

Ontario College of Pharmacists Putting patients first since 1871

PHARMACY SUMMER 2017 • VOLUME 24 NUMBER 3

> THE OFFICIAL PUBLICATION OF THE ONTARIO COLLEGE OF PHARMACISTS

ENHANCING MEDICATION SAFETY:

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COUNCIL MEMBERS

Elected Council Members are listed below according to District. PM indicates a public member appointed by the Lieutenant-Governor-in-Council. U of T indicates the Dean of the Leslie Dan Faculty of Pharmacy, University of Toronto. U of W indicates the Hallman Director, School of Pharmacy, University of Waterloo.

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Statutory Committees

- Accreditation
- Discipline
- Executive
- Fitness to Practise
- Inquiries Complaints & Reports
- Patient Relations
- Quality Assurance
- Registration

Standing Committees

- Drug Preparation Premises
- Elections Finance & Audit
- Professional Practice



Ontario College of Pharmacists

- T Vacant
 - TH Goran Petrovic

The objectives of *Pharmacy Connection* are to communicate information about College activities and policies as well as provincial and federal initiatives affecting the profession; to encourage dialogue and discuss issues of interest to pharmacists, pharmacy technicians and applicants; to promote interprofessional collaboration of members with other allied health care professionals; and to communicate our role to members and stakeholders as regulator of the profession in the public interest.

We publish four times a year, in the Fall, Winter, Spring and Summer.

We also invite you to share your comments, suggestions or criticisms by letter to the Editor. Letters considered for reprinting must include the author's name, address and telephone number. The opinions expressed in this publication do not necessarily represent the views or official position of the Ontario College of Pharmacists.

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PHARMACYNNECTION

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Nancy Lum-Wilson, R.Ph., B.Sc.Phm., MBA **CEO and Registrar**

As trusted pharmacy professionals, you all play an important role in patient safety. This means doing what you can to protect patients from harm and to work with patients as partners in their care along with other members of a collaborative care team.

For the College, an important part of our role as a regulator that has served the public for nearly 130 years is to develop the standards to help the entire profession achieve this goal consistently and to continue to promote high quality pharmacy practice.

Together, we have a collective responsibility to keep patients at the centre of everything we do. In this issue of *Pharmacy Connection*, we're pleased to provide important updates on a number of initiatives designed to help us all fulfill our shared responsibilities to put patients first and promote safe and high quality, patient-centred practice within a constantly evolving health system.

For example, you'll learn more about the work behind the development of the College's Opioid Strategy as we prepare to bring a draft framework to Council this fall. We believe that pharmacy can play a vitally important role in helping to curb this public health crisis and it is our hope that this strategy will define what that role will be and shape the work that we all can do to reduce the real and tragic impact this crisis has had on our communities to date. You'll learn about our Scope of Practice Strategy which we believe will help support all pharmacy professionals to practice to their full scope and thereby influence better patient outcomes and access to timely pharmacy care. Our health system continues to transform and patients will continue to rely on pharmacy professionals – who are well positioned to play an increasingly active role in their health and well being.

And you'll learn more about our Continuous Quality Assurance (CQA) Program for Medication Safety and the next steps in development of this important patient safety initiative. As many of you now know, our CQA program will require pharmacy professionals to anonymously report medication incidents to a third party. This will help us - through the analysis of aggregate and de-identified data to recognize trends in practice and learn from each other to address system issues before they occur. While this may seem like a big step for some, we all share that same objective: to promote a safety culture within pharmacy that focuses on quality improvement and the sharing of learnings to help reduce the risk of medication incidents and prevent errors that can sometimes result in tragic consequences for patients and their families.

As we begin to roll out the first phase of the CQA program starting this fall, we'll be looking for community pharmacies interested in getting a head start by volunteering to be among the first 100 pharmacies in the province to adopt the program. Those who volunteer will not only benefit from an earlier implementation of this patient-safety program into their operations, but they will also help inform, shape and influence the success of the program as we move forward with full implementation in late 2018.

Patients are partners, and their perspectives matter

The CQA program is an excellent example of how we brought together professional, public and patient perspectives into the development of a framework for what will become Ontario's first medication safety program for community pharmacies once fully implemented. The patient perspective in particular was key to grounding our discussions and reminding us all why we need to do better. After all, at the end of every prescription is a patient.

As regulations related to the Protecting Patients Act (2017) are developed, and as our health system continues to evolve and transform, we anticipate increasing opportunities that we as a College and you as professionals can and should embrace to invite patients to participate in and inform our work. It is in fact fast becoming a perfect convergence of opportunity and desire that is compelling all of us to make every effort possible to explore how we can more firmly bring the patient voice into our world. With that voice comes a better understanding of how our programs, standards and Code of Ethics have an impact on health outcomes.

As a regulator, we're looking forward to welcoming more public and patient input into what we do, including working closely with our Patient Relations Committee as we strengthen our commitment to supporting patients. We're also looking forward to collaborating with our regulatory colleagues in benefiting from the contributions of a Citizen Advisory Group. This group will help us learn from important perspectives and insights of people from all walks of life who, like all Ontarians, have a rightful stake in quality and safe patient care.

Perhaps most importantly, we're looking forward to exploring with pharmacy professionals throughout the province how we can all further promote patient safety and quality care by encouraging meaningful and appropriate opportunities to engage, learn from, listen to and participate with patients in the delivery of quality pharmacy practice.

Our patients deserve nothing less.

JUNE 2017 COUNCIL MEETING

As recorded following Council's regularly scheduled meeting held at the College offices on June 12th, 2017.

NEW PUBLIC MEMBER APPOINTED TO COUNCIL

Council welcomed Ms. Christine Henderson who was recently appointed to College Council for a period of three years. Ms. Henderson will serve on the Discipline and the Inquiries, Complaints and Reports Committees of the College.

CONTINUOUS QUALITY ASSURANCE (CQA) PROGRAM FOR MEDICATION SAFETY APPROVED BY COUNCIL

Council received an update on the outcome of the public consultation on the CQA for Medication Safety Program – which received broad support from pharmacy professionals, stakeholders and members of the public – and the recommendations related to the implementation of this important patient safety initiative. Council expressed its unanimous support for the program to move forward.

Implementation will be in stages, beginning with approximately 100 community pharmacies this fall. Learnings will inform further roll out, eventually expanding to include all community pharmacies in the province by the end of 2018.

A comprehensive education and communication plan is being developed to support the successful roll out of the program. More details will be available within the coming weeks.

CANNABIS FOR MEDICAL PURPOSES

Council discussed the issue of cannabis and what role the profession will play while governments at both the federal and provincial level establish the framework for legalization. Regulatory expert Mr. Richard Steinecke was invited to address Council on the conflict of interest provisions of the Governance Manual before Council engaged in the discussion on this issue.

Council first reviewed the position statement developed by the National Association of Pharmacy Regulatory Authorities (NAPRA) on the role of pharmacy practitioners in the distribution of cannabis for medical and non-medical purposes. Council endorsed the fundamental points contained in the statement including those aimed at preserving the integrity of the healthcare system through regulatory safeguards. NAPRA anticipates finalizing this statement at its meeting later this fall.

Council then considered the development of a formal position on distribution within Ontario consistent with the College's public protection mandate. Those members who declared a real or perceived conflict excused themselves from the meeting for the duration of this discussion. Although there was general consensus around the table that the College should make a statement on distribution of cannabis for medical use, there was agreement that more information was needed in order to make an informed decision on the direction that the statement should take. Accordingly, information will be gathered and this issue will be brought to Council for further discussion at its meeting in September.

LEGISLATION AND GOVERNANCE

Protecting Patients Act 2017

This new legislation (formerly known as Bill 87) was introduced by the Ontario government to further protect patients by strengthening and reinforcing Ontario's zero-tolerance policy on sexual abuse of patients by any regulated health professional. The Bill, which includes a schedule to amend the *Regulated Health Professions Act, 1991* (RHPA), received Royal Assent on May 30th.

Former College Registrar Deanna Williams has been engaged by the Ministry to undertake the work relating to recommendations of the Sexual Abuse Task Force. It is anticipated that extensive consultations will held prior to the development of regulations. The College looks forward to working collaboratively with the Ministry on this matter.



Since the Protecting Patients Act, 2017, requires the amendment of multiple statutes, the College asked for, and was successful in obtaining, changes to the Drug and Pharmacies Regulation Act, 1990 (DPRA), to enable implementation of the proposed registration and quality assurance regulations as well as to permit the interim suspension of certificates of accreditation of pharmacies where imminent risk of patient harm is identified. This latter provision will mirror the process followed for interim orders relating to members. The College appreciates the All Party support for these amendments, which were accepted and passed with Bill 87 on May 30th.

Governance

The Protecting Patients Act also includes amendments that will increase powers of the Minister to make regulations controlling all aspects of the structure of College statutory committees. It is anticipated that the Minister will consult with all colleges before any regulations are made.

In anticipation of these changes, the Advisory Group for Regulatory Excellence (AGRE) recently held a Governance Roundtable. One of the key best practices that has received significant interest amongst the colleges is that the selection of members serving on Council and Committees should be based on competency (i.e. knowledge, skills and attitude). At this June meeting, Council endorsed the recommendation that, going forward, applications for service on College committees (i.e. Non Council Committee Members) will be screened to assess competency before being considered for appointment. This information is posted on our website.

Furthermore, to strengthen its governance processes, Council members will participate in a year end assessment to evaluate how Council performs as a group, as well as individually. The results of the evaluation will assist Council in understanding and recognizing what is working well and identifying areas for improvement as it advances the College's mandate to serve and protect the public interest.

MAID UPDATE

Council was also updated on the passage of Bill 84 — Ontario's *Medical Assistance in Dying Statute Law Amendment Act.* The Bill, which came into force on May 10, 2017, aligns with the federal MAiD legislation and addresses areas relevant to MAiD that fall under provincial jurisdiction. The legislation provides greater clarity and legal protection for healthcare providers (including institutions and clinicians) as well as patients navigating this care option. The legislation also establishes a new role for the coroner in overseeing medically assisted deaths.

A provincial Care Co-ordination Service, a referral service for MAiD, was put in place on May 31. Pharmacists who are unable or unwilling to dispense drugs for the purposes of MAiD can now contact the care coordination service to make a referral. Patients can also contact the service directly.

The College's guidance document was developed last year to assist pharmacy professionals to comply with legal obligations and professional expectations with respect to MAiD, including effective referral. Given the recent passage of Bill 84 and the experience the province now has in providing MAiD, the College will be reviewing and updating this guidance material to identify how we can provide further clarity and support to pharmacy professionals.



PHARMACY ACT – PROFESSIONAL MISCONDUCT AND CONFLICT OF INTEREST REGULATION

Amendments to the Professional Misconduct regulation, originally approved by Council in 2013, (which addressed the addition of a new class of registrants, the expanded scope of practice, and the expectation that members will exercise professional judgement in choosing to deliver services and/or referring patients to another health professional as needed) came into force on May 5, 2017.

SCOPE OF PRACTICE STRATEGY

As reported at the March Council meeting, the College has been developing a strategy to address the underutilization and integration of pharmacy technicians, particularly in community practice. Pharmacy technicians play an important role in enabling pharmacists to maximize their clinical role as medication therapy experts. However, pharmacists have not achieved this objective despite the regulation of technicians and additional scope for pharmacists. It therefore became clear that a broader strategy was needed to include initiatives that would optimize the scope of practice of both professions.

At this meeting, Council received a presentation on an integrated Scope of Practice Strategy. The Strategy includes the following elements, which were endorsed by Council:

- **1.** Create an Advisory Committee (to inform, support, align and identify partnerships with stakeholders);
- **2.** Define best practice models (and the value proposition) and create a community of best practice to help facilitate growth;

- **3.** Identify barriers and facilitators impacting utilization of pharmacy technicians to optimize pharmacist scope;
- **4.** Establish an education and training agenda for entry and continuing education to enhance professional engagement for both professions; and
- **5.** Develop quality indicators to measure the impact of collaborative practice models on clinical pharmacy services and patient outcomes.

Regular progress updates will be provided to Council as the Strategy is implemented.

COUNCIL MEETINGS IN 2017:

- Monday 18 and Tuesday 19 September, 2017
- Monday 11 December, 2017

Council meetings are open to the public, and are held at the College: 483 Huron Street, Toronto, ON M5R 2R4. If you plan to attend, or for more information, please contact Ms. Ushma Rajdev, Council and Executive Liaison at <u>urajdev@ocpinfo.com</u>

LIVE TWEETING AT COUNCIL

As part of our commitment to transparency and a broader integrated communications strategy for pharmacy professionals and the public, the College is now live-tweeting Council meetings. Check out our <u>Twitter account</u> for the tweets from the June Council meeting and be sure to check in with us for our next meeting in September.



FAKE FENTANYL PATCHES

There have been <u>reports of fake</u> <u>fentanyl patches being returned</u> <u>to pharmacies</u> under the Patch for Patch program. The manufacturing of these counterfeit patches is increasingly sophisticated and they may appear very similar to legitimate patches.

Pharmacy professionals are reminded of their <u>obligations</u> <u>under the Patch for Patch</u>

program. Pharmacy professionals must use their clinical judgment and awareness of the product to examine the returned patches for potential tampering and verify that they are legitimate. Some manufacturers have developed resources to assist pharmacists in determining whether returned patches are authentic. Pharmacy professionals must also document the returned patches and store them in a secure location until they can be properly destroyed.

If the pharmacist has concerns that criminal activity (e.g. counterfeiting) has occurred, they should notify the police. Pharmacists are encouraged to collaborate with the prescriber and alert the prescriber to any concerns they have regarding patient misuse of the medication.

The College is currently developing a comprehensive Opioid Strategy that will align with provincial and national strategies. It will address how the College and the profession of pharmacy can do more to help prevent opioid addiction and abuse. Read more on page 14.

This feature in *Pharmacy Connection* is a place to find information about news stories we're following. Here, you'll read summaries of recent stories relating to pharmacy in Ontario and Canada. For the latest updates, stay tuned to e-Connect and <u>www.ocpinfo.com</u>

MIFEGYMISO

The government of Ontario has <u>announced that they will</u> <u>publicly fund the drug Mifegymiso</u> as of August 10, 2017 for all Ontarians with a valid Ontario health card number and valid prescription. Mifegymiso has been available to the Canadian public since January 2017.

In collaboration with the College of Physicians and Surgeons of Ontario, OCP has created <u>Guidance</u> for Pharmacy Professionals Who <u>Are Dispensing Mifegymiso</u>. The College will continue to keep pharmacy professionals informed on any changes to the prescribing and dispensing of Mifegymiso.

MEDICAL ASSISTANCE IN DYING COORDINATION SERVICE LAUNCHES

On May 31, the government of Ontario's <u>new care co-ordination</u> <u>service</u> to support patient access to medical assistance in dying (MAiD) was launched. Through the service, patients and caregivers can access information about end of life options, including hospice and palliative care. They can also request to be connected to doctors or nurse practitioners who can provide MAiD services.

The service will also help doctors and nurse practitioners (NP) to connect with other doctors/ NPs that can provide the second assessment and/or assist with the prescribing or administration of the drugs, and connect with community pharmacists who will dispense the drugs required. The care coordination service can be reached by calling toll free 1-866-286-4023. To support the operation of the service, your participation in completing <u>the Care co-ordination</u>. <u>Service for Medical Assistance in</u> <u>Dying survey</u> is requested.

Pharmacy professionals should be aware of the College's <u>Guidance</u> on <u>Medical Assistance in Dying</u> and the <u>Frequently Asked Questions</u> on <u>MAiD</u>. The College will continue to monitor developments related to MAiD and will adjust guidance as needed.

The Drug Information and Resource Centre (DIRC) at the Ontario Pharmacists Association has set up a service to answer pharmacists' and pharmacy technicians' clinical questions about medical assistance in dying (MAiD). The service is now available to all pharmacy professionals, including those who are not OPA members. Questions can be submitted via email to <u>maid@opatoday.com</u>. For more information visit <u>www.opatoday.com/maid</u>.

NEW ACCESS TO DRUGS IN URGENT PUBLIC HEALTH SITUATIONS

Health Canada is <u>implementing</u> <u>new regulations</u> that allow for the import of medications that are urgently needed in Canada. These are medications that may be available in the United States, European Union or Switzerland but have not yet been authorized in Canada. These drugs will now be permitted to be imported into provinces or territories that have notified Health Canada of an urgent public health need.

An initial <u>list of drugs for urgent</u> <u>public health need</u> has been published. Many of these are for the treatment of opioid use disorder, such as injectable Vivitrol and orally dissolving Suboxone. Drugs will remain on the list for one year. After this point, they will be removed, unless Health Canada receives a notification for continued access from the province or territory.

NARCAN NALOXONE NASAL SPRAY

The Canadian authorized version of NARCAN has now transitioned into the market. In June 2017, <u>Health Canada announced the</u> <u>transition</u>, NARCAN is a nasal spray form of naloxone.

Previously, NARCAN has been imported from the United States under an Interim Order issued by the Minister of Health in July 2016. On July 5, 2017, that Interim Order expired. While product obtained under the Interim Order can still be used, new orders should be for the Canadian authorized NARCAN product. Minor labelling differences are the only distinctions between the Canadian and American versions.

Pharmacy professionals are reminded that the College has a document on <u>Guidance on</u> <u>Dispensing or Selling Naloxone</u>.

SAVE the DATE! OCP Regional Meetings 2017!

The Ontario College of Pharmacists will be hosting a series of regional meetings this fall. Please save the date in your calendar and plan to join your colleagues for an update and presentation by College CEO and Registrar Nancy Lum-Wilson. Program details to follow. Registration for this free event will open in mid-August.

- Toronto: October 10, 2017 Sheraton Centre Toronto Hotel
- Ottawa: October 12, 2017 Sheraton Ottawa Hotel
- London: October 26, 2017 Four Points London Hotel
- Sudbury: November 1, 2017 Holiday Inn Sudbury

All meetings will be hosted from 6:30 pm to 8:00 pm. Light refreshments will be served.

WE HOPE TO SEE **YOU** THERE!

Webcast option: To make participating in the regional meetings easier for those who can't attend in person, the College will also live webcast the meetings in Toronto and London. Stay tuned for more details on how to sign up for the webcasts.





