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Submission to:

National Association of Regulatory Authorities
Consultation on:

Model Documents for PRA Use – Non-sterile and Sterile Compounding Standards

March 15, 2026

Submitted by:
Neighbourhood Pharmacy Association of Canada

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) appreciates the opportunity to provide input to the National Association of Pharmacy Regulatory Authorities (NAPRA) regarding the proposed updates to the Model Standards for Pharmacy Compounding of Sterile and Non-Sterile Preparations.

Neighbourhood Pharmacies represents pharmacy operators across the country including chain pharmacies, grocery and mass-merchandiser pharmacies, banner and franchise pharmacies, independent community pharmacies, and pharmacies providing specialty pharmacy services. Collectively, our members operate thousands of pharmacies that serve as essential community health hubs and access points to medications and healthcare services in in urban, suburban, rural, remote and First Nations neighbourhoods.

Neighbourhood Pharmacies supports NAPRA's objective of modernizing and streamlining compounding standards so that compounding practices across Canada can both meet and improve patient safety, product quality, and professional accountability. At the same time, we believe regulatory frameworks should recognize the diversity of pharmacy practice models and ensure that standards remain risk-proportionate, outcomes-focused, and operationally achievable.

Our submission provides both high level commentary applicable to sets of model standards (Sterile and Non-Sterile Compounding) as well as considerations and recommendations regarding a small number of individual standards and indicators.

We have grouped our feedback into the following categories

1. **Emerging Risks**
2. **Operational Impacts:**
    - **Risk Assessments**
    - **Environment and Equipment**
    - **MFRs and BUD Requirements**
    - **Training and Assessment**
3. **Accessibility and Sustainability Considerations**

1. Emerging Risks

The compounding landscape continues to evolve as patient demand and medication markets change. International regulators have recently highlighted concerns related to potentially inappropriate compounding of certain high-demand medications, such as GLP-1 receptor agonists. The federal government has also expressed its concern with these risks and is considering the development of a framework for the oversight of outsourced drug preparation activities in Canada. **We applaud NAPRA taking proactive steps to strengthen the pharmacy regulator system to address these concerns, which should do much to reassure federal policy makers in the drug supply chain that Canadians are well protected by the pharmacy regulatory process.**

However, current Health Canada measures may limit pharmacies' ability to respond effectively to drug shortages. During shortages, pharmacies often compound medications for other pharmacies within and across provinces. Under Health Canada's *Policy on Manufacturing and*

Compounding Drug Products in Canada, certain shortage-related compounding activities risk being interpreted as manufacturing. **We therefore recommend that the draft standards include a clear exemption permitting compounding during any drug shortages as reported on Health Canada's drug shortages website, ensuring these activities are recognized as compounding and remain under NAPRA's jurisdiction.**

2. Operational Impacts on Pharmacies

The proposed standards will have meaningful operational implications across the pharmacy sector, requiring significant infrastructure, facilities and resource enhancements to deliver compounding services. Not all pharmacies that currently provide, or wish to provide, compounding services will be able to meet the proposed requirements, particularly smaller community pharmacies whose limited compounding activities may not support the cumulative operational and compliance demands.

Risk Assessments (Section 2; both Sterile and Non-Sterile Standards.)

A structured framework is required to support Facility Risk Assessments in both sets of Standards. Key terms should be clearly defined, and practical evaluation criteria, processes, or assessment tools should be established to enable pharmacy staff to consistently determine appropriate levels of risk. In particular, the concept of "overall cumulative risk" is currently broad and undefined, leaving significant room for interpretation.

Without a clearly articulated framework, Pharmacy Regulatory Authorities and individual pharmacies may apply the standards inconsistently. This could lead to variation in how risks are interpreted and managed across settings, which may ultimately result in inconsistent delivery of patient care and pharmacy services.

