Newfoundland and Labrador Pharmacy Board

Implementation Schedule for Non-Sterile Compounding Standards

Approved February 2019
Revised May 2020

Introduction

Compounding plays an important role in pharmacy practice, allowing individual ingredients to be mixed together in personalized strengths and dosages based on patients' needs.

Pharmacists and pharmacy technicians must be familiar with Health Canada's Policy on *Manufacturing and Compounding Drug Products in Canada*[1]. Health Canada considers compounding to be the following:

> *The combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing. It can involve raw materials or the alteration of the form and strength of commercially available products. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug's labelling material (Aside added: "within the normal practice of pharmacy").*

High-quality standards are needed to ensure preparation quality and safety when compounding drugs for patients. Evolving practice as well as increased awareness of the risks associated with compounding, led the National Association of Pharmacy Regulatory Authorities (NAPRA) to develop new model standards for pharmacy compounding of non-sterile products, and the NL Pharmacy Board (NLPB) to subsequently adopt these standards[2]. NLPB also adopted NAPRA's *Guidance Document for Pharmacy Compounding of Non-Sterile Preparations*[3] to further clarify the non-sterile compounding standards and provide guidance for implementation.

The *Standards for Pharmacy Compounding of Non- Sterile Preparations* are intended to better protect the safety of both patients and personnel involved in non-sterile compounding, and to promote consistency in the provision of this service. These are the minimum standards that registrants engaged in non-sterile compounding are expected to meet. Regardless of position or practice environment, when a registrant performs a specific role, they must perform it to the level specified in Standards of Practice and meet all of the standards associated with that role.

Implementation Plan

It is recognized that the new non-sterile compounding standards may represent significant changes to pharmacy practice, and that pharmacy teams will require time to: develop or revise policies and procedures, perform risk assessments of compounds, appropriately train personnel, upgrade equipment and facilities, and develop and implement a quality assurance program.

This implementation plan is intended to provide guidance for assessing gaps in compliance and to assist with prioritizing action items. Each phase in the plan includes what work should be started and what specific standards must be met by the end of that phase. The phases divide implementation deadlines over a two-year or three-year timeframe, depending on the complexity of compounding services, to ensure successful implementation of the standards.

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[1] Available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/policy-manufacturing-compounding-drug-products.html
[2] http://www.nlpb.ca/media/SOPP-Compounding-Nonsterile-Standards-March2018.pdf
[3] http://www.nlpb.ca/media/SOPP-Compounding-Nonsterile-Guidance-March2018.pdf

Pharmacies and pharmacy professionals currently involved in Level A non-sterile compounding must be in full compliance with the approved standards **by no later than December 31, 2020.** Pharmacies that require significant modifications in order to meet Level B or C facility requirements must complete renovations **by no later than December 31, 2021.** New pharmacies, or existing pharmacies that wish to initiate new compounding activities, are required to meet the standards in their entirety before engaging in this practice.

It is the responsibility of pharmacy management and personnel to ensure the safety and quality of pharmacy practice, and to mitigate any risks that compounding activities may pose to patients and personnel. Registrants must make every effort to fully meet the *Standards for Pharmacy Compounding of Non-Sterile Preparations* at the earliest possible date.

Non-Sterile Compounding Standards - Implementation Schedule	

Phase 1:
• Review Standards and Guidance documents
• Complete gap analysis
• Create action plan
 	