A Continuous Quality Assurance Program for Medication Safety **FOSTERING A CULTURE OF PATIENT SAFETY**

On June 12, 2017, Council approved Continuous Quality Assurance Program for Medication Safety (CQA) for implementation. The program will be formally integrated into College operations in a similar manner as other practice standards and requirements.

The CQA program will support continuous quality improvement in all pharmacies and put in place a mandatory, consistent standard for responding to medication incidents. In addition to requiring the anonymous reporting of medication incident data to a third party, the CQA program will enable pharmacy professionals to learn from medication incidents and better understand why they happened and how they can be prevented. Through aggregate data analysis provided by the third party, the College will also be able to identify areas of risk and provide appropriate guidance to pharmacy professionals.

The approval for implementation follows the March 20, 2017 meeting where Council unanimously supported a framework for a CQA program and directed the College to begin public consultation to help determine the critical factors to support a successful rollout of the program. The consultation attracted 89 responses, demonstrating broad support for the development of a mandatory, standardized program. Feedback received related to the implementation details will inform the College's next steps in regards to development and implementation.

PROMOTING A SAFETY CULTURE

Understanding why errors happen can help reduce the risk of recurrence, prevent future incidents, including near misses, and ultimately advance patient safety.

The CQA program promotes the principles of a safety culture within pharmacies, similar to what exists in other parts of the health system. It emphasizes accountability and quality improvement, open reporting of incidents, and opportunities to share learnings with other professionals and organizations to inform pharmacy and system wide improvements.

The CQA program:

- Enables sharing of lessons learned from medication incidents through reporting, resulting in ongoing process improvements to minimize errors and maximize health outcomes, thereby improving patient safety;
- Requires shared accountability between operators of pharmacies, for the systems they design and how they respond to staff behaviour, and pharmacy professionals, for the quality of their choices and for reporting their errors;
- Emphasizes learning and accountability through developing a culture where individuals are comfortable bringing forward medication incidents without fear of punitive outcomes; and
- Ensures a consistent approach within the profession towards continuous quality improvement (CQI) processes and the outcomes achieved.

While mandatory reporting is a major aspect of the CQA program, all components of the program must be implemented together to enhance safe medication practices. The required components of an effective standardized quality assurance program for pharmacies address both medication errors that reach the patient as well as near misses that are intercepted prior to dispensing, and must achieve all of the following four elements:



REPORT

• Enable and require anonymous reporting of all medication incidents by pharmacy professionals to a specified independent, objective third-party organization for population of an aggregate incident database to identify issues and trends to support patient safety improvement.



DOCUMENT

- Require pharmacy professionals to document appropriate details of medication incidents and near misses in a timely manner to support the accurateness of information reported.
- Document CQI plans and outcomes of staff communications and quality improvements implemented.

SHARE LEARNING

- Require prompt communication of appropriate details of a medication incident to all pharmacy staff, including causal factors of the error and actions taken to reduce the likelihood of recurrence.
- Ensure the scheduling of regular CQI communication with pharmacy staff to educate pharmacy team members on medication safety, encourage open dialogue on medication incidents, complete a medication safety self-assessment (MSSA), and develop and monitor quality improvement plans.
- Support the development and monitoring of CQI plans, outcomes of CQI communications and quality improvements implemented.

ANALYZE

- Necessitate that when a medication incident occurs, pharmacy professionals analyze the error in a timely manner for causal factors and commit to taking appropriate steps to minimize the likelihood of recurrence of the incident.
- Require completion of an MSSA within the first year of implementation of the Program, then at least every 2-3 years. The Designated Manager may determine an MSSA is required more frequently if a significant change occurs in the pharmacy.
- Analyze individual and aggregate data to inform the development of quality improvement initiatives.







The move towards a standardized medication incident reporting and analysis system is part of larger national and global movement.

The World Health Organization recently launched their third Global Patient Safety Challenge with the theme of Medication Safety. The overall goal is to **"reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally."** They specifically note that harm resulting from errors or unsafe practices due to weaknesses in health systems should be addressed. The provinces of Nova Scotia and Saskatchewan have already established medication safety programs, and there continues to be ongoing dialogue among other provinces on establishing their own similar programs.

NEXT STEPS AND TIMELINES

The College will now move forward with finalizing a comprehensive implementation plan, incorporating the feedback from the consultation and other stakeholders.

A phased approach for implementation will begin in late fall 2017, involving approximately 100 pharmacies, and will provide an opportunity to assess the program requirements and incorporate changes and best practices that are identified. An evaluation will be conducted to determine the extent of achievement of the four core elements of the program in the early adopters, in order to make recommendations to enhance the uptake and sustainability in all pharmacies.

The College anticipates that the CQA program will move forward with full implementation in all community pharmacies by December 2018. The College will also continue working with hospital stakeholders to determine the best way to strengthen current hospital quality and reporting systems and improve alignment with community systems and CQA program requirements to gain the benefit of more fulsome data and shared learnings.

Updates will be posted to the website as this program moves forward.

Want to Help Establish an Effective Medication Safety Program? Volunteers Needed!

The College is seeking volunteer pharmacies across Ontario for initial implementation and testing of the CQA program. Training will be provided, including an in-person session, and support (e.g. reference materials, technical help) will be available. This is a great opportunity for you and your staff to get a head start on this requirement and help contribute to establishing an effective reporting system.

Please contact <u>communciations@ocpinfo.com</u> if your pharmacy is interested in participating.



BUILDING AN OPIOID ACTION PLAN FOR PHARMACY

Ontario is facing a serious public health and safety issue related to the abuse and misuse of opioids, including prescription narcotics and other controlled substances. Opioid misuse is a leading cause of accidental death in Ontario and opioid-related causes of death continue to increase each year.¹

PHARMACY STEWARDSHIP FOR PATIENT SAFETY

Pharmacy professionals play an important role in the procurement and distribution of narcotic and controlled substances for use in patient care. Therefore, they have a professional responsibility to take action to decrease the burden of current opioid issues faced by society.

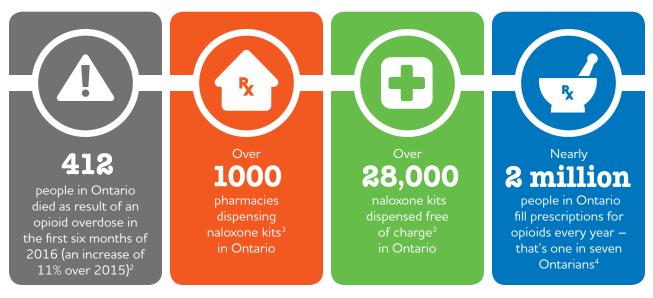
The Code of Ethics, Standard 2.1 notes that members shall "utilize their professional judgment to make every reasonable and conscientious effort to prevent harm to patients and society." As medication experts, pharmacists are in a unique position to support the appropriate use and access to narcotic and controlled substances and collaborate with other health care professionals to enhance patient safety.

A COMPREHENSIVE OPIOID STRATEGY

The College is committed to implementing a comprehensive opioid strategy. The strategy, which is being developed by the newly established Opioid Task Force, will address relevant areas of practice, and will consider the health and social factors that are related to opioid abuse and misuse. It will incorporate short, medium and long term initiatives.

Additionally, the strategy will align with and build on strategies already established by federal, provincial and municipal governments, including <u>Ontario's</u> <u>Strategy to Prevent Opioid Addiction and Overdose</u> and the <u>Joint Statement of Action to Address the</u> <u>Opioid Crisis</u>. The National Association of Pharmacy Regulatory Authorities (NAPRA) is also developing a national strategy – this work is being co-led by OCP CEO and Registrar Nancy Lum-Wilson and Nova Scotia Registrar Beverley Zwicker.

The strategy will be presented to College Council at its September meeting. \blacksquare



RESOURCES ON OPIOIDS

• OCP Opioid Practice Tool

The Opioid Practice Tool provides opioid-related OCP guidance and resources and links to external naloxone and opioid related information.

• <u>The 2017 Canadian Guideline for</u> <u>Opioids for Chronic Non-Cancer Pain</u>

This guideline incorporates medical evidence published since the previous national opioid use guideline was made available in 2010. While primarily recommendations for physicians, pharmacists are encourage to review the guideline to inform how they review and dispense opioid prescriptions and engage collaboratively with prescribers.

OCP Narcotics Practice Tool

The Narcotics Practice Tool provides OCP resources and guidance on narcotic reconciliation and security, narcotic reporting and destruction of narcotics.

RESOURCES ON NALOXONE

- <u>Naloxone: Five Things Pharmacists Need to Know</u> An article published by CAMH in the Winter 2017 edition of *Pharmacy Connection*.
- <u>Guidance for Pharmacy Professionals</u> who are Dispensing or Selling Naloxone

Guidance from the College for pharmacists who are dispensing or selling naloxone.

• <u>Centre for Addiction and Mental Health (Portico Network)</u> – <u>Pharmacist's Checklist for Naloxone Training and Other Resources</u> Resources prepared by CAMH on opioid risks and naloxone, including a pharmacist's checklist for naloxone training.

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- 2. Government of Ontario. News Release: Joint Statement on Opioid Data. May 24, 2017. <u>https://news.ontario.ca/mohltc/ en/2017/05/joint-statement-on-opioid-data.html</u>
- 3. Government of Ontario. News Release: Naloxone Now Available in Over 200 Cities and Towns in Ontario. April 11, 2017. <u>https:// news.ontario.ca/mohltc/en/2017/04/naloxone-now-available-inover-200-cities-in-ontario.html</u>
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ECHO ONTARIO: EDUCATION AND SUPPORT ON OPIOIDS FOR COMMUNITY BASED PRIMARY CARE PROVIDERS*

ECHO (Extension for Community Healthcare Outcomes) is a collaborative model of education and care management that empowers primary care providers to provide better care for more people within their own communities. ECHO connects community based health care providers, including pharmacists, physicians and nurses, with a specialist team during weekly videoconferencing sessions. The two hour sessions include a short didactic presentation followed by case presentations by participants. Case presenters are provided with a list of recommendations and all participants gain from rich case discussions and shared knowledge. Following this model, ECHO transfers knowledge from 'one to many', building confidence, efficacy and capacity for treatment of complex, chronic conditions. In Ontario there are currently ECHOs for chronic pain and opioid stewardship, rheumatology,

hepatitis C, mental health and addictions, and pediatrics.

Sandy Lu is a pharmacist with the Hamilton Family Health Team who has been participating in ECHO Ontario at UHN Chronic Pain/Opioid Stewardship. She shares part of her experience with ECHO here:

"As part of a Family Health Team, I often receive referrals from family physicians to assist with care of chronic pain patients. The majority of the referrals are to assist with opioid initiation, taper or rotation following the recommendations from the Canadian Opioid Guidelines for Chronic Non-Cancer Pain. Oftentimes, I would encounter resistance to changes to opioid medications. As a comprehensive chronic pain management strategy involves more than using pain medications, there is a need to tap into the expertise of various disciplines in chronic pain

management offered by the ECHO model.

In the past year, I have learned a great deal about the art of tapering opioids and opioid rotations from the numerous didactic presentations, which are done in a practical format with numerous case studies. The cases presented are often complex, usually when the health care providers have exhausted numerous options. I have also learned a lot of tips on communication techniques when encountering patient resistance with opioid-related issues. I find that I always learn something new at each ECHO session, so I encourage all pharmacists involved with chronic pain management to utilize this great resource."

To register for ECHO or learn more, please visit <u>www.echoontario.ca</u>.

*information provided by ECHO



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ISMP Canada Safety Bulletin

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Death Due to Pharmacy Compounding Error Reinforces Need for Safety Focus

- Before a compounded product is prepared, each ingredient and its measured amount should be verified through an independent check.
- Each ingredient in compounding formulas should have a unique identification number.
- Pharmacies should incorporate automated identification of ingredients (e.g., bar code scanning) into the compounding process.
- Labelling and packaging of compounding chemicals should be designed to minimize the risk of identification and/or selection errors.
- Pharmacies should have written policies, procedures, and/or checklists, based on professional standards and guidelines, for pharmacy staff to follow when preparing compounded products.

Some patients may require a medication in a dose or dosage form that is not commercially available. Such medications must be specially prepared for the patient in a pharmacy and are referred to as compounded medications. As part of ongoing collaboration with a provincial death investigation service, ISMP Canada received a report regarding the death of a child who had ingested a prescribed, compounded oral liquid suspension that contained the wrong medication. This bulletin shares some of the contributing factors identified in the case analysis, and provides recommendations to guide pharmacies and other compounding facilities, as well as standard-setting organizations in their efforts to reduce the likelihood of similar errors in the future.

Case Description

For about 18 months, a young child had been receiving a 3 gram (20 mL) dose of tryptophan 150 mg/mL suspension by mouth at bedtime to treat a complex sleep disorder. A refill of the tryptophan prescription was ordered and picked up from the compounding pharmacy that had prepared the suspension in the past. That night, the child was given the usual dose of medication; the next morning, the child was found deceased in bed.

A post-mortem toxicology test identified lethal levels of the antispasticity agent baclofen. Baclofen had not been prescribed for the child. Testing of the suspension refill revealed that tryptophan, the intended active ingredient, was not present; however baclofen was detected, at the expected concentration of tryptophan. This finding was consistent with a selection error having been made at the pharmacy, whereby one ingredient was inadvertently substituted for another. It was determined that the child had received a dose of baclofen more than 20 times the maximum recommended pediatric dose.

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Background

Tryptophan (or L-tryptophan) is an essential amino acid converted in the body to serotonin and other proteins. Commercially, it is available without prescription in capsule form. Tryptophan can be used on an off-label basis to treat sleep disorders, such as sleep terrors in children.¹ Tryptophan is not commercially available in an appropriate dosage form for pediatric patients and therefore must be compounded if prescribed for a young child.

Baclofen is a skeletal muscle relaxant used to treat spasticity in conditions such as multiple sclerosis or spinal cord injury.² It is taken by mouth or given by intrathecal injection³ for these indications. It is not officially approved for use by children less than 12 years of age;² however pediatric dosing information is available. Baclofen is occasionally prescribed, on an off-label basis, as an ingredient in compounded pain preparations intended for topical application.

Health Canada considers compounding to be "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."⁴

Most pharmacies provide some compounding services. However the scope of such services and the complexity of products compounded are highly variable. Figure 1 outlines some of the key activities in the preparation and verification phases of compounding.

Discussion

In the described case, it could not be determined how the selection error was missed during the compounding verification process. The incorrect ingredient may have been misidentified during the final check. Alternatively, there may have been a delay in conducting the final check of the completed product. In this latter scenario, the incorrect ingredient used to prepare the product may have been inadvertently put away before being checked, with the correct ingredient being retrieved later for the final check.

Figure 1: Brief overview of the key activities for compounding in a pharmacy

Preparation

- Select appropriate standard formula to be followed.
- Calculate amount required for each ingredient.
- Gather ingredients and document required information for each ingredient.
- Measure each ingredient using appropriate equipment.
- Prepare compounded product as per accepted procedure.
- Label final product with required information, including beyond-use date.
- Complete and sign preparation documentation.
- Secure all materials and documentation together for final checking.

Verification

- Verify formula and calculated amounts for each ingredient.
- Confirm individual ingredients selected prior to preparation.
- Confirm quantity of each ingredient.
- Verify ingredient information documented on the compounding record.
- Confirm the correct preparation process was followed.
- Verify all information on the final label, including beyond-use date.
- Approve the final prepared product and sign the compounding record.

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Several factors were identified that might have increased the likelihood of this compounding error.

- *Missing independent verification step:* There was a lack of independent verification of ingredients before mixing, which increased the likelihood that if an incorrect ingredient was inadvertently selected and incorporated into the final compounded product, the error would not be detected.
- *Similar label design:* The 2 compounding chemicals (tryptophan and baclofen) were supplied by the same manufacturer, which uses a similar design for all product labels and packages. The following specific labelling factors were identified at the time of the incident:
 - prominence of the manufacturer's name on the label
 - type size of the drug name (less than half the size of the manufacturer's name)
 - presentation of the drug name in capital letters only. This reduces legibility and readability.⁵
- *Similar physical appearance:* Both tryptophan and baclofen are white powders which, upon visual inspection, show little appreciable difference.
- *Confirmation bias:* This phenomenon, which leads individuals to "see" information that confirms their expectations, rather than information that contradicts their expectations,⁶ may have played a role. Similarity of labels and packages can increase the potential for selection and verification errors related to confirmation bias.
- *Lack of use of a unique identifier:* The formula and compounding record did not contain a unique identifier that could be used to verify the ingredients selected and used in the preparation. In contrast, for commercially available medications, pharmacy staff typically uses the drug identification number (DIN) to confirm the product selected and dispensed.
- Lack of segregated storage of oral and topical compounding chemicals: Mixed storage of many compounding ingredients intended for either oral or topical use, combined with similar product appearance, increased the likelihood that a product selection error could occur without detection.

Recommendations

Analysis of this case led to a number of system-based recommendations.

Regulatory Agencies

- Require an independent check for each critical step. These steps include calculations, selection and measurement of ingredients, and mixing technique (if applicable), as well as a final check of the finished product, regardless of the individual(s) preparing the product.
- When conducting routine on-site inspections of pharmacies and drug preparation facilities, review policies and procedures for compounding to ensure compliance with accepted standards of practice, especially the performance of independent checks during the preparation process.

Manufacturers of Compounding Chemicals

- Enhance the labelling of compounding chemicals in accordance with recommendations in Health Canada's Good Label and Package Practices Guide for Prescription Drugs⁵ until such time as guidance specific to safe label design for chemical products is available.
- Label compounding chemicals with unique item numbers and bar codes that can be used to verify their identity when selecting and checking ingredients for a compounded product.
- Include a unique chemical identifier for each ingredient in formulas provided to pharmacies.

Pharmacy Managers, Pharmacists, and Pharmacy Technicians

- Designate an area for compounding that is separate from other activities.⁷
- Ensure written policies, procedures, and/or checklists are readily available for pharmacy staff to follow when they prepare a compounded product. Validate newly created procedures and checklists through user testing before full implementation.