The draft Standards also rely heavily on assumption-based decision-making, which may leave pharmacists feeling legally exposed due to the absence of clear guidance. The Standards also advise supervisors to default to the most stringent interpretation when risk is uncertain, which, while precautionary, may limit service provision if applied overly conservatively or inconsistently.

We recommend NAPRA develop standardized definitions, a clear process or methodology for conducting and documenting risk assessments, and practical examples or templated assessment tools. Establishing this level of guidance would help promote greater consistency in the application of the standards across pharmacy sites and jurisdictions while supporting informed, defensible decision-making by pharmacy professionals.

In addition, the standards require referencing reputable hazardous substance lists, specifically mentioning NIOSH (Indicator 2.2.2). Frequent NIOSH updates (e.g., 2020/2024) can re-categorize common drugs like estrogens, necessitating immediate and costly facility changes. **We recommend that NAPRA adopt a static reference (e.g., NIOSH 2016) or provide a mandatory 12-month lag period following the release of new updates.**

Environment and Equipment (Section 3, both Sterile and Non-Sterile Standards)

The proposed Non-Sterile Compounding standards introduce a strict tiered system (Level A, B, and C). Level B requires an enclosed room with ventilation, while hazardous compounding activities may be directed toward the more stringent Level C requirements. The proposed Sterile Compounding standards introduce a new Level 1 and Level 2 framework.

Pharmacies may need to make substantial infrastructure changes to meet these standards for both Level 2 (Sterile) and Level C (Non-Sterile) activities. For Non-Sterile activities, pharmacies currently operating at Level B may become non-compliant under the proposed framework. Many pharmacies, particularly those operating central fill facilities, have already invested considerably in Level B infrastructure. Requiring a transition to Level C for all hazardous preparations, regardless of preparation volume, would create a significant financial and operational burden. In some cases, the cost of compliance may be too high for pharmacies to continue offering basic compounding services. If pharmacies discontinue these services due to the cost or complexity of compliance, this could create meaningful risks to patient access to timely care.

In addition, the new requirements may create barriers to providing compounding services until facilities are brought into compliance. Pharmacies may be forced to rely on existing compliant facilities even for relatively simple compounds. This reliance could delay patient care, and even one- to two-day delays may be clinically significant in acute situations such as pediatric urinary tract infections where timely access to compounded medications is essential.

Given the significant investment requirement, we recommend NAPRA consider a 3-to-5-year grace period for facilities to achieve full compliance with the new Level C (Non-Sterile) or Level 2 (Sterile) environment standards.

In addition, we also encourage NAPRA consider establishing grandfathering clause for existing Level B facilities that process low volumes of hazardous drugs, provided a robust, documented Assessment of Risk (as per Section 2.1) is on file.

Additional commentary on specific standards:

- 3.1 (Non-Sterile) The definition of “Unauthorized access” in a Level A environment needs clearer interpretation, especially for small pharmacies without the ability to create separate rooms.
- 3.8 (Non-Sterile) Equipment that does not come into direct contact with the mixture being compounded should not necessarily be required to be dedicated exclusively to hazardous compounding. A risk-based approach that distinguishes between direct-contact and ancillary equipment would be more practical and cost-effective, particularly for community pharmacies with limited resources.
- 3.1.7 (Sterile) Clarify when sharps containers must be decontaminated

Master Formulation Records and Beyond Use Dates (Section 6, both Sterile and Non-Sterile Standards)

The purpose of the Master Formulation Records (MFRs) are essentially the same in both the Sterile and Non-Sterile standards but contain expanded requirements. The Non-Sterile standards introduce new documentation expectations related to the development and ongoing maintenance of MFRs for each preparation, as well as the requirement to determine and justify

beyond-use dates (BUDs) using documented evidence. The new level of information required within each MFR will take increased and significant time to compile, maintain, and update for every compounded preparation. While these requirements are intended to strengthen quality assurance, they may create a meaningful operational burden for pharmacy teams, including:

- Heavy documentation demands associated with creating and maintaining detailed MFRs for each compounded preparation.
- Increased internal labour requirements to gather references, complete documentation fields, and maintain revision records.
- Operational strain on pharmacy workflow, particularly for smaller teams with limited administrative capacity.
- Technology limitations, as many pharmacy software platforms do not currently support the additional fields required (e.g., PPE requirements, risk assessment outcomes and rationale, references, calculations, and supporting documentation).

