Ontario College of Pharmacists
Putting patients first since 1871

# PHARMACY CONNECTION

WINTER 2018 • VOLUME 25 NUMBER 1
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THE OFFICIAL PUBLICATION OF
THE ONTARIO COLLEGE OF PHARMACISTS

*Towards a Safer System:*
## AN INTERVIEW WITH PATIENT ADVOCATE MELISSA SHELDRICK 13

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

**Standing Committees**
- Drug Preparation Premises
- Elections
- Finance & Audit
- Professional Practice

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# Strategic Framework
2015-2018

**Mission**
The Ontario College of Pharmacists regulates pharmacy to ensure that the public receives quality services and care.

**Vision**
Lead the advancement of pharmacy to optimize health and wellness through patient-centred care.

**Values**
Transparency ♦ Accountability ♦ Excellence

**Strategic Priorities**
Core Programs Fulfillment of Mandate ♦ Optimize Practice within Scope ♦ Inter & Intra Professional Collaboration

**Strategic Initiatives**
Patients First
Effective Communications
Continuous Quality Improvement

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

Last fall, I and members of the College leadership team hosted a number of regional meetings to update members on key initiatives and activities underway aimed at advancing our shared goal of putting patients first. Our work to promote patient-centred and safe pharmacy care and the conversations we've had with professionals – both those just entering the profession and those with established practices – about our shared goals since then have not waned. And they never should.

Putting patients first means keeping patients safe. While we've made patient safety a focus of this issue of *Pharmacy Connection*, in reality patient safety must be a focus in all of our work, all of the time. This applies to what we do as a regulator and what all of you do as pharmacy professionals and stakeholders.

We believe that pharmacy professionals, as trusted members of a patient's care team, can be agents of positive change in our health system and can – and should – play a vital role in building healthier communities. As the regulator of pharmacy in the province, we have an obligation, first and foremost to the public, to have the right systems and tools in place to support quality and safe pharmacy care.

Doing so means that we must evolve as our health system evolves. Being a responsive regulator, after all, doesn't mean always doing more of the same. It means challenging the traditional notion of what a regulator should be and the role we all play as a part of a broader healthcare system.

## AFFECTING POSITIVE OUTCOMES AND CONTRIBUTING TO A BETTER HEALTH SYSTEM

It's often said that 'you can't improve what you can't measure', which is why the College has started to move towards adopting a systems-based focus in its work to better define, measure and influence positive patient outcomes.

Our medication safety program is a wonderful example of how we will all be able – for the first time in Ontario – to benefit from anonymously reported data that, ultimately, will help reduce the risk of preventable harm caused by medication errors in pharmacies. Read more about the progress we're making on the program, including an interview with patient advocate Melissa Sheldrick and the invaluable role of our phase-one pharmacy ambassadors, in this issue of *Pharmacy Connection*.

As the role of regulatory colleges evolves and as stakeholder and public expectations continue to change, the College recognizes the extraordinary opportunity to work with broader health system partners to influence high quality, safe pharmacy care and promote good outcomes for patients. We see ourselves – both us as the regulator and you as pharmacy professionals – as playing an important role in supporting the goals of Ontario's *Patients First Action Plan for Healthcare*.

Over the past several months, the College has established important collaborative relationships as we look to leverage our mandate to advance our strategic priorities in new and innovative ways.

As you'll read in this issue of our magazine, we've formed new partnerships with organizations such as Health Quality Ontario (HQO) and with Local Health Integration Networks (LHINs). Along with directly supporting initiatives such as our Opioid Strategy and implementation of sterile compounding standards, these new collaborations are strong examples of how we're building vital regional and diversified approaches to quality and safety while also building bridges between pharmacy and primary care and with other areas of the health system. Through more effective systems-based and data-informed strategies, we strongly believe that we can contribute to effective and sustainable health system improvements and promote quality and safe pharmacy practice throughout the province.

As the College moves closer to the development and launch of a new strategic plan later this year, we must always keep in mind that patients are our first priority. Look for us to continue to introduce new ways of integrating the patient perspective into our activities and to establishing even more partnerships with health system organizations as we work – together with all of you – to strengthen public confidence in the role of the College and the safety of pharmacy in our communities.

