

Infusion Center Operations

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Purpose of This Overview

- **Objectives**
 - Provide a high-level overview of infusion center operations
 - Describe how patient care is delivered safely and efficiently
 - Highlight legal and regulatory challenges under current California pharmacy law
 - Identify areas where regulatory misalignment creates operational constraints without improving patient safety

What Is an Infusion Center Pharmacy?

- **Core Characteristics**
 - Provides **on-site preparation and administration** of parenteral therapies
 - Common therapies include:
 - Monoclonal antibodies / Biologics
 - Supportive agents
 - Chemotherapy
 - Operates under **direct physician order and provider administration**
 - Medications are typically **not dispensed for self-administration at home**
- **Key Distinction**
 - Clinical treatment environment — not retail dispensing

Patient Care Workflow (High-Level)

- **End-to-End Process**

- Provider-ordered treatment plan
- Pharmacist clinical verification
- Sterile compounding under USP standards
- Direct handoff to nursing
- On-site administration
- Real-time monitoring and documentation

- **Patient Safety Emphasis**

- Immediate administration
- Closed-loop clinical oversight
- Interdisciplinary coordination

Operational Infrastructure

- **Facility & Staffing Model**

- Restricted clinical suites (not public retail access)
- Cleanrooms compliant with **USP <797> / <800>**
- Pharmacists focused on:
 - Order verification
 - Sterile compounding oversight
 - Clinical coordination
- Technicians functioning in compounding and infusion support roles



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Regulatory Framework: Where the Challenge Begins

- **Current Legal Definition**

- California law defines “pharmacy” primarily as:
 - Community (retail) pharmacy, or
 - Hospital inpatient pharmacy

- **Problem**

- Infusion centers fit **neither model**
 - Resulting compliance expectations are **retail-focused**, not matching operations

(c) For purposes of this section, “community pharmacy” includes any pharmacy that dispenses medication to an outpatient, but does not include facilities of the Department of Corrections and Rehabilitation.

A hospital pharmacy means:

- “A pharmacy licensed by the Board of Pharmacy;”
- “Located within a hospital facility, including organized facilities for diagnosis, care, and treatment of human illnesses where patients may be admitted for overnight stay;”
- “If the pharmacy is located outside the hospital building, it must be under the same hospital’s consolidated license and provide services only to registered hospital patients on that physical

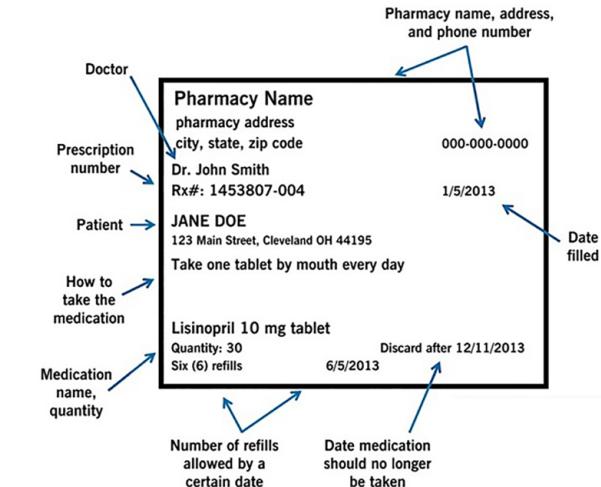
Challenge #1: Retail-Specific Requirements

- **Examples of Inapplicable Requirements**

- Public consultation counters
- Walk-up consumer signage and language posters
- 18-point font patient-facing labeling standards
- Retail pricing disclosures and point-of-sale rules

- **Why This Matters**

- Infusion patients receive care on site
- Medications are never dispensed for self-administration
- These requirements add complexity without improving safety



Challenge #2: Labeling and Patient Communication Rules

- **Retail Assumptions**

- Labels designed for patient readability
- Multilingual auxiliary warnings
- Consumer-directed container labeling

- **Infusion Reality**

- Labels are for **internal identification and verification**
- Administration occurs under licensed supervision
- Patient counseling is clinical, not transactional



Challenge #3: Staffing and Workflow Constraints

- **Retail-Driven Expectations**
 - Fixed technician-to-pharmacist ratios
 - Posted lunch closures
 - Chain pharmacy staffing disclosures
- **Operational Impact**
 - Infusion centers operate on scheduled treatment days
 - Staffing is aligned with sterile workload and patient acuity
 - Retail constructs disrupt clinical efficiency

Challenge #4: Scope-of-Practice Mismatch

- **Retail Activities Required but Not Performed**

- CURES dispensing workflows
 - Emergency contraception furnishing
 - CLIA-waived testing
 - Refill authorizations and auto-refill programs

- **Infusion Practice**

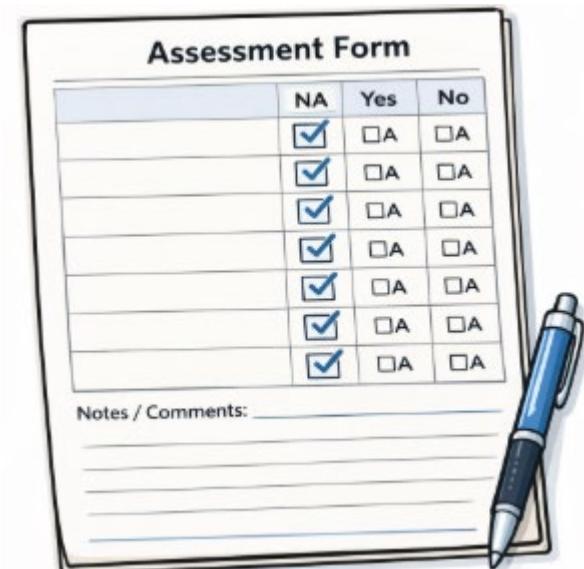
- Provider-ordered, non-refillable treatment plans
 - One-time or cyclical dosing under medical supervision

Compliance Burden vs. Patient Safety

- **Current State**
- Significant compliance effort devoted to:
 - Retail signage
 - Consumer-facing requirements
 - Dispensing constructs
- **Gap**
 - These efforts do **not** address the highest-risk areas:
 - Sterile integrity
 - Hazardous drug handling
 - Clinical coordination

Summary of Regulatory Misalignment

- Retail pharmacy law ≠ infusion center reality
- Current framework creates:
 - Operational inefficiency
 - Compliance confusion
 - Regulatory distraction from true safety risks



Closing Takeaways

- Infusion centers deliver **direct, supervised clinical care**
- Patient safety is driven by **sterile compounding and clinical oversight**, not retail constructs
- Existing legal definitions do not reflect modern infusion practice
- Clarifying regulatory alignment would:
 - Improve compliance clarity
 - Focus inspections on real risk
 - Support patient access and safety