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- Verify selection of the correct formula, the identity of all ingredients and their measured quantities through an independent check.
 - Ensure ingredients are not returned to stock until verification has occurred.
 - To support verification, include a unique product number, if available, for each chemical ingredient in standard formulas.
- Require documentation for each critical verification step.⁸ Document that:
 - calculations, if required, have been checked;
 - the identity of each ingredient has been verified before mixing;
 - lot number and expiry date of each ingredient have been captured;⁹
 - the weight and/or measurement of each ingredient has been verified; and
 - a final check of the finished product has been conducted.
- Incorporate automated identification (e.g., bar code scanning) of ingredients into the compouding process.
- Specialty compounding pharmacies may wish to consider video recording of the compounding process that can be accessed by staff to confirm preparation activities.
- Store products in a way that optimizes label readability (e.g., well-lit and organized storage spaces, ideally at eye-level). Avoiding counter storage of drugs and chemicals will reduce clutter and increase available workspace.
- Segregate oral and topical compounding ingredients on separate, labelled shelves.
- Make use of educational resources, such as training videos. These can be especially helpful for complex compounding processes and/or preparation techniques that are used infrequently.

Conclusion

Compounding of medications is a high-risk activity that results in a final product for which ingredients cannot be verified through physical examination. Before compounding is undertaken, commercially available alternatives should be considered and there should be an evidence-based rationale for the use of the compounded product. The selection error described above, with its tragic result, could have occurred in any community or hospital pharmacy or drug preparation facility that compounds medications. ISMP Canada is working with the National Association of Pharmacy Regulatory Authorities (NAPRA) to inform updated standards of practice¹⁰ which will be available in 2017/2018, and will continue its work with other stakeholders to advance compounding safety.

Acknowledgements

ISMP Canada extends appreciation to the child's family for allowing details of this medication incident to be shared, with the goal of preventing harm to others in similar situations. ISMP Canada gratefully acknowledges expert review of this bulletin by the following individuals (in alphabetical order):

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WHO's Third Global Patient Safety Challenge: Medication Without Harm

Following on its 2 previous global patient safety challenges, related to infection control and safer surgery,

the World Health Organization (WHO) recently announced the launch of its international campaign for safer medication use. Participating countries will be asked to develop interventions targeting 3 priority areas: high-risk situations, polypharmacy, and transitions of care.

Five Working Groups have been established to support implementation of the Challenge: Patients and Public, Health Care Professionals, Medicines, Systems and Practices, and Monitoring and Evaluation. Since April 2016, Canada has been assisting the WHO in the preparation and development phases of the Challenge. ISMP Canada, the Canadian Patient Safety Institute (CPSI), and Patients for Patient Safety Canada are expert contributors to several of the Working Groups. Through these efforts, Canadian organizations continue their work with the WHO to advance medication safety.

More information is available from: http://www.who.int/patientsafety/medication-safety/en/ and http://middleeast.thelancet.com/journals/lancet/article/PIIS0140-6736(17)31047-4/fulltext

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Magara Apothecary EXPERIENCE AN 1869 PHARMACY

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Implementing the Safe Handling of Oral Anti-cancer Drugs (OACDs) in Community Pharmacies: **A Pan-Canadian Consensus Guideline**

Authors: Dr. Kathy Vu^{1,2}, Ms. Heather Logan³, Ms. Erika Brown³, Ms. Suzzette Oriasel²

INTRODUCTION

Community pharmacists will encounter more oral anti-cancer drugs (OACD) in their pharmacies. Approximately 46%¹ to 60%² of cancer drugs that are coming out of the oncology pipeline are oral agents. OACD are commonly used alone or in combination with intravenous (IV) systemic treatment as part of a regimen. These agents may also be referred to as take-home cancer drugs (THCD) as it allows the patient a more convenient and less invasive approach to cancer treatment at home. With the shift in the delivery of treatment to the community setting, there is concern regarding the management of occupational hazard risk associated with inadvertent exposure to these drugs in a community pharmacy setting.

RATIONALE FOR THE GUIDELINE

Ontario has a decentralized dispensing model, therefore THCD may be filled at any community pharmacy in Ontario. While standards and guidelines have been developed to ensure safe dispensing and administration of IV chemotherapy, there are few published for OACD with specific considerations for dispensing in community pharmacies.³

Cancer Care Ontario (CCO) launched the Systemic Treatment Provincial Plan 2014 - 2019 which aims to improve the safety, quality, and accessibility of systemic treatment in Ontario. One of the priority areas is to ensure the safety and quality of THCD dispensed in community pharmacies. To address this priority focus. CCO collaborated with the Canadian Association of Provincial Cancer Agencies (CAPCA) and the Canadian Pharmacists Association (CPhA) to develop the Safe Handling of Oral Anticancer Drugs in Community Pharmacies: A Pan-Canadian Consensus Guideline to provide guidance around the safe dispensing and handling of oral anti-cancer drugs in low-volume settings unique to the community pharmacy setting.

The guideline was informed by existing evidence and through discussions with executive level community pharmacy leaders. Each recommendation was reviewed and revised through an iterative process to obtain consensus. It was also reviewed by more than 30 external organizations with mandates in patient or medication safety, occupational health and safety, transportation of hazardous drugs, and/or pharmacy practice. The whole process was guided by a group of experts with knowledge in medication and patient safety,

community pharmacy practice, oncology pharmacy practice, health system design, as well as individuals who represent patients and their families (the "Task Force"). The guideline provided recommendations for each point of medication lifecycle where exposure to the drug can occur. It addressed manufacturer packaging and labelling, receiving and unpacking, storage, preparation and handling, verification and dispensing, disposal and waste management, spill protocols, personal protective equipment, training and education, staffing, and incident reporting.

The guideline is intended to supplement mandatory legislative standards. It complements existing legislation, regulation, and professional practice standards. When there is inconsistency or conflict between the recommendations, the mandatory or more restrictive requirements should take precedence.

The full published guideline is

available at: https:// www.cancercare. on.ca/common/ pages/UserFile. aspx?fileId=372017

RECOMMENDED STARTING POINTS

It is expected that the full implementation of these guidelines will be challenging because of their complexity, the novelty with respect to established practice and the infrastructure needed to support their implementation. As part of the work of developing the recommendations, feedback on implementation timelines was requested from those responsible for change management (see Figure 3).

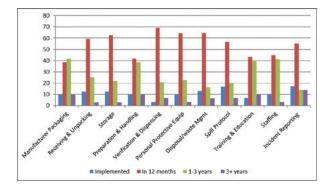


Figure 3: Expected Implementation by External Review Respondents (n=32)

To address the need to balance safety and feasibility of incorporating the recommendations into practice, the Task Force took a pragmatic approach and considered alternatives that minimize contamination and eliminate confusion to enhance adoption of the recommendations. An example is wearing two pairs of gloves when handling OACDs to eliminate confusion over the number of gloves and the associated task. In doing so, there is a risk of non-adherence to double gloving and potential inconsistencies with other guidelines. However, the Task Force felt that a consistent approach was important, thus the message is to wear gloves when handling OACD with less emphasis on the number of gloves.

We recommend that pharmacy staff, managers and owners review the guideline and have open discussions to understand the concerns and where to focus resources to implement the recommendations. We further suggest starting with the following, unless there are other priority areas identified.

A. Train staff

CCO collaborated with the Leslie Dan Faculty of Pharmacy at the University of Toronto, and the Canadian Association of Pharmacy Oncology (CAPhO) to develop the <u>Oncology Program for Pharmacists:</u> <u>A Person-Centred Approach to Cancer Care</u> for pharmacists in all practice settings. This two-part program (Essentials of Oncology and Advanced Oncology) aims to provide standardized education for pharmacists to ensure safe and high quality care to cancer patients and their caregivers. For more information, visit <u>http://cpd.pharmacy.utoronto.ca/</u> <u>oncology.html.</u>

Staff should be encouraged and given an opportunity to participate in continuing education programs as appropriate for their knowledge, skills, and job functions. We recommend that clinical verification of a THCD prescription should be done by a pharmacist with experience and training in cancer treatment. If such a pharmacist is not available onsite, it is important that another experienced and trained pharmacist is available for consultation. The use of a clinical checklist is highly recommended. Cancer Care Ontario developed a checklist that can be customized and adapted for the purpose of documentation (see https://www.cancercare.on.ca/common/pages/UserFile. aspx?fileld=362139).

Similarly, all staff who handle hazardous drugs should have training at the start of their job and routinely when job functions change or after a prolonged absence. Pharmacy managers should ensure that a trained backup staff is available for unpacking and dispensing of OACDs in case of absences.

B. Create a list of hazardous drugs encountered in the pharmacy

Drugs that are considered hazardous to humans or animals are associated with one of the following characteristics: 1) carcinogenicity; 2) teratogenicity or other developmental toxicity; 3) genotoxicity; 4) reproductive toxicity; 5) organ toxicity at low doses; and 6) structure and toxicity profiles of new drugs that mimic existing drugs determined by the above criteria⁴. OACDs pose hazards through dermal absorption, inhalation, and ingestion via contaminated surfaces. Coated tablets or capsules that are solid and intact without modifications when administered to patients may pose less significant risk.⁴ However, uncoated tablets are at risk of forming dust when subjected to stress (e.g. when poured in and out of a container, and repeatedly counted), which can contaminate the workplace.4

While there is no single list of hazardous drugs that is accepted worldwide, the National Institute of Occupational Safety and Health (NIOSH) produces and updates a list periodically that can be used as a guide from which to develop a workplace or setting-specific



hazardous drug list based on an inventory of the drugs handled and the potential for exposure. Guidance on how these workplacespecific lists should be developed is available through NIOSH at https://www.cdc.gov/niosh/topics/ antineoplastic/pdf/hazardousdrugs-list_2016-161.pdf.

We suggest that the Designated Manager or a delegate and staff compile a list of hazardous drugs that require additional caution (e.g. segregated space or the use of personal protective equipment). This list should be posted in all areas of the pharmacy where there may be contact with OACD (e.g. receiving, storage, dispensing and disposal areas). The list should be reviewed annually at a minimum and with each new drug that enters the pharmacy. All OACD on this list should have a visible label to indicate that they require additional precaution (e.g. personal protective equipment).

C. Physically separate OACDs

It is best practice to have a separate room for receiving,

unpacking of OACD shipments and storage where access is restricted to staff who have received appropriate training. However, since space may be limited within the community pharmacy setting, all activities involving OACD should (at minimum) be done in a designated, low-traffic area that is clearly marked off and labelled distinctly to indicate extra caution is required. We further recommend that storage of OACD in the dispensary be segregated from all other non-hazardous drugs. This will help to limit staff exposure, lower the risk of medication error through incorrect selection of medication, and provide a visual indication that special handling is required.

In addition to dedicating separate physical space for handling and storing OACD, it is also important to dedicate separate equipment to be used solely with hazardous drugs. This includes a dedicated counting tray and spatula as well as disposal containers for hazardous drugs only. Disposal containers should be rigid with a lid and clearly marked for hazardous drugs only. These containers should be made available where OACD are handled and disposed of by incineration by an appropriate company.

D. Evaluate available tools and current compounding practices

In some cases, the prescribed dose of an OACD is not commercially available and compounding is required. Class I Biological Safety Cabinet (BSC) is recommended for the compounding of non-sterile hazardous drugs. When a containment cabinet is not available for non-sterile compounding, consider other alternative tools and practices to minimize contamination to the work area and staff. Safe work practices while wearing personal protective equipment (PPE) in a low-traffic, designated area, along with the use of tools that minimize exposure may be sufficient. Examples include crushing tablets with mortar and splitting tablets inside an enclosed clear and re-sealable bag, wetting the tablet prior to crushing to minimize aerosolization, and using devices such as Dissolvea-Dose[™] containers.

When dispensing, the final packaging should prevent or minimize access and exposure to unintended individuals. Whenever possible, the medications should be dispensed in their original packaging, in containers with childproof lids (unless otherwise requested), and/or have additional packaging such as resealable plastic bags to contain inadvertent spills. OACDs should be dispensed in a ready-to-use formulation that reduces the need for cutting/crushing in order to eliminate/minimize patient/caregiver exposure.

E. Ensure availability of personal protective equipment (PPE)

While engineering and administrative controls are being considered for implementation and when other safety controls cannot be obtained, PPE is the last line of defense. Community pharmacies should have the following PPE available; ASTM standard D-6978-05 chemotherapy gloves, certified hazardous waste protective gowns, fitted respiratory protective masks (N95 or better), and protective eyewear. The following are recommended:

- Two (2) pairs of non-sterile gloves during all activities involving OACD (except transport, receiving and handling in final dosage form.)
- A gown when cleaning preparation areas (including containment cabinets), handling waste (including damaged packages and spills) and compounding if there is a risk of splash or spill (e.g. liquids).

- Respiratory protection mask when cleaning the containment cabinet or handling damaged packages and spills.
- Eye protection when cleaning preparation areas (including containment cabinets), compounding if there is a risk of splash or spills (e.g. liquids) and handling damaged packages and spills.
- Hair cover when cleaning the containment cabinet.
- Shoe cover when cleaning the containment cabinet and when handling damaged packages and spills.

SUMMARY

The set of recommendations were made to be practical and introduce a reasonable approach that encourages a system-wide and gradual change in community pharmacy practice. However, it is not unexpected that the complete adoption of the above recommendations will be challenging, especially those vastly different to established practices and infrastructure.

Designated Managers are encouraged to assess their current practices, address possible barriers to implementation, and discuss ways in which the recommendations can be adopted. As oral anti-cancer drugs become more prevalent in community settings, pharmacies must be prepared to handle them safely.

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INTER- AND INTRAPROFESSIONAL COLLABORATION: Learnings from Family Health Teams

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Case Vignette 1: Colleen* was in the office again. She was a complex patient. Suffering from schizophrenia and post-traumatic stress disorder (PTSD), she also had other medical concerns. Her Hb A1c was 14.1%. Her blood pressure was 150/90 mmHg. Colleen was tentative about the referrals her doctor was recommending. A dietitian sounded like the last thing she wanted – someone to judge her for what she ate! The idea of a pharmacist to start insulin sounded even more intimidating.

When Colleen met the Family Health Team (FHT) pharmacist, and Julie, the dietitian, she told them that they were much nicer than she was expecting. Usually people would just tell her what to do - stop drinking pop, and no more candy. Instead, the focus was on realistic goals based on her current lifestyle. Julie coached her gently and gradually she decreased her pop intake from 8 to 2 cans per day. The pharmacist titrated her insulin slowly, celebrating the small victories along the way as her sugars improved. The pharmacist also worked with her psychiatrist to switch to medications with fewer metabolic side effects. Todav her Hb A1c is 6.9% and her blood pressure is 128/77 mmHg.

Colleen's story is not unusual in primary health care practice. Complex patients like her are becoming more common as our population ages and more people live with multiple chronic conditions. In order to rise to this challenge, we need interprofessional teams and strong collaboration to provide optimal care.

WHAT DOES EFFECTIVE INTERPROFESSIONAL COLLABORATION LOOK LIKE?

Interprofessional collaboration comes in many forms. For a pharmacist, whether practicing in a FHT or out in the community, it can mean partnering with other professions to optimize patient care, as described above. It can also mean playing the role of educator by keeping physicians and the broader interprofessional team up to date on new medications and changing guidelines. Interprofessional collaboration often begins by providing other health professionals with details of the pharmacist role and scope of practice and describing how the pharmacist can benefit their practice and patients. This dialogue can also highlight opportunities for enhancing knowledge and skills, such as certifications that will support patient care.

Examples of interprofessional collaboration in a FHT that could be utilized in the community:

- Pharmacist and physician working together to identify and deprescribe unsafe or no longer appropriate medications in the elderly.
- Pharmacist collaborating with a case coordinator to support a complex care patient in the community.
- Pharmacist and nurse reviewing immunization guidelines together to create a catch-up schedule for a new patient.
- Pharmacist and dietician working together to create a comprehensive workshop for patients addressing Type 2 Diabetes.

Case Vignette 2: The physician was frustrated when she asked the FHT pharmacist to look at the latest fax from the pharmacy. "So much back and forth!" she exclaimed. Looking at the trail of messages, the pharmacist could see the problem – the physician colleague had written a vague prescription that required clarification. However, the FHT pharmacist thought that if this community pharmacist knew the rationale behind the prescription, they could have interpreted it. A current FHT deprescribing initiative meant lots of prescribers were writing taper prescriptions for various medications - always a risk for confusion and miscommunication. So, the FHT pharmacist invited the local community pharmacists to a meeting, and explained the initiative. The community pharmacists provided feedback on how FHT clinicians could write better and clearer prescriptions. Since that meeting, the FHT has received fewer faxes for clarification, and the community colleagues have helped identify possible candidates for deprescribing, increasing the success of the initiative

WHAT DOES EFFECTIVE INTRAPROFESSIONAL COLLABORATION LOOK LIKE?

Collaborating with other pharmacists is just as important as collaboration with other professions. This collaboration can occur in order to smooth transitions in patient care, or for the sake of advocacy or better coordination within the profession. Pharmacists need to build strong partnerships across the continuum of care to ensure safe and effective medication use as patients traverse the health care system.

PROVIDING PATIENT-CENTRED CARE

The common thread highlighted by the examples above is that when professionals collaborate, both inter- and intraprofessionally, patient care improves. After all, not only is collaboration a standard of practice¹ but it's also the means by which we can do the best for our patients, in line with the principle of beneficence². When conducted well, both types of collaboration offer the added benefit of being professionally rewarding, and as health care professionals there is no greater outcome than accomplishing patient goals and improving patient care.

Examples of intraprofessional collaboration among pharmacists:

- MedsChecks at community level improving quality of medication reconciliation in a FHT or hospital setting.
- Hospital pharmacist collaboration with a pharmacist in a FHT regarding therapeutic drug monitoring (i.e. warfarin or anti-epileptics at time of discharge).
- A pharmacist in a FHT working with a community pharmacist to help transition a patient with dementia to compliance packaging.
- Medication reconciliation between an elderly patient's current community pharmacist and the pharmacist in their new long-term care home to ensure a smooth transition when relocating.

*names and details have been changed for patient privacy

REFERENCES:

- 1. <u>Model Standards of Practice for</u> <u>Pharmacists</u>
- 2. <u>The Code of Ethics</u>

NEW PROFESSIONAL MISCONDUCT REGULATIONS IN EFFECT



The provincial government has approved changes to the <u>Professional Misconduct Regulations</u> (O. Reg 130/17) under the Pharmacy Act, 1991. The changes, which the College <u>previously</u> <u>consulted on</u> in 2013, have been made to ensure that the regulations reflect adjustments to the Drug and Pharmacies Regulation Act, 1990 and other legislation, the growth of the scope of practice of pharmacy professionals, and the addition of pharmacy technicians as regulated health professionals. They are also intended to provide increased clarity regarding conflicts of interest.

