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
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

People
- Pharmacists
- Pharmacy Technicians

Place
- Community Pharmacies
- Drug Preparation Premises
- Hospitals & Other Facilities
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

#### Choose one of the following to search by member or pharmacy:
- [ ] Member
- [ ] Pharmacy
- [ ] Remote Dispensing Location (RDL)
- [X] Drug Preparation Premises

#### Enter your search criteria in one or more of the following fields:
- Accreditation Number:
- Company Name:
- City: [Select City]
- Postal Code:

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### List of Drug Preparation Premises

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<tr>
<th>Accreditation Number</th>
<th>Company Name</th>
<th>Address</th>
<th>City</th>
<th>Postal Code</th>
<th>Company Status</th>
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<tr>
<td>304889</td>
<td>ApoLab ULC</td>
<td>5 - 3750 Laird Rd</td>
<td>Mississauga</td>
<td>L5L 0A6</td>
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<td>303583</td>
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<td>L4W 4Y3</td>
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<td>41 Brockley Dr</td>
<td>Hamilton</td>
<td>L8E 3P1</td>
<td>Active</td>
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<td>303733</td>
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<td>540 Davis Drive</td>
<td>Newmarket</td>
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**Terms of Use**

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Follow Us
Accreditation Number: 303733
Name: Fresenius Kabi Compounding Solutions
Open Date: Dec 20, 2013

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<tr>
<td>Phone: +1 (905) 624-1234</td>
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<td>Fax: +1 (905) 629-0123</td>
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Inspection Information after July 1, 2013

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<tr>
<td>Ahmad, Nwar</td>
<td>604858</td>
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<td>Chong, Gordon</td>
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<td>Krasnoff, Bette</td>
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<td>Mayer, Jana</td>
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<td>Oravska, Laura</td>
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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

CSHP 2015
Targeting Excellence in Pharmacy Practice

ACCREDITATION CANADA

FIP
ADVANCING PHARMACY WORLDWIDE

Ontario College of Pharmacists
Putting patients first since 1871
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. Erie St. Clair  8 Hospital Sites
2. South West  31 Hospital Sites
3. Waterloo Wellington  10 Hospital Sites
4. Hamilton Niagara Haldimand Brant  22 Hospital Sites
5. Central West  3 Hospital Sites
6. Mississauga Halton  6 Hospital Sites
7. Toronto Central  26 Hospital Sites
8. Central  12 Hospital Sites
9. Central East  16 Hospital Sites
10. South East  14 Hospital Sites
11. Champlain  22 Hospital Sites
12. North Simcoe Muskoka  7 Hospital Sites
13. North East  33 Hospital Sites
14. North West  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
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
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

“Certificate of Accreditation”
Early 2016
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
Focus on continuous quality improvement to enhance patient health outcomes
"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.