

Hospital and Other Healthcare Facilities

Council Progress Report December 2015



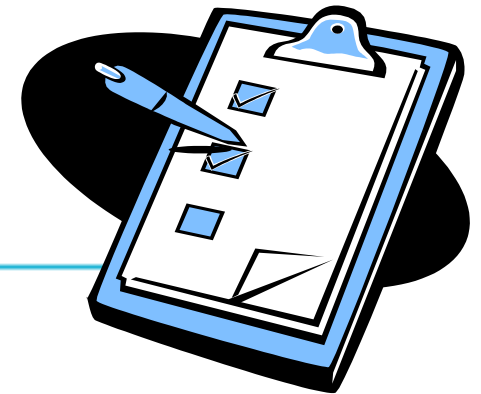
Ontario College
of Pharmacists

Putting patients first since 1871

Judy Chong, RPh, BScPhm
Manager, Hospital and Other
Healthcare Facilities

Agenda

- **Background**
- **Drug Preparation Premises (DPPs)**
- **OCP Hospital Oversight**
- **Next Steps**
- **Discussion**



Under-dosing of chemotherapy medication

March 2013

Incident discovered

April 2013

Thiessen named to lead independent study

August 2013

Thiessen Report and recommendations released to the public and accepted by government

September 2013

Implementation Task Force established

A Review of the Oncology
Under-Dosing Incident

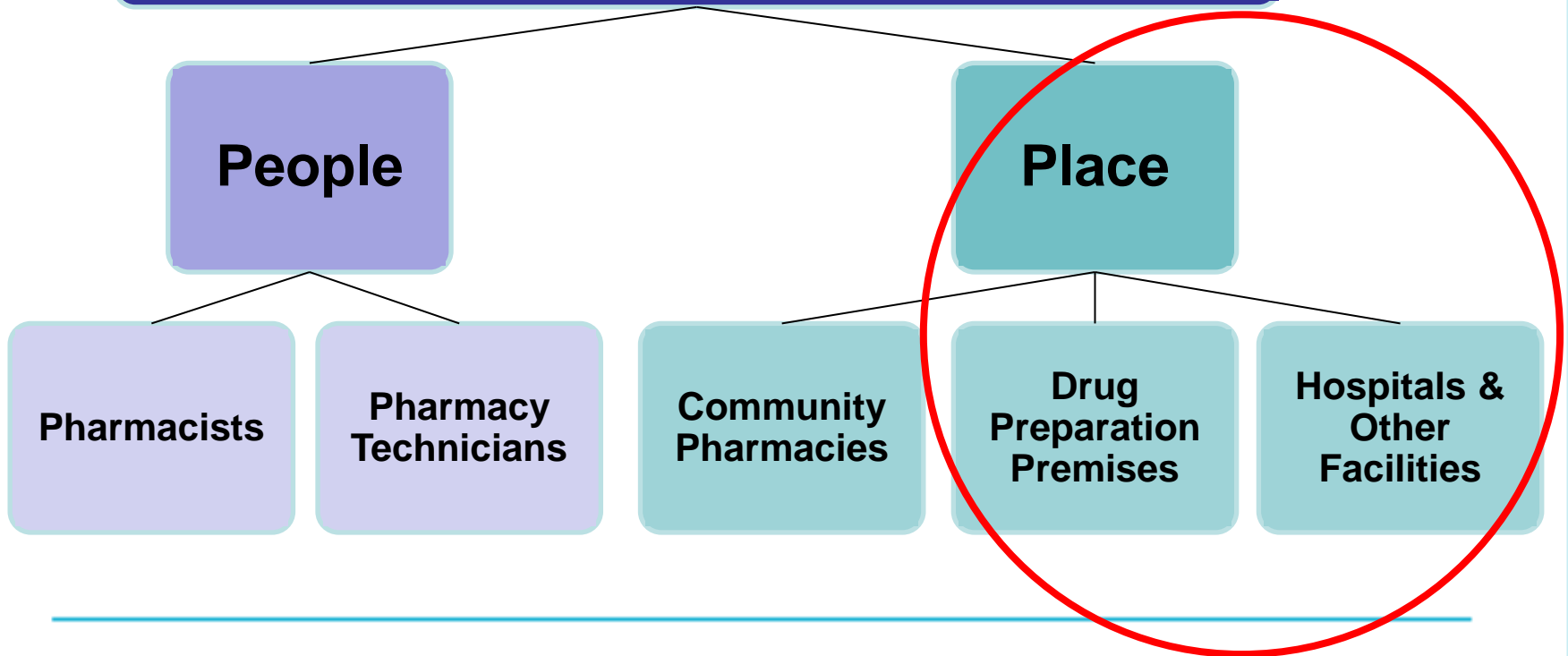
Jake J. Thiessen, Ph.D.

