

## **FAQ Patient Specific Prescriptions Dispensed by a California Licensed Outsourcing Facility within or into California.**

A new statute effective January 1, 2022, allows for California licensed outsourcing facilities to dispense patient specific prescriptions. To qualify, an outsourcing facility must: 1) be licensed with the federal Food and Drug Administration as an outsourcing facility; 2) be licensed with the Board of Pharmacy in the State of California as a resident or nonresident outsourcing facility; and 3) comply with same requirements of a pharmacy when dispensing patient-specific prescriptions. The purpose of these FAQs is to generally describe the requirements under California law governing patient-specific dispensing by licensed outsourcing facilities. For a full understanding of the requirements, please read the cited sections of California Pharmacy Law.

A California licensed outsourcing facility, when dispensing patient-specific prescriptions in or into California, will need to comply with California law governing the dispensing of patient-specific prescriptions that a pharmacy would have to comply with including, but not limited to, the duty to provide consultation, requirements regarding prior review of drug therapy and labeling of prescriptions and other miscellaneous requirements.

References to BPC refers to California's Business and Professions Code, references to HSC refers to California's Health and Safety Code, references to CCR refers to sections of Title 16 of the California Code of Regulations, and references to CFR refers to sections of Title 21 of the Code of Federal Regulations. Additionally, the [provisions of law](#) can be found on the Board's website.

### **1) Is patient consultation required?**

Yes, under specified conditions including:

- (1) upon request;
- (2) whenever the pharmacist deems it warranted in the exercise of their professional judgment;
- (3) whenever the prescription drug has not previously been dispensed to a patient;
- (4) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed.

**Note:** The pharmacist must review a patient's drug therapy and medication record prior to consultation. Further, consultation must be performed in a manner suitable for patient confidentiality (Civil Code 56.10, CCR 1714(a), 1764)).

**Reference:** CCR sections 1707.2 & 1707.3

### **2) What is the required information on the prescription document?**

BPC sections 4040 and 4070 detail the required information on the prescription.

### **3). How can I receive a prescription?**

- Effective January 1, 2022, most prescriptions must be sent and received electronically subject to certain exemptions. The Board has [FAQs](#) available that provide further information on those requirements.
- Prescriptions that are orally transmitted can only be received and reduced to writing by a pharmacist or a pharmacist intern, working under the direct supervision of a pharmacist.
- A faxed or electronically submitted prescription must be received only from a prescriber's office unless otherwise provided in the law.

**Note:** Records must include identification of the pharmacist and be retained for a period of three years.

**Reference:** BPC 688, 4040, 4070, 4071 and CCR 1712, 1717.

### 3) Can we accept written prescriptions for a controlled substance for a California patient?

Yes, under specified conditions. The prescriptions must be comply with Division 10, Chapter 4 of the HSC. [Add link]. Prescriptions must be on forms with certain security features as specified in this chapter. Also, California law imposes a duty of corresponding responsibility on pharmacists who dispense a controlled substance that it is issued for a legitimate medical purpose.

**Note:** Controlled substances prescriptions are valid for a limited period of time and have additional requirements if e-prescribed.

**Reference:** HSC sections 11153, 11159.2, 11159.3, 11162.1, HSC 11164(a), 11166, 21 CFR 1306.08, 1306.11, 1311.100

### 4) Do we have to follow California requirements for the prescription label?

Yes. Requirements for prescription labeling are established in provisions of state and federal law described below.

- The prescription label must contain all the required information established in BPC section 4076, the prescription label must be formatted in accordance with patient-centered labeling requirements. Also, the expiration date of a drug's effectiveness must be accurately identified on the label. (Reference: BPC 4076 and CCR 1707.5.)
- The trade name or generic name and manufacturer of the prescription drug must be accurately identified on the label and prescription record and includes the statement "generic for \_\_\_\_\_" where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist, if the brand name is no longer widely used, the label may list only the generic name of the drug and the manufacturer's name may be listed outside the patient-centered area. (Reference: BPC 4076, CCR 1717[b][2], CCR 1707.5[a][1][B])
- The federal warning label prohibiting transfer of controlled substances must be on the prescription container. (Reference: 21 CFR section 290.5)
- If the prescription is filled by a pharmacy technician or a pharmacy technician trainee, before dispensing, the prescription must be checked for accuracy by a pharmacist and

that pharmacist must initials the prescription label or records by their identity as the reviewing pharmacist in a computer system by a secure means. (Reference: BPC 4115, 4115.5, CCR 1793.7, CCR 1712)

