Implementation Schedules for Sterile and Non-sterile Compounding Standards

Objectives

- Introduce new implementation guidelines for compounding standards
- Address questions from registrants
- Seek feedback on implementation challenges to guide NLPB communications and educational activities

NEWFOUNDLAND & LABRADOR
PHARMACY BOARD

Definition of Compounding

Health Canada's Policy on Manufacturing and Compounding Drug Products in Canada.

- *"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"*

- *While reconstitution is not included in definition of compounding, 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*

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

History

Sterile Compounding

- **NAPRA Model Standards**
  - Standards for Pharmacy Compounding of Hazardous Sterile Preparations (adopted February 2016)
  - Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations (adopted February 2017)
- Primarily carried out in hospital pharmacies in NL
- Represent significant changes
  - Policy development, personnel training, infrastructure, quality assurance
- Sterile compounding is a complex practice with complex regulatory requirements
- Feedback from hospital pharmacy management and personnel that guidance would be helpful in implementation planning and process, and to manage cost implications

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

History

Non-Sterile Compounding

- **NAPRA Model Standards**
  - Standards for Pharmacy Compounding of Non-Sterile Preparations
  - Guidance Document for Pharmacy Compounding of Non-Sterile Preparations (Companion Document)
  - Both adopted in principle February 2018
- ALL pharmacies (community and hospital) compound to some degree
- Feedback from hospital pharmacy personnel that it would be helpful to coordinate the development of implementation plans for sterile and non-sterile compounding standards

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Implementation Guidelines

- Implementation Plan for Non-Sterile Compounding Standards
- Implementation Plan for Sterile Compounding Standards

*Both approved in February 2019

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Development of Implementation Plans

Implementation plan for sterile compounding standards

- Fall 2018- Task force of registrants struck to review plans from other provinces and provide feedback on a NL-specific plan
  - Representatives from across province, management and frontline staff, pharmacists and technicians
  - Board members- Hospital and Public Representatives
- Feedback used to develop draft
- Draft circulated to all task force members for review and additional feedback as well as Department of Health representative
- Final draft presented to Board

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Development of Implementation Plans

Implementation plan for non-sterile compounding standards

- Summer 2018- Call for interest circulated to all registrants
- August 2018- Task force struck
  - Representatives from various compounding backgrounds, pharmacists and technicians, community and hospital
- Reviewed proposed implementation schedule that was being discussed nationally and provided feedback
- Draft NL plan developed and discussed
- Final plan presented to Board

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

General Concepts

- Phased plans
  - Phase 1- Assessment and planning
  - Phase 2- People and processes
  - Phase 3- Completion of major renovations
- New pharmacies, or existing pharmacies that wish to initiate new compounding activities, are required to meet the standards in their entirety priority to offering service
- 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 at the earliest possible date
- If unsure, assume the highest level of risk

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Implementation Plan for Sterile Compounding Standards

- **Phase 1- (Complete by December 31, 2019)**
  - Familiarize with applicable Standards (hazardous and/or non-hazardous)
  - Complete gap analysis within 3 months (from release of tool) and send to NLPB when complete
  - Identify risk mitigation measures and implement to the extent that is possible
- Key action items:
  - Identify a compounding supervisor and roles of personnel
  - Identify gaps in training and prioritize implementation of competency assessments
  - Identify policies and procedures that need to be developed and prioritize, start the development
  - Identify equipment and facility upgrades that will be required and start renovation planning- Don't forget to submit an application in advance!
  - Meet product preparation requirements
  - Assign appropriate BUDs, prioritizing patient safety
  - Familiarize with QA requirements, prioritize QA activities for personnel

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Implementation Plan for Sterile Compounding Standards

- **Phase 2 (Complete by December 31, 2020)**
  - Train compounding and cleaning Personnel
  - Complete development of policies and procedures
  - Develop and partially implement quality assurance program
- Action Items:
  - Complete work that was planned and started in Phase 1
  - Implement record keeping processes for cleaning, equipment and facility maintenance
  - Implement QA program, with the exception of components contingent on renovation completion

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Implementation Plan for Sterile Compounding Standards

- **Phase 3 (Complete by December 31, 2021)**
  - Complete facility upgrades
  - Complete quality assurance program
- Action items:
  - Complete renovations
  - Implement last stages of QA program related to facility (e.g. equipment verification, environmental monitoring)
  - Update BUDs as necessary

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Implementation Plan for Non-sterile Compounding Standards

- **Phase 1 (complete by December 31, 2019)**
  - Review Standards and Guidance document
  - Complete gap analysis
  - Create action plan
- Key action items:
  - Learn the standards and related-guidelines
  - Complete risk assessments for compounds currently made by the pharmacy and determine level of requirements needed at the site (A, B, C)
  - Identify a compounding supervisor, personnel roles and required training, including cleaning staff
  - Identify policies that need to be developed, create a timeline, and start development
  - Identify what equipment and facility upgrades are needed
  - Start creating master formulation records and assigning BUD
  - If hazardous compounding, implement risk mitigation measure, utilize PPE, establish decontamination/deactivation/cleaning processes

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Implementation Plan for Non-sterile Compounding Standards

- **Phase 2: Complete by December 31, 2020**
  - Train Compounding and Cleaning Personnel
  - Develop and partially implement Quality Assurance (QA) Program
  - **Meet all Level A compounding requirements**
- Key action items:
  - Complete staff training program
  - Complete master formulation records
  - Complete policy development
  - If applicable, submit renovation application to NLPB
  - Develop and implement QA processes for personnel, equipment, and facility
  - Implement policies and procedures related to hazardous preparations

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Implementation Plan for Non-sterile Compounding Standards

- **Phase 3: Complete by December 31, 2021**
  - Meet all Level B and C requirements, including final aspects of QA program
- Key action items:
  - Complete renovations to meet level B and C requirements
  - Complete equipment and facility maintenance log
  - Implement QA processes, including environmental monitoring

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Key Messages

- Implementation plans provide guidance for assessing gaps in compliance and assist with prioritizing action items
- Each phase includes what work should be started and what specific standards must be met by the end of that phase
- Implementation deadlines span a 2-3 year timeframe, depending on the complexity of compounding services, to support registrants in successfully meeting standards
  - But, registrants standards are expected to meet standards at the earliest possible date
- Goals are to reduce risks to patients associated with compounding as much as possible, and provide safe work environments for compounding personnel

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Applying the Code of Ethics

- Registrants hold the health and safety of each patient to be of primary consideration
- Registrants respect the patient's right to receive care
- Registrants continuously improve their professional knowledge and skills
- Registrants cooperate with colleagues and other health professionals to ensure optimal patient-centred care
- Registrants contribute to the health system and societal health needs

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

Next Steps

Registrants:

- Start reviewing the standards and related guidelines
- Complete self-assessment and start prioritizing action items
  - Compounding self-assessments to be released by May
- Contact NLPB if you have any questions

Further webinars are planned to support registrants

NEWFOUNDLAND & LABRADOR PHARMACY BOARD

We want to hear from you!

- What do you see as implementation challenges?
- How can the Board support you in meeting the standards?
- Do you have any suggestions for future webinars on this topic?

NEWFOUNDLAND & LABRADOR PHARMACY BOARD