Thiessen Recommendations

- #6 – Define best practices and contemporary **standards for non-sterile and sterile** product preparation
 - #7 – Stipulate specialized **electronic material records and label requirements** for non-sterile and sterile product preparation
 - #8 – **Inspection of Drug Preparation Premises** (DPPs) where pharmacists and pharmacy technicians work
 - #9 – **Specified credentials** for personnel engaged in sterile and non-sterile compounding
 - #12 – **License** all pharmacies operating within **Ontario's clinics or hospitals**
-

OCP Quality Assurance

Ontario College of Pharmacists



Drug Preparation Premises

- **May 2013 – authority provided through changes to the regulatory framework**
 - **May to July 2013**
 - **Inspection Criteria developed through collaborative process**
 - **DPPs identified and inspected**
 - **August 2013 – initial inspections complete; outcomes (pass) posted on public register**
 - **August / September 2014 & 2015 – annual inspections complete; outcomes (pass)**
 - **2016 review of inspection criteria**
-



MEMBER/PHARMACY SEARCH

[About Public Register](#)

Choose one of the following to search by member or pharmacy:

- Member Pharmacy Remote Dispensing Location (RDL) Drug Preparation Premises

Enter your search criteria in one or more of the following fields:

Accreditation Number:

Company Name:

City:

Postal Code:

LIST OF DRUG PREPARATION PREMISES

Total records found: 8 | Page 1 of 1

[Export to CSV](#)

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ACCREDITATION NUMBER	COMPANY NAME	ADDRESS	CITY	POSTAL CODE	COMPANY STATUS
304889	ApoLab ULC	5 - 3750 Laird Rd	Mississauga	L5L 0A6	Active
303583	Baxter Pharmacy Services	13/14 - 2785 Skymark Ave	Mississauga	L4W 4Y3	Active
303666	Fresenius Kabi Compounding Solutions	41 Brockley Dr	Hamilton	L8E 3P1	Active
303733	Fresenius Kabi Compounding Solutions	2-2785 Skymark Ave	Mississauga	L4W 4Y3	Active
303584	Marchese Hospital Solutions	Unit 4 - 6905 Kenderry Gate	Malton	L5T 2Y8	Active
303770	Skycare Compounding Labs	540 Davis Drive	Newmarket	L3Y 2P3	Active

[TERMS OF USE](#)

Accreditation Number: 303733

Name: Fresenius Kabi Compounding Solutions

Open Date: Dec 20, 2013

Type: Drug Preparation Premises

Status: Active

Summary

Company Name: Fresenius Kabi Compounding Solutions

Accreditation Number: 303733

Address: 2-2785 Skymark Ave

City: Mississauga

Province: ON

Postal Code: L4W 4Y3

Phone: +1(905)624-1234

Fax: +1(905)629-0123

Allegations: No

Discipline History: No

Inspection Information after July 1, 2013

More Information

Date	Status/Outcome	Attachment
Dec 20, 2013	Pass	View Attachment
Aug 19, 2014	Pass	View Attachment
Nov 24, 2015	Pass	View Attachment