For member conduct occurring after May 5, 2017, a determination of whether a member committed acts of professional misconduct will be assessed under the new Professional Misconduct Regulations. All pharmacy professionals are expected to be aware of and review the regulations, which are accessible in full on the <u>Ontario e-laws website</u>.

MAJOR CHANGES TO THE REGULATIONS

The College has prepared a <u>clause by clause</u> <u>comparison document</u> containing all the changes made to the regulations. Some of the significant changes are highlighted below.

The following is considered to be professional misconduct:

Failing to advise a patient to consult another member of a health profession (Part I, 3.)

When a pharmacy professional knows or ought to know that they do not have the knowledge, skills, judgment or scope of practice to provide a service that a patient requires, they must advise the patient to consult another professional. For example, a pharmacy professional cannot diagnose an illness and would need to advise a patient to consult a physician.

Performing a professional service without the knowledge, skill or judgment required (Part I, 4.)

Pharmacists and pharmacy technicians must have the appropriate knowledge, skill and judgment before performing a professional service. For example, a pharmacist cannot administer injections without completing the appropriate requirements (and registering their training with the College).

Failing to provide an appropriate level of supervision to a person whom the member is professionally obligated to supervise (Part I, 11.)

Pharmacists and pharmacy technicians who are responsible for supervising students, interns or other

pharmacy staff must be aware of their obligations to ensure good patient care in accordance with all legislation, standards and policies. This includes ensuring that students and interns only practice within their allowed scope (see the College's <u>Supervision</u> <u>of Pharmacy Students and Interns</u> Fact Sheet). The requirement extends beyond just the pharmacy professional who has taken on formal obligations as a workplace monitor to supervise the practice of another professional. It also includes those pharmacy professionals who may be working in the pharmacy while the formal supervisor is not available. Designated Managers have <u>additional obligations</u> to ensure that the pharmacy is appropriately staffed and supervised.

Failing to keep confidential personal health information or other personal information (Part I, 18.)

Pharmacy professionals must have consent of the patient (or otherwise are permitted by law) to disclose personal health information.

Soliciting an individual for professional services except under certain conditions (Part I, 25.)

Pharmacy professionals are allowed to solicit individuals only to provide information about the availability of professional services. The pharmacy professional must advise the person, as soon as possible, that the purpose of the solicitation is the use of the member's professional services, and the person may choose to have the solicitation end immediately or at any time. For example, a pharmacist could email a patient to offer to conduct a medication review. However, he would need to provide a clear opportunity for the patient to unsubscribe at any time and ensure that he complied with that request.

Returning to stock or re-selling or re-dispensing a drug that was previously sold or dispensed (Part I, 28.)

There are some exceptions to this clause. Schedule II and III drugs that do not require refrigeration and

THE MEANING OF "OUGHT TO KNOW"

Pharmacy professionals can be found guilty of professional misconduct for committing an act that they know or ought to know is inappropriate. What this means is that where a pharmacy professional imparts that they did not know they have done something wrong, but a panel of peers finds that in the situation being reviewed most pharmacy professionals would have known to act differently, it is therefore a reasonable assumption that the pharmacy professional should have known what they did was wrong. Consequently, the pharmacy professional can be found to have committed professional misconduct.

are in their original packaging may be returned to stock. Additionally, pharmacy professionals can accept the return of a drug from a patient for the purposes of re-packaging and re-dispensing the drug to the same patient where it is appropriate to do so. For example, if a patient returns to the pharmacy with medications that they would like to have dispensed in a compliance aid and the pharmacy professional confirms that the medications would be suitable for compliance packaging.

Dispensing, selling or compounding a drug, or administering a substance that is not of good quality or does not meet the standards required by law (Part I, 29)

Pharmacy professionals are accountable for the products that they prepare and dispense. Pharmacy professionals must ensure that drugs dispensed are stable and of good quality (e.g. are not past expiry or exposed to conditions that would alter the effectiveness of the drug such as a cold chain breach).

Failure to cooperate with the College (Part I, 33-38)

It is professional misconduct for a member to not co-operate with an inspector of the College, the Registrar or a College committee, including not replying in a timely manner to a written or electronic request from the College. Pharmacy professionals must also carry out or abide by undertakings or agreements they have made with the College.

PRACTICING WHEN IN A CONFLICT OF INTEREST (PART II)

The new Professional Misconduct Regulations bring significant clarity regarding conflicts of interest. Pharmacy professionals must not practice the profession while in a conflict of interest, including a perceived conflict of interest, or participate in an arrangement that constitutes a conflict of interest, even if it is initiated by someone other than themselves. Examples of conflict of interest include, but are not limited to:

- The member's personal or financial interest appears to conflict with their professional or ethical duty to a patient or the exercise of their professional judgment.
- The member requests, accepts or receives a benefit by reason of the referral of a patient or anyone else.
- The member offers, makes or confers a benefit to a person by reason of the referral of a patient to the member or their pharmacy.
- The member enters into any agreement that influences or encourages a prescriber to promote the services of the member or their pharmacy.

All pharmacy professionals must recognize that the patient's best interests must always override their own interests. or the interests of the business which the member owns, has a financial interest in or is employed by. Pharmacists, pharmacy technicians, Designated Managers, and directors must also recognize that the responsibility for effective and ethical pharmacy services is a shared one. Read Close Up on Complaints: A Shared Responsibility for Ethical and Effective Pharmacy Services, published in the Winter 2017 edition of Pharmacy Connection. Re

EXAMPLE OF CONFLICT OF INTEREST

<u>Close Up on Complaints – Avoiding Actual of Perceived Conflicts of Interest in Business Dealings</u> (Pharmacy Connection Spring 2017)

REMINDER: STERILE COMPOUNDING GAP ANALYSIS DOCUMENT AVAILABLE

In September 2016, Council adopted the <u>Model Standards for Non-hazardous Sterile</u> <u>Preparations</u> (NAPRA, 2016) and the <u>Model Standards for Pharmacy Compounding</u> <u>of Hazardous Sterile Preparations</u> (NAPRA, 2016) and approved implementation by January 1, 2019. The standards will apply to all pharmacies where sterile compounding is performed, including community pharmacies, drug preparation premises and hospital pharmacies.

The College has produced <u>gap analysis documents</u> based on the current community and hospital assessment criteria and is working on aligning the documents with the Model Standards. These documents have been provided as tools to assist pharmacy professionals in assessing gaps in their sterile compounding practice and determining next steps required. They can also be used to track and monitor progress. The documents are not meant to replace the standards. If you have a practice assessment coming up, you are encouraged to fill out the document ahead of time for discussion with your practice advisor. While the College does not require you to fill out or submit this analysis (and you are welcome to use other resources that might be available), it can be very helpful in ensuring that your pharmacy is prepared for upcoming deadlines.

Access the <u>Gap Analysis for Hazardous Sterile</u> <u>Preparations</u> and the <u>Gap Analysis for Non-hazardous</u> <u>Sterile Preparations</u>.



Every pharmacy in Ontario needs to have certain references available, including an annual subscription to a drug information service. Learn more about what's needed in your pharmacy's library: <u>http://www.ocpinfo.com/regulations-standards/additional-resources/reference-guide/</u>

Follow @OCPinfo on Twitter and get a helpful practice tip each week. #OCPPracticeTip



REPORTING ADVERSE REACTIONS to Vaccines and Medications

As healthcare professionals, pharmacists and pharmacy technicians are required by <u>law</u> to make certain reports when they become aware of adverse reactions to vaccines. The Standards of Practice also require that pharmacists, when providing patient care, report the occurrence of adverse reactions involving medication or health products.



RESOURCES RELATED TO VACCINE REPORTING FROM PUBLIC HEALTH ONTARIO

- Fact sheet: Adverse Event Following Immunization Reporting for Health Providers
- Adverse Events Following Immunization
 Reporting Form

An adverse reaction is defined as a harmful and unintended effect from use of a health products.¹ Pharmacy professionals are not required to be certain that a particular health product caused a reaction in order to report it – only suspect that it had an effect.

It is extremely important to report adverse reactions as reports can help with the identification of potentially severe reactions, result in changes to the information provided with the product, and assist in improving the health and safety of all Canadians.

ADVERSE EVENTS FOLLOWING IMMUNIZATION

An adverse event following immunization (AEFI) is an unwanted or unexpected health effect that occurs after someone receives a vaccine.² Pharmacy

professionals do not need to be certain that the effect was caused by the vaccine itself.

Reports on AEFIs can be made using the <u>Ontario AEFI</u> <u>Reporting Form</u> and the completed form should be sent to the local Public Health unit. This is in addition to any other reporting that may take place, such as to a designated manager, institution, MedEffect Canada or the manufacturer.

Aside from mandatory reporting to Public Health, pharmacy professionals should document circumstances relating to any adverse reaction experienced by the patient and treatment recommended or administered as a result. Refer to the College's <u>Administering Injections Guideline</u> and the <u>Administering Injections practice tool</u>.

ADVERSE REACTIONS TO MEDICATION OR OTHER HEALTH PRODUCTS

<u>MedEffect Canada</u> is Health Canada's program for reporting of adverse reactions to health products, including medications (both prescription and non-prescription), natural health products, and vaccines. Health professionals are asked to report all suspected adverse reactions, particularly if they are:

HEALTH CANADA'S DEFINITION OF A SERIOUS ADVERSE REACTION

Requires hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death. Adverse reactions that require significant medical intervention to prevent one of these outcomes are also considered to be serious.¹

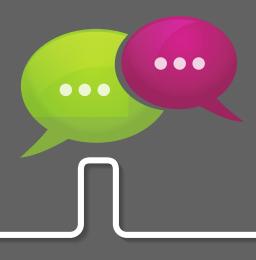
- Unexpected i.e. not consistent with patient information or labelling;
- Serious; or
- Related to a health product that has been on the market less than five years.¹

Be prepared to provide patient information (e.g. age, weight and other non-identifying information), a description of the reaction, the name of the health product and contact information. Reports can be made <u>online</u>, by mail or by phone at 1-866-234-2345.

Pharmacy professionals can stay informed on new or emerging information about health product safety and effectiveness by <u>subscribing</u> with MedEffect Canada or regularly visiting their <u>Advisories</u>, <u>Warnings</u> <u>and Recalls</u> page.

REFERENCES

- 1. Health Canada. Adverse Reaction Reporting and Health Product Safety Information Guide for Health Professionals (2011). Cited 2017 June 9. Available from: <u>https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/adverse-reaction-reporting-health-product-safety-information-guide-health-professionals-health-canada-2011.html</u>
- 2. Public Health Ontario. Vaccine Safety (2017). Cited June 9, 20-17. Available from: http://www.publichealthontario.ca/en/BrowseByTopic/ InfectiousDiseases/Pages/Vaccine-Safetyaspx? cldee=dGFyYS5oYXJyaXNAb2FocHAuY2E%3d&recipientid=contact-09f7f1fb-2c2e41191f10050569e0009-347c2740fdb84ffeac2b3a9e1dd63727&esid=54d2d5dc-8c35-e711-89df-0050569e0009



HEALTH CANADA CONSULTATION ON MANDATORY REPORTING OF SERIOUS ADVERSE DRUG REACTIONS AND MEDICAL DEVICE INCIDENTS

Health Canada is currently seeking feedback from health professionals and healthcare institutions on proposed changes to the Food and Drug Regulations and Medical Devices Regulations, which would make it mandatory for healthcare institutions to report serious adverse drug reactions and medical device incidents. These changes are part of the implementation of the *Protecting Canadians from Unsafe Drugs Act* (or Vanessa's Law). Learn more and provide your feedback on the Health Canada website.

STRENGTHENING THE PROTECTION OF PATIENTS IN ONTARIO



The <u>Protecting Patients Act, 2017</u> (formerly known as Bill 87) was introduced by the Ontario government to amend four statutes and enact one new statute to support Ontario's Patients First: Action Plan for Health Care. The legislation will protect patients by strengthening and reinforcing Ontario's zero tolerance policy on sexual abuse of patients by any regulated health professional through changes to the Regulated Health Professions Act, 1991 (RHPA) and the Drugs and Pharmacies Regulation Act, 1990 (DPRA). It also supports more accountability and transparency within the health care system and emphasizes patient safety and protection as the foremost priority for health care professionals. The Act received royal assent on May 30.

The College strongly supported the objectives of this legislation to strengthen the sexual abuse and transparency provisions of the RHPA. The College is already well on the way to meeting the requirements of the Act regarding posting of information on the Public Register and supports both expanding access to funding for victims of sexual abuse as well as mandatory revocation for any conduct relating to sexual abuse.

Selected legislative amendments under the *Protecting Patients Act* include:

- Expanding the list of acts of sexual abuse that will result in mandatory revocation of a certificate of registration.
- Removing the ability of a health regulatory college to impose any gender-based terms, conditions or limitations on a member's certificate of registration.
- Ensuring more timely access to therapy and counselling for patients who make a complaint of sexual abuse.
- Requiring that more information regarding the current and past conduct of regulated health professionals is available to the public.
- Allowing the Inquiries, Complaints and Reports Committee (ICRC) to make an interim order for the

suspension of a member's certificate of registration at any point after the filing of a complaint or the appointment of an investigator if it is of the opinion that the conduct of the member exposes or is likely to expose the member's patients to harm or injury.

- Allowing the Accreditation Committee to make an interim order for the suspension or imposition of terms, conditions or limitations on a certificate of accreditation if it is of the opinion that the conduct or operation of a pharmacy is likely to expose a patient or member of the public to harm or injury.
- Increasing the potential fines for failure to make a mandatory report to not more than \$50,000.

The Act also allows for regulations to be made regarding the definition of a patient. It is anticipated that these regulations will clarify that a patient for whom a health professional is caring will continue to be defined as his/her patient (for the purposes of sexual abuse provisions) for a period of one year, or longer as prescribed or intended by a College, after the last patient interaction.

Additional information on this legislation will be provided in upcoming editions of *Pharmacy Connection*.

REPORTING OBLIGATIONS FOR PHARMACY PROFESSIONALS

Under the Act, Pharmacy professionals must report to the College:

- Findings of professional misconduct or incompetence made against them by a body governing the profession outside of Ontario; and/or
- If they are charged with an offence and any bail conditions or restrictions related to that charge

Reporting should be done in writing and as soon as reasonably practical following notice of the finding, charge, condition or restriction.

What's Next?

THE MINISTRY OF HEALTH AND LONG-TERM CARE

The Ministry of Health and Long Term Care has engaged Deanna Williams, a former OCP Registrar, to provide advice and expertise related to the <u>recommendations</u> <u>of the Sexual Abuse Task Force</u>. This work is separate from the *Protecting Patients Act*, and any changes as a result would likely be implemented via regulation or policy changes. She will be providing expertise on:

- Best practices on intake of complaints, investigations and discipline of misconduct matters;
- Best practices with regards to patient supports and patient relations with the Colleges;
- Best practices on College governance and committee membership; and

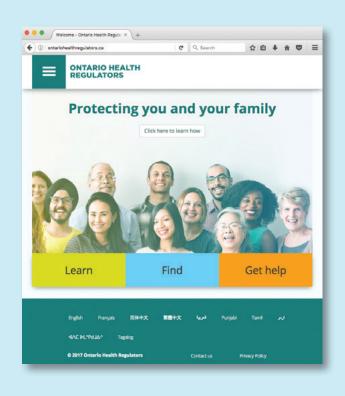
• Review of the Task Force recommendations to establish an independent body for investigation and adjudication of sexual abuse matters

The College will work with Ms. Williams and the Ministry to support the protection of patients.

THE COLLEGE

It is the mandate and responsibility of a regulator to serve and protect the public interest. In addition to working with the Ministry of Health and Long-Term Care as regulations are developed, the College will continue to explore opportunities to enhance the public register and information that is shared about pharmacy professionals and pharmacies to help patients and the public make decisions about their care. Work will continue with the Patient Relations Committee to ensure programs related to sexual abuse are meeting the needs of patients who may have been sexually abused. Given the invaluable contribution patients and their advocates make to supporting a high-quality health system in Ontario, the College will also work with the Committee to explore opportunities to engage directly with patients to get their feedback and perspectives related to College processes, activities and priorities.

As one of Ontario's 26 health regulatory colleges, the College will collaborate with the other health regulators to adopt consistent approaches where possible and to facilitate greater patient and health care provider understanding of the roles, systems and programs of the colleges.



New Ontario Health Regulators Website

The Federation of Health Regulators of Ontario (FHRCO) has created a website, <u>OntarioHealthRegulators.ca</u>, to help patients find a regulated health professional, understand the rights they're entitled to and get help from a health regulator when they have a concern about the care they have received. Information is available in 10 languages.

Pharmacy professionals are encouraged to recommend this website where a patient has questions or concerns about a non-pharmacy regulated health professional.

HEALTH PROFESSION ACT

WHO CAN PRESCRIBE DRUGS IN ONTARIO?

The Regulated Health Professions Act, 1991 (RHPA) sets out the governing framework for Ontario's 26 regulated health professionals, including defining 13 "controlled acts" which may pose a risk to the public if not performed by a qualified practitioner.

Each health profession has a Health Profession Act that defines the specific health profession's scope of practice, restricted titles, and the controlled acts they are authorized to perform. At present, eight of the 26 Health Profession Acts include authorization of the controlled act of "prescribing, dispensing, selling or compounding a drug". Any terms, conditions or limitations on this authority are determined in the regulations, such as any educational requirements or specific classes of drugs that may be prescribed.

Healthcare professionals are responsible for ensuring that they practice within their defined scope of practice. If a pharmacy professional is uncertain of the prescribing authority of a regulated health professional regarding a prescription, they can contact the prescriber or consult <u>the relevant</u> <u>regulatory College</u>. If the prescriber is licensed outside Ontario, prescribing authority is determined by the laws regulating practice in that particular province or territory. Out of province prescribers may not be familiar with Ontariospecific legislation, such as the *Narcotic Safety and Awareness Act*, and collaboration may be required to ensure a prescription contains all the required elements to be valid.

All health professional colleges in Ontario are required to maintain a public register of their members. Pharmacy professionals are encouraged to verify the status of the prescriber through the appropriate public register to ensure the prescriber is a member in good standing and has the authority to prescribe the specific drug or device (for example, verifying that a nurse practitioner has the requisite authority to prescribe controlled substances).