These requirements may have enhanced impacts on pharmacies providing high-volume compounding services who will require substantial lead time for re-calibrating Master Formulation Records (MFRs) across multiple provincial jurisdictions.

These combined administrative responsibilities may shift pharmacy professionals' time and attention away from patient care and clinical activities, placing greater emphasis on documentation and record management rather than direct service to patients.

To minimize some of the additional burden, we urge NAPRA to consider:

Removing the requirement for Master formulation records (and risk assessment records) to include specific DINs, CAS numbers, or other unique identifiers. Active pharmaceutical ingredients and Health Canada–approved products may be interchangeable. Instead, these records should contain sufficient detail to clearly identify the specific product to be used in a given formulation where such specificity is necessary. This approach provides the appropriate level of traceability while accommodating the practical realities of ingredient sourcing and substitution.

Implementing a 3-to-5-year grace period for facilities to achieve full compliance with new documentation requirements.

Training and Assessment of Personnel (Section 1, both Sterile and Non-Sterile Standards)

We recognize that NAPRA is also consulting on the *Components for PRA Approach to Compounding Competence,* which is intended to guide educators, accreditors, and regulators. As such, any new Standards related to training, competency assessment, or ongoing professional development must be aligned with the final approach resulting from the parallel consultation.

Mandatory competency assessments, potential training requirements, and ongoing reassessment expectations may introduce additional administrative responsibilities and costs for pharmacies and pharmacy professionals and may not be feasible across diverse pharmacy practice environments. For example, in-person practical assessments or frequent reassessment

requirements may be challenging for some pharmacy staff, particularly those practicing in rural or remote communities or in settings with limited staffing resources. Access to qualified assessors may also present challenges, particularly for pharmacists and technicians seeking to practice in sterile or hazardous compounding environments where the pool of trained assessors may be limited. Requirements that rely heavily on mandatory in-person training or assessments could create significant logistical and financial burdens for both individuals and organizations.

We recommend NAPRA consider flexible and scalable training and assessment models to ensure competency expectations are achievable across diverse practice settings. Implementation should also incorporate phased timelines, recognition of prior learning and professional experience, and accessible training pathways to support patient safety while minimizing unintended impacts on workforce capacity and patient access to compounding services.

Additional recommendations relating to individual Non-Sterile Standards

- 1.1.1 With appropriate training and supervision, pharmacy assistants could serve as compounding personnel, helping address community workforce shortages without compromising patient safety.
- 1.2.3. Mandating prior compounding experience as a prerequisite for Compounding Supervisors may limit the pool of eligible professionals; alternative competency pathways such as mentorship, accredited education, or supervised training should be considered to maintain a sustainable pipeline
- 1.5.1 Competency assessments should allow qualified pharmacists or technicians within the compounding facility to conduct evaluations using a structured, objective methodology. All assessors, whether internal staff or third-party, should also be actively engaged in compounding practice and trained in all required competencies
- 1.5.3. A three-year interval for competency assessments in non-sterile hazardous compounding would be a more reasonable approach, particularly in cases where there have been no significant changes to the facility, workflow, or risk assessments. Annual assessments may impose an undue administrative burden without a corresponding improvement in safety outcomes in stable environments.
- 1.6. Consider if required training may be developed internally by the compounding pharmacy or delivered by a qualified third-party training provider. This flexibility would allow facilities to adopt fit-for-purpose training solutions while maintaining compliance with the standard.
- 1.6.2, 1.6.3: While this Standard may be managed when pharmacy staff perform cleaning, requiring third-party cleaning personnel to complete separate knowledge and skills assessments for each facility may be impractical and administratively burdensome. A streamlined approach for third-party cleaners should be considered to meet the intent of the requirement without imposing disproportionate oversight obligations.

