

# Non-Sterile Compounding Standards and Implementation

## Key Resources to Support Implementation

- [Checklist for each phase of implementation](#)
- [Recording of November 4, 2020 webinar on non-sterile compounding](#)
- Slides also available in [Part 1](#), [Part 2](#) and [Part 3](#)
- [Frequently asked questions](#)

*Additional resources available on this page, including assessment criteria and relevant Pharmacy Connection articles.*

**Please note that on March 23, 2020, Board (Council) approved an extension to the deadlines for implementation of the non-sterile compounding standards (see implementation section below).**

In December 2017, Board (Council) [adopted](#) the National Association of Pharmacy Regulatory Authorities (NAPRA) [Model Standards for Pharmacy Compounding of Non-Sterile Preparations](#). The standards are accompanied by a [Guidance Document for Pharmacy Compounding of Non-Sterile Preparations](#).

**The standards apply to ALL pharmacies that perform any type of non-sterile compounding in any quantity, whether once in a while or every day.**

It is the responsibility of Designated Managers and pharmacy professionals to ensure that they stay up-to-date by reviewing this page and College communications regularly.

## About the Standards

The implementation and adherence to these standards is an important way pharmacy professionals can protect patients, increase patient safety and protect pharmacy personnel.

Model standards represent the minimum requirements that must be met by all pharmacists and pharmacy technicians who compound non-sterile preparations. All practice sites must meet this standard and the performance of pharmacy professionals engaged in the practice of non-sterile preparation will be measured with these standards.

These standards have replaced the College's *2006 Guideline for Compounding Preparations*.

## Implementation

In recognition of the evolving COVID-19 pandemic situation and the need for pharmacy professionals to focus on continuity of care and minimizing public risk, on March 23, 2020, Board (Council) approved an extension of the deadlines for pharmacies to meet the standards. The updated timelines for completion of each phase are:

- **Phase 1:** January 1, 2020 – Assessing Risks and Gaps
- **Phase 2:** July 1, 2021 – Personnel Training and Quality Assurance
- **Phase 3:** January 1, 2022 – Facilities and Equipment

**In Phase 1**, evaluating the pharmacy's current practice environment is a priority, with the goal of implementing appropriate procedures and quality controls to protect patients and compounding personnel. For more information on Assessing Risks and Gaps, please refer to the Pharmacy Connection article [Implementation Timeline for Non-Sterile Compounding Standards](#).

**In Phase 2**, the priority will be the training and assessment of all personnel engaged in non-sterile compounding. Quality assurance processes need to be put in place to monitor compliance with the standards and safety in the system.

**In Phase 3**, the focus will be on ensuring that the facility and equipment for the preparation of hazardous and non-hazardous non-sterile compounds are in compliance with the standards. A quality assurance program will need to address facilities, equipment, personnel, compounded non-sterile preparations and documentation.

**It is the College's expectation that pharmacies are currently engaged in preparing for the implementation of the standards by January 1, 2022.**

## Key Resources from the College

To assist pharmacy professionals as they work to implement the standards, the College has provided:

- **a fillable checklist for each phase of implementation**
- **frequently asked questions**
- **recording of a webinar held on November 4** (*depending on your system, it may be necessary to download Adobe Connect to view the recording*)
  - Part 1 Slides (timelines and implementation dates, rationale for standards, overview of standards and guidance documents)
  - Part 2 Slides (risk assessments, requirements for all levels, level B&C requirements, compounding hazardous preparations)
  - Part 3 Slides (risk-based approach, patient assessment, challenges and alternatives, key resources, assessment criteria)

In addition, please see the assessment criteria document and list of relevant Pharmacy Connection articles below.

## Assessment Criteria

The College has produced a [Non Sterile Preparations Assessment Criteria](#) document. This document is intended to be used by pharmacy professionals to assess the gaps between current processes/practices at the pharmacy and the requirements of the standards.

The document lays out each standard and the accompanying section in the guidance document to illustrate specific insights or activities required to ensure adherence to the standard. Pharmacy professionals can “check off” each standard as it is met and track their progress at meeting the standards. However, this document is not meant to replace the standards.

As outlined above, it is the College's expectation that pharmacies will have assessed their risks and gaps by January 1, 2020 to prepare for the implementation of the personnel training and quality assurance components by July 1, 2021.

## Pharmacy Connection Articles

- [Master Formulation Records and Compounding Records: What's the Difference?](#) (Winter/Spring 2021)
- [Non-Sterile Compounding Phase 2: How to Meet the July 1, 2021 Deadline](#) (Winter/Spring 2021)
- [Training and Facilities Questions](#) (Fall 2020)
- [Staying on Track for Full Implementation](#) (Spring/Summer 2020)
- [Phase 2 Implementation](#) (Winter 2020)
- [Preparing for Phase 2](#) (Fall 2019)
- [The Community Pharmacy Experience](#) (Summer 2019)
- [A Closer Look at Personal Protective Equipment](#) (Summer 2019)
- [Non-Sterile Compounding FAQs](#) (Summer 2019)
- [Preparing for the First Phase of Non-Sterile Compounding Compliance: The Hamilton Health Sciences Experience](#)
- [Timelines Announced for Non-Sterile Compounding Standards](#) (Winter 2019)
- [How Are You Preparing for the New Standards on Non-Sterile Compounding?](#) (Summer 2018)
- [New Model Standards Apply to All Pharmacies Performing Non-Sterile Compounding](#) (Spring 2018)
- [Compounding: Are You Doing It?](#) (Winter 2018)



## Helpful Links

[MASTER FORMULATION RECORDS AND COMPOUNDING RECORDS: WHAT'S THE DIFFERENCE?](#) ▶

[MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS \(NAPRA\)](#) ▶

[GUIDANCE DOCUMENT: MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS \(NAPRA\)](#) ▶

[FAQS ON IMPLEMENTATION OF STANDARDS FOR NON-STERILE COMPOUNDING](#) ▶

---

[NAPRA DECISION ALGORITHM](#) ▶

---

[PRINTABLE AND FILLABLE FORMS AND CHECKLISTS \(NAPRA\)](#) ▶

---

[COMPOUNDING PRACTICE TOOL](#) ▶

---

[NON STERILE PREPARATIONS ASSESSMENT CRITERIA](#) ▶

---



483 HURON STREET  
TORONTO, ON M5R 2R4  
TEL: 416-962-4861  
(1-800-220-1921)

Copyright © 2021 Ontario College of Pharmacists. All Rights Reserved.