Regulated Health Professionals who can prescribe a drug

(subject to any terms, conditions or limitations)

- Chiropodists (Podiatrists)
- Dentists
- Midwives
- Naturopaths
- Nurses
- Optometrists
- Pharmacists
- Physicians and Surgeons

ADDITIONAL RESOURCES:

- Physician Prescribing Status Fact Sheet
- Out of Province Prescriptions Fact Sheet
- Ontario Health Colleges
- Ontario's Physician Assistants (Pharmacy Connection Fall 2014)



"Close-Up on Complaints" presents errors that occur when providing patient care so that pharmacy professionals can use them as learning opportunities. Ideally, pharmacists and pharmacy technicians will be able to identify areas of potential concern within their own practice, and plan and implement measures to help avoid similar incidents from occurring in the future.

CLOSE-UP ON COMPLAINTS: ENSURING THE APPROPRIATE THERAPY FOR THE APPROPRIATE PATIENT

SUMMARY OF THE INCIDENT

The incident occurred when a mother was picking up a prescription at the pharmacy for her two year old daughter. The pharmacist reviewed the prescription, asked her daughter's age and weight, confirmed that the medication was appropriate and instructed the mother on how to use the medication. The mother then provided her daughter the first dose and took her to daycare.

Later that day, the mother received a call from the daycare stating that the medication label indicated that it was actually for a different patient, not her daughter. The mother had been dispensed a prescription intended for a patient who was a higher weight than her daughter, but who was receiving the same medication. The mother returned to the pharmacy, where staff apologized and provided the correct medication. The mother was very concerned that she had overdosed her daughter that morning. The mother observed that the issue was only

caught because the daycare had strict procedures on checking medication.

WHY DID THIS HAPPEN?

This incident was the result of the pharmacist missing a very basic step during counselling: checking that the correct patient received the correct medication.

In her response to the complaint, the pharmacist indicated that the pharmacy was very loud and busy at the time of dispensing, and that when she counselled the mother, she was slightly distracted and did not have the worksheet on which she had checked the prescription against the original with her. While the symptoms of the patient seemed to fit the medication, she neglected to both note the higher dosage and to perform a double check that the medication was for this specific patient.

COMPLAINT OUTCOME

The College's Inquiries, Complaints & Reports Committee (ICRC) oversees investigations of each complaint the College receives. The Committee considers a pharmacy professional's conduct, competence and capacity by assessing the facts of each case, reviewing submissions from both the complainant and the pharmacy professional, and evaluating the available records and documents related to the case.

ADVICE/RECOMMENDATION

Advice/recommendations allow an opportunity for pharmacy professionals to improve conduct or care.

Advice/recommendations are issued as a remedial measure for matters which are not serious in nature and are considered to pose low risk of harm to the public.

This incident was the result of the pharmacist missing a very basic step during counselling: checking that the correct patient received the correct medication.

While the panel noted that the pharmacist provided a good response to the incident once it was raised, they emphasized that a basic check had been skipped during patient counselling.

The panel emphasized that pharmacists should not be too busy to provide good patient care and are required to follow the Standards of Practice regardless of the volume of prescriptions or other conditions in the pharmacy. While this medication did not ultimately cause harm to the patient, it could have if she had received a full adult dose or the incorrect medication.

The Committee issued advice and recommendations to assist the pharmacist in how she may be more thoughtful in her practice when performing appropriate checks on prescriptions.

LEARNINGS FOR PHARMACY PROFESSIONALS

Patient Care

The Standards of Practice require that pharmacists apply their medication and medication use expertise to ensure patients receive the appropriate therapy. Prior to dispensing or counselling a patient, it is imperative to ensure that the right patient is receiving the correct medication. Pharmacists must also ensure that clear, legible and accurate records are kept for each patient and should have systems and checks in place to ensure that a patient's prescription is entered under the correct patient record.

Pharmacy professionals must never forget that patients, especially parents of young children, rely on pharmacy professionals to use their knowledge, skills and judgment to make decisions that positively enhance health outcomes and provide patientfocused care. This means ensuring that the medication their loved ones receive will not only not harm them, but will also treat their condition appropriately.

A child is a "red flag", or particularly vulnerable, patient and therefore more care and attention must be provided, given the potential seriousness of outcomes that could occur in this population. While the error that occurred was clinically minor, dosing with an incorrect dosage or administering an incorrect medication in a child has the potential to be much more severe.

Safety and Quality

Pharmacy professionals must accept responsibility for ensuring that the practice environment in which they have selected to work supports their provision of quality pharmacy care and services – they cannot forgo this requirement due to a busy environment or high volume of prescriptions.

The Standards of Practice require all pharmacists to support quality assurance and quality improvement and respond to safety risks when they appear. Pharmacy professionals must disclose medical errors and "near misses" and share information appropriately to manage risk of future occurrences. When an incident does occur, pharmacy professionals must act with honesty and transparency and assume responsibility for disclosing this harm to the patient and initiating steps to mitigate the harm. Pharmacies should have reliable emergency contact information for patients (or a patient's guardian) to enable early notification and reduce unnecessary stress in the event of a medication incident. Prompt notification should also be made to any other healthcare providers involved.

Designated Managers are responsible for reviewing errors and incidents to determine patterns and causal factors that contribute to patient risk, and developing and implementing policies and procedures that minimize errors, incidents and unsafe practices. This includes supporting staff in their obligation to report adverse events and close-calls.

Designated Managers must make sure that the pharmacy has the processes and procedures to ensure that a safe and effective system of medication supply is maintained at all times. They must also ensure the necessary equipment, system and staffing are in place to allow pharmacy professionals to meet the Standards of Practice of the profession and support the provision of appropriate pharmacy services.

If a pharmacy is too busy to complete basic checks and provide good patient care, then additional prescriptions should be directed elsewhere. Pharmacy professionals have an obligation to follow the Standards of Practice and provide safe and quality patient care at all times.

THE COLLEGE'S NEW SCOPE OF PRACTICE STRATEGY: EMPOWERING CHANGE TO MAXIMIZE PATIENT HEALTH OUTCOMES

The College has developed a Scope of Practice Strategy to support pharmacists and pharmacy technicians practicing to scope. A lack of integration and an underutilization of technicians, particularly in community practice, has been a barrier in optimizing the scope of practice for both professionals. It's a fact that under 25% of pharmacies employ technicians and utilize them to their full scope.¹

Pharmacy technicians play an important role in supporting pharmacists to maximize their clinical role as medication therapy experts and it is key that the profession recognizes the value that these professionals bring to practice from both an overall patient care perspective and business perspective. Ultimately, better utilizing and integrating technicians means that patients benefit from a higher standard of care.

PREPARING FOR THE FUTURE

Pharmacy services have evolved over the years. Where in the

past the focus of pharmacists was mainly that of "dispensing", the expectation today, from the healthcare system and from patients, is that they assume the role of counsellor, advisor, and clinical decision-maker. Patient needs require the expertise of pharmacists now more than ever before. But pharmacists are time-pressed and feel they have to manage two time-consuming activities: product distribution and the provision of clinical services.

For this reason, in 2010 the College regulated pharmacy technicians – a healthcare professional dedicated to product distribution who is held responsible and accountable for their work. Technicians could handle product distribution so pharmacists could focus their time on the delivery of clinical services. But this can only occur if technicians are integrated into practice and their skills fully utilized.

The level of this integration and utilization has been disappointingly low, and while it is not always clear why, challenges include the absence of defined business models that articulate the role of pharmacy technicians in practice, lack of understanding of the value technicians bring, and financial constraints (perceived or real).

Below, the College's Scope of Practice Strategy elements and key steps have been outlined. It's essential that barriers are addressed so technicians can be more effectively integrated, pharmacists can practice to scope, and patients can benefit from the highest quality of care. The pharmacy profession has to continue to evolve while the needs and demands of patients change, and pressures on the healthcare system grow.

SCOPE OF PRACTICE STRATEGY KEY ELEMENTS:

Professional Engagement

Strengthening professional engagement of pharmacists and technicians is crucial in achieving the strategy. Professional identify, confidence, professionalism, competence and ethics, trust, clearly defined roles, and inter- and intraprofessional relationships will prove instrumental. Many of these factors are interconnected. For instance, it's likely that confidence is key to achieving effective inter- and intraprofessional collaboration.

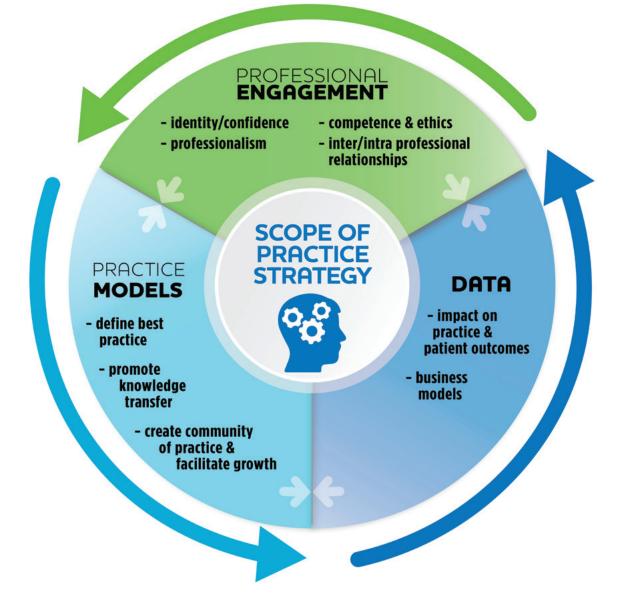
Professional engagement will support the development of new or revised education and training programs for entry to practice and continuing education.

Practice Models

The College will identify pharmacies fully utilizing technicians to help define best practice models incorporating these professionals. These best practice models will take into consideration the ideal physical layout of a pharmacy, appropriate staffing ratios, and appropriate delegation of tasks. Once the models are developed, this group will be important and helpful in promoting knowledge transfer to others within the profession and creating a community that will facilitate practice change and growth.



The College will work with partners to collect and analyze data to understand the impact of practicing to scope on pharmacy services and patient outcomes, as well as on the barriers and facilitators related to the utilization of pharmacy technicians and enhanced clinical services by pharmacists. The data and impacts will relate to both patient outcomes and economic/ business benefits needed to inform decision-making.



SCOPE OF PRACTICE STRATEGY'S 5 KEY STEPS



Create an Advisory Committee to inform, support, align and identify partnerships with stakeholders;



Define best practice models (and the value proposition) and create a community of best practice to help facilitate growth;



Identify barriers and facilitators impacting utilization of pharmacy technicians to optimize pharmacist scope;



Establish an education and training agenda for entry to practice and continuing education to enhance professional engagement for both professions; and



Develop quality indicators to measure the impact of collaborative practice models on clinical pharmacy services and patient outcomes.

WHAT'S NEXT?

In addition to the implementation of core College programs, such as introducing Quality Assurance for technicians, that will impact the integration of pharmacy technicians in practice, OCP will engage educators, pharmacy owners, corporations and other stakeholders with aligned objectives to support the strategy outlined

above. Updates will be provided as the strategy progresses and evolves. $\ensuremath{\mathbb{R}}$

*1 Number of Technicians working to scope based on community pharmacy assessments between December 5, 2014 and January 24, 2017



Pharmacists, registered pharmacy students, interns, and pharmacy technicians have different legal authority for scopes of practice. Be sure you understand the differing scopes between each. This helpful chart clarifies: <u>http://www.ocpinfo.com/library/practice-related/download/Legal%20</u> <u>Authority%20Scopes.pdf</u> #OCPPracticeTip

Follow @OCPinfo on Twitter and get a helpful practice tip each week. #OCPPracticeTip

Reminder: Requirement to Maintain Personal Professional Liability Insurance



All members engaged in the practice of pharmacy, including students, interns, pharmacists (with the exception of Part B pharmacists) and pharmacy technicians are required to maintain personal professional liability insurance coverage.

When applying for a certificate of registration and upon annual registration renewal, members, with the exception of Part B pharmacists, are required to complete a declaration confirming that they have obtained and will maintain personal professional liability insurance as specified in the <u>College By-law</u>. Documentation must be available to the College upon request. The College will be in touch with you if and when we require documentation. The College has the obligation to ensure pharmacy professionals are upholding their legal and ethical obligations to comply with all legislation and standards. Therefore, the College will, from time to time, engage in random audits of member compliance with the requirement that members hold personal professional liability insurance. It is the expectation of the College that members will comply with this request in a timely manner.



GET A NEW PRACTICE TIP EVERY WEEK ON TWITTER

As you may be aware, the College has an official <u>Twitter account</u>. On a daily basis, we tweet out helpful regulatory news and updates, new practice tools, important member reminders, and much more. Every week we give you a new practice tip (followed by the hashtag #OCPPracticeTip).

Tips are developed from actual observations and encounters in practice and include: record keeping and documentation, methadone dispensing, narcotics reconciliation, clinical decision making, patient counselling, and much more.

Be sure to follow OCP on Twitter so you can see each new tip once it is published!

WHAT WE HEARD

Last November, the College reached out to pharmacy professionals^{*} to understand their use of our communications channels and tools and ideas for ways to enhance them. Here's some of what we learned:

WHERE AND HOW



view communications at home



>50% view communications on the computer

25 to 39 more than twice as likely to access communications through mobile than those over 39



READERSHIP AND ENGAGEMENT

92% read e-Connect

90% find OCP's social media posts helpful

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TOP4 MOST USEFUL CHANNELS FOR EDUCATING ON PROFESSIONAL RESPONSIBILITIES



Website Pharmacy

Pharmacy Connection

e-Connect

Vautuka

*Results gathered from two focus groups and 1,386 survey respondents

FROM YOU

FUN FACTS

95% Said our communications belos them

communications helps them perform effectively in their position 90% Said our communications gives them information they need to know

90%

Said our communications discusses topics that are current Said our communications could help enhance their practice

88%

87%

communications are easy to read

> Ontario College of Pharmacists

Thank you

for taking

the survey!

8

OPPORTUNITIES

Based on what the College learned from our survey and focus groups, we will explore how to:

- Use more mobile-friendly ways to share content, including e-Connect, *Pharmacy* Connection and our website
- Integrate more images, infographics, lists, bullet points, colours and other visual aspects to emphasize important content points and engage readers
- Develop more content tailored to pharmacy technicians, as well as pharmacy professionals in particular practice settings, such as hospitals
- Keep videos short and to the point, breaking up longer video content into a number of short

and digestable videos as part of a series

- Improve the search functionality on our website, including the ability to search for individual articles, and look for opportunities to enhance website navigation and how we organize our resources
- Better utilize website, e-Connect, and social media to remind pharmacy professionals of key dates and each time *Pharmacy Connection* and other important resources are published

DISCIPLINE DECISIONS



Dilip Jain (OCP#204400)

At a hearing on April 10, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Jain with respect to the following incidents:

- Between about 2009 and 2013, he dispensed prescriptions issued by prescriber [Name] to herself and/or to members of the prescriber's family, and/or failed to take and/or document any steps to verify the propriety of the prescriptions;
- Between about 2009 and 2013, he dispensed prescriptions that were clinically inappropriate, having regard to the quantities and/or combinations of drugs dispensed and/or the frequency of dispensing, and/or failed to take and/or document any steps to verify the propriety of the prescriptions, with respect to the prescriptions issued by prescriber [Name], for herself and/or for members of the prescriber's family;
- On about November 10, 2011, he dispensed a prescription while inaccurately recording the directions for use and/or recording improper directions for use;
- As Designated Manager of the Pharmacy, and majority owner and director of the corporation that owned the Pharmacy, he permitted a prescriber, [Name], and members of her family, to have sufficient interest in and authority over the affairs of the Pharmacy that a reasonable person informed of the facts would perceive a conflict of interest; and
- As a majority owner and director of the corporation that owned the Pharmacy, he operated the pharmacy and/or permitted it to operate while the pharmacy was in a conflict of interest as defined in s. 53 of O. Reg. 58/11.

In particular, the Panel found that he

- Failed to maintain a standard of practice of the profession
- Practised the profession while in a conflict of interest
- Contravened the Act, the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991, or the regulations under those Acts, and in particular, sections 155 and/or 156 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H-4, as amended

• Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as unprofessional

The Panel imposed an Order which included as follows:

- 1. A reprimand
- 2. Directing the Registrar to impose specified terms, conditions or limitations on the Member's Certificate of Registration, and in particular:
 - a. that the Member complete successfully, with an unconditional pass, at his own expense, the ProBE course offered by the Centre for Personalized Education for Physicians, before the Member resumes the practice of pharmacy;
 - b. that the Member shall be prohibited from having any proprietary interest in, or acting as a Designated Manager in, any pharmacy, for 5 years from the time the Member obtains an active Certificate of Registration;
- Directing the Registrar to suspend the Member's Certificate of Registration for a period of 12 months, or until such time as the Member successfully completes the ProBE course as set out in subparagraph 2(a) above, whichever is longer. The period of suspension shall start to run upon the Member obtaining an active Certificate of Registration.
- 4. Costs to the College in the amount of \$5,000.

In its reprimand, the Panel noted that members of the profession are held in high regard, and that Mr. Jain failed in his professional obligation to conduct himself in a manner that was respectable, responsible, and maintained public confidence. The Panel noted that pharmacy is a self-regulating profession and that there is an obligation to ensure that the public is protected and that public confidence in the profession's ability to govern its members is maintained. The Panel expressed its expectation that pharmacists engaged in the business side of the profession will have a keen awareness for conflicts of interest and will make any necessary adjustments to avoid such situations. The Panel related its hope that Mr. Jain will take the necessary steps to improve his practice, should he decide to return to the profession.