Yours in patient safety,

Nancy Lum-Wilson
**CEO and Registrar**

# DECEMBER 2017 COUNCIL MEETING

*As recorded following Council's regularly scheduled meeting held at the College offices on December 11th, 2017.*

### COUNCIL APPROVES PROPOSED AMENDMENTS TO *PHARMACY ACT* REGULATIONS FOR SUBMISSION TO GOVERNMENT

This past September, Council was presented with draft amendments to the quality assurance and registration regulations. These amendments were aimed at implementing an Intern Pharmacy Technician class of registration, incorporating pharmacy technicians into the quality assurance regulations, eliminating unnecessary steps in registration, and shifting from an hourly reporting of practice to a self-declaration of competency in conjunction with practice assessments. Council subsequently directed the College to move forward with a 60-day open consultation on the proposed amendments.

A total of 41 submissions were received from pharmacy professionals and the public including a submission from the Ontario Pharmacists Association. The majority of the feedback indicated overall support for the regulation amendments and no further changes were recommended to Council. At its December 2017 meeting, Council received the final report from staff and approved the proposed regulations for submission to the Ministry of Health and Long-Term Care for consideration.

### COUNCIL ADOPTS MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS

In the fall of 2016, the College posted on its public website draft Model Standards for Pharmacy Compounding of Non-Sterile Preparations, which were developed by the National Association of Pharmacy Regulatory Authorities (NAPRA), for consultation. Model Standards represent the minimum requirements that must be met regardless of practice site and against which performance can be measured.

Responses were received from a number of stakeholder groups including pharmacists, pharmacy technicians and pharmacy organizations. The submissions were generally supportive with suggestions to aid clarity; the College provided this feedback to NAPRA's National Advisory Committee on Pharmacy Practice. In all, nation-wide consultation elicited over 800 comments, many of which were extremely detailed, leading NAPRA to take a new approach with the Standards.

The release of the Standards will now be accompanied by a Guidance document which will provide pharmacists and technicians who compound non-sterile preparations with the details necessary to evaluate their practice, develop service-related procedures, and implement appropriate quality controls for the protection of both patients and compounding personnel. NAPRA is expected to finalize and publish the Standards and the Guidance document in early 2018.

Following Council's approval to adopt the Model Standards for Pharmacy Compounding of Non-Sterile Preparations at its December 2017 meeting, the College will now work toward establishing an appropriate implementation date and will develop a comprehensive communication and education plan for members and stakeholders. More information on this issue will be available in the coming months.

### GOVERNANCE

Council welcomed Mr. Azeem Khan (Public Member) who was recently appointed to College Council for a period of three years. Mr. Khan will be serving on the Inquiries, Complaints and Reports Committee (ICRC) and the Discipline Committee. The recent addition of several public members to Council is very much appreciated as it allows for more public participation on panels of college adjudicatory committees.

At this meeting, Council also considered and supported the Executive Committee's

recommendation to create a task force which will examine the legal and practical requirements of instituting a competency screening process for members seeking election to College Council.

Screening for competence is consistent with action being considered by the Advisory Group for Regulatory Excellence (AGRE), which is developing a proposed Eligibility and Competency-Based Committee Appointment Framework which will set out a process for how a person who might be interested in being considered for appointment to a College statutory committee would travel through the application and selection journey. The framework, which is part of AGRE's governance project, aligns with government priorities and the changes set out in the *Protecting Patients Act, 2017*.

The intent and overall objectives contained in changes set out in the *Protecting Patients Act, 2017* align with the College's own values and commitment to transparency and accountability. The College supports actions that provide better patient protection and strengthen its ability to maintain society's trust in our regulatory role to serve and protect the public.

Council also welcomed representatives from the College of Nurses of Ontario (CNO) who were invited to address Council about their own governance renewal journey in the pursuit of their public interest mandate.

**STRATEGIC PLANNING UPDATE**

As the 2017 year draws to a close, College Council is now looking to the development of a new multi-year strategic plan. A planning group consisting of Council members and senior College staff has now been struck to move this work forward, with a goal of establishing and launching a new strategic plan later in 2018.

**CEO AND REGISTRAR'S REPORT HIGHLIGHTS**

Nancy Lum-Wilson, CEO and Registrar, provided Council members with a comprehensive update on the College's progress in advancing its strategic priorities. Key highlights included the development of several new collaborative initiatives with health system partners such as Local Health Integration Networks, the announcement of Pharmapod as the selected vendor for our medication safety continuous quality assurance program, the initial steps being made to advance our Opioid Strategy, and the success of the most recent regional meetings held earlier this fall. Also included in the CEO and Registrar Report was an update from Todd Leach, Manager of Communications, who provided Council with a brief overview of the communications plan for 2018 which will increase its focus on public- and stakeholder-facing communication, education and engagement activities in an effort to build greater awareness and confidence in the College's public interest mandate.