PERSONNEL

ALLEGATIONS

HEARINGS

Member Name	Member Number	Member Type	Designated Manager	Narcotic Signer
Ahmad, Nwar	604858	Pharmacist	No	No
Chong, Gordon	83747	Pharmacist	No	No
Krasnoff, Bette	605009	Pharmacist	No	No
Mayer, Jana	604948	Pharmacist	No	No
Micetich, Angela	79855	Pharmacist	No	No
Oravska, Laura	115134	Pharmacist	No	No
Rashid, Saheed	108542	Pharmacist	No	No
Wang, Lu	607810	Pharmacist	No	No
Wong, Barbara	201998	Pharmacist	No	No

OCP Oversight of Hospitals

- Dec 2014 – Bill 21 *Safeguarding Healthcare Integrity Act 2014* passed by government
- June 2015 – Enabling DPRA regulations, following public consultation, approved by council and submitted to government
- Baseline Assessments of Hospital currently underway – target for accreditation January 2016



OCP Oversight of Hospitals

Overriding Objectives:

- **Assess pharmacy and practitioner adherence to operational and practice standards**
- **Prioritize focus based on patient and/or public risk**
- **Support and mentor facilities and individuals to develop necessary action plans and timelines to meet required standards**
- **Identify and share best practices amongst facilities and individuals – continuous quality improvement (CQI)**



OCP Oversight of Hospitals

Principle-Based Approach

1. Collaborative

- In process development and inspection process

2. Flexible

- Adaptable to various practice sites and activities

3. Continuous Quality Improvement (CQI)

- Solid base already in place (system is not broken)
- Supportive and educational (not punitive)

4. Mandate of Public Interest

- Safe and effective delivery of pharmacy services

OCP Oversight of Hospitals

Development of Inspection Criteria:

- Intent was to not duplicate but rather compliment and enhance what already exists

Criteria Cross Reference



Hospital – Baseline Assessments

- Early 2015 – Baseline Assessments of Hospital pharmacies began
- Approximately 225 hospital sites in Ontario
- Current Status – approximately 99% complete
- Anticipate all baseline assessments will have been completed by the end of 2015



Hospital – Baseline Assessments

Assessment Criteria - Overview:

- 3 categories of criteria – legislation, emerging and organizational
- Each criteria evaluated against applicable criteria
 - Meets (3)
 - Partially Meets (2)
 - Does not Meet (1)
 - N/A or N/I
- Continuous quality improvement process with realistic action plans and timelines established
- Follow up visit and/or remediation as required