Lise St-Denis (OCP #80551)

As a result of a referral by the Inquiries, Complaints and Reports Committee, it is alleged that Ms. St-Denis committed professional misconduct in that she:

- submitted accounts or charges for services that she knew and/or reasonably ought to have known were false or misleading to the Ontario Drug Benefit program for one or more drugs, products and/or professional services
- falsified pharmacy records relating to her practice in relation to claims made to the Ontario Drug Benefit Program for one or more drugs, products and/or professional services
- dispensed and/or billed for drugs not prescribed or otherwise authorized, and/or not actually dispensed, and/or failed to keep accurate records regarding prescriptions and dispensing transactions, in relation to certain transactions and/or drug products
- signed or issued, in her professional capacity, a document that she knew and/or reasonably ought to have known contained a false or misleading statement in relation to claims made to the Ontario Drug Benefit Program for one or more drugs, products and/or professional services
- failed to ensure that the Pharmacie Lise St-Denis Pharmacy complied with all legal requirements, including, but not limited to, requirements regarding record keeping, documentation and billing the Ontario Drug Benefit Plan with respect to certain drugs, products and/or professional services

In particular, it is alleged that she:

- failed to maintain a standard of practice of the profession
- dispensed or sold drugs for an improper purpose
- failed to keep records as required respecting her patients
- falsified records relating to her practice
- signed or issued, in her professional capacity, a document that she knew and/or reasonably ought to have known contained a false or misleading statement

- submitted accounts or charges for services that she knew and/or reasonably ought to have known to be false or misleading
- contravened s. 40 of Ontario Regulation 58/11 made under the Drug and Pharmacies Regulation Act
- contravened a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular sections 5 and 15(1)(b) of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10, as amended, and/or ss. 19, 25(2)1 and 29 of Ontario Regulation 201/96 made thereunder, and Section 23 of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10, as amended, and/or sections of Ontario Regulation 201/96 made thereunder
- engaged in conduct or performed an act or acts relevant to the practice of pharmacy that, having regarding to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable or unprofessional

Ms. St-Denis passed away on January 12, 2016, while the hearing in this matter remained pending.

On June 28, 2016, the College brought a motion before a Panel of the Discipline Committee to permanently stay allegations of professional misconduct against Ms. St-Denis. On the basis of Ms. St-Denis' death, the Discipline Committee accepted the submission of the College and issued an Order permanently staying the allegations of professional misconduct against Ms. St-Denis.

Bhavesh Kothari (OCP #217389)

At a hearing on April 12, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Kothari with respect to the following incidents:

- That he failed to comply with the Order of the Discipline Committee Panel of the Ontario College of Pharmacists (the "College") dated September 24, 2015 (the "Order") and, in particular, failed to pay costs to the College as required by subparagraph (4) of the Order; and/or
- That he failed to respond to the College's communications to him from in or about September, 2015 to in or about January, 2016 regarding the

Order and his obligation to pay costs pursuant to the Order.

In particular, the Panel found that he

• Engaged in conduct or performed an act or acts relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable and unprofessional.

The Panel imposed an Order which included as follows:

- 1. A reprimand
- The Registrar is directed to suspend the Member's certificate of registration for a minimum of four (4) months, the suspension to commence on April 26, 2017 and run without interruption until August 25, 2017. As of August 26, 2017, the suspension shall be suspended, and shall remain suspended, providing the Member has met/meets the following conditions:
 - i. On or before August 25, 2017, the Member pays to the College, in a single lump sum by certified cheque, the sum of \$40,000, on account of the costs award in paragraph 4 of the Discipline Committee's September 24, 2015 Order.
 - ii. On or before October 1, 2017, and on or before the first day of each and every subsequent month, up to and including April 1, 2018, the Member pays the sum of \$20,000 to the College, in a single lump sum by certified cheque, on account of the costs award in paragraph 4 of the Discipline Committee's September 24, 2015 Order, such that the total sum of \$180,000 has been paid to the College under paragraphs 2(i) and 2(ii) of this Order as of April 1, 2018.

In the event that the Member fails to meet any of the conditions set out in paragraphs 2(i) and 2(ii) of this Order, the Member's suspension shall not be suspended (or shall cease to be suspended, as the case may be), and shall continue to run until such time as the Member has paid to the College the entire balance of the costs award in paragraph 4 of the Discipline Committee's September 24, 2015 Order.

In any event, the suspension shall end on the later of August 26, 2017, or the date on which the Member has paid to the College the entire balance of the costs award in paragraph 4 of the Discipline Committee's September 24, 2015 Order.

3. Costs to the College in the amount of \$15,000.00

In its reprimand, the Panel noted that the Member, through his actions, tainted the entire profession in the eyes of the public and completely disregarded the governing authority of the College. The Panel pointed out that the practice of Pharmacy is a privilege that carries with it significant obligations to the public, the profession, and oneself, and that through his misconduct the Member has eroded the public trust in the pharmacy profession and cast a shadow over his own integrity. The Panel expressed its hope that this hearing has given the Member the opportunity to pause for reflection and move forward in practising pharmacy within the standards of the profession, and that he will not appear before a panel of the Discipline Committee again.

John Gerges, R.Ph. (OCP #613990)

At a hearing on April 28, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Gerges with respect to incidents set out in four referrals by the Inquiries, Complaints and Reports Committee.

Regarding the first referral, the Panel made findings against Mr. Gerges with respect to the following incidents:

- Between about June 2014 and about December 2014, he dispensed to a patient, [Patient 1], quantities of letrozole, a generic substitute for Femara, whereas [Patient 1] had in fact been prescribed a different medication, namely Feramax 150mg;
- In the fall of 2014, he dispensed medications to [Patient 1] in the form of dosettes that did not contain a correct set of tablets, having regard to [Patient 1]'s prescriptions;
- He did not maintain accurate records of prescriptions dispensed to [Patient 1] between about June 2014 and December 2014;
- He signed a patient record for [Patient 1] dated January 20, 2015, which suggested that the medications had been dispensed by Mill Street to [Patient 1] throughout the summer of 2014, whereas he ought to have known that [Patient 1] had not attended the Pharmacy during the summer

of 2014, but rather that Mill Street had dispensed a long-term supply of medications to [Patient 1] in or about June 2014; and

 In or about January and February 2015, while [Patient 1]'s complaint to the College was being investigated, and without being solicited to do so, he offered significant compensation to [Patient 1] in respect of the Feramax 150mg dispensing error, and repeatedly contacted her and attempted to contact her to discuss the offer.

In particular, with respect to the first referral, the Panel found that he:

- Failed to maintain the standards of the profession;
- Failed to keep records as required respecting his patients; and
- Engaged in conduct relevant to the practice of pharmacy that, having regard to all of the circumstances, would reasonably be regarded by members of the profession as unprofessional and, with respect to the offer of compensation only, dishonourable.

Regarding the second referral, the Panel made findings against Mr. Gerges with respect to the following incidents:

- On July 25, 2014, August 28, 2014, and September 18, 2014, he submitted claims to third party insurers regarding certain identified items that were not dispensed to patients;
- On July 25, 2014, August 28, 2014, and September 18, 2014, he created records of dispensing and/or billing transactions in relation to the claims submitted to third party insurers that he ought to have known were false or misleading; and
- He ought to have known that these claims were false and/or misleading, and that these records contained a false and/or misleading statement.

In particular, with respect to the second referral, the Panel found that he:

- Failed to maintain a standard of practice of the profession
- Engaged in conduct relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by

members as unprofessional

Regarding the third referral, the Panel made findings against Mr. Gerges with respect to the following incidents:

- In August 2015, before filling a purported prescription for narcotics issued to [Patient 2], he failed to take steps to verify the prescription with the apparent prescriber, whereas verification was warranted in the circumstances;
- Between at least April 2014 and April 2016, he failed to ensure that Mill St. Pharmacy had policies and procedures in place to ensure the safe and accurate preparation of compliance packages;
- Between at least April 2014 and April 2016, he failed to ensure that Mill St. Pharmacy had policies and procedures in place to ensure that the billing of medications contained in compliance packages corresponded to the dates on which those medications were dispensed;
- Between at least April 2014 and April 2016, he failed to ensure that Mill St. Pharmacy had policies and procedures in place to ensure adequate record-keeping in respect of medications dispensed in the form of compliance packages;
- He did not maintain accurate records of prescriptions dispensed to a patient, [Patient 1], between about June 2014 and December 2014, including:
 - i. no record of prescriber authorization or other reason for refills of Tecta dispensed in June and July 2014;
 - ii. hardcopies indicating "new Rx" for Teva-Rosuvastatin and Mylan-Paroxetine dispensed November 21, 2014, but no actual prescription or other authorization;
 - iii. no hardcopies for certain items on [Patient 1]'s Patient Medical Record;
 - iv. duplicate hardcopies for certain items on [Patient 1]'s Patient Medical Record;
- Between at least June 2014 and December 2014, he created records in respect of a patient, [Patient 1], which suggested that medications were dispensed by Mill St. Pharmacy to [Patient 1] in the form of a one-week supply on a weekly basis,

whereas the medications were dispensed to [Patient 1] in the form of a longer-term supply, on a less frequent basis;

- Between at least June 2014 and December 2014, he submitted claims to the Ontario Drug Benefit Program in respect of a patient, [Patient 1], which suggested that medications were dispensed by Mill St. Pharmacy to [Patient 1] in the form of a one-week supply on a weekly basis, whereas he ought to have known that the submitted claims were false or misleading because medications were dispensed to [Patient 1] in the form of a longerterm supply, on a less frequent basis; and
- Between at least June 2014 and December 2014, he created records of dispensing and/or billing transactions in relation to the claims submitted to the Ontario Drug Benefit Program in respect of [Patient 1] that he ought to have known were false or misleading.

In particular, with respect to the third referral, the Panel found that he:

- Failed to maintain the standards of the profession
- Failed to keep records as required respecting his patients
- Engaged in conduct relevant to the practice of pharmacy that, having regard to all of the circumstances, would reasonably be regarded by members of the profession as unprofessional

Regarding the fourth referral, the Panel made findings against Mr. Gerges with respect to the following incidents:

- Between at least January 2015 and April 2016, he failed to ensure that Mill St. Pharmacy in Tilbury. Ontario ("the Pharmacy") had policies and procedures in place to ensure the safe and accurate preparation of compliance packages, including policies and procedures to ensure that changes to a patient's prescriptions were noted and reflected in the patient's compliance packages in a timely fashion;
- Between at least January 2015 and April 2016, he failed to ensure that the Pharmacy had policies and procedures in place to ensure that the billing of medications contained in compliance packages corresponded to the dates on which those medications were dispensed;

- Between at least January 2015 and April 2016, he failed to ensure that the Pharmacy had policies and procedures in place to ensure adequate record-keeping in respect of medications dispensed in the form of compliance packages;
- In June 2015, on successive days, he filled two prescriptions for Tecta 40mg for the same patient, [Patient 3], that were written by different prescribers;
- He did not maintain accurate records of prescriptions dispensed to a patient, [Patient 3], between about January 2015 and June 2015, including:
 - i. [Patient 3]'s Patient Medical Record did not accurately reflect the dates on which medications were dispensed to the patient;
 - ii. No hardcopies for certain items listed on [Patient 3]'s Patient Medical Record;
- Between at least January 2015 and June 2015, he created records in respect of a patient, [Patient 3], which suggested that medications were dispensed by the Pharmacy to [Patient 3] in the form of a one-week supply on a weekly basis, whereas the medications were dispensed to [Patient 3] in the form of a longer-term supply, on a less frequent basis;
- Between at least January 2015 and June 2015, he submitted claims to the Ontario Drug Benefit Program in respect of a patient, [Patient 3], which suggested that medications were dispensed by the Pharmacy to [Patient 3] in the form of a one-week supply on a weekly basis, whereas he ought to have known that the submitted claims were false or misleading because the medications were dispensed to [Patient 3] in the form of a longer-term supply, on a less frequent basis; and
- Between at least June 2014 and December 2014, he created records of dispensing and/or billing transactions in relation to the claims submitted to the Ontario Drug Benefit Program in respect of [Patient 3] that he ought to have known were false or misleading.

In particular, with respect to the fourth referral, the Panel found that he:

- Failed to maintain the standards of the profession
- Failed to keep records as required respecting his patients

• Engaged in conduct relevant to the practice of pharmacy that, having regard to all of the circumstances, would reasonably be regarded by members of the profession as unprofessional

The Panel imposed an Order which included as follows:

- 1. A reprimand;
- 2. That the Registrar be directed to suspend the Member's certificate of registration for five (5) months, one (1) month of which to be remitted if the Member satisfies all of the conditions set out in paragraph 3a., b. and c. The suspension shall commence on May 1, 2017, and run until August 31, 2017, inclusive. If the remitted portion of the suspension is required to be served by the Member because he fails to satisfy the conditions set out in paragraph 3a., b. and c., that portion of the suspension shall commence on April 29, 2020 and shall continue until May 28, 2020, inclusive;
- 3. That the Registrar be directed to impose the following conditions and limitation on the Member's certificate of registration:
 - a. that the Member shall complete successfully, at his own expense and within twelve (12) months of the date of this Order, the ProBE Program on Professional/Problem Based Ethics for Healthcare Professionals, with an unconditional pass;
 - b. that the Member successfully complete, within eighteen (18) months of the date of the Order, if he has not already done so within the twelve (12) months prior to the date of this Order, a review of his practice pursuant to the Medication System Safety Review for a Community Pharmacist On-Site Assessment program of ISMP Canada, which shall include delivery of the reviewer's report to the Registrar. The review will take place at the Member's practice site at Mill St. Pharmacy in Tilbury, Ontario. The Member shall be responsible for the cost of the review;
 - c. that the Member successfully complete, within three (3) years of the date of this order, the following courses (or, if these courses are no longer available at the relevant time, a comparable course of study approved in advance by the Registrar):
 - i. CPS I Toronto Module 3 (Professional Practice & Pharmacy Management 1) from the Canadian

Pharmacy Skills Program offered through the Leslie Dan Faculty of Pharmacy at the University of Toronto;

- ii. CPS II Toronto Module 3 (Professional Practice & Pharmacy Management II) from the Canadian Pharmacy Skills Program offered through the Leslie Dan Faculty of Pharmacy at the University of Toronto;
- d. That the Member:
 - i. retain, at the Member's expense, a practice mentor acceptable to the College, who is a Designated Manager, within three (3) months of the date of this Order;
 - ii. meet at least six (6) times with the practice mentor, at the mentor's place of practice, for the purpose of reviewing the Member's practice with respect to
- a. appropriate billing to ODB and other third party insurers;
- b. appropriate refill reminder practice;
- c. general supervision of a pharmacy, including supervision of pharmacy staff;
- d. and any other matter that the mentor determines is appropriate.

to this end, the Member shall provide the practice mentor with the following documents related to this proceeding:

- 1. a copy of the Notices of Hearing;
- 2. a copy of the Agreed Statement of Facts;
- 3. a copy of this Joint Submission on Order; and
- 4. a copy of the Decision and Reasons, when available.
 - iii. develop a learning plan to address the areas requiring remediation;
 - iv. demonstrate to the practice mentor that the Member has achieved success in meeting the goals established in the learning plan; and
 - v. direct the practice mentor to provide a report to the Manager, Investigations and Resolutions

at the College, identifying the learning plan and the mentor's assessment of whether the Member has satisfactorily completed the learning plan, no later than eighteen (18) months from the date of this Order.

- e. that the Member be prohibited from acting as a Designated Manager for any pharmacy, for a period of three (3) years from the date the Order is imposed, with one year of this restriction to be remitted on condition that the Member successfully complete the learning plan described in paragraph 3(d), as reported by the mentor to the College.
- f. For a period of three (3) years following the period of restriction described in paragraph 3(e), the Member be prohibited from acting as Designated Manager for more than two (2) pharmacies at any given time. If the Registrar is satisfied with the results of the assessments described in paragraph 3(g), below, this term, condition or limitation will be lifted at the end of this three (3) year period. If the Registrar is not satisfied with the results of the assessments described in paragraph 3(g), below, this term, condition or limitation will remain on the Member's certificate of registration, and may only be varied on application by the Member to the Discipline Committee.
- g. For a period of three (3) years following the end of the period of restriction described in paragraph 3(e), the Member's practice and all activities at any pharmacies in which the Member has a proprietary interest of any kind shall be monitored by the College by means of unannounced practice assessments by a representative or representatives of the College to a maximum of three (3) inspections across all pharmacies. The practice assessments may be in addition to any of the routine inspections conducted by the College pursuant to the authority of section 148 of the Drug and Pharmacies Regulation Act. The Member shall cooperate with the College during the practice assessments and, further, shall pay to the College in respect of the cost of monitoring, the amount of \$1,000.00 per assessment, such amount to be paid immediately after completion of each of the assessments.
- h. That the Member ensure that, at any pharmacy of which he is a shareholder, director, or Designated Manager, refills of medication are not billed until the pharmacy staff have confirmed that the refill is required.

4. Costs to the College in the amount of \$10,000.

In its reprimand, the Panel noted that the practice of pharmacy is a privilege that carries with it significant obligations to the public, the profession and to oneself. The Panel expressed its view that the Member's conduct was totally unacceptable to his fellow pharmacists and fell well below the standards of practice expected of pharmacists and Designated Managers. The Panel indicated that it was necessary to impress upon the Member the seriousness of his misconduct.

The Panel agreed that the Member's conduct was unprofessional and in some circumstances dishonourable. The Panel expressed its expectation that the remediation ordered will result in improvement to the Member's practice as a pharmacist and a Designated Manager, and will also ensures that the public interest will be safeguarded. The Panel related its expectation that the Member will make the necessary adjustments to his practice, and will not appear before the Discipline Committee of the Ontario College of Pharmacists again.

Alexandre Mihaila, R.Ph. (OCP #219201)

At a hearing on May 8, 2017 a Panel of the Discipline Committee made findings of professional misconduct against Mr. Mihaila with respect to the following incidents:

- That he failed to actively and effectively participate in the day-to-day management of the Pharmacy, including but not limited to, drug procurement and inventory management, record keeping and documentation, and professional supervision of the pharmacy;
- That he failed to ensure that the Pharmacy complied with all legal requirements, including but not limited to, requirements regarding record keeping and documentation;
- That he falsified pharmacy records relating to his practice, in relation to prescriptions for domperidone and/or Parsitan; and/or
- That he misappropriated and/or obtained domperidone and/or Parsitan from the Pharmacy that had not been prescribed for him.

