Implementation of the Non-Sterile Compounding Standards in Ontario

Webinar held November 4, 2020

Ontario College of Pharmacists
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Webinar: Part Three

Slides in Part 3 of the webinar cover:

- Risk-based Approach
- Patient Assessment
- Challenges and Alternatives
- Key Resources
- Assessment Criteria

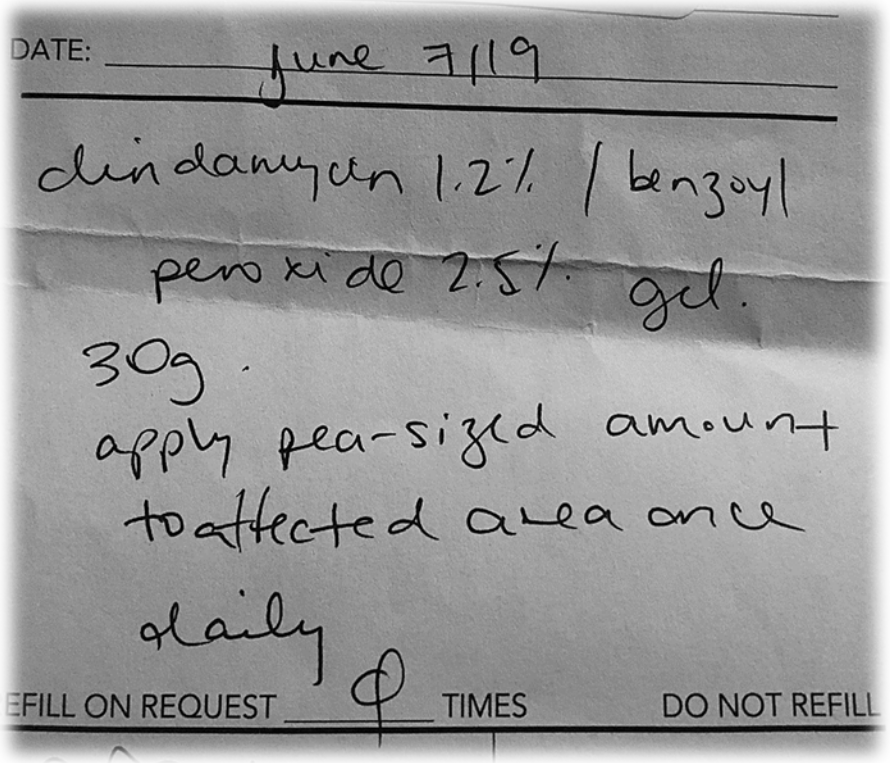
Moving Forward

- No “one size fits all”
  - Although compounding may seem like it should be more black and white, there will still be grey because, like patients and situations, not all pharmacies – or what they are compounding – are identical.
- Risk-based approach
  - Identify, assess and mitigate
  - Work towards implementing safety measures or administrative controls to mitigate the risk.
  - Algorithm is a tool to illustrate how risk stratification can be applied to compounding

Moving Forward

- Patient Assessment
  - Is a compounded product the most appropriate?

- Define, Defend, Document
  - Apply the decision-making principles and problem-solving skills used when exercising professional judgement in clinical scenarios



Food for thought

- Patient care challenges
  - Continuity of care
    - Risk of fragmented care
    - Risk mitigation plans during transition
- Explore viable alternatives
  - Is there a suitable commercial product available?
  - Can it be safely compounded in the pharmacy?
  - Refer to another pharmacy?

Key Resources to Assist in Implementing the Standards

NAPRA

- Guidance Document for Pharmacy Compounding of Non-Sterile Preparations
- Printable and Fillable Forms and Checklists

OCP

- Checklist Overview Of Phases 1, 2 and 3 (Spring/Summer 2020)
- Frequently Asked Questions
- Non-Sterile Preparations Assessment Criteria

Resources

PHARMACY CONNECTION ARTICLES

- Compounding: Are You Doing It? (*Winter 2018*)
- New Model Standards Apply to All Pharmacies Performing Non-Sterile Compounding (*Spring 2018*)
- How Are You Preparing for the New Standards on Non-Sterile Compounding? (*Summer 2018*)
- Timelines Announced for Non-Sterile Compounding Standards (*Winter 2019*)
- Consider These Steps While Preparing for the First Phase of Non-Sterile Compounding Compliance: The Hamilton Health Sciences Experience (*Spring 2019*)

Resources

PHARMACY CONNECTION ARTICLES

- Frequently Asked Questions on Non-Sterile Compounding Standards Implementation (*Summer 2019*)
- Implementing the Non-Sterile Compounding Standards: A Closer Look at Personal Protective Equipment (PPE) (*Summer 2019*)
- Implementing the Non-Sterile Compounding Standards: The Community Pharmacy Experience (*Summer 2019*)
- Preparing for Phase 2 of the Non-Sterile Compounding Standards (*Fall 2019*)
- Non-Sterile Compounding Phase 2 Implementation (*Winter 2020*)
- Staying on Track for Full Implementation of the Non-Sterile Compounding Standards (*Spring/Summer 2020*)