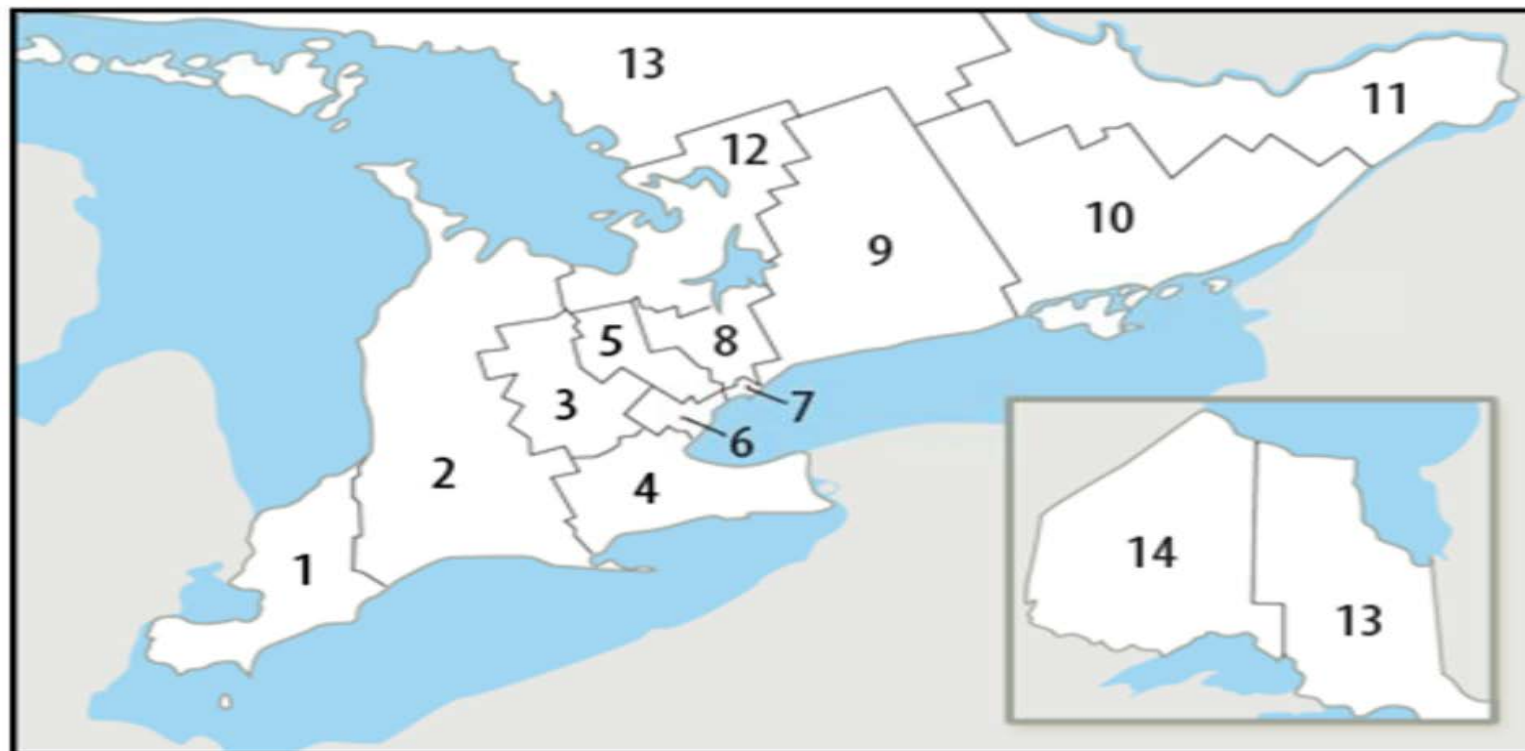
Hospital – Baseline Assessments

Assessment Criteria - Overview:

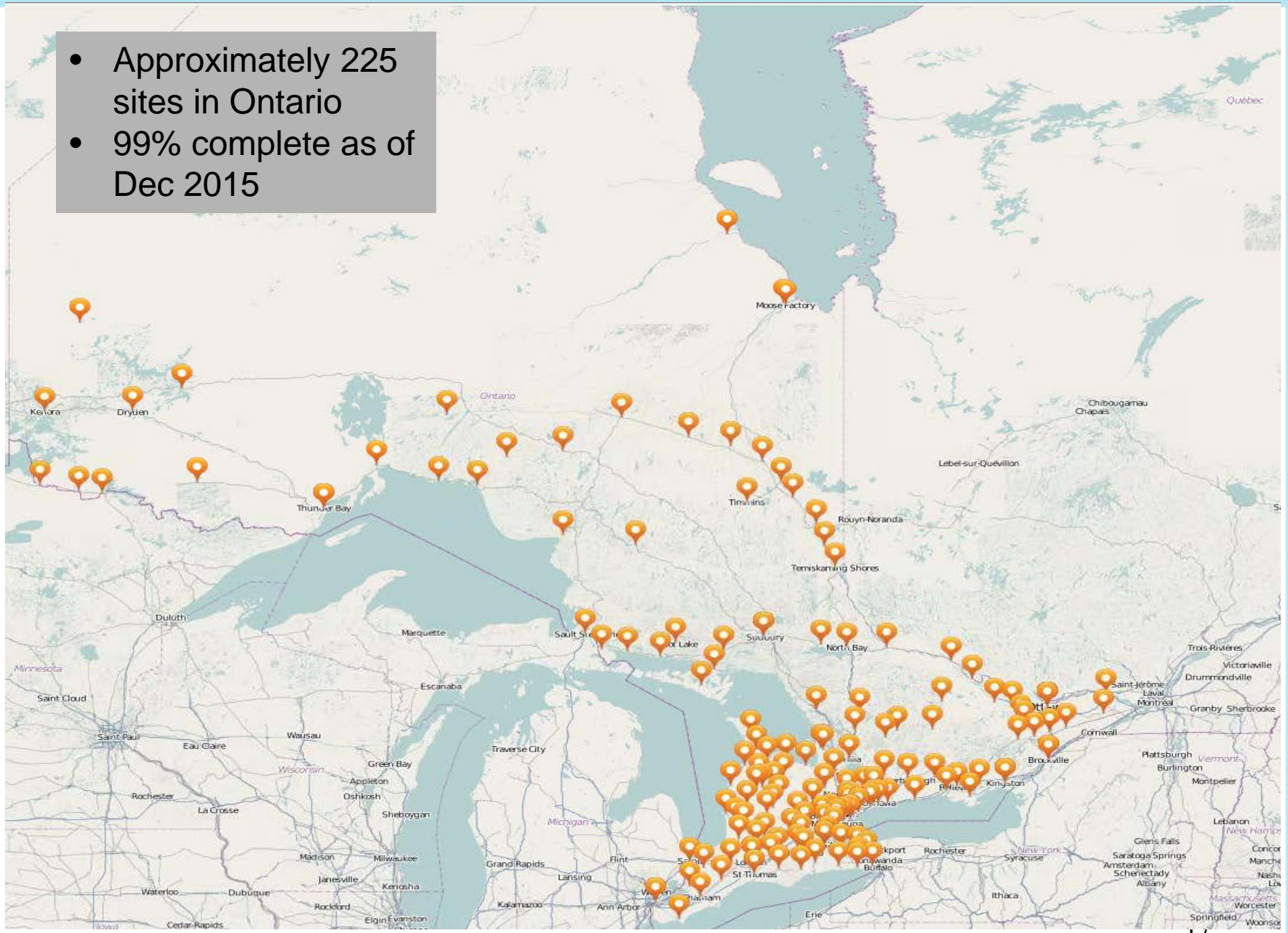
- A. Systems to Provide Safe, Effective and Appropriate Pharmacy Services
- B. Order Processing, Verification, Dispensing and Distribution
- C. Preparation, Packaging and Labelling of Medication
- D. Pharmaceutical Compounding
- E. Safe Medication Use Systems in Patient Care Areas
- F. Medication Therapy Management
- G. Documentation and Record Keeping
- H. Evaluation of Pharmacy Services

Ontario LHINs Map

- | | | | |
|--|-------------------|---------------------------------|-------------------|
| 1. <u>Erie St. Clair</u> | 8 Hospital Sites | 8. <u>Central</u> | 12 Hospital Sites |
| 2. <u>South West</u> | 31 Hospital Sites | 9. <u>Central East</u> | 16 Hospital Sites |
| 3. <u>Waterloo Wellington</u> | 10 Hospital Sites | 10. <u>South East</u> | 14 Hospital Sites |
| 4. <u>Hamilton Niagara Haldimand Brant</u> | 22 Hospital Sites | 11. <u>Champlain</u> | 22 Hospital Sites |
| 5. <u>Central West</u> | 3 Hospital Sites | 12. <u>North Simcoe Muskoka</u> | 7 Hospital Sites |
| 6. <u>Mississauga Halton</u> | 6 Hospital Sites | 13. <u>North East</u> | 33 Hospital Sites |
| 7. <u>Toronto Central</u> | 26 Hospital Sites | 14. <u>North West</u> | 16 Hospital Sites |



- Approximately 225 sites in Ontario
- 99% complete as of Dec 2015



Themes of Findings

Operations (place):

- Policies and Procedures
- Traceability and Record Keeping
- Compounding (USP 795, 797 and 800)

Practice (people):