Entry to Practice Education changes

Although not explicitly stated in the draft standards, we understand the parallel competency framework under development may remove sterile compounding from pharmacy technician

entry-to-practice education requirements, making it an optional post-graduate competency. Given existing shortages of pharmacy technicians across Canada, this shift would likely increase training burdens on employers, create additional recruitment challenges for sterile compounding roles, and add costs for health systems developing in-house training programs. For example, past changes to non-sterile compounding requirements reduced the number of practitioners maintaining these competencies and, in some cases, affected patient access. **We therefore recommend that NAPRA retain sterile compounding as a required entry-to-practice competency for pharmacy technicians in Canada.**

3. Access and Sustainability Considerations

Neighbourhood Pharmacies encourages NAPRA to consider the broader access and sustainability implications associated with the implementation of new compounding standards.

Community pharmacies invest significantly to support the capital, operational, and workforce required to comply with new regulatory requirements. **While pharmacy operators ultimately make independent business decisions about the services they offer, regulatory changes that increase infrastructure, training and administrative obligations can create additional financial pressures for pharmacies seeking to maintain compounding services.**

These pressures may be particularly significant for smaller community pharmacies and independent compounding pharmacies, which may face greater challenges related to infrastructure investments, workforce capacity, and administrative requirements. The investments required to meet new standards may be difficult to absorb within existing pharmacy reimbursement models, particularly in jurisdictions where pharmacies cannot charge fees that fully reflect the additional resources required to provide compliant compounding services. In such circumstances, some pharmacies may determine that continuing to offer certain compounding services is no longer financially sustainable.

Neighbourhood Pharmacies recognizes that NAPRA's primary mandate is to protect public safety rather than regulate pharmacy economics. However, regulatory changes can have downstream impacts on patient access and service availability. If the costs and operational requirements associated with compliance increase significantly without mechanisms to support implementation, some pharmacies may reduce or discontinue compounding activities. This could result in reduced patient choice and diminished local access to compounded medications, particularly in smaller or rural communities.

In this context, consideration could be given to approaches that support sustainable access to compounding services, such as enabling hub-and-spoke models or pharmacy-to-pharmacy collaborations that allow pharmacies to work together to meet compounding needs. Finally, it is also important to remain mindful of the potential for fragmented interpretation and adoption of standards across different provincial regulatory authorities. Inconsistent implementation across jurisdictions may contribute to inequitable access to compounding services for patients depending on where they live. Efforts to promote alignment and consistency in interpretation and application of the standards would help support equitable access to care across Canada.

Summary:

Ensuring that the final standards remain proportionate to the level of risk associated with different types of compounding activities will be important to maintaining patient access to necessary compounded medications. The proposed standards will introduce new operational demands for pharmacies of all sizes, including those operating large-scale compounding facilities as well as smaller organizations performing limited compounding activities. These demands may include infrastructure modifications, financial investments, expanded administrative requirements, and increased staff time devoted to compliance activities rather than patient care and medication management.

Taken together, these changes may create challenges for some pharmacies seeking to maintain compounding services in a manner that meets the proposed standards. In certain cases, the cumulative operational and financial pressures may lead pharmacies to reduce or discontinue some compounding activities, which could have implications for patient access to these important medications.

The comments and recommendations in this submission are intended to support the practical implementation of the proposed standards across diverse pharmacy practice settings, ensuring pharmacies can continue delivering safe, high-quality compounding services while maintaining equitable patient access. We encourage NAPRA to adopt an outcomes-focused approach that preserves flexibility for pharmacy operators to meet the standards in ways that align with their practice models and community needs, supporting patient safety alongside sustainable access to compounded medications.

We welcome further dialogue and engagement to support pan Canadian implementation of these Standards that is consistent, sustainable, scalable and in the best interest of the public safety