Newfoundland and Labrador Pharmacy Board

Implementation Schedule for Sterile Compounding Standards

Approved February 2019

Introduction

Compounding plays an important role in pharmacy practice, allowing individual ingredients to be mixed together in personalized strengths and dosages based on patient's 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 of compounding sterile preparations on the health of both patients and compounding personnel, led the National Association of Pharmacy Regulatory Authorities (NAPRA) to develop new model standards for pharmacy compounding of both hazardous and non-hazardous sterile products in 2015 and 2016, respectively, and the NL Pharmacy Board (NLPB) to subsequently adopt these standards[2,3].

It is important note that, while reconstitution is not included in Health Canada's definition of compounding, the Standards state that sterility is also required for reconstitution and certain manipulations (according to manufacturer's instructions) of sterile products approved by Health Canada and for the repackaging of approved sterile products, regardless of the route of administration [2,3].

According to Health Canada, "c*ompounding of sterile products is only permitted in hospitals or other practice settings where carefully established standards for the operation of clean rooms and the preparation of sterile products are in place and documented, in accordance with a recognized source"*.[1]

The *Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations* and the *Standards for Pharmacy Compounding of Hazardous Sterile Preparations* are intended to better protect the safety of both patients and personnel involved in sterile compounding, and to promote consistency in the provision of this service. These are the minimum standards that registrants engaged in 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.

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[1] Policy on Manufacturing and Compounding Drug Products in Canada POL-0051 (January 2009): 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] Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations (February 2016): http://www.nlpb.ca/media/SOPP-Compounding-Sterile-Non-Hazardous-Feb2016.pdf

[3] Standards for Pharmacy Compounding of Hazardous Sterile Preparations (February 2017): http://www.nlpb.ca/media/SOPP-Compounding-Sterile-Hazardous-Feb2017.pdf

Implementation Plan

While current pharmacy practice for the preparation of sterile products should already include many of the patient and quality assurance requirements contained in the sterile compounding standards, it is recognized that for some pharmacies implementation of these standards requires significant time and resources to:

- Develop or revise policies and procedures;
- Appropriately train compounding and cleaning personnel;
- Upgrade equipment and facilities; and
- Develop and implement a quality assurance program for sterile compounding.

This three-year implementation plan is intended to provide guidance for assessing gaps in compliance, to assist with prioritizing action items, and to ensure successful implementation of the Standards. Each phase in the plan includes what work should take place during that phase and what specific standards must be met by the end of that phase.

Pharmacies and pharmacy professionals currently involved in sterile compounding must be in full compliance with the approved standards for pharmacy compounding of sterile products **by no later than December 31, 2021.** New pharmacies, or existing pharmacies that wish to initiate sterile 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-Hazardous Sterile Preparations* and the *Standards for Pharmacy Compounding of Hazardous Sterile Preparations* at the earliest possible date.

Sterile Compounding Standards Implementation Schedule	
Phase 1 (Assessing Risks and Gaps): • Familiarize with applicable Standards (hazardous and/or non-hazardous) • Complete gap analysis within 3 months and send to NLPB when complete • Identify risk mitigation measures and implement to the extent that is possible **Complete by December 31, 2019**	• **Standard 5.1 – Personnel** ○ Familiarize with roles and responsibilities ○ By the end of Phase 1, sterile compounding supervisor should be assigned to facilitate implementation planning, or a plan in place to assign this role early in Phase 2. ○ Gaps in training and assessment of compounding and cleaning personnel must be identified, and upgrades to the training program and staff training started. ○ Plans should be made to implement competency assessments of compounding personnel at the earliest possible date. • **Standard 5.2 – Policies and Procedures** ○ Identify policies and procedures that must be developed and complete a policy development schedule that permits completion of all policies and procedures by the end of 2020. Policy development should start in Phase 1. • **Standard 5.3 – Facilities and Equipment** ○ Review Standards and identify equipment needs and facility upgrades that are required; start planning any necessary equipment upgrades or facility renovations. **Note that pharmacists-in-charge must apply to NLPB in order to complete renovations.** ○ Appropriate personal protective equipment and clothing, and appropriate agents for decontamination, deactivation and disinfection must be identified and utilized at the earliest opportunity. (5.3.3.3; 5.4) • **Standard 6 – Product and Preparation Requirements** ○ Assign appropriate beyond-use-dates (BUDs) to compounded sterile preparations (CSPs), prioritizing patient safety and mitigating any risks associated with the facility to the extent that is possible. ○ Standards associated with the compounded sterile preparation log, patient file, conduct of sterile compounding personnel, aseptic technique, packaging, receipt of hazardous products, transport and delivery of CSPs, recall of CSPs, incident and accident management, and waste management must be in place (6.3-6.12, with the exception of

	6.8.2. if renovations are required in order to meet requirements for storage of hazardous products). ○ The pharmacy team should start reviewing and revising CSP protocols in this phase. (6.2, Appendix 7) • **Standard 7 – Quality Assurance Program** ○ Review quality assurance program requirements and consider timeline required for implementation. Quality assurance of personnel involved in aseptic compounding should be implemented at the earliest opportunity to reduce risk of product contamination.
Phase 2: • Train compounding and cleaning Personnel • Complete development of policies and procedures • Develop and partially implement quality assurance program **Complete by December 31, 2020**	• **Standard 5.1 – Personnel** ○ All requirements must be fully met. • **Standard 5.2 – Policies and Procedures** ○ All requirements must be fully met. • **Standard 5.4 – General Maintenance Log** ○ Records must be in place for cleaning and disinfecting, and certification, maintenance, and verification of equipment and facilities. This may not be fully complete until the end of Phase 3, pending completion of facility renovations; however, cleaning, disinfecting and maintenance activities must be implemented and documented to the extent that is possible. • **Standard 6.2 – Compounded Sterile Preparation Protocols** ○ CSP protocols must be completed by the end of this phase. • **Standard 7 – Quality Assurance Program** ○ Quality assurance program must be fully developed and implemented, with the exception of aspects of 7.3 that are dependent on completion of renovations.
Phase 3: • Complete facility upgrades • Complete quality assurance program **Complete by December 31, 2021**	• **Standard 5.3 – Facilities and Equipment** ○ All necessary renovations must be complete and the facility must meet all requirements outlined in the Standards. • **Standard 7.3 – Quality Assurance Program** ○ Final components of the program for verification of equipment and facilities must be implemented. • **Standard 6.1 – Beyond-Use Date and Dating Methods** ○ Establish documented beyond-use dates and dating methods based on completion of facility upgrades, and update CSP protocols where necessary. By the end of Phase 3, the *Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations* and *Standards for Pharmacy Compounding of Hazardous Preparations* must be fully met.