In particular, the Panel found that he

- Failed to maintain a standard of practice of the profession
- Dispensed or sold drugs for an improper purpose
- Failed to keep records as required respecting patients
- Falsified a record relating to his practice
- Signed or issued, in his professional capacity, a document that he knew contained a false or misleading statement
- Contravened the Act, the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991 and/or the regulations under those Acts, including but not limited to sections 140, 155, 156, and 166 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H.4, as amended
- Contravened, while engaged in the practice of pharmacy, any federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, namely section C.01.041 of the Food and Drug Regulations, C.R.C., c. 870, as amended
- Knowingly permitted the premises in which the pharmacy is located to be used for unlawful purposes
- Engaged in conduct or performed an act or acts relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as dishonourable or unprofessional

The Panel imposed an Order which included as follows:

- 1. A reprimand
- 2. An Order directing the Registrar to suspend the Member's certificate of registration for a period of six (6) months, with one (1) month of the suspension to be remitted on the condition that the Member completes the remedial training specified in paragraph 3(i) below. This suspension shall commence on May 9, 2017 and shall continue until October 8, 2017, inclusive. If the remitted portion of the suspension is required to be served by the Member because he fails to complete the remedial training as specified in paragraph 3(i), that portion of the suspension shall commence on May 9, 2018

and shall continue until June 8, 2018, inclusive;

- 3. an Order directing the Registrar to impose specified terms, conditions or limitations on the Member's certificate of registration as follows:
 - (i) within twelve (12) months of the date when this Order is imposed, the Member must successfully complete, at his own expense:
 - a) the PROBE Program on Professional / Problem-Based Ethics for healthcare professionals offered by the Center for Personalized Education for Physicians, with an unconditional pass; and
 - b) the College's Jurisprudence e-learning modules and examination;
 - (ii) for a period of three (3) years from the date when this Order is imposed:
 - a) the Member shall be prohibited from acting as a Designated Manager at any pharmacy; and
 - b) the Member shall be prohibited from having. keeping or acquiring any ownership interest, direct or indirect, controlling or otherwise, in any pharmacy in the Province of Ontario, either outright or as a shareholder of a corporation that owns a pharmacy, or as a director of a corporation that owns a pharmacy in the Province of Ontario, excepting only that he may be permitted to own shares in a publicly traded corporation that has an interest in a pharmacy;
 - (iii) for a period of three (3) years from the date when this Order is imposed:
 - a) the Member shall only engage in the practice of pharmacy if he has notified the College in writing of any employment in any pharmacy, which notification shall include the name, address, and telephone number of the employer and the date on which he began or is to begin employment, within seven (7) days of commencing such employment; and
 - b) the Member shall only engage in the practice of pharmacy for an employer in a pharmacy who provides confirmation in writing from the Designated Manager of that pharmacy (and any subsequent Designated Manager, if there is a change in the Designated Manager at the

same pharmacy during the Member's tenure) to the College, within seven (7) days of the Member's commencement of employment at the pharmacy (and within seven (7) days of a change in Designated Manager), that the Designated Manager received and reviewed a copy of this Order and the Decision and Reasons of the Discipline Committee in this matter before the Member commenced his employment;

- c) with one year of these restrictions, as set out in paragraphs 3(iii)(a) and 3(iii)(b) above, to be remitted on condition that the Member complete the programs, modules and examinations set out in paragraph 3(i) above as specified; and
- 4. Costs to the College in the amount of \$3,500.

In its reprimand, the Panel noted that, through his actions, the Member failed to maintain the responsibilities and obligations that are expected of him as a member of this profession. The Panel observed that the Member breached the standards of practice, regulations, and pharmacy legislation.

The Panel pointed out that pharmacy is a selfregulated profession, the practice of which is a privilege, and which comes with significant obligations to the public, the profession, and oneself.

The Panel related that the Member's actions may have, in his opinion, been conducted on compassionate grounds, however, he have failed to meet the expected standards of practice of this profession.

The Panel observed that, in the future, the Member is expected to practice pharmacy within the standards of the profession. The Panel expressed its trust that the Member will take this opportunity to reflect on his actions and complete the required remediation, and that in so doing, he will change the way he practices and will not appear before a panel of the Discipline Committee again.

Neda Toeg, R.Ph. (OCP #606687)

At a hearing on May 9, 2017 a Panel of the Discipline Committee made findings of professional misconduct against Ms. Toeg with respect to the following incidents:

- That she admitted the patients, [Patient 1] and/or [Patient 2], to the dispensary area of the Pharmacy on several occasions, in or about July 2014; and/or
- That she dispensed methadone that had not been prescribed, and/or failed to supervise dispensing of methadone to the patient, [Patient 2], on or about May 2, 2014.

In particular, it is alleged that she

- Failed to maintain a standard of practice of the profession
- Contravened the Act, the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991, or the regulations under those Acts, and in particular, section 155 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H-4, as amended, and/or section 4 of O.Reg. 58/11
- Contravened a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular, section C.01.041 of the Food and Drug Regulations, C.R.C., c. 870, as amended, under the Food and Drugs Act, and/or sections 31 and/or 43 of the Narcotic Control Regulations, C.R.C., c.1041, as amended
- Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members as unprofessional

The Panel imposed an Order which included as follows:

- 1. A reprimand
- 2. Directing the Registrar to impose specified terms, conditions or limitations on the Member's certificate of registration requiring:
 - (a) that the Member successfully complete, within 6 months of the date of the order, a course with Gail E. Siskind Consulting Services, or another professional ethics consultant chosen by the College, to be designed by the consultant, with the purpose of addressing the professional misconduct issues raised in this case; the following terms shall apply to the course:
 - (i) the number of sessions shall be at the discretion of the consultant, but shall be a minimum of 2 meetings and a maximum of 3 meetings;

- (ii) the manner of attendance at the session(s)
 (e.g. in person, via Skype, etc.) is a matter to be discussed in advance between the Member and the consultant, but shall ultimately be at the discretion of the consultant;
- (iii) the Member shall be responsible for the cost of the course;
- (iv) the Member shall provide to the consultant the following documents, in advance of the course, to facilitate the design of the course:
- a) the Notice of Hearing;
- b) the Agreed Statement of Facts;
- c) this Joint Submission on Order; and
- d) the Panel's Decision and Reasons, when available; and
 - (v) the consultant shall agree to confirm to the College once the Member has completed the course to the satisfaction of the consultant within 6 months of the date of this Order;
- 3. Directing the Registrar to suspend the Member's Certificate of Registration for a period of one (1) month with the suspension to commence on May 10, 2017 and to continue without interruption until June 9, 2017.
- 4. Costs to the College in the amount of \$2,500.00.

In its reprimand, the Panel noted that pharmacists provide care to the public and in return are held in high regard for the role played in the provision of healthcare in Ontario. The Panel noted that, though this was the Member's first appearance in front of the Discipline Committee, the allegations she admitted to were of concern, and her actions with respect to the allegations were not consistent with the Standards of Practice for pharmacists.

The Panel pointed out that all health care professionals are expected to conduct themselves in a manner that maintains public confidence and safety. The Panel expressed its expectation that the remediation ordered will result in improvement to the Member's practice as a pharmacist and that the public interest will be safeguarded, and that the Member will not appear before the Discipline Committee of the Ontario College of Pharmacists again.

Ayman Mikhael (OCP #111279)

Findings of Professional Misconduct

At a hearing on May 17, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Mikhael with respect to incidents set out in two referrals by the Inquiries, Complaints and Reports Committee.

Regarding the first referral, the Panel made findings against Mr. Michael with respect to the following incidents:

- That he submitted accounts or charges for services that he knew were false or misleading to the Ontario Drug Benefit program for one or more drugs and/or products, from on or about November 1, 2009 to on or about October 31, 2011; and/or
- That he falsified pharmacy records relating to his practice in relation to claims made to the Ontario Drug Benefit program for one or more drugs and/or products, from on or about November 1, 2009 to on or about October 31, 2011; and/or
- That he failed to keep records of monthly Ontario drug benefit eligibility cards or a copy of the cards with respect to each person for whom a drug was dispensed, as required by section 29 of Ontario Regulation 201/96, under the Ontario Drug Benefits Act, R.S.O. 1990, c. O.10, as amended, from on or October 1, 2011 to on or about October 31, 2011.

In particular, the Panel found that he

- Failed to maintain a standard of practice of the profession;
- Failed to keep records as required respecting his patients;
- Falsified records relating to his practice;
- Submitted accounts or charges for services that he knew to be false or misleading;
- Contravened a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular sections 5 and 15(1)(b) of the Ontario Drug Benefits Act, R.S.O. 1990, c. O.10, as amended, and/or Ontario Regulation 201/96 made thereunder; and/or section 29 of Ontario Regulation

201/96, under the Ontario Drug Benefits Act, R.S.O. 1990, c. O.10, as amended;

• Engaged in conduct or performed an act or acts relevant to the practice of pharmacy that, having regarding to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable and unprofessional.

Regarding the second referral, the Panel made findings against Mr. Michael with respect to the following incidents:

- That he failed to report to the Registrar that he had been charged with offences under the Criminal Code of Canada in February of 2014
- That he failed to report to the Registrar that he had been convicted of an offence under the Criminal Code of Canada on July 14, 2015
- That he submitted false or inaccurate information in response to questions on the annual renewal application submitted to the College in March of 2014 regarding the charges under the Criminal Code of Canada in February of 2014

In particular, the Panel found that he

- Contravened a term, condition or limitation imposed on his certificate of registration
- Failed to maintain a standard of practice of the profession
- Signed or issued, in his professional capacity, a document that he knew contained a false or misleading statement
- Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable and unprofessional
- Was found guilty of an offence relevant to his suitability to practise

The Panel imposed an Order which included as follows:

- A reprimand
- Directing the Registrar to revoke the Member's certificate of registration

• Costs to the College in the amount of \$40,000.00

In its reprimand, the Panel indicated that they were appalled by the facts presented to them.

The Panel observed that Mr. Mikhael put his own personal needs ahead of the trust of his patients and took advantage of his position in society.

The Panel pointed out that Mr. Mikhael's decision to defraud the public purse of millions of dollars was deliberate, and that such conduct significantly impacts the profession and its ability to provide healthcare to the most vulnerable patients. The Panel observed that Mr. Mikhael's actions jeopardized the public's trust in all pharmacists and that he betrayed the people of Ontario.

The Panel expressed its view that the public and the members of the profession are well served by the revocation of Mr. Mikhael's licence to practice.

Acknowledgment & Undertaking

Mr. Mikhael entered into an Acknowledgment & Undertaking as part of the resolution of allegations of professional misconduct at a hearing of before a Panel of the Discipline Committee.

Pursuant to the Acknowledgment & Undertaking dated May 17, 2017, Mr. Mikhael undertook that he will not reapply to the College or in any way seek the reinstatement of his certificate of registration with the College for any class of membership.

Stay of Allegations

On May 17, 2017, the College brought a motion before a Panel of the Discipline Committee to stay allegations of proprietary misconduct against Mr. Mikhael. The allegations are as follows.

As a result of a referral by the Accreditation Committee, it is alleged that Mr. Mikhael established or operated a pharmacy, Wilson Medical Centre Pharmacy. in Hamilton, Ontario, owned and/or operated by Safaa Pharmacy Inc., of which Mr. Mikhael is a director, and to which Certificate of Accreditation No. 19190 was issued, and of which Mr. Mikhael is the Designated Manager, and failed to conform to the requirements of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H.4 or the regulations, and committed acts of proprietary misconduct as follows:

• That he failed to take all reasonable steps that were



necessary to protect narcotics, controlled drugs and targeted substances on his premises or under his control against loss or theft or to take steps necessary to ensure their security, including failure to count and reconcile narcotics, controlled drugs and targeted substances at least every six months from on or about January 19, 2012 to on or about February 19, 2013; and/or

- That he failed to keep records as required of narcotic prescriptions from on or about April 27, 2012 to on or about February 19, 2013; and/or
- That he failed to keep records as required of patient consent for prescriptions to be dispensed by MT Cross Pharmacy from on or about February 23, 2012 to on or about February 19, 2013; and/or
- That he transferred prescriptions to another pharmacy (MT Cross Pharmacy) without the consent of the patient from on or about February 23, 2012 to on or about February 19, 2013; and/or
- That he arranged for prescriptions to be dispensed by MT Cross Pharmacy without patient consent from on or about February 23, 2012 to on or about February 19, 2013; and/or
- That he failed to keep confidential personal health information concerning a patient by transferring prescriptions to another pharmacy without the consent of patients from on or about February 23, 2012 to on or about February 19, 2013.

In particular, it is alleged that Mr. Mikhael:

• Contravened a law of Canada or Ontario or any municipal by-law with respect to the distribution, purchase, sale or dispensing of any drugs or product in a pharmacy, and in particular, s. 43 of the Narcotic Control Regulations, C.R.C., c. 1041, as amended, under the Controlled Drugs and Substances Act, S.C. 1996, c. 19, as amended, and/or s. G.03.012 of the Food and Drug Regulations, C.R.C., c. 870, as amended, to the Food and Drugs Act, R.S.C. 1985, c. F-27, as amended, and/or s. 7(1)(a) of the Benzodiazapines and Other Targeted Substances Regulations, S.O.R./2000-271 under the Controlled Drugs and Substances Act, S.C. 1996, c. 19, as amended, as well as ss. 153 to 156 of the Drug and Pharmacies Regulation Act, as amended, and ss. 54 to 56 of Ontario Regulation 58/11, as amended, and s. 40 of the Narcotic Control Regulations, C.R.C., c. 1041, as amended, as well as s. 43 of Ontario Regulation 58/11, as amended;

- Failed to keep records required to be kept by the pharmacy respecting the patients and the practice of the pharmacy;
- Failed to keep confidential personal health information or other personal information concerning a patient without the patient's consent unless permitted or required to do so by law;
- Engaged in conduct or performed an act relevant to the business of a pharmacy that would reasonably be regarded by members as disgraceful or dishonourable;
- Failed to conform to the requirements of the Drug and Pharmacies Regulation Act or the regulations with respect to record-keeping, and contravened, sections 153 to 156 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c.H.4, as amended, and/ or sections 54 to 56 of Ontario Regulation 58/11, as amended;
- Failed to conform to the requirements of the Drug and Pharmacies Regulation Act or the regulations with respect to transferring of prescriptions, and contravened, section 43 of Ontario Regulation 58/11, as amended.

The College brought the motion before a Panel of the Discipline Committee in light of the fact Mr. Mikhael entered into an Acknowledgment & Undertaking with the College whereby he undertook that will not reapply to the College or in any way seek the reinstatement of his certificate of registration with the College for any class of membership, and will no longer engage in the practice of pharmacy in Ontario.

Accordingly, the parties made a joint submission to the Panel to issue an Order for a stay of the allegations of proprietary misconduct against Mr. Mikhael. On the basis of the Acknowledgment & Undertaking Mr. Mikhael entered into with the College, the Panel accepted the joint submission of the parties and issued an Order staying the allegations of proprietary misconduct against Mr. Mikahel. The stay shall remain in effect only as long as the Acknowledgment & Undertaking remains in full force and effect and Mr. Mikhael remains in compliance with all of the terms of that Acknowledgment & Undertaking.

Mohamed Saleh (OCP #79200)

On April 18, 2017, the College brought a motion before a Panel of the Discipline Committee to stay

allegations of professional misconduct against Mr. Saleh. The allegations are as follows.

As a result of a referral by the Inquiries, Complaints and Reports Committee, it is alleged that Mr. Saleh, as pharmacist and/or Designated Manager at Al's Care Pharmacy in Ottawa, Ontario, and/or as director and shareholder of the corporation that owned and operated the Pharmacy, committed professional misconduct in that he

- Dispensed an extra dose of methadone 11mg to the patient, [Patient 1], without authorization, on or about July 14, 2014;
- Failed to report to Health Canada the theft or other loss of methadone from the Pharmacy on or about August 4, 2014;
- Dispensed a dose of methadone 130mg to the patient, [Patient 2], in excess of the dose authorized, on or about September 29, 2015; and/or
- Dispensed a dose of methadone 130mg to the patient, [Patient 2], without authorization and/or contrary to the directions of the prescriber, on or about October 12, 2015

In particular, it is alleged that he

- Failed to maintain a standard of practice of the profession
- Contravened the Act, the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991, or the regulations under those Acts, and in particular, sections 155 of the Drug and Pharmacies Regulation Act , R.S.O. 1990, c. H-4, as amended
- Contravened, while engaged in the practice of pharmacy, a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular, section C.01.041 of the Food and Drugs Regulations, C.R.C. c. 870, as amended, and/ or sections 31 and/or 42 of the Narcotic Control Regulations, C.R.C., c.1041, as amended
- Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional

The College brought the motion before the Discipline Committee in light of the fact Mr. Saleh entered into an Undertaking. Agreement and Acknowledgment with the College whereby he resigned permanently as a member of the College, irrevocably surrendered his Certificate of Registration, and will no longer work or be employed in a pharmacy, in any capacity whatsoever, in Ontario.

Accordingly, the parties made a joint submission to the Discipline Committee to issue an Order for a stay of the allegations of professional misconduct against Mr. Saleh. On the basis of the Undertaking, Agreement and Acknowledgment Mr. Saleh entered into with the College, the Discipline Committee accepted the joint submission of the parties and issued an Order staying the allegations of professional misconduct against Mr. Saleh.

Abhaya Dixit, R.Ph. (OCP #214669)

At a hearing on June 20, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Dixit with respect to the following incidents:

- That he falsified pharmacy records relating to his practice in connection with certain identified claims made for drugs and/or other products;
- That he signed or issued, in his professional capacity, a document that he knew contained a false or misleading statement in connection with certain identified claims made for drugs and/or other products;
- That he submitted an account or charge for services that he knew was false or misleading in connection with certain identified claims made for the drugs and/or other products

In particular, the Panel found that he

- Failed to maintain the standards of practice of the profession
- Falsified pharmacy records relating to his practice
- Signed or issued, in his professional capacity, a document that he knew contained a false or misleading statement
- Submitted an account or charge for services that he knew was false or misleading

- Contravened the Act, the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991, or the regulations under those Acts, and in particular, sections 155 and 156 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H-4, as amended
- Contravened a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular, sections 5, and 15(1) of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10, as amended
- Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as dishonourable or unprofessional

The Panel imposed an Order which included as follows:

1. A reprimand

- 2. That the Registrar is directed to impose specified terms, conditions or limitations on the Member's Certificate of Registration, and in particular:
 - (a) that the Member shall be prohibited, for a period of 3 years to commence on June 20, 2017, from:
 - (i) Having any proprietary interest in a pharmacy of any kind;
 - (ii) Acting as a Designated Manager in any pharmacy;
 - (iii) Receiving any remuneration for his work as a pharmacist other than remuneration based only on hourly or weekly rates, and not on the basis of any incentive or bonus for prescription sales.
 - (b) that the Member shall be required, for a period of three years commencing on June 20, 2017, to notify the College in writing of any employment in a pharmacy.
 - (c) that the Member, for a period of three years commencing on June 20, 2017, shall ensure that his employer has confirmed in writing to the College that they have received and reviewed a copy of the Discipline Committee Panel's decision and order in this matter, and confirming the nature of the Member's remuneration. This

term is only applicable where the member is employed by a pharmacy, in the pharmaceutical industry, or otherwise employed as a pharmacist.