**FUTURE COUNCIL MEETINGS:**

- Sunday March 25, 2018
- Monday June 11, 2018
- Monday September 17 & Tuesday September 18, 2018
- Monday December 10, 2018

For more information respecting Council meetings, please contact Ms. Ushma Rajdev, Council and Executive Liaison at urajdev@ocpinfo.com.

# *White Coat Ceremonies at* UNIVERSITY OF TORONTO *and* UNIVERSITY OF WATERLOO

*The University of Toronto and University of Waterloo recently hosted ceremonies to formally mark the beginning of incoming pharmacy students' professional journey. During the ceremonies, students make their commitment to ethics and integrity and are welcomed into the professional community. College CEO and Registrar Nancy Lum-Wilson and Deputy Registrar Anne Resnick attended the ceremonies.*

University of Toronto's Pharmacy Class of 2021

Photo by: Vincent Nguyen and Qiqi Lin

Photo by: Vincent Nguyen and Qiqi Lin


University of Waterloo's Pharmacy Class of 2021


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 www.ocpinfo.com

## ONTARIO PASSES LEGISLATION THAT WILL REQUIRE THE DISCLOSURE OF PAYMENTS MADE TO HEALTHCARE PROFESSIONALS

The government of Ontario has passed legislation that will make Ontario the first province to require the medical industry, including pharmaceutical and medical device manufacturers, to publicly disclose payments made to healthcare professionals and organizations. The industry will need to report information on transfers of value, such as meals, hospitality, travel associated expenses, financial grants and fees paid for consulting or speaking events. The public will be able to search a database for this information. The date of proclamation of the Act has not yet been announced.

## UPDATED LABELLING FOR PRESCRIPTION OPIOID PRODUCTS

Following recommendations from the Government of Canada's Scientific Advisory Panel on Opioid Use and Contraindications, Health Canada has announced that it is working with manufacturers to update the Canadian labelling of all prescription opioid products. Changes include:

- Recommendation for a daily threshold dose for management of chronic, non-cancer, non-palliative pain
- Recommendation to limit quantity of opioids prescribed for acute pain
- Clarification of warnings for special populations

The labelling for all prescription opioids is expected to be completed by January 2019.

## FEDERAL GOVERNMENT PROPOSES NEW MAID MONITORING SYSTEM

The Canadian government has proposed new regulations that would require physicians, nurse practitioners and pharmacists to file reports when a patient requests medical assistance in dying (MAiD). The data collected through the reporting would be publicly reported in aggregate in order to promote transparency and accountability. At this time, the proposed regulations would require pharmacists to report every time they dispense drugs necessary for the procedure.

Reports released by the federal government so far have indicated that more than 2,000 Canadians have received MAiD, most of whom were between 56 and 85 years of age and suffering from terminal cancer. Consultation on the proposed regulations closed February 13, 2018.

## *SAFE ACCESS TO ABORTION SERVICES ACT* CAME INTO EFFECT FEBRUARY 1

The *Safe Access to Abortion Services Act*, intended to help protect the safety, security, health and privacy of persons accessing or providing abortion services, including mifegymiso, came into effect on February 1, 2018.

Under this legislation, requests may be made by pharmacies who are providing abortion services to establish safe access zones of up to 150 metres around the pharmacy. Prohibited activities within safe access zones include protests, physical interference or intimidation, recording patients or providers and advising a person to refrain from accessing abortion services.

In addition, safe access zones of 150 metres will be automatically established around the homes of "protected service providers," including pharmacists.

Review the information provided regarding applying for a safe zone for a pharmacy.

