

# NON-STERILE COMPOUNDING PHASE 2 IMPLEMENTATION:



## *Placing the Focus on Training, Quality Assurance and Policies and Procedures*

The [NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations](#) apply to every pharmacy and pharmacy professional engaged in compounding.

The standards are accompanied by a [Guidance Document for Pharmacy Compounding of Non-Sterile Preparations](#) which provides pharmacists and technicians who compound non-sterile preparations with the details necessary to evaluate their practice, develop service-related procedures, and implement appropriate quality controls for the protection of both patients and compounding personnel.

The standards have been developed to support the safety and quality of pharmacy care in the province. Meeting and adhering to these standards is an important way to protect patients and prevent harmful incidents. The standards are also an important way to protect pharmacists, pharmacy technicians and others involved in compounding from the potential harmful effects of these drugs and substances.

### **THE IMPORTANCE OF CONTINUITY OF CARE**

Compounding is within the scope of practice and authorized acts for pharmacy professionals defined in the *Pharmacy Act*, and compounding non-sterile

preparations according to recognized guidelines and standards is an entry-to-practice competency for both pharmacists and pharmacy technicians. It is reasonable that the public and other health practitioners expect any pharmacy to provide some compounding services. The requirements for “all levels of compounding” (Section 5 in the NAPRA standards), corresponding to Level A, should be attainable for all pharmacies already engaged in compounding. Moreover, the [Code of Ethics](#) expects that “members make every reasonable effort to provide quality cost-effective pharmacy care and services to patients and society.”

As explained in the standards, “given that pharmacists and pharmacy technicians are expected to maintain competency in basic compounding skills, they are also expected to provide compounded preparations within their level of expertise and within the limitations of available and appropriate facilities and equipment.” The Designated Manager/department head must ensure, with the best interest of the patient in mind, that the pharmacy has the resources necessary to compound a preparation in a safe

and appropriate manner. When this is not possible, they have an ethical obligation to “assume responsibility for making reasonable efforts to ensure continuity of patient care when they are unable to provide requested pharmacy services.” Patient care should not be jeopardized by abrupt cessation of compounding services due to the transition to the new standards.

### **AN OVERVIEW OF PHASES 1, 2 AND 3**

The College has prepared a checklist to provide guidance to pharmacy professionals and pharmacies as they work to implement the requirements but it is not intended to replace the standards. It is the responsibility of the pharmacy professional/pharmacy to review and ensure compliance with the standards. For more information about implementation, please visit the [Non-Sterile Compounding Key Initiative](#) on the OCP website.

All sections referred to in parentheses are from the Guidance Document for Pharmacy Compounding of Non-Sterile Preparations document.

## PHASE 1 – DEADLINE JANUARY 1, 2020

Verify that the following requirements have been completed, according to the deadline for implementation of Phase 1. Pharmacies and registrants should now be working towards completing the requirements for Phase 2.