- Professional Responsibilities
 - Individual practitioner
- Intra-Professional and Inter-Professional Relationships
 - Pharmacists and Pharmacy Technicians
 - Pharmacy team with other healthcare professionals

Compounding Standards

- Identified need to develop Standards at a national level
- Accelerated work already begun by NAPRA
 - Working group established Spring 2013
- Objective to develop 3 Standards documents:
 - Sterile Compounding – Hazardous
 - Sterile Compounding – Non-Hazardous
 - Non-Sterile Compounding

Compounding Standards

- Sterile – Hazardous & Non-Hazardous
 - Primary drivers – USP 795, 797 and Quebec Compounding Standards
 - Draft documents developed through consultative process:
 - Initial circulation to stakeholders – Summer 2014
 - Working Group revised documents and recirculated (to Regulatory Bodies) – Early 2015
 - Final revisions made (with USP 797 expert)
 - NAPRA **approved** document – April 2015

Compounding Standards

Next Steps / Timeline:

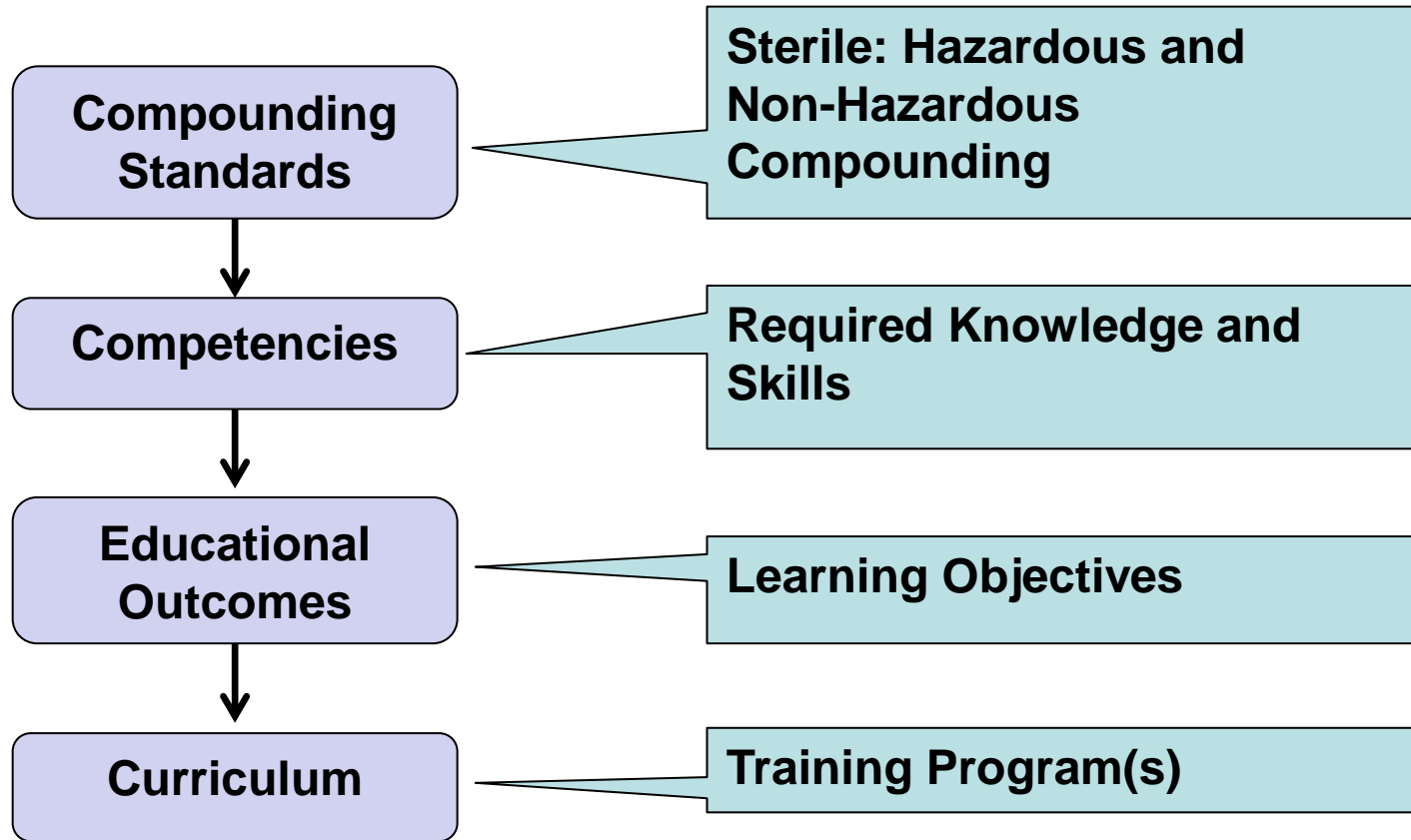
- Sterile – Hazardous & Non-Hazardous
 - Editing and formatting (including French translation)
 - Non-hazardous to be made available by NAPRA – end of 2015
 - Hazardous to be made available by NAPRA – early 2016
 - Each Regulatory Body in Canada will then need to consider; adopting or adapting (similar process to National Standards of Practice)
 - May include implementation dates

