



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

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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 Non-Sterile Summary Response:

- **Role Clarity and Feasibility:** While the standards establish accountability, operational responsibilities are disproportionately concentrated on the Compounding Supervisor.
 - CSHP recommends redistributing responsibilities across pharmacy leadership, clarifying the role of Compounding Supervisor, and allowing flexibility (e.g., pharmacy manager vs. supervisor).
- **Differentiation of Training and Competency Requirements:** Training expectations are applied across all personnel, which is not appropriate, given the varying responsibilities and breadth of each role.
 - CSHP recommends differentiating requirements for pharmacy managers, supervisors, third-party assessors, and cleaning staff, recognizing varying competency needs.
- **Recognition of Existing Training and National Alignment:** The standards reference competency mapping but lack clarity on recognizing accredited programs.
 - CSHP recommends recognizing accredited training (e.g., CCAPP, CCCEP), ensuring national harmonization, and clarifying recognition of prior learning.
- **Administrative Burden and System Capacity:** Requirements for competency assessment, documentation, QA programs, and monitoring may create significant burden, particularly in smaller or resource-limited settings.
 - CSHP recommends a risk-based, proportionate approach with flexibility where robust QA systems exist.
- **Third-Party Assessment and Workforce Limitations:** Concerns exist regarding feasibility, cost, limited assessor pools, and workflow disruptions.
 - CSHP recommends a flexible, scalable model appropriate for a publicly funded system.
- **Risk-Based Approach to Standards Implementation:** Many requirements are overly prescriptive.
 - CSHP recommends outcome-based standards allowing clinical judgment and local risk assessment to guide practices.
- **Facility, Environmental, and Operational Considerations:** While risk assessments are appropriate, there is a need for practical tools and examples. Feasibility concerns include cleaning frequency, monitoring, and infrastructure requirements.
 - CSHP recommends clear implementation guidance and flexibility based on facility type and compounding volume.
- **Workforce, Infrastructure, and Implementation Timelines:** Implementation has system implications, including workforce capacity and infrastructure demands, with potential impacts on service availability.
 - CSHP recommends phased implementation, alignment with system capacity, and ensuring standards do not limit patient access to compounding services.