- Review the [NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations](#) and the [Guidance Document for Pharmacy Compounding of Non-Sterile Preparations](#).**
  - ▶ Read the *Pharmacy Connection* article [Timelines Announced for Non-Sterile Compounding Standards \(Winter 2019\)](#).
  - ▶ Read the *Pharmacy Connection* article [Implementing the Non-Sterile Compounding Standards: The Community Pharmacy Experience \(Summer 2019\)](#).
  - ▶ Read the *Pharmacy Connection* article [Consider These Steps While Preparing for the First Phase of Non-Sterile Compounding Compliance: The Hamilton Health Sciences Experience \(Spring 2019\)](#).
- Designate a regulated pharmacy professional to be the non-sterile compounding (NSC) supervisor. (Section 5.1)**
  - ▶ Identify all personnel engaged in non-sterile compounding and associated cleaning.
- Evaluate the pharmacy's current and/or anticipated compounding services and preparations to assess and determine risk. (Section 4)**
  - ▶ Identify the non-sterile preparations being compounded and the compounding ingredients (including any Active Pharmaceutical Ingredients) required. (Section 6.3)
  - ▶ Determine if each preparation is still being made or if a comparable manufactured product is commercially available, therefore eliminating the need for compounding. (Section 2.1 and 3)
  - ▶ Identify ingredients classified as hazardous by reviewing the [NIOSH List of Hazardous Drugs](#).
  - ▶ Identify ingredients that pose a potential health hazard according to WHMIS by reviewing the safety data sheets (SDS) provided by the supplier or manufacturer.
  - ▶ Perform a risk assessment for each preparation compounded by the pharmacy using the [Decision Algorithm for Risk Assessment](#) as a guide. (Section 4.2)
- Determine, using the results of the risk assessments and taking into account the frequency and quantity of compounding and risk mitigation measures, if your pharmacy compounding space currently meets the requirements needed to prepare Level A, B, or C compounds (Section 8)**
  - ▶ Read the *Pharmacy Connection* article [Implementing the Non-Sterile Compounding Standards: A Closer Look at Personal Protective Equipment \(Summer 2019\)](#).
  - ▶ Read the [Non-Sterile Compounding FAQs](#)
- Perform a gap analysis to compare the pharmacy's current practices to the minimum standards.**
  - ▶ The [Non-Sterile Compounding Assessment Criteria document may be used for this activity](#).
  - ▶ Identify any gaps in the knowledge and skills of compounding/cleaning personnel. (Section 5.2)
  - ▶ Develop a plan of action to address the identified gaps based on the Phase 2 and 3 implementation deadlines.
  - ▶ Read the *Pharmacy Connection* article [Preparing for Phase 2 of the Non-Sterile Compounding Standards \(Fall 2019\)](#).

## PHASE 2 – DEADLINE JULY 1, 2021

In Phase 2, policies and procedures to meet and maintain the standards, including personnel training, should be developed along with a quality assurance program. Planning for Phase 3 should happen in tandem with Phase 2, as the physical or space changes needed may require additional time and resources.

- Create Master Formulation Records for each preparation, which must include all necessary information to compound the preparation. (Section 6)**
  - ▶ Assign a beyond-use date for each preparation. (Section 6.1)
- Develop policies and procedures for all aspects of non-sterile compounding. (Section 5.3)**
  - ▶ Begin with those related to personnel (e.g., conduct, hygiene, attire).
  - ▶ Hazardous preparations require additional policies and procedures. (Section 9.3, 9.4, 9.5)
- Complete a skills assessment for existing non-sterile compounding/cleaning personnel. (Section 5.2)**
- Develop a training program for non-sterile compounding personnel. (Section 5.2)**
  - ▶ Ensure there is training on policies and procedures as they are developed.
- Develop a quality assurance (QA) program for personnel to verify ongoing effectiveness of, and compliance with, policies and procedures. (Section 7.3, 7.4)**
- Begin developing other components of the pharmacy's QA program. (Section 7)**

## PHASE 3 – JANUARY 1, 2022

In Phase 3, the focus will be on ensuring that the facility and equipment required for the preparation of all non-sterile compounds are in compliance with the standards.

- Establish protocols and schedules for cleaning and maintenance of the compounding area facilities and equipment to maintain the quality and integrity of the final preparations. (Section 5.4)**
  - ▶ Document these activities in the general maintenance log. (Section 5.4)
  - ▶ Ensure facilities and equipment (including C-PEC) is certified and maintained as per standards. (Table 6)
  - ▶ Implement proper deactivation, decontamination, and cleaning procedures for hazardous preparations. (Section 9.2, 9.3)
  - ▶ Ensure that an environmental monitoring plan is in place for hazardous preparations. (Section 9.6)
- Ensure that the proper facilities are in place for Level C requirements, including lighting, heating, ventilation and air conditioning systems, water supply, work surfaces, furniture, walls and flooring. (Section 9.1)**
- Develop a quality assurance program for facilities, equipment, preparation processes (including those in Section 6), and documentation (Section 7).**