Department of Consumer Affairs

Title 16. Board of Pharmacy

Proposed Regulation Text

Add Section 1707.11 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.11 Outpatient Pharmacy Service Definitions

(a) This section applies to outpatient pharmacies licensed by the Board. "Outpatient Pharmacy" has the same meaning as described in subsection (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 licensed pursuant to Business and Professions Code section 4029.

(c) For purposes of this article, the following definitions and exemptions apply to different outpatient pharmacy services.

1. A. "Closed-door pharmacy" means an outpatient pharmacy that provides pharmacy services exclusively to a defined patient population in one or more of the settings defined in Health and Safety Code section 1250.
   B. An outpatient pharmacy that solely operates as a closed-door pharmacy shall be exempt from the following:
   i. The requirements set forth in Section 1707.6, Notice to Consumers, if the pharmacy provides the information required in Business and Professions Code section 4122 as part of a written receipt.
   ii. The requirement set forth in subsection (a) of Section 1714, Operational Standards and Security.
2. A. "Home infusion pharmacy" means an outpatient pharmacy that prepares and dispenses sterile parenteral medications for administration to patients in their homes.
   B. An outpatient pharmacy that solely operates as a home infusion pharmacy shall be exempt from the following:

i. The requirements set forth in Section 1707.6, Notice to Consumers, if the pharmacy provides the information required in Business and Professions Code section 4122 as part of a written receipt.

ii. The requirement set forth in subsection (a) of Section 1714, Operational Standards and Security.

3. A. "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 a medical office, pharmacy or health care facility where patients receive medical care.
   B. An outpatient pharmacy that solely operates as an infusion center pharmacy shall be exempt from the following:
   i. The requirements set forth in Section 1707.2, Duty to Consult.
   ii. The requirements set forth in Section 1707.6, Notice to Consumers if the pharmacy provides the information required in Business and Professions Code section 4122 as part of a written receipt.
   iii. The requirement set forth in subsection (a) of Section 1714, Operational Standards and Security.
4. A. "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.
   B. An outpatient pharmacy that solely operates as a mail order pharmacy shall be exempt from the following:
   i. The requirements set forth in Section 1707.6, Notice to Consumers, if the pharmacy provides the information required in Business and Professions Code section 4122 as part of a written receipt.
   ii. The requirement set forth in subsection (a) of Section 1714, Operational Standards and Security.
5. A. "Nondispensing clinical pharmacy" means an outpatient pharmacy that does not hold inventory or dispense drugs or devices but provides clinical pharmacy services.
   B. An outpatient pharmacy that solely operates as a nondispensing clinical pharmacy shall be exempt from the following:
   i. The requirements set forth in Section 1707.2, Duty to Consult.
   ii. The requirements set forth in Section 1707.6, Notice to Consumers, if the pharmacy provides the information required in Business and Professions Code section 4122 as part of a written notice.

iii. The requirements set forth in Section 1715.65, Inventory Activities and Inventory Reconciliation Reports of Controlled Substances.

iv. The requirement set forth in subsection (a) of Section 1714, Operational Standards and Security.

(d) Nothing in this section shall be construed to limit a pharmacy to providing a single type of outpatient pharmacy service. The definitions in this section shall be used solely for the purpose of application of the Board's regulations.

(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, and if so, which definition(s) are applicable. The self-assessment completed by the pharmacist-in-charge shall reflect the outpatient pharmacy service(s) applicable to the pharmacy, if any.

(f) If an outpatient pharmacy falls within more than one service model defined in this section, and one or more of the applicable exemptions are the same under each service model definition, then the outpatient pharmacy may apply such overlapping exemptions.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4037, 4001, 4014 and 4110, Business and Professions Code.