Implementation of the Non-Sterile Compounding Standards in Ontario

Webinar held November 4, 2020

Ontario College of Pharmacists
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Webinar: Part One

Slides in Part 1 of the webinar cover:

- Timelines & Implementation Dates
- Rationale for Standards
- Overview of Standards and Guidance Documents

Questions Received from Registrants

GENERAL

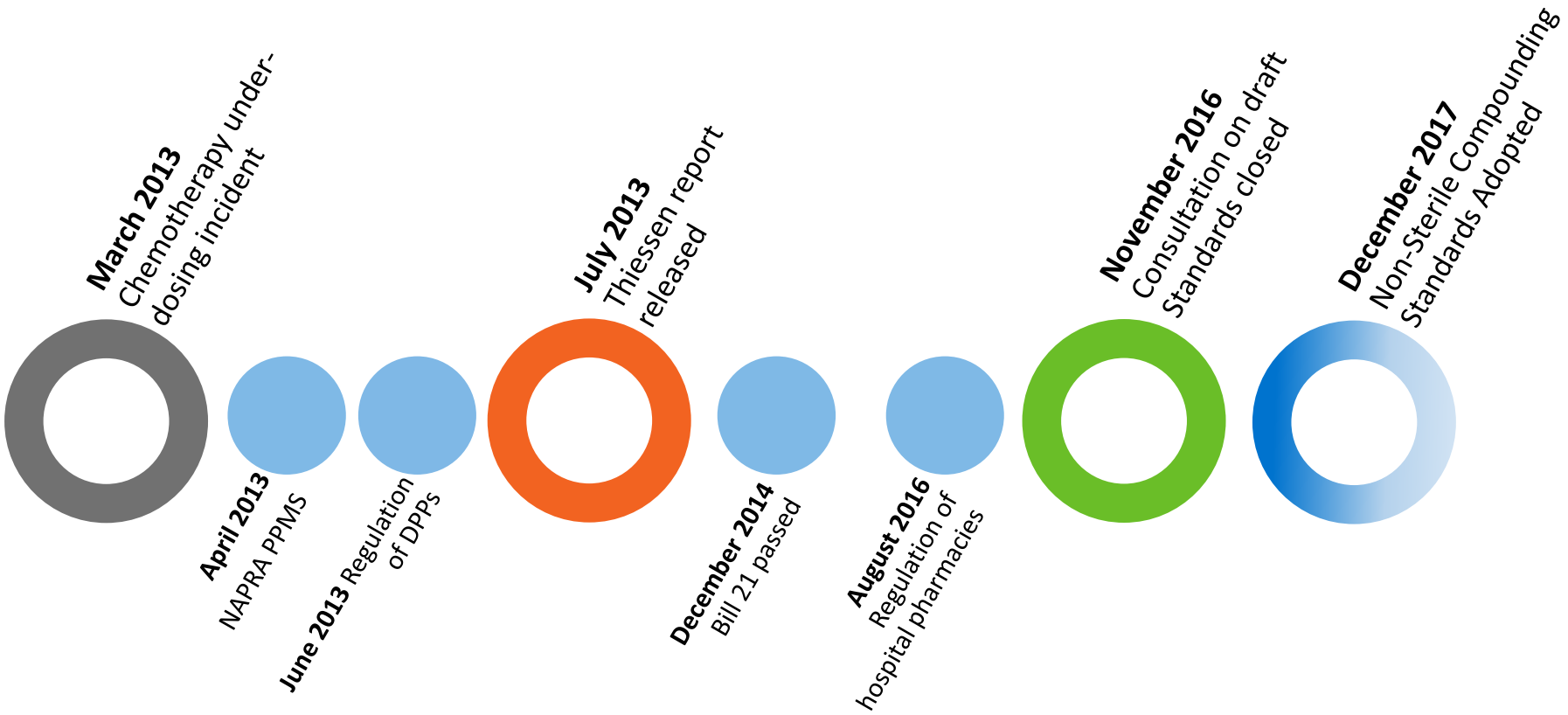
- How to implement new standards
- Requirements for non-sterile compounding
- Simple breakdown of what is expected for documentation, how often it should be reviewed
- A clear indication of what differentiates non-sterile compounding from sterile
- Exact paperwork required for each compound
- Resources for implementing
- Steps to prepare at each phase
- What day-to-day steps of using guidelines looks like

