



New Brunswick  
College of Pharmacists

Ordre des pharmaciens  
du Nouveau-Brunswick

Building a framework that promotes and supports patient safety is the primary objective behind the introduction of the new Model Standards for Pharmacy Compounding of Non-sterile Preparations published by the National Association of Pharmacy Regulatory Authorities (NAPRA).

### **Member Consultation Update**

**September – October, 2018** The College circulated the *Model Standards for Pharmacy Compounding of Non-sterile Preparations* (the Standards) to all members during an open consultation held between September 20 and October 20, 2018. *Consultation with members is an important step in the process of adopting new direction that affects practice.*

**January, 2019** The Non-sterile Compounding Working Group (WG) reviewed the few submissions and comments received and were satisfied that no evidence was provided that would support amending the Standards as published by the National Association of Pharmacy Regulatory Authorities (NAPRA). Therefore, they were unanimous in their recommendation that Council adopt the Standards as written, in New Brunswick.

The WG was comprised of the following members:

Pharmacy Technicians Judy Kennedy and Aimee Kohler;

Pharmacists Katina Williams, Shelonie Cooley, Elaine Godin and Nathalie Losier-Mallet

### **Adoption of the Standards**

**February, 2019** At its meeting on February 4th, 2019 Council adopted the *Model Standards for Pharmacy Compounding Non-Sterile Preparations* [[LINK](#)] as the minimum standards for non-sterile compounding in New Brunswick pharmacies and by New Brunswick pharmacists and pharmacy technicians.

The *Guidance Document for Pharmacy Compounding of Non-sterile Preparations* [[LINK](#)] published by NAPRA in conjunction with the Standards was accepted by Council as a resource for pharmacy professionals, if needed.

### **Implementation**

**2019 - 2021** Council approved **July 1, 2019** as “Day 1” of the implementation period, allowing current compounding pharmacies up to 24 months from “Day 1” to be fully compliant. The Working Group recommended an implementation timeline and plan that was also accepted by Council at its February meeting.

1. ***How does this affect you?***

Pharmacies that are already engaged in non-sterile compounding today must adhere to the implementation plan [[LINK](#)] for the new Standards and be fully compliant by July 1, 2021.

New pharmacies who plan to offer non-sterile compounding services, or pharmacies that have yet to begin offering the service, must be compliant effective July 1, 2019.

The Working Group felt preparation of additional guidance for members would aid with implementation of the new Standards and recommended the following as part of the implementation plan:

- **FAQ document** - to address some of the issues either not in the Standards or Guidance Document, or that lack specificity
- **Commentary: Assessing Knowledge and Technique when Compounding** - to accompany the Standards and Guidance documents, which will serve as a caution to members. The WG felt some risks inherent in compounding were not adequately addressed, and concerns raised during consultation needed to be acknowledged.

**July 1, 2019**

**“Day 1” - Model Standards for Pharmacy Compounding of Non-sterile Preparations come into force**

Implementation of the Standards may be carried out in phases over 24 months for pharmacies currently engaged in compounding, although adherence of the full standards may also be met prior to the deadlines. Compliance requirements are set out in six-month intervals from “Day 1”, with the following deadlines:

**Phase 1 – January 1, 2020: Gap analysis**

**Phase 2 – July 1, 2020: Risk Assessment, personnel training, policies and procedures**

**Phase 3 – January 1, 2021: Quality assurance**

**July 1, 2021: Fully compliant**

**Visit the Practice Requirements page on the College website**

**<https://www.nbpharmacists.ca/site/practice-rqmts> or access the links below for more information.**

Model Standards for Pharmacy Compounding Non-Sterile Preparations [[LINK](#)]

The *Guidance Document for Pharmacy Compounding of Non-sterile Preparations* [[LINK](#)]

Implementation Timeline & Checklist for Pharmacies Currently Engaged in Compounding [[LINK](#)]

Commentary: Assessing Knowledge and Technique when Compounding [[LINK](#)]

FAQ [[LINK](#)]

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