From: Martinez, Sam
To: McFall, Julie@DCA; Anne.Sodergren@pharmacy.ca.gov
Subject: Comments for Full Board Meeting
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Attachments: BoP comments.pdf

Dear Executive Officer Anne Sodergren, I have attached my comments related to the licensing committee agenda item on the possibility of creating a new licensing program for infusion centers for the full board meeting on November 5th. Thank You.

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October 29, 2025

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Submitted via electronic mail to Anne.Sodergren@pharmacy.ca.gov

Subject: Proposal Establishment of a Separate License Type for Infusion Center Pharmacies in California

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I. Introduction

Current California Pharmacy Law under BPC §4037 defines "pharmacy" primarily through a retail or hospital framework, neither of which aligns with the clinical, sterile-compounding, and on-site-administration functions of an infusion center.

Infusion centers deliver parenteral medications such as monoclonal antibodies, biologics, and chemotherapy under direct clinical supervision — not as take-home retail prescriptions. Yet, under current licensing definitions, they must operate under a community or hospital pharmacy license, creating operational and compliance mismatches that do not improve patient safety.

II. Problem: Misalignment Between Retail Pharmacy Requirements and Infusion Operations

The Community Pharmacy Self-Assessment (Form 17M-13 [Draft Rev 4/10/2025]) illustrates how the Board's current compliance expectations impose retail-specific obligations that are irrelevant to infusion centers. Trying to further modify the retail license with further carve outs for infusion as some suggested at the last licensing meeting would just create a more confusing situation.

A. Patient-Facing Retail Elements (Inapplicable)

Section 1.1 – Confidential patient consultation area requirement.
Infusion patients are treated on site; counseling is clinical and interdisciplinary, not retail counter-based.

Sections 1.7–1.9 – "Notice to Consumers," "Point to Your Language," and 18-point nametag font provisions.
These are designed for walk-up consumer transactions, not for scheduled infusion appointments within a closed clinical suite.

Section 13 (Labeling) – Font size, English/translated labeling, auxiliary warnings, and accessible labels under CCR §1707.5 and BPC §4076.8.
Infused medications are administered under direct supervision and never dispensed to patients for self-use; the container labels are for internal identification, not patient readability.

B. Retail Pricing and Staffing Provisions (Inapplicable)

§§ 1.18–1.26 – Retail price disclosure, point-of-sale cost-sharing, chain staffing ratios, and lunch-hour closure postings.
Infusion centers have no point-of-sale or cash register function.

§ 1.24–1.26 – Chain-store quotas, required technician staffing hours, and posted lunch breaks.
Infusion centers follow scheduled treatment days with clinical staffing models akin to hospital outpatient departments.

C. Retail Practice Activities (Inapplicable)

§§ 6.4–6.7 – CURES, emergency contraception furnishing, CLIA-waived testing.
Infusion pharmacists do not perform retail screenings or contraceptive therapy; they verify physician-ordered and nurse administered medications.

§ 9.3 – Technician 18-point name tags for consumer visibility.
Technicians function in compounding cleanrooms and infusion support roles, not public counters.

§§ 10–15 – Non-licensed clerk roles, oral consultations, refill authorizations, auto-refill programs.
Infusion prescriptions are order-based, provider-verified, and administered in one-time or cyclical doses.

D. Miscellaneous Provisions Needing Revision or Exemption

§§ 17.4, 18 – Internet and transferred prescriptions.
Infusion orders are clinical treatment plans, not refillable prescriptions.

§§ 20.3–20.6, 23, 26–32.47 – Advertising, patient records for refills, complaint handling, and mail-order storage.
Infusion centers operate under facility accreditation (e.g., TJC, URAC) with integrated EMR documentation and direct physician oversight.

III. Distinct Nature of Infusion Center Practice

Infusion centers combine hospital-grade sterile compounding (USP 797/800) with ambulatory patient care. They:

Prepare patient-specific doses for immediate administration.

Maintain sterile environments and compounding logs equivalent to hospital satellites.

Are inspected under sterile-compounding standards, not retail dispensing rules.

Rely on physician-ordered treatment plans, not consumer prescriptions.

This model warrants regulatory recognition distinct from “retail” or “hospital inpatient” categories.

IV. Proposal: Create a New License Category – “Infusion Center Pharmacy”

A. Scope of Practice

Authorize preparation, verification, and administration of medications under provider supervision for patients receiving treatment on site.

B. Core Regulatory Standards

Must comply with USP 797/800 for sterile compounding.

Maintain on-site pharmacist oversight and direct nursing collaboration.

Ensure drug traceability and documentation under BPC §4105 & §4081.

Exempt from retail-specific labeling, signage, and consumer consultation requirements.

C. Inspection and Oversight Focus

Sterile compounding facilities, environmental monitoring, and HD controls.

Medication order verification and clinical coordination.

Adverse-event reporting and quality assurance under CCR 1711 (retained).

D. Ownership and Structural Flexibility

Permit licensure by hospitals, health systems, or independent clinical operators under medical supervision without requiring a general acute care hospital license.

V. Benefits of a Separate Infusion Center License

Dimension	Current Barrier (Retail License)	Proposed Resolution (Infusion License)
Regulatory Fit	Retail consumer focus	Clinical infusion focus
Labeling & Font Rules	Patient readability, multilingual labels	Internal labeling per sterile compounding policy
Space/Layout	Public access & consultation area	Restricted clinical suite
Staffing Rules	Fixed retail ratios, lunch posting	Flexible tech-to-pharmacist ratios aligned with sterile workflow
Patient Interaction	Walk-in dispensing	Scheduled provider-based infusion
Compliance Oversight	Retail inspection	Sterile compounding inspection

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VI. Conclusion

The current licensing framework under BPC §4037 and §4029 fails to capture the operational realities of modern infusion centers. Creating a distinct Infusion Center Pharmacy license would modernize oversight, remove irrelevant retail obligations (e.g., font size, multilingual poster, retail price disclosure), and focus regulatory scrutiny where it matters most: sterile integrity, clinical safety, and patient access.

Recommendation

The Board should:

1. Develop draft statutory and regulatory language establishing an Infusion Center Pharmacy license type.
2. Solicit stakeholder feedback (hospital outpatient, oncology, ambulatory infusion, specialty compounding).
3. Align future self-assessment tools with sterile-compounding and clinical infusion operations, excluding retail-specific elements enumerated above. The sterile compounding could essentially serve as the self-assessment tool for infusion centers with some modifications.