Compounding Standards

- **Non-Sterile**

- Primary drivers – USP 795 and Quebec Compounding Standards
- NAPRA working group will develop through 2015
- Consultation process through 2016
- Final NAPRA approval anticipated before the end of 2016
 - Each Regulatory Body in Canada will then need to consider; adopting or adapting

Specified Credentials



System Gaps / Priority Setting

Overriding Objectives of Oversight:

- Assess pharmacy and practitioner adherence to operational and practice standards
- Prioritize focus based on patient and/or public risk
- Support and mentor facilities and individuals to develop necessary action plans and timelines to meet required standards
- Identify and share best practices amongst facilities and individuals – continuous quality improvement (CQI)

System Gaps / Priority Setting

Themes of Findings:

- Understanding of requirements for a safe medication management system
- Integration of regulated pharmacy technicians and role of unregulated staff
- After hours support by tele pharmacy service for order entry verification
- Automated dispensing cabinets
- Traceability and auditability for high risk products (chemotherapy, methadone and patient specific compounds)

System Gaps / Priority Setting

- Action plans required to achieve compounding standards (facilities, people & processes, quality monitoring and cleaning)
- Action plans to increase security for narcotics and other medications
- Action plans to achieve standards for chemotherapy preparation
- Processes in place that consistently ensure therapeutic checks for all orders
- Storage of medications in syringes for both parenteral and oral usage

System Gaps / Priority Setting

Themes of Recommendations:

1. Re-assess ability to safely and effectively provide specific services; explore alternative options such as centralizing, regionalizing and/or outsourcing
2. Continuous improvement plans should be prioritized based on areas of highest risk and include education to all relevant staff on enhancements to processes and procedures
3. Where gaps exist, develop policies and procedures to ensure accountability and consistency of services

System Gaps / Priority Setting

Themes of Recommendations:

4. Identify opportunities to enhance professional responsibilities e.g. work to full scope
5. OCP recognizes the opportunity to bring best practices from the community to hospital practice
6. Review and conduct risk assessment of storing medications in syringes

Regulatory Framework - Update

- Proposed amendments to College By-laws
 - Sept 2015 – Council approved proposed amendments for 60-day public consultation
 - Consultation ended Nov 20, 2015
 - Dec 2015 – Council to consider approval of proposed amendments reflective of comments received through the consultation process



Next Steps – 2016 and beyond

- Review and revise baseline assessment criteria
- Finalize business processes for accreditation
- Develop schedule, including frequency, for ongoing assessments
- Incorporate individual practitioner assessment component



EVOLUTION!

**Focus on continuous quality improvement to
enhance patient health outcomes**

Questions?

"If you can't fly, then run,
if you can't run, then walk,
if you can't walk, then crawl,
But whatever you do,
you have to
KEEP MOVING FORWARD."

~ Martin Luther King Jr.