Questions Received from Registrants

TIMELINES & IMPLEMENTATION DATES

- Timelines and dates for implementation
- Can OCP extend the deadlines/timelines?
  - So busy since COVID and now flu season
  - Preoccupied with the pandemic
  - Seeing higher and longer absences with staff due to COVID, reduces time we have to spend on this
  - COVID causing resource challenges, lack of supplies for construction
- When is the deadline to implement the changes?
- Are we still allowed to compound as usual up to January 2022?

Timeline: Adoption



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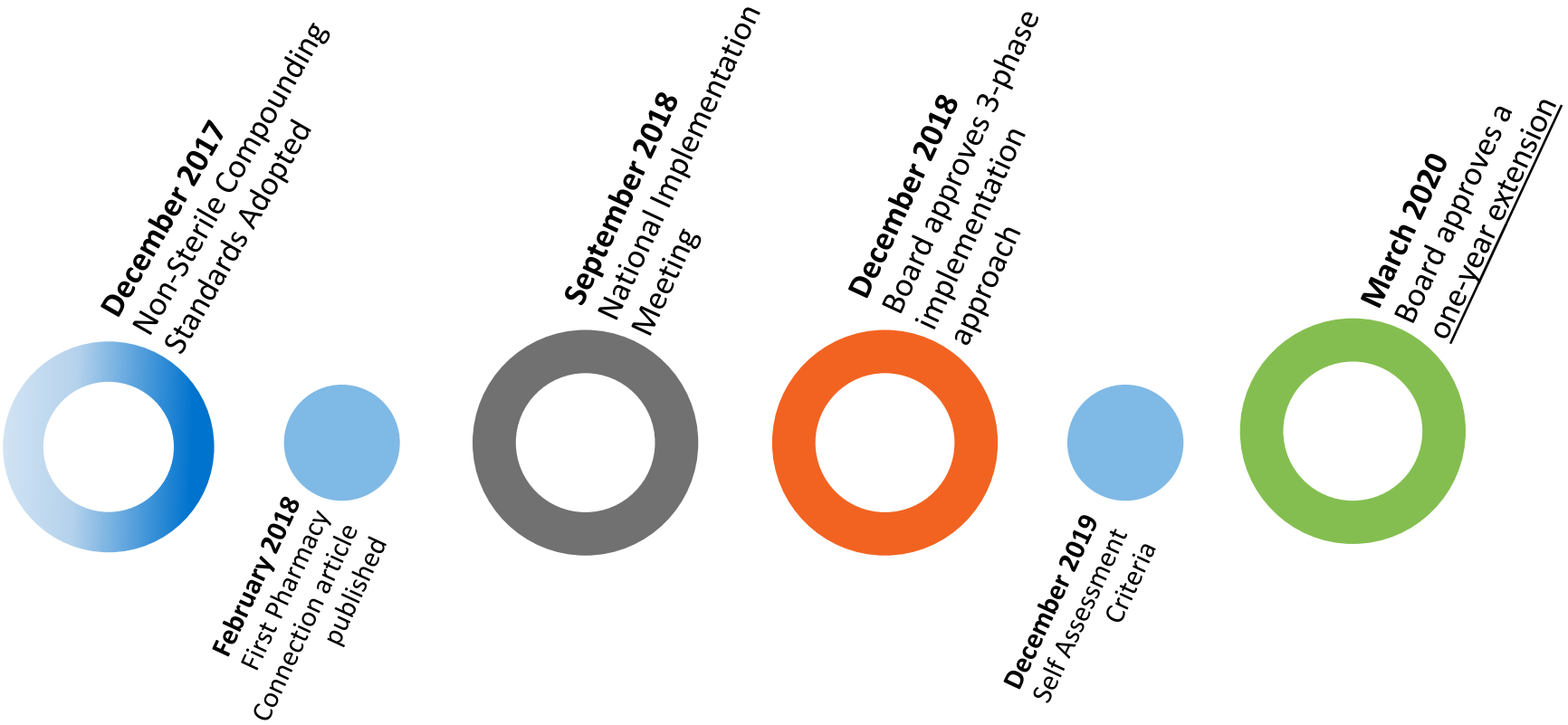
Timeline: Implementation