Complete by December 31, 2019
	• **Standard 4 – Assessing Risk for Compounding Non-Sterile Preparations**
	  ○ Identify the levels of requirements for the compounds that are prepared (refer to algorithm in the NAPRA guidance document- GD 4.1-4.3).
	  ▪ Refer to the NIOSH list, MSDS and WHMIS to determine level of risk to the compounding personnel.
	• **Standards 5.1, 5.2 – Compounding Personnel; Training and Skills Assessment**
	  ○ Familiarize with compounding personnel roles and responsibilities outlined in the Standards.
	  ○ By the end of Phase 1, a compounding supervisor should be assigned to facilitate implementation planning, or a plan in place to assign this role early in Phase 2. (GD 5.1.2)
	  ○ Identify all personnel who will require training and skills assessment, including cleaning personnel.
	• **Standard 5.3 – Policies and Procedures**
	  ○ Determine policies and procedures that need to be developed and construct timeline for development. (GD 5.3.1)
	  ▪ Policy development should start in Phase 1, and carry forward in Phase 2 and 3 based on the requirements of that phase. (GD 5.3.2)
	• **Standard 5.4 – Facilities and Equipment**
	  ○ Identify any equipment upgrades and renovations that are necessary in order to meet general facility requirements.
	• **Standard 6 – Product and Preparation Requirements**
	  ○ A pharmacist must review/approve Beyond-Use Dates (BUDs) for all compounds as part of the risk assessment process. (GD 6.1)
	  ○ Start the process of completing master formulation records (all compounds must have a master formulation record by end of Phase 2). Ensure master formulations are comprehensive and evidence-based with safety data sheets for each chemical used. (GD 6.2)
	  ○ Meet the standards for ingredients used for compounding (GD 6.3), compounding records (GD 6.4), conduct of personnel (GD 6.5), and verification of compounds (GD 6.6).
	• **Standard 8 – Levels of Requirements**
	  ○ Determine the level of requirements (Level A, B, or C) applicable to the practice site.
	  ○ Complete renovation plan, also taking into account Standard 5.4. **Note that pharmacists-in-charge must apply to NLPB in order to complete renovations.**
	• **Standard 9 – Requirements for Hazardous Preparations**
	  ○ Facility requirements for level C compounding must be in place by the end of Phase 3. However, pharmacy management must implement risk mitigation measures wherever possible in the interim.
	  ○ Compounding personnel must wear appropriate PPE for hazardous non-sterile compounding activities. (GD 9.2.3)
	  ○ Ensure processes are in place for:
	  ▪ Deactivating, decontaminating, and cleaning in areas reserved for the compounding of hazardous non-sterile preparations; and

	▪ Incident, accident, and hazardous waste management. (GD 9.3, 9.4, 9.5)
Phase 2: • Train Compounding and Cleaning Personnel • Develop and partially implement Quality Assurance (QA) Program • Meet all Level A compounding requirements **Complete by December 31, 2020** **Revised Deadline: December 31, 2021**	• **Standards 5.1, 5.2 – Compounding Personnel; Training and Skills Assessment** ○ Refer to the template checklist regarding responsibilities for pharmacy personnel (regulated and non- regulated) and delineate these responsibilities, noting the responsibilities for non-hazardous and hazardous non-sterile compounding. (GD 5.1.3, 5.1.4, 5.2.1, 5.2.1.1) ○ Appropriately train all personnel involved in non-sterile compounding, and develop a skills assessment program that considers the type and complexity of compounding. ○ Train and assess cleaning personnel. (GD 5.2.2) • **Standard 5.3 – Policies and Procedures** ○ Complete policies and procedures, with the exception of those related to facility upgrades for Level B and C compounding and final stages of the QA program. • **Standard 5.4, 8 – Facilities and Equipment; Levels of Requirements for Level A, B, C** ○ Meet all requirements for Level A. ○ Renovations to meet facility requirement for B and C compounding should be in progress. • **Standard 6 – Product and Preparation Requirements** ○ Complete master formulation records, including all necessary information to compound a non-sterile preparation. (GD 6.2, Template 2) • **Standard 7 – Quality Assurance** ○ Develop policies and procedures for components of quality assurance program (GD 7.6). ○ Implement quality assurance processes for personnel (GD 7.3), and adherence to policies and procedures. (GD 7.4) ○ Implement quality assurance processes for equipment and compounding areas as facility and equipment upgrades take place; note that appropriate refrigerators for drug storage, with continuous temperature monitoring, should already be in place as a requirement of the *Standards of Pharmacy Operation* for both community and hospital pharmacies. (GD 7.2) ○ Document quality control activities. (GD 7.5) • **Standard 9 – Requirements for Hazardous Preparations** ○ Complete policies and procedures for Standards 9.3, 9.4, and 9.5.
Phase 3: • Complete QA program • Meet all Level B and C requirements **Complete by December 31, 2021** **Revised Deadline: December 31, 2022**	• **Standard 5.4, 8.2, 8.3, 9.1, 9.2, 9.6 – Facilities and Equipment; Levels of Requirements for Level B, C; Requirements for Hazardous Preparations** ○ Meet all requirements for Level B and C compounding. ○ Complete facilities and equipment to meet the requirements for lighting, heating, ventilation and air conditioning systems, water supply, work surfaces, furniture, walls, and flooring. (9.1) ○ Ensure appropriate C-PEC is installed, maintained, and verified. (GD 9.2, 9.3, 9.6) ○ Implement environmental monitoring. (GD 9.6.3) ○ Establish protocols and schedules for cleaning facilities and equipment in order to ensure proper deactivation and decontamination (if applicable), and to maintain quality and integrity of the final preparations. (GD 5.4.2, 9.3) ○ Plan routine maintenance for all facilities and equipment, and establish a general maintenance log. (GD 5.4.2) • **Standard 7– Quality Assurance** ○ Complete the development and implementation of the quality assurance program for Level B and C compounding.