- That the Registrar suspend the Member's Certificate of Registration for a period of 14 months. The suspension shall commence on June 20, 2017 and shall continue until August 19, 2018, inclusive.
- 4. Costs to the College in the amount of \$3,500.00

In its reprimand, the Panel noted that integrity and trust are paramount to the profession of pharmacy, and that, in return, pharmacists are held in high regard for the role they play in the provision of healthcare in Ontario.

The Panel expressed its disappointment in the Member's actions, and observed that he committed professional misconduct and knowingly submitted false claims and billings to the Ontario Drug Benefit Program for reimbursement. The Panel pointed out that the volume of the inappropriate activities, to the order of approximately \$238,000 over a two-year period of time, is an example of the Member's disregard for the trust that has been placed on the profession of Pharmacy.

The Panel acknowledged the Member's efforts to atone for his misdeeds, and encouraged him to keep on that path of professional improvement. The Panel expressed its expectation that the Member will never appear before a panel of the Discipline Committee again.

George Oduro, R.Ph. (OCP #215645)

At a hearing on November 18, 2016, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Oduro with respect to the following incidents:

- That he failed to provide details to the Registrar of charges relating to four offences under the Criminal Code of Canada made in or about December 2011, including but not limited to in responses to questions for the annual renewal applications submitted to the College in 2012, 2013, and 2014
- That he submitted false or inaccurate information in response to questions on the annual renewal applications submitted to the College in March of 2012, March of 2013, and March of 2014 regarding these charges under the Criminal Code of

Canada and the current proceedings in respect of them

- That he was found guilty of uttering a threat to cause bodily harm to a person, which is an offence contrary to section 264.1(1)(a) of the Criminal Code of Canada, and assault, which is an offence contrary to section 266 of the Criminal Code of Canada
- That he failed to provide details to the Registrar of findings of guilt relating to two offences under the Criminal Code of Canada made on or about June 14, 2014
- That he submitted false or inaccurate information in response to questions on the Self-Reporting Form submitted to the College in March of 2015 regarding these findings of guilt of offences under the Criminal Code of Canada

In particular, the Panel found that he

- Was found guilty of offences that are relevant to his suitability to practise
- Contravened a term, condition or limitation imposed on his certificate of registration
- Failed to maintain a standard of practice of the profession
- Falsified a record relating to his practice
- Signed or issued, in his professional capacity, a document that he knew contained a false or misleading statement
- Contravened the Act and/or the Regulated Health Professions Act, 1991 and/or the regulations under those Acts, including subsection 5(1) of Ontario Regulation 202/94 under the Act
- Engaged in conduct or performed an act or acts relevant to the practice of pharmacy that, having regarding to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable or unprofessional

In a decision dated May 19, 2017, a Panel of the Discipline Committee imposed an Order against Mr. Oduro which included as follows:

- 1. A reprimand
- 2. Directing the Registrar to suspend the Member's

certificate of registration for a period of three (3) months, with one (1) month of the suspension to be remitted on the condition that the Member completes the course specified in paragraph (3)(a) below. The suspension shall be served commencing on June 21, 2017 and shall continue until August 20, 2017, inclusive. If the balance of the suspension is required to be served by the Member because he fails to complete the course as specified in paragraph 3(a), that portion of the suspension shall commence on June 21, 2018 and shall continue until July 20, 2018, inclusive.

- 3. Directing the Registrar to impose specified terms, conditions or limitations on the Member's certificate of registration as follows:
 - (a) the Member must successfully complete, within twelve (12) months of the date that this Order is imposed, a course with Gail E. Siskind Consulting Services, or another professional ethics consultant acceptable to the College, to be designed by the consultant, with the purpose of addressing the professional misconduct issues raised in this case, and the following terms shall apply to that course:
 - i. the number of sessions shall be at the discretion of the consultant;
 - ii. the manner of attendance at the session(s) (e.g. in person, via Skype, etc.) is a matter to be discussed in advance between the Member and the consultant, but shall ultimately be at the discretion of the consultant;
 - iii. the Member shall be responsible for the cost of the course; and
 - iv. the consultant shall agree to confirm to the College once the Member has completed the course to the satisfaction of the consultant; and
- 4. Costs to the College in the amount of \$3,500.00

In its reprimand, delivered on June 20, 2017, the Panel noted that members of the profession of pharmacy are held to a high standard of conduct and ethics, which is expected not only by the profession of but also the public of Ontario. Integrity, trust, and conduct as a professional are at the very core of the practice of pharmacy and the delivery of care to the public. The Panel observed that the pharmacy is a selfregulated profession and to practice as a pharmacist is not a right but a privilege. All Members of the College bear the responsibility to ensure the practice of pharmacy is conducted at a high standard.

The Panel noted that the Member was charged and convicted of offences contrary to the Criminal Code of Canada. The Panel expressed its view that such a conviction is disgraceful, dishonourable, and unprofessional. The Panel indicated that the Member tarnished his image as a pharmacist and the profession as a whole. The Panel reported that although this did not involve a patient or pharmacy personnel, this conviction reflects poorly on the Member as an individual and on his future practice as a pharmacist.

The Panel observed that the remaining matters have to do with the Member's intentional non-reporting of the criminal charges to the Ontario College of Pharmacists.

The Panel explained that Ontario College of Pharmacists is responsible for the practice of Pharmacy in this province. In order to do this effectively the College depends on an honour system to report to the College when a member has been charged with any offence in any jurisdiction. The Panel noted that a charge under the Criminal Code is serious and must be reported.

The Panel related that the questions asked during the Annual Renewal related to findings of guilt or current proceedings are straightforward, and that answering "No" for three consecutive years at the time of licence renewal is unacceptable and unprofessional.

The Panel noted that the vast majority of pharmacists would never expect to receive a reprimand during their careers. The Panel expressed its expectation that the Member will make amends for his past actions and work to restore his reputation as a pharmacist.

Eiman Amin, R.Ph. (OCP #202872)

At a hearing on June 21, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Ms. Amin with respect to the following incidents:

• That she falsified pharmacy records relating to her practice in connection with claims made for certain identified drugs and/or other products;

- That she signed or issued, in her professional capacity, a document that she knew contained a false or misleading statement in connection with claims made for certain identified drugs and/or other products;
- That she submitted an account or charge for services that she knew was false or misleading in connection with claims made for certain identified drugs and/or other products;
- That she altered purchase invoices, purportedly from McKesson Canada and Bayer Inc. and bearing dates ranging from September 9, 2010 to September 25, 2012, and provided them to the Ministry between October 4, 2012 and November 2, 2012;
- That she failed to submit accurate information to the Narcotics Monitoring System, in particular the correct prescriber registration number, in respect of certain identified prescriptions

In particular, the Panel found that she

- Failed to maintain the standards of practice
- Falsified pharmacy records relating to her practice
- Signed or issued, in her professional capacity, a document that she knew contained a false or misleading statement
- Submitted an account or charge for services that she knew was false or misleading
- Contravened, while engaged in the practice of pharmacy, a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular:
 - o Sections 5, and 15(1) of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10, as amended;
 - o Section 8 of the Narcotics Safety and Awareness Act, 2010, S.O. 2010, c. 22
- Permitted, consented to or approved, either expressly or by implication, the commission of an offence against any Act relating to the practice of pharmacy or to the sale of drugs by a corporation of which she was a director in particular:
 - o An offence pursuant to s. 15(1) of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10, as amended

• Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable and unprofessional

The Panel imposed an Order which included as follows:

- 1. A reprimand
- 2. That the Registrar is directed to impose specified terms, conditions or limitations on the Member's Certificate of Registration, and in particular:
 - a. that the Member complete successfully with an unconditional pass, at her own expense, within 12 months of the date of this Order, the ProBE Program on professional/problem-based ethics for health care professionals;
 - b. the member shall be prohibited having any proprietary interest in a pharmacy as a sole proprietor or partner, or director or shareholder in a corporation that owns a pharmacy, or in any other capacity, and/or receiving remuneration for her work as pharmacist other than remuneration based on hourly or weekly rates only, for a period of five (5) years from the date the Order is imposed;
 - c. that the Member be prohibited, for a period of five (5) years from the date of this Order from acting as a Designated Manager for any pharmacy;
 - d. that for a period of five (5) years from the date the Order is imposed, the Member shall be required to notify the College in writing of the name(s), address(es) and telephone number(s) of all pharmacy employer(s) ("employers") within fourteen (14) days of commencing employment in a pharmacy;
 - e. that for a period of five (5) years from the date the Order is imposed, the Member shall provide her employer with a copy of the Discipline Committee Panel's decision in this matter and its Order
- 3. A suspension of sixteen months, with two months of the suspension to be remitted on condition that the Member complete the remedial training specified in subparagraph 2(a) above.
- 4. Costs to the College in the amount of \$5,000.00

In its reprimand, the Panel noted that integrity and trust are paramount to the profession of pharmacy and that, in return, pharmacists are held in high regard by the public for the role they play in the provision of healthcare in Ontario

The Panel expressed its disappointed with the Member's actions. The Panel noted that, as a Designated Manager, the Member was entrusted by this College and the public to operate in a manner that is honest and ethical. The Panel pointed out that the Member's actions violated the standards of practice and the code of ethics expected by the public and the profession.

The Panel pointed to the volume of these inappropriate activities, to the order of approximately \$900,000 over a two-year period of time, as an example of the Member's disregard for the trust that has been placed on the profession of Pharmacy.

The Panel acknowledged that the Member has made restitution. It expressed its expectation that she will practice pharmacy within the standards of this profession and the code of ethics, and its hope that she will take this opportunity to reflect on her actions and complete the required remediation.

Naresh Jain, R.Ph. (OCP #604710)

At a hearing on June 22, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Jain with respect to the following incidents:

- That a finding of guilt was made on February 4, 2011 by the United States District Court for the Middle District of Florida in relation to embezzling more than \$1000 from the United States
- That he failed to report to the College that he had been convicted of a criminal offence in the United States District Court in February, 2011 and/ or that he had been the subject of a professional misconduct proceeding before the Florida Board of Pharmacy beginning in November, 2011, and/ or that he had been found to have committed professional misconduct by a Final Order of the Florida Board of Pharmacy dated December 26, 2014
- That on his annual renewal forms submitted in 2011, 2012, 2013, 2014, and/or 2015, he falsely answered "no" to the questions asking whether in

the past 12 months he had been the subject of criminal or professional misconduct proceedings or findings

In particular, the Panel found that he

- Was found guilty of an offence that is relevant to his suitability to practise
- Contravened a term, condition or limitation imposed on his certificate of registration
- Failed to maintain a standard of practice of the profession
- Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as unprofessional

The Panel imposed an Order which included as follows:

- 1. A reprimand
- 2. That the Registrar is directed to impose specified terms, conditions or limitations on the Member's Certificate of Registration, and in particular: that the Member complete successfully with an unconditional pass, at his own expense, within 12 months of the date of this Order, the ProBE Program on professional/problem-based ethics for health care professionals.
- That the Registrar suspend the Member's Certificate of Registration for a period of two months, with one month of the suspension to be suspended on condition that the Member complete the remedial training specified in paragraph 2, above.
- 4. Costs to the College in the amount of \$3,500.00

In its reprimand, the Panel noted that the practice of pharmacy is a privilege that comes with obligations. The Panel noted that the Member did not uphold these obligations and, as a result, compromised the integrity of the profession.

The Panel pointed out that the mandatory reporting requirements rely heavily on the honour system, and that any violation is of significant concern to both the College and the public. The Panel noted that the process is not open to interpretation as to what should be reported. The Panel emphasized that the onus and accountability to report truthfully and accurately is on the Member alone.

The Panel expressed its belief that the Member now realizes the importance of this responsibility and that he will benefit from the professional ethics course he has agreed to participate in. The Panel indicated its confidence that he will return to the profession with honour and integrity and will not appear a panel of the discipline committee again.

Nancy Mousa, R.Ph. (OCP #216717)

At a hearing on June 28, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Ms. Mousa with respect to the following incidents:

• That she submitted claims, and/or failed to cancel and/or reverse such claims, for prescriptions that were not picked up by certain identified patients, in or about January 2014-January 2015

In particular, the Panel found that she

- Failed to maintain a standard of practice of the profession
- Failed to keep records as required respecting her patients
- Charged a fee that was excessive in relation to the service provided
- Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members as unprofessional

The Panel imposed an Order which included as follows:

- 1. A reprimand
- 2. Directing the Registrar to impose specified terms, conditions or limitations on the Member's certificate of registration requiring:
 - (a) that the Member successfully complete, within six (6) months of the date of the order, a course with Gail E. Siskind Consulting Services, or another professional ethics consultant chosen by the College, to be designed by the consultant, for the purpose of addressing the professional and

ethical obligations with respect to maintaining accurate records; and the following terms shall apply to the course:

- (i) the number of sessions shall be at the discretion of the consultant, but shall be a minimum of 2 meetings and a maximum of 3 meetings;
- (ii) the manner of attendance at the session(s)
 (e.g. in person, via Skype, etc.) is a matter to be discussed in advance between the Member and the consultant, but shall ultimately be at the discretion of the consultant;
- (iii) the Member shall be responsible for the cost of the course;
- (iv) the Member shall provide to the consultant the following documents, in advance of the course, to facilitate the design of the course:
- 1. the Notice of Hearing;
- 2. the Agreed Statement of Facts;
- 3. this Joint Submission on Order; and
- 4. the Panel's Decision and Reasons, if and when available; and
 - (v) the consultant shall agree to confirm to the College once the Member has completed the course to the satisfaction of the consultant within six (6) months of the date of this Order.
- 3. Directing the Registrar to suspend the Member's Certificate of Registration for a period of two (2) months, with one (1) month of the suspension to

be remitted on condition the Member complete the remedial training program as specified in paragraph 2 above.

4. Costs to the College in the amount of \$3,000.00

In its reprimand, the Panel noted that the Member failed to maintain the responsibilities and obligations expected of her as a member of this profession, and as a Designated Manager.

The Panel noted that pharmacy is a self-regulated profession, which bears the responsibility to ensure that it maintains the trust of the public. The Panel explained that the practice of pharmacy is a privilege and it comes with significant obligations to the public, the profession, and oneself.

The Panel expressed its expectation that the Member will practice pharmacy within the standards of this profession, and that she will take this opportunity to reflect on her actions and complete the required remediation. The Panel related its belief that the Member will change the way she practices and that she will not be seen again in front of a panel of the Discipline Committee.

The full text of these decisions is available at <u>www.canlii.orq</u>

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FOCUS ON ERROR PREVENTION

By Ian Stewart B.Sc.Phm., R.Ph.

IDENTICAL DRUG IDENTIFICATION NUMBERS

Pharmacy professionals usually use the assigned Drug Identification Number (DIN) of a drug product to confirm that the correct product is being dispensed.

The DIN is a computer-generated number assigned by Health Canada to a drug product that uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; and route of administration¹.

Pharmacists should be aware of the potential for error when two different product formulations are assigned the same DIN.

CASE:

Rx:

Amoxicillin 125mg/5ml Sig: Give 9mls three times daily Mitte: 10 days' supply

The above prescription was taken to a local community pharmacy for dispensing. A pharmacy assistant correctly entered the prescription into the computer. However, when preparing the medication for dispensing, the pharmacy assistant selected one 150ml bottle of Apo-Amoxi®125mg/5ml and one 150ml bottle of Apo-Amoxi®125mg/5ml sugar free in error. Both products are similar in appearance and have the same DIN (see photograph).

To reconstitute the 150ml bottle of Apo-Amoxi®125mg/5ml,

the pharmacy assistant added 103mls of water as per the label instructions. The pharmacy assistant added the same volume of water to the 150ml bottle of Apo-Amoxi®125mg/5ml sugar free. However, the final volume was much less than 150mls.

Upon checking the label of the sugar free product, it was noted that 148mls of water (not 103mls) should be added to reconstitute the product. The error was therefore detected.

POSSIBLE CONTRIBUTING FACTORS:

 Pharmaceutical manufacturers often use similar packaging and labelling for consistency. As a result, the packaging and labelling of Apo-Amoxi®125mg/5ml and Apo-Amoxi®125mg/5ml sugar free are similar in size, shape and appearance.

- Both products have identical DINs.
- The 'sugar free' indication on the label of the Apo-Amoxi®125mg/5ml sugar free is not bolded and therefore easy to miss.
- Both products were stored together in the same location.
- The pharmacy assistant assumed that both products were identical and hence assumed the instructions for reconstitution would be the same.

RECOMMENDATIONS:

- Educate all pharmacy staff about the potential for error when storing and dispensing drugs with identical DINs.
- Store the sugar free product in a separate location which should be clearly labelled.



- Consider changing the brand of one of these products to reduce the potential for error.
- Due to the similarity in a manufacturer's packaging and labelling, when dispensing multiple products, check each

carefully to ensure they are all the same product.

- Consider having the pharmacist or technician double check the products selected and/or the amount of water to be added prior to reconstitution.
- Check the prescription for accuracy and appropriateness before reconstituting the product.

REFERENCES:

1. Drug Identification Number (DIN), available at: <u>https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/drug-identification-number.html</u> Accessed June 30th, 2017.

Please continue to send reports of medication errors in confidence to Ian Stewart at: <u>ian.stewart2@rogers.com</u>. Please ensure that all identifying information (e.g. patient name, pharmacy name, healthcare provider name, etc.) are removed before submitting.

Note: Presently, Apotex has two approved DINs listed for Apo-Amoxi in <u>Health Canada's Drug Product Database</u>. Apotex has confirmed that only one of the products is available for sale (DIN 00628131).



As members of a self-regulated profession, pharmacists must be able to rationalize the clinical decisions that they make, to their peers and to any person or organization which may be affected by their actions, including individual patients, the public, their employers, and other health care professionals.

 $\underline{http://www.ocpinfo.com/library/practice-related/download/Professional\%20Judgment.pdf}$

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