years from the date each CNSP is dispensed.

[Reference: CCR 1735.7(a)(1)]

16) Question: If the names of the compounding facility and the dispensing facility is different, are they both required to be included on a CNSP's label?

Answer:

Yes, a CSNP's label shall include the name of the compounding facility and the name of the dispensing facility, if different.

[Reference: CCR 1735.9(a)(2)]

17) Question: Can a facility use antimicrobial effectiveness testing provided by a current FDA-registered drug establishment or an outsourcing facility?

Answer: Yes, if the testing is compliant with USP Chapter 51, Antimicrobial Effectiveness Testing. If such testing is used, or if relying upon current published peer-reviewed literature sources, the reference or test in its entirety shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.

[Reference: CCR 1735.10(c)]

18) Question: Prior to compounding, must the facility's SOPs for nonsterile compounding include how the facility selected the ingredients for each CNSP?

Answer: Yes, the facility's SOPs for nonsterile compounding must include the methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.

[Reference: CCR 1735.11(a)(2)(C)]

19) Question: What do the regulations say about adding flavoring?

Answer:
Under the regulations, a facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent is exempt from certain sections of the regulations, as specified in subdivision (i) of section 1735.1. However, for such facilities, section 1735.15 requires, among other things, that the pharmacist adding the flavoring agent must document the compounding in the prescription or compounding record.

A facility that performs any other form of nonsterile compounding at any time does not qualify for the exemption described above.

Licensees are advised to read the regulations referenced below in their entirety for a full understanding of the requirements regarding adding flavoring agents.

[Reference: CCR 1735.1(i), 1735.15]

Sterile Compounding FAQs

20) Question: When can a pharmacy compound for immediate administration or immediate use?

Answer:
Except as described in the two bullet points below, compounded sterile preparations (CSPs) for direct and immediate administration as provided in USP Chapter 797 shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient.

- If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient; however, this provision may only be used for 48 hours after such failure(s).

- If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in section 1395i-4(c)(2)(B) of title 42, United States Code, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient; however, this provision may only be used for 120 hours after such failure(s).

  Licensees are advised to read the regulation in its entirety for a full understanding of the requirements that apply to immediate-use CSPs.

  [Reference: CCR 1736.1(b)]

21) Question: How much CSP can a pharmacy furnish to a veterinary office for use by the veterinarian?

Answer:

A reasonable quantity of a CSP may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office.

(2) for furnishing of not more than a 7-day supply for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing, with the exception of a topical ophthalmic where up to a 28-day supply may be furnished to the veterinarian's office for an individual patient; provided that such topical ophthalmics shall be compliant with USP Chapter 797 section 14.5, Multiple-Dose CSPs.

[Reference: CCR 1736.1(d)]

22) Question: Can garbing and hand hygiene competencies and aseptic manipulation competencies from one premises be used for another premises?

Answer:
Yes, if all of the following conditions are met:

- The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical.
- The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs.
- The Primary Engineering Controls (PECs) are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

[Reference: CCR 1736.2(b)]

23) Question: What happens if compounding personnel fail any part of aseptic manipulation training and competency evaluation?

Answer:
Compounding personnel or persons with direct supervision and control of compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.

A person with only direct supervision and control of personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct supervision and control of personnel for no more than 30 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.

[Reference: CCR 1736.2(d)]

24) Question: If the pharmacy uses a Segregated Compounding Area (SCA), can a wall be considered part of the SCA?

Answer: Yes, as long as the wall is smooth, impervious, free from cracks and crevices, and non-shedding so it can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

[Reference: CCR 1736.4(b)]

25) Question: Does the temperature in the designated compounding area, such as an SCA, need to be monitored?

Answer: The temperature shall be monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.

[Reference: CCR 1736.4(c)]

26) Question: If on October 1, 2025, a pharmacy has an existing secondary engineering control that has a pass-through that is not an interlocking device, is the pharmacy required to install an interlocking device?

Answer:
No, an existing secondary engineering control that has a pass-through that is not an interlocking device may continue to be used if the SOPs document that two doors may not be opened at the same time.

Where a pass-through is installed in a secondary engineering control After October 1, 2025, the doors must be interlocking.

[Reference: CCR 1736.4(d)]

27) Question: What standards apply to the certification and testing of the pharmacy's classified compounding areas?