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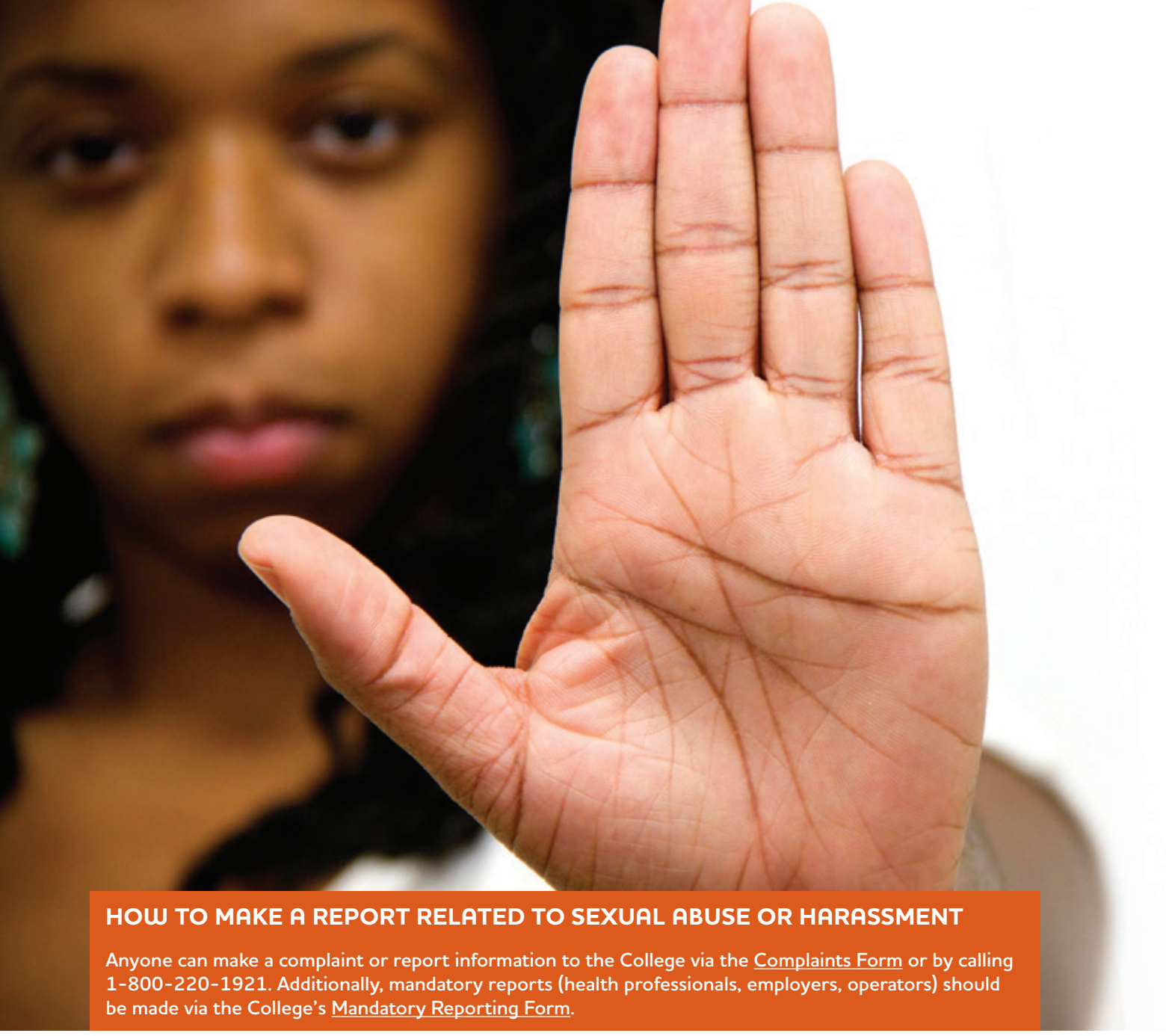


## HOW TO MAKE A REPORT RELATED TO SEXUAL ABUSE OR HARASSMENT

Anyone can make a complaint or report information to the College via the Complaints Form or by calling 1-800-220-1921. Additionally, mandatory reports (health professionals, employers, operators) should be made via the College's Mandatory Reporting Form.

# ZERO TOLERANCE OF SEXUAL ABUSE AND HARASSMENT

*Recently, there has been increasing awareness and discussion of incidents of sexual abuse and sexual harassment within society. As healthcare professionals, pharmacists and pharmacy technicians must be particularly committed to preventing sexual abuse of patients and sexual harassment of colleagues.*

Sexual abuse of a patient by a pharmacy professional can include sexual intercourse, touching of a sexual nature and remarks of a sexual nature, among other behaviours[1]. Workplace sexual harassment means engaging in a course of knowingly unwelcome vexatious comment or conduct against a worker because of sex, sexual orientation or gender identity, or making a knowingly unwanted sexual advance where the person making the advance is in a position to confer, grant or deny a benefit or advancement to the worker[2]. Some of these actions would also be considered sexual assault in the criminal jurisdiction.

The College has been clear on this: any act of abuse and harassment of a patient, customer, staff person or colleague is **unacceptable**. Such actions are subject to investigation as professional misconduct. Moreover, ignoring harassment or abuse can be equal to condoning the perpetrator's actions, which further harms the victim and may itself be subject to sanction.

