Consultation: NAPRA Model Documents for PRA Use – Non-sterile & Sterile Compounding Standards (Sterile Response)

Submitted: March 15, 2026

Executive Summary: The National Association of Pharmacy Regulatory Authorities (NAPRA) released draft model standards to support pharmacy regulatory authorities (PRAs) in implementing consistent requirements for non-sterile and sterile compounding practices across Canada.

CSHP's Sterile Summary Response:

- **Need for Introduction Clarity and Foundational Definitions:** CSHP recommends clarifying compounding vs. manufacturing, batching vs. patient-specific preparation, and outsourcing expectations, strengthening the glossary (e.g., BSC, Level B environments, APIs, biologics, CSTDs), and clearly emphasizing exclusions (reconstitution, manipulation, repackaging).
- **Role Clarity, Governance, and Workload:** The Compounding Supervisor role carries excessive operational responsibility, creating feasibility concerns. CSHP recommends redistributing responsibilities to pharmacy leadership and organizational structures, and allowing flexibility (e.g., Pharmacy Manager vs. Supervisor responsibilities).
- **Training, Competency, and Accreditation Alignment:** CSHP recommends differentiating training and assessment requirements by role, recognizing accredited training programs (e.g., CCAPP, CCCEP), harmonizing competency expectations across jurisdictions, allowing flexibility where existing quality assurance systems are in place, and minimize administrative burden of frequent reassessment.
- **Overly Prescriptive Standards vs. Risk-Based Approach:** CSHP recommends shifting to outcome-based, risk-driven standards, and allowing clinical judgment and facility-level risk assessment to guide: PPE and garbing, cleaning and disinfection practices, environmental controls, and waste handling.
- **Operational Feasibility and System Capacity:** The cumulative requirements introduce significant operational and administrative burden, including extensive documentation and policies, quality assurance and monitoring programs, and frequent competency reassessment, which is particularly challenging for smaller sites, rural, and remote settings. CSHP recommends a proportionate, scalable approach.
- **Infrastructure, Engineering, and Cost Considerations:** Some requirements may not align with existing healthcare infrastructure. CSHP recommends greater flexibility and alignment with engineering and infection control standards, and consideration of cost implications in publicly funded systems.
- **Technology and Implementation Limitations:** CSHP recommends recognizing technology variability across facilities and allowing alternative approaches where needed.
- **Drug Shortages, BUDs, and Waste Reduction:** Rigid requirements (e.g., shortened beyond-use dates, mandatory disposal) may increase medication waste, and exacerbate drug shortages. CSHP recommends allowing evidence-based flexibility in BUDs and supporting risk-based decisions for hazardous waste disposal.
- **Monitoring, QA Programs, and Audit Frequency:** CSHP recommends an ongoing risk-based monitoring approach with focus on identifying and addressing deviations, rather than fixed frequencies of documentation and audits.

38 promenade Auriga Drive, suite/bureau 200, Nepean, Ontario K2E 8A5
Tel./Tél.: 613.736.9733 | Fax/Télec.: 844.438.9397
cshp.ca