- Prescriptions must be dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (Reference: 15 USC section 1473[b], 16 CFR section 1700.15, CCR section 1717)
- The label must include a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (Reference: BPC 4076)

#### **5) Are there are other requirements for patient specific prescriptions?**

Yes

- Patient package inserts must be dispensed with all estrogen medications. (Reference: 21 CFR section 310.515)
- The pharmacy must provide patients with Black Box Warning Information in conformance with 21 CFR section 201.57[c].
- Medication guides must be provided on required medications. (Reference: 21 CFR, Part 208, Section 208.24[e])
- The drug container must contain a written label indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (Reference: BPC 4074, 4076.7, and CCR 1744)
- The written label on the drug container must alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container. (Reference: BPC 4074, CCR 1744)
- Whenever an opioid prescription drug is dispensed to patient for outpatient use, the label or container must contain a flag or other notification on the container, with a notice that states, "Caution: Opioid. Risk of overdose and addiction." (Reference: BPC 4076.7)
- When requested by a patient or a patient's representative, the outsourcing facility must provide translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appears on the prescription container or label, the English-language version of the directions for use should also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If the English-language directions are not able to appear on the container or label, the English-language directions must be provided on a supplemental document. (Reference: BPC 4076.6)
- No drug preparation may be compounded prior to receipt by the outsourcing facility of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally by the prescriber, that approval shall be noted on the prescription prior to

compounding. There are two exceptions to this prohibition of prior compounding of a drug preparation of: 1) a limited quantity to ensure continuity of care for an identified population of patients of the outsourcing facility based on a documented history of prescriptions for that patient population; and 2) a reasonable quantity that may be compounded for prescriber office use as authorized by BPC section 4052(a)(1). (Reference: CCR 1735.2).

**6) Is there a limit on the days' supply or quantity of a non-controlled medication we can send pursuant to a patient specific prescription?**

No, generally prescriptions for non-controlled substances can be filled for more than the prescription allows; however, there are several exceptions. Please see the referenced law section for more information about the specific provisions conditions.

**Reference:** BPC 4064.5

**7) Is there a limit on the day's supply or quantity that can be dispensed for a controlled substance.?**

Yes, there are limits. Requirements vary based on the schedule.

**Reference:** HSC 11200

**8) We have an auto ship option; can we use this for patient specific prescriptions?**

- Refill authorization from the prescriber must be obtained before refilling a prescription (BPC section 4063) and refills must be documented. (Reference: CCR 1717).
- Refills for Schedule II controlled substances are prohibited. (Reference: HSC 11200)
- Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together may not exceed a 120-day supply. (Reference: HSC 11200)

**Note:** Effective July 1, 2022, [Board regulations](#) will establish parameters for automatic refill programs generally related to obtaining informed patient consent to enroll in such programs and how to withdraw from such programs.

**9) Are there required actions that must be done in the event of a medication error?**

Yes, a quality assurance process is necessary to meet the requirements of California Law.

**Reference:** BPC 4125, CCR 1711

**10) Is there a requirement to exercise corresponding responsibility before dispensing a controlled substance?**

Yes, a pharmacist must fulfill their corresponding responsibility.

**Note:** The Board has issued a [precedential decision](#) on this point, the *Pacifica Pharmacy* matter, which can be found on the Board’s website in addition to [educational information](#) and a [video](#) on corresponding responsibility.

**Reference:** HSC 11153, CCR 1761

**11) Do we need to report our controlled substance prescription dispensing to the California Department of Justice?**

Yes, schedule II-V controlled substances must be reported to the CURES system.

**Note:** The Board has information on the CURES system on its [website](#), including how to register for access to the CURES system.

**Reference:** HSC 11165, 21 CFR 1308.12, 1308.13, 1308.14, 11308.15.

**12) Can we advertise our products directly to consumers?**

Yes. There is no express prohibition against advertising per se. See Business and Professions Code section 17500.1. However, false and misleading advertising by any licensee of the Board could constitute violations of BPC sections 17500, 651 and 4301. Also, California law regulates different arrangements including rebates and referrals and you should consult California law, including but not limited to, BPC sections 650 through 657 in structuring arrangements to ensure compliance with California law.

**Reference:** BPC 650, 4301, 17500 and CCR 1766

**13) Is there any other information guides to assist us with the requirements under California law?**

Yes. The Board of Pharmacy has adopted [self-assessment](#) forms to assist pharmacists in maintaining compliance with Pharmacy Law. Review of the form may provide additional information and guidance on requirements for dispensing prescriptions to California patients.

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