## PROTECTING PATIENTS FROM ABUSE

The recent passage of the *Protecting Patients Act (2017)* is a reminder that healthcare professionals and regulatory colleges have an obligation to protect patients from sexual abuse. As the remaining provisions and regulations of the Act come into effect, the College will continue to reinforce the fact that inappropriate behaviour towards patients is not acceptable and that disciplinary action will be taken as appropriate.

As regulated healthcare professionals, pharmacists and pharmacy technicians have obligations to maintain appropriate boundaries with their patients, meaning that their behaviour aligns with the Code of Ethics. Examples can be found in the College guideline on Preventing Sexual Abuse and Harassment. Pharmacy professionals must never become sexually involved with a patient and must not harass or otherwise intimidate patients.

Pharmacists and pharmacy technicians must also make mandatory reports where they have reasonable grounds to believe that another regulated healthcare professional has sexually abused a patient. Designated managers or anyone else who is operating a facility and has reasonable grounds to believe that a regulated healthcare professional practicing there has sexually abused a patient must also make a report.

## NO TOLERANCE FOR WORKPLACE SEXUAL HARASSMENT

Everyone should have an expectation that they are safe at work and free from harassment and abuse. Employers should understand their obligations under the *Occupational Health and Safety Act* in this regard. Inappropriate behaviour towards colleagues, including unwanted touching and remarks of a sexual nature, may be considered dishonourable, disgraceful and unprofessional conduct by the College's disciplinary processes.

Pharmacy professionals are expected to demonstrate personal and professional integrity and to maintain professional boundaries at all times. These boundaries are based on trust, respect and appropriate use of power. The Code of Ethics specifically requires that pharmacy professionals do not exploit power imbalances in professional working relationships for their own personal, physical, emotional, or sexual gain.

Owners and managers have inherent obligations to support a safe and effective working environment. This includes recognizing their obligations towards workers under workplace and human rights legislation. The tone set for the organization by leadership determines how staff interact among each other and with patients. Intimidation and harassment are also detrimental to a culture of patient safety and may cause additional risks to patients.

## A SHARED OBLIGATION

Patients and caregivers expect that pharmacy professionals will act in their best interests and uphold the honour of the profession and practice in accordance with the Code of Ethics and Standards of Practice. Employees expect that they will be safe when they go to work every day and that their employer will support them in this regard. The College expects that pharmacy professionals will govern themselves in accordance with the law, the Code of Ethics and the Standards of Practice and will not engage in any dishonourable or unprofessional conduct. Meeting these expectations is a shared obligation among individuals, managers and corporations.

There is no room for sexual abuse and harassment in pharmacy, in the workplace or in the community. Rooting out this behaviour is a responsibility that everyone shares.

1. *Regulated Health Professions Act*
2. *Occupational Health and Safety Act*

# Moving Ontario's Medication Safety Program FORWARD

In June 2017, Council approved a mandatory medication safety incident reporting program for all of Ontario's pharmacies. The program supports ongoing continuous quality improvement and puts in place a mandatory consistent standard for all pharmacies in the province, ultimately helping to prevent incidents from reoccurring and enhancing patient safety. In addition, data collected through the program will enable the identification of trends and the development of resources to support safety improvements in pharmacies. Following the announcement that Pharmapod Ltd. had been selected to create and manage the program reporting system, the College has been working closely with them to develop training and begin implementation for the first phase participants.

While Pharmapod will be responsible for providing training and tools for Ontario pharmacies, analyzing provincial medication incident data and providing reports to individual pharmacies, the College oversees the program. The College will receive aggregate data in order to support activities, tools and resources to address gaps that may be identified.

Training for the 102 first-phase participants took place in January. These pharmacies and their staff from across Ontario will ultimately play a critical role in the province-wide implementation and success of this program by testing the reporting system. As program ambassadors, they will provide ongoing feedback throughout 2018 to inform any required changes to the program, thus facilitating full adoption and success when it is implemented in all 4,200+ community pharmacies in Ontario.

While the focus is currently on this first phase, full implementation of the medication safety reporting program is expected to commence by the end of 2018. Pharmapod will be reaching out to all pharmacies in Ontario later in 2018 to provide training and support leading up to the province-wide implementation.

## DATA LICENSE AGREEMENTS AND PROGRAM FEES

During the pharmacy accreditation process this year, the Director Liaison of each pharmacy will be required to review and sign a license agreement with the College and program partner Pharmapod. The agreement signals consent to provide certain data to the Pharmapod platform, once implemented at individual pharmacies, in order to facilitate the operation of the program. In advance of the accreditation process, Director Liaisons will be provided with the opportunity to review the data license agreement. Please look for future communication from the College regarding the agreement.