Answer:
In addition to the requirements of USP Chapter 797, testing and certification of all ISO classified areas shall be performed by a qualified technician in accordance with Controlled Environment Testing Association's (CETA) Certification Guide for Sterile Compounding Facilities (CAG-003, Revised October 2022). The CETA standard(s) used to perform certification testing in all ISO classified areas shall be recorded on the report issued by the certifying technician in accordance with the Certification Guide for Sterile Compounding Facilities.

[Reference: CCR 1736.5]

28) Question: What standards apply to environmental sampling?

Answer:
In addition to the requirements of USP Chapter 797, environmental sampling shall be done in accordance with the Controlled Environment Testing Association's Certification Application Guide USP <797> Viable Environmental Monitoring for Sterile Compounding Facilities (CAG-009, Revised September 2020).

[Reference: CCR 1736.6]

29) Question: If the pharmacy is using an incubator, how should the incubator be maintained?

Answer:
Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results shall be reviewed and documented as described in the facility's SOPs.

[Reference: CCR 1736.9(b)]

30) Question: Can facilities compound with FDA Category 1 bulk drug substances?

Answer:

If a component included in the published 503A Category 1 Bulk Drug Substances List is used, it must be found suitable for sterile drug preparations as provided in USP Chapter 797, Section 9.3 Components. The facility's SOPs shall establish a process to determine the quality of the API, and the SOPs, which must comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, must define both the methods by which the pharmacist compounding or supervising the compounding will ensure the quality of compounded drug preparations and the methods used to determine and approve components and the compounding process for each preparation before compounding begins.

Licensees are advised to read Article 4.6 (Sterile Compounding) of the regulations in its entirety for a full understanding of the requirements that apply to components used to compound CSPs.

[Reference: CCR 1736.9(f), 1736.17(a)]

31) Question: Can a pharmacy compounding CSP from a nonsterile component send the CSP to another facility for sterilization (for example, by e-Beam radiation)?

Answer:
Section 1736.10 of the regulations describes requirements, in addition to the requirements in USP Chapter 797, that apply to sterilization and depyrogenation. Subdivision (e) of section 1736.10 states that no compound of a CSP from nonsterile components shall be prepared when the licensed location cannot also sterilize the CSP as described in section 1736.10.

[Reference: CCR 1736.10(e)]

32) Question: Is a USP Category 1 injectable CSP compounded from a nonsterile component required to be tested for endotoxins prior to dispensing?

Answer:
Yes. A pharmacist performing or who has direct supervision and control of compounding personnel is responsible for ensuring injectable CSPs made from nonsterile components, regardless of the USP Category, are tested to ensure that they do not contain excessive bacterial

endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results shall be
reviewed and documented in the compounding record prior to furnishing.

[Reference: CCR 1736.12(c)]

33) Question: Can a CNSP compounded following USP 795 be used as a stock solution to compound a CSP?

Answer:
A compounded stock solution intended for use in a CSP must comply with all provisions of Article 4.6 (Sterile Compounding) of the regulations and USP Chapter 797 Category 1, Category 2, or Category 3.

[Reference: CCR 1736.16(a)]

34) Question: Can a pharmacy obtain a CSP for use as a component from an outsourcing facility?

Answer:
Yes, as long as the outsourcing facility is licensed in California.

Note: To verify if an outsourcing facility is licensed in California, go to: https://search.dca.ca.gov/?BD=7200&TP=180

[Reference: CCR 1736.16(b)]

HAZARDOUS DRUGS (HD) FAQs

35) Question: Our facility compounds HD in a containment secondary engineering control (C-SEC) which has a pass-through without interlocking doors. Under the regulations that took effect on October 1, 2025, is our facility exempt from changing to interlocking doors since the facility has an existing sterile compounding license?

Answer:
No, although the regulations provide a grace period to come into compliance. Where there is a pass-through in a C-SEC, the doors must be gasketed and interlocking by January 1, 2027.

[Reference: CCR 1737.5(c)]

36) Question: Our facility installed a pass-through in our cleanroom, but it is not a HEPA purge type pass-through. Do the regulations that took effect on October 1, 2025, require that we replace and install a new pass-through?

Answer:
On or after January 1, 2028, prior to installing a new pass-through, a facility must consider the use of a HEPA purge type pass-through. Documentation shall be maintained showing compliance with this requirement if such a pass-through is not used.

[Reference: CCR 1737.5(d)]