

Department of Consumer Affairs

Title 16. Board of Pharmacy

Proposed Regulation Text

Add Section 1707.11 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.11 Outpatient Pharmacy Definitions

(a) This section applies to outpatient pharmacies licensed by the Board. "Outpatient Pharmacy" has the same meaning as described in (b).

(b) An "Outpatient Pharmacy" means a pharmacy that dispenses drugs and devices as defined in Business and Professions Code section 4024, or provides clinical services, to the general public. Such a pharmacy does not include a hospital pharmacy as described in Business and Professions Code section 4029 and California Code of Regulations, title 16, section 1710(a).

(c) For purposes of this article, the following definitions apply to different outpatient pharmacy business models.

1. Chain Community Pharmacy means an outpatient pharmacy that is part of a chain of 75 or more pharmacies in California under the same ownership.
2. Independent Community Pharmacy means an outpatient pharmacy owned by a person or entity that owns no more than four pharmacies in California.
3. Central Fill Pharmacy means a pharmacy located in California that, pursuant to a contract or on behalf of a pharmacy under common ownership, prepares and packages prescriptions for another pharmacy to dispense to the patient, as defined in California Code of Regulations, title 16, section 1707.4.
4. Closed-Door Pharmacy means an outpatient pharmacy that provides pharmacy services exclusively to a defined patient population in one or more of the following settings:
 - A. Skilled nursing facilities
 - B. Intermediate care facilities
 - C. Assisted living facilities

- D. Nursing homes
 - E. Hospice or mental health facilities
 - F. Board and care facilities
 - G. Drug and alcohol treatment facilities
5. Federally Qualified Healthcare Pharmacy means an outpatient pharmacy that is operated by or contracted with a Federally Qualified Health Center (FQHC) as defined in title 42 of the United States Code at section 1395x(aa)(4), to provide pharmacy services to patients of the FQHC.
 6. Health System Pharmacy means an outpatient pharmacy that is wholly owned and operated by an integrated health care system that is responsible for managing all aspects of medication used by outpatients of that health care system.
 7. Home Infusion Pharmacy means an outpatient pharmacy that prepares and dispenses sterile parenteral medications for administration to patients in their homes.
 8. Infusion Center Pharmacy means an outpatient pharmacy that prepares and dispenses sterile parenteral medications for administration to patients by a licensed health care provider in any of the following settings:
 - A. Medical office
 - B. Pharmacy
 - C. Health care facility where patients receive medical care
 9. Mail Order Pharmacy means an outpatient pharmacy that dispenses and delivers greater than 75 percent of its total aggregate prescriptions directly to a patient's home or designated address through any mail or courier service.
 10. Nondispensing Clinical Pharmacy means an outpatient pharmacy that does not hold inventory or dispense drugs or devices but provides clinical pharmacy services.
 11. Online Pharmacy means an outpatient pharmacy providing pharmacy-related services by means of the internet.
 12. Specialty Pharmacy means an outpatient pharmacy that provides high-cost drugs and devices for complex conditions requiring special handling, monitoring, and patient support.

(d) Nothing in this section shall be construed to limit a pharmacy to a single business model.

(e) The pharmacist-in-charge of an outpatient pharmacy shall determine whether any of the definitions set forth in subsection (c) apply to the pharmacy's operations, and if so, which definition(s) are applicable. The self-assessment shall reflect the applicable outpatient pharmacy business model(s) determined to apply to the pharmacy's operations, if any.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4037, 4001 and 4110, Business and Professions Code.