The program, which will be mandatory for all accredited community pharmacies, is paid for by the College. The cost for the program, just as all other programs administered by the College as part of our regulatory responsibilities and public-protection mandate, are recovered through fees paid by registrants and accredited pharmacies. The program is scheduled to be rolled out to all pharmacies in 2019. As always, when preparing the budget for the fiscal year 2019, the College will assess fee levels necessary to cover expenses and maintain our regulatory programs and appropriate reserves. Given the cost of the program, we anticipate that this will have an impact on fees for 2019, subject to Council approval in September 2018. Any impact on fees will be communicated promptly.

# *Towards a Safer System:* AN INTERVIEW WITH PATIENT ADVOCATE **MELISSA SHELDRICK**

Melissa Sheldrick (centre) with CEO and Registrar Nancy Lum-Wilson (left) and Deputy Registrar Anne Resnick.

*In late 2016, the Ontario College of Pharmacists embarked on a journey that would result in the introduction of the largest medication safety program of its kind among Canadian pharmacies. An advocate behind this critical work is elementary school teacher Melissa Sheldrick, who lost her son Andrew, 8, to a medication error. Melissa was invited to be a part of the College's Medication Safety Task Force as it reviewed options related to medication error reporting and provided an invaluable perspective as a patient advocate. The Task Force recommended the development and implementation of a continuous quality assurance program for medication safety which was approved unanimously by College Council in June 2017. The first phase of the program is now underway, with a full roll out among all of the province's community pharmacies commencing later in 2018.*

*Pharmacy Connection interviewed Melissa as she participated in the training session for pharmacy ambassadors involved in the first phase of the roll out of the medication safety program in Ontario, hosted recently at the College in collaboration with program partner Pharmapod Ltd. She shared with us her thoughts on the program, its objective of reducing the risk of preventable harm caused by medication errors and where she sees programs like this benefiting all Canadians.*

### *What is your vision when it comes to medication safety and programs such as this? In Ontario? Nationally?*

I truly believe that we are fortunate to live in a province and country where we have a safe and effective health care system. All of us will at some point in our lives need to use this system and we all should be able to trust it and rely on it when we need it.

I feel that safety improvement and quality assurance programs such as the medication safety program that the College is now launching in Ontario, and that other provinces are moving forward with, will make the healthcare system that much safer. So that when we go to a pharmacy and pick up our medications, we can feel assured that it is the right medication, in the right dose, for the right patient. We know that sometimes that doesn't happen. Therefore, quality assurance programs need to be in place to lessen the number, frequency and severity of medication incidents.

The World Health Organization (WHO) has called on countries to make medication safety and the reduction of medication related errors and patient harm a global priority. I believe that Ontario, as the largest province to move forward in this direction, is taking patient safety to a new level. Conversations in other provinces have been very positive and productive. Every province I've spoken to is on board in some manner for this type of program or approach, which I am very encouraged about.

Recently, I spoke to a group of pharmacy ambassadors in Manitoba leading that province's medication safety pilot project. I received great feedback and even had pharmacists expressing how grateful and inspired they were and understood how important it is. I have now been asked to speak at the Canadian Pharmacists Association (CPhA) national conference in New Brunswick this summer. I'd like to see more federal government involvement and support for these types of programs in response to the WHO's global challenge. They, too, have a role to play.

### *What role do pharmacy professionals play in protecting patients from medication errors?*

Medication errors are preventable. Pharmacy professionals are part of a patient's healthcare team and, as such, are trusted that they are doing everything they can to protect patients from harm. Everyone can appreciate how busy pharmacies can be. However, no matter what they're involved in or what they're doing, pharmacy professionals must make patient safety their number one goal.

Collaboration is so very important between all professionals in a pharmacy, and they all have to work together and they must have effective and open communication with colleagues, including prescribers, and their patients to help reduce the chances of an error occurring. When the College begins to roll out the medication safety program in Ontario, it will be crucially important that all pharmacy team members know how to use this program, how they can benefit from it, and why it is so important that they learn from their own experiences and the experiences of others through sharing of incident data and best practices.

### *What do you think having a program like this in place communicates to the public and other health professionals?*

I think it communicates to the general public and the thousands of people who interact with pharmacies every day that pharmacies and pharmacy professionals are committed to patient safety, that they're doing the right things and taking all the right steps to make sure patients get the right medication. This is an important public assurance message and one that cannot be overstated.

By opening themselves up to doing better and doing everything they can to learn and work with others, pharmacy professionals are showing leadership and are making a significant impact on promoting patient and public safety.