Resources

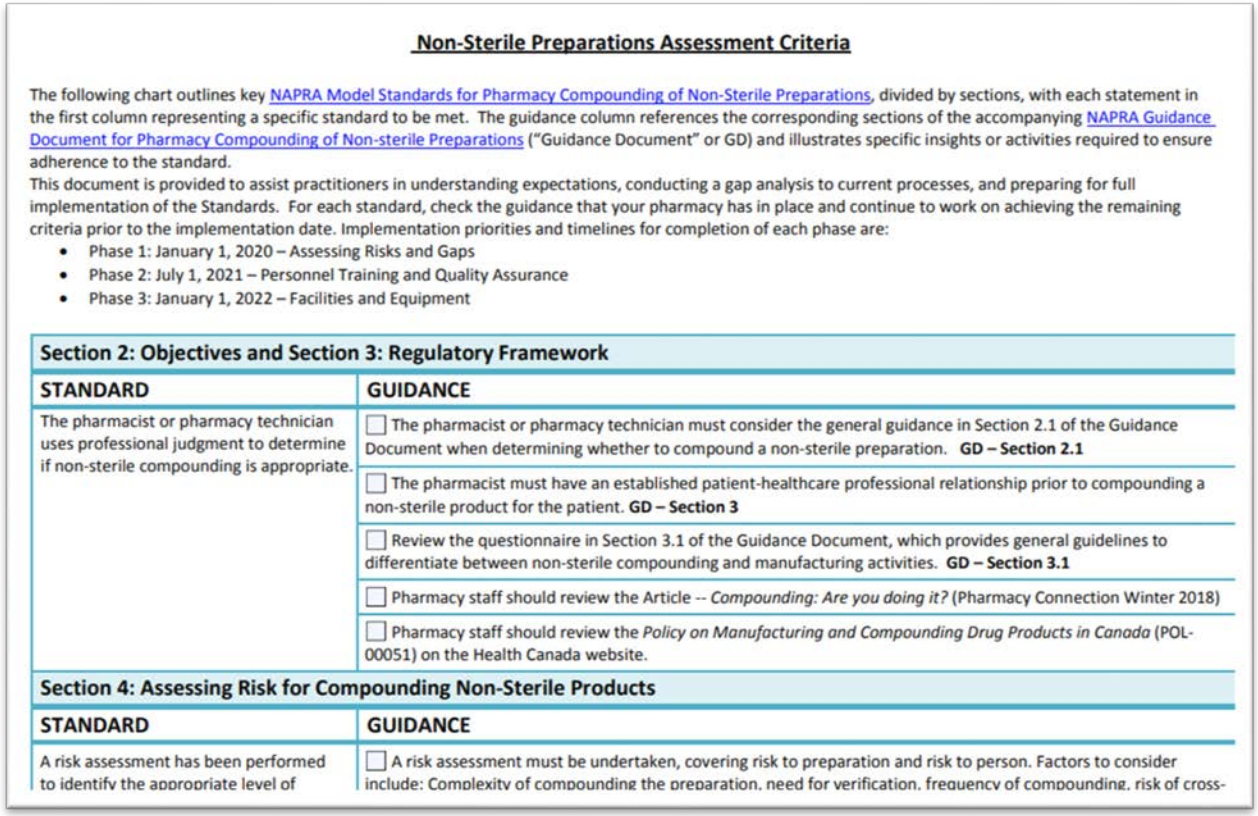
EXTERNAL

- Alberta College of Pharmacy resources
    - Note that Alberta has different implementation deadlines
  - Non-Sterile Compounding Essentials
  - Master formulation record vs compounding record
- References provided in Standards, Guidance, and articles
- Compounding journals, texts, literature

Assessment Criteria

What are OCP inspectors specifically looking for during a practice assessment?

- Non-Sterile Preparations Assessment Criteria



Non-Sterile Preparations Assessment Criteria

The following chart outlines key NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations, divided by sections, with each statement in the first column representing a specific standard to be met. The guidance column references the corresponding sections of the accompanying NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations ("Guidance Document" or GD) and illustrates specific insights or activities required to ensure adherence to the standard.

This document is provided to assist practitioners in understanding expectations, conducting a gap analysis to current processes, and preparing for full implementation of the Standards. For each standard, check the guidance that your pharmacy has in place and continue to work on achieving the remaining criteria prior to the implementation date. Implementation priorities and 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

Section 2: Objectives and Section 3: Regulatory Framework	
STANDARD	**GUIDANCE**
The pharmacist or pharmacy technician uses professional judgment to determine if non-sterile compounding is appropriate.	☐ The pharmacist or pharmacy technician must consider the general guidance in Section 2.1 of the Guidance Document when determining whether to compound a non-sterile preparation. **GD – Section 2.1**
	☐ The pharmacist must have an established patient-healthcare professional relationship prior to compounding a non-sterile product for the patient. **GD – Section 3**
	☐ Review the questionnaire in Section 3.1 of the Guidance Document, which provides general guidelines to differentiate between non-sterile compounding and manufacturing activities. **GD – Section 3.1**
	☐ Pharmacy staff should review the Article -- *Compounding: Are you doing it?* (Pharmacy Connection Winter 2018)
	☐ Pharmacy staff should review the *Policy on Manufacturing and Compounding Drug Products in Canada* (POL-00051) on the Health Canada website.
Section 4: Assessing Risk for Compounding Non-Sterile Products	
STANDARD	**GUIDANCE**
A risk assessment has been performed to identify the appropriate level of	☐ A risk assessment must be undertaken, covering risk to preparation and risk to person. Factors to consider include: Complexity of compounding the preparation, need for verification, frequency of compounding, risk of cross-

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KEY TAKEAWAYS

To compound or not?

The importance of **patient assessment**

Don’t lose sight of the overall outcomes

Patient (and **personnel) safety**

Risk-based Approach

Define, Document, Defend