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Key Initiative

Timeline: Implementation

Fillable Checklist

Key Initiative

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Rationale for Standards

INCREASE PATIENT SAFETY

- Compounding services provided by most pharmacies
  - "Controlled act" authorized for pharmacy professionals
- Compounding is a **complex, high-risk activity**
  - Final preparation **cannot** be verified through physical examination
  - Scope and complexity of preparations are highly variable
- Update to existing OCP/NAPRA Guidelines (2006)
  - Evaluate current practices and procedures
  - Develop and implement appropriate quality controls

Rationale for Standards

INCREASE PATIENT SAFETY (continued)

- "Risk to preparation"
  - Errors in calculation, labelling, ingredient selection
  - Potential for microbial and cross-contamination
  - Ingredient quality
- Benefit the patient & prevent harm
  - Ensure compounded preparation most appropriate option
  - Establish recall procedures
  - Evidence-based formulas and stability data
  - Consistency in replicating compounding procedures

Rationale for Standards

PROTECT PHARMACY PERSONNEL

- "Risk to person(s)"
  - The compounder must be protected from materials that may be hazardous or harmful
  - The compounding area must be contained, so that it does not create a hazardous environment for others
  - Incident and accident management
  - Hazardous waste management



Sections 4, 5, 8, 9

Rationale for Standards

PROTECT PHARMACY PERSONNEL

- Occupational Exposure Risk
  - Federal *Hazardous Products Act* & *Regulations*
  - Provincial *Occupational Health & Safety Act*
    - Workplace Hazardous Materials Information System (WHMIS) Regulations (*R.R.O. 1990, Reg. 860*)
  - National Institute for Occupational Safety and Health (NIOSH)
- External resources
  - Canadian Centre for Occupational Health and Safety (CCOHS)
  - American Society of Health-System Pharmacists (ASHP)
  - Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales (ASSTSAS)

Overview of Standards and Guidance Document

- Adapted from standards developed by the Ordre des Pharmaciens du Québec (OPQ)
  - Based on United States Pharmacopeia (USP) <795>
- Guidance Document accompanying Standards
  - Developed to assist with implementation
  - More details on how the standards can be achieved
  - Sections are numbered the same for cross-referencing
- Policies, procedures and operational processes must be developed by the pharmacy based on evaluation of their compounding practice and space/layout

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Sections 1, 2

Overview of Standards and Guidance Document

- Health Canada Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)
  - Compounding is considered the mixing together of two or more ingredients (at least one is a pharmacologically active component) to create a final product in an appropriate form for dosing
  - Can involve raw materials or alteration of form and/or strength of commercially available products to allow for a novel drug delivery
  - **Does not** include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use

Sections 1, 2

Overview of Standards and Guidance Document

Sterility is not about the drug; it's about risk of microbial contamination and route of administration

- Non-sterile preparations include:
  - Topical, oral, otic (external), rectal, vaginal
- Sterile preparations include:
  - Injections, parenteral nutrition, dialysis solutions
  - Ophthalmic, otic (intratympanic)
  - Nasal inhalation, respiratory therapy solutions
  - Allergen extracts
  - Topical preparations where sterility is essential to therapy (e.g., cream for burns, irrigation solutions for body cavity)