### *What is the single most important message you want all pharmacy professionals to know and understand from your perspective as a patient advocate?*

That there is a human life on the other side of the counter. Healthcare is delivered by people, and mistakes can and do happen, sometimes tragically. What would be equally tragic is if there is no learning that comes from the mistake, no sharing of solutions, that results in more patients being put at risk. Medication errors are


Melissa shares her story with participants of Phase 1 of Ontario's medication safety program at the OCP office in mid January.

preventable and everyone has to be committed to the goal of reducing preventable harm and to continuous learning on how to prevent them from recurring. It's as simple as that.

## *What is the most important part of this program? What do you see as having the most significant impact on helping to prevent errors?*

As an educator, I can appreciate that learning must be a life-long commitment. We owe it to ourselves, to our colleagues and to those whom we are here to serve. If we don't learn from mistakes, or take advantage of information and data about the experiences of others and how to prevent those same mistakes from recurring, we are not moving forward, not growing and not improving.

The real value in the program being introduced in Ontario is in the learning that comes from quality data that is fed into the incident program and the opportunities to work together as a healthcare system to make real improvements in reducing preventable harm.

## *What does this mean to you personally?*

Losing Andrew was a devastating experience to our family that we will live with for the rest of our lives. For me to be able to be a part of a program that promotes patient safety, it is one way that I can experience some healing.

The knowledge that volunteer ambassadors are participating in the first phase of Ontario's medication safety program roll out to me means that the industry recognizes, and is committed to, patient safety strategies and solutions. I believe that building a safer health system is Andrew's legacy and I am determined to work hard to make that a reality for all Canadians.

# *Update on the* COLLEGE'S OPIOID STRATEGY

*In the Fall 2017 issue of Pharmacy Connection, the College published its Opioid Strategy. The strategy focuses on four strategic priorities, which all have an emphasis on reducing opioid use disorder and preventing overdose and addiction, and is in support of efforts by governments and other health system stakeholders.*

With the overall strategy in place, the College has been busy confirming, reviewing and developing work plans for specific key initiatives that support each priority.

## OPIOID STRATEGY EXTERNAL WORKING GROUP

In order to support and advise on the development of specific initiatives under the strategy, the College has created an external working group. This group is comprised of pharmacy professionals with expertise in addiction, pain and other specialties, in addition to other key healthcare stakeholders. To gather participants, the College invited applications through e-Connect. Almost 200 pharmacy professionals submitted an application – evidence of how engaged and motivated the pharmacy profession is to take action on the opioid crisis. It is anticipated that the first meeting will take place in March.

Those who were not chosen for the working group will form a special practice community that will support the opioid strategy by reviewing and providing feedback on tools, resources and policies for the College on an occasional basis.

## COLLABORATION

There are many external groups working to address opioid-related harms. Recognizing that collaboration can more effectively address shared goals, representatives from the College participate in many of these groups, including:

- The Provincial Opioid Emergency Task Force, which brings together many partners to strengthen the province's response to the opioid crisis.
- CAMH's opioid-related committees, including the Opioid Internal Network, which ensures alignment and coordination of CAMH opioid-related initiatives and activities and the Opioid Dependence Treatment Advisory Committee, which informs the enhancement of the Opioid Use Disorder Treatment Certificate Program.
- NAPRA's opioid-related working groups, which were established to meet NAPRA commitments identified in the Joint Statement of Action to Address the Opioid Crisis.
- The Prescription Monitoring Leadership Roundtable, which ensures that the narcotic monitoring system (NMS) data is used by the ministry in a consistent and evidence-based manner, helping to identify potentially inappropriate prescribing and dispensing practices.

The College is also engaged in other collaborative efforts with Health Quality Ontario, as well as participating in the Ministry of Health and

Long Term Care's monthly opioid health system coordination call.

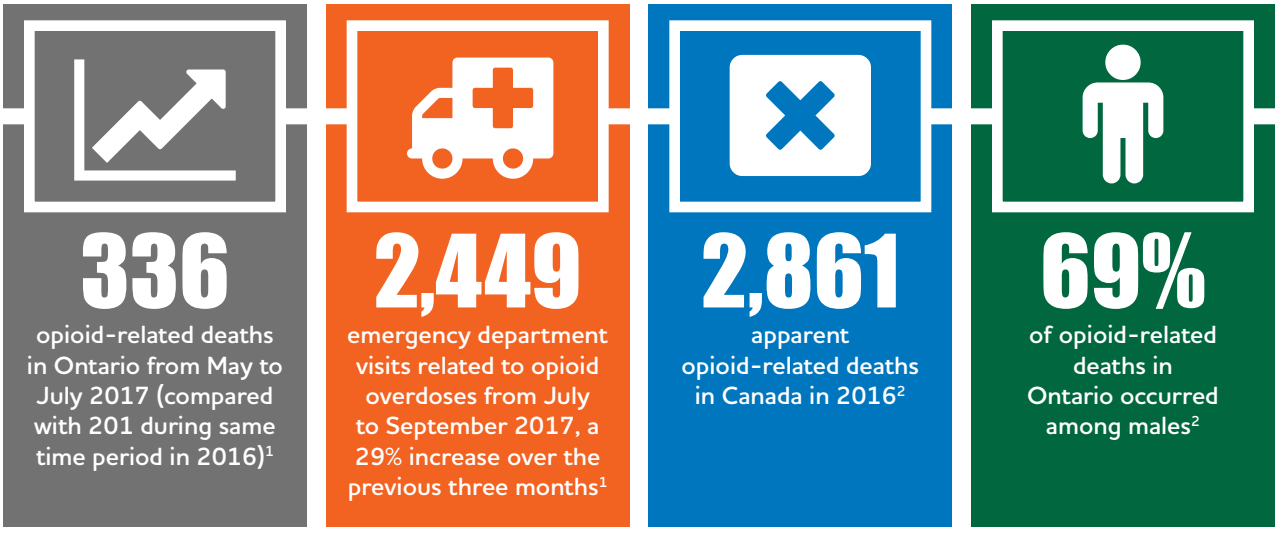
## HIGHLIGHTING KEY ACTIONS IDENTIFIED UNDER THE STRATEGY

Supporting the strategy and the four priorities are a number of specific initiatives and actions that are being taken by the College, including:

- Developing an opioid treatment policy, which will support the application of standards and the implementation of best practices including expectations regarding opioid dispensing and security.
- Working with the University of Waterloo to develop an opioid module for Pharmacy5in5.
- Identifying a set of pharmacist-centric morphine equivalent dosing (MED) tools.
- Building stronger expectations into the self-assessment process regarding continuing education related to opioids.
- Developing and implementing a pharmacist-patient communication tool that will provide guidance to pharmacists on how to have difficult conversations with patients regarding opioid use.
- Developing tools to support improved documentation, monitoring and follow-up of patients with chronic pain in close alignment with Health Quality Ontario's Quality Standard for Opioid Prescribing for Chronic Pain.
- Engaging government in discussions regarding the need for access to electronic health records and system-wide data analysis.
- Working with stakeholders to address opioid security and enhance public protection, for example reducing loss and diversion from pharmacies and using existing data (e.g. NMS, narcotic loss reporting) to identify substandard practices.

The College regularly adds tools and resources to its website regarding opioid-related issues, including to the Opioids Practice Tool, the Narcotics Practice Tool and the Opioids Continuing Education Listings. Pharmacy professionals are encouraged to review these pages frequently. A recently added tool is the OPA's Pharmacist Clinical Tool for Initiating Naloxone Discussions: a conversation tree, providing prompts and guidance for pharmacists on how they can engage patients or their caregivers in discussions about naloxone. It also includes a checklist to help identify patients at the highest risk of opioid-related respiratory depression.

## THE OPIOID CRISIS IN NUMBERS

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Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
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ISMP Canada Safety Bulletin

Volume 18 • Issue 1 • January 4, 2018

# Death Associated with an IV Compounding Error and Management of Care in a Naturopathic Centre

Patients with a diagnosis of cancer may choose to use complementary and alternative medicine, such as naturopathy, to support conventional medical therapies (e.g., surgery, chemotherapy).[1] The complementary and alternative medicine treatment plan is usually prescribed by a naturopathic doctor and carried out in a complementary care centre (CCC). As part of an ongoing collaboration with a provincial death investigation service, ISMP Canada received a report about the death of an individual who had received, by intravenous (IV) administration at a CCC, a tissue- and wound-healing formulation containing selenium at a much higher concentration than intended. This bulletin highlights some contributing factors identified in the incident analysis, and provides recommendations to prevent similar incidents in the future.

## Case Description

A patient was discharged from hospital after surgical excision of a cancerous tumour and was further treated, in a collaborative arrangement, by a conventional medical team and a naturopathic doctor at a CCC. The naturopathic doctor prescribed a complex tissue- and wound-healing formulation, which included selenium, for twice-weekly IV administration. The selenium solution was prepared by a compounding pharmacy and was added to the formulation on site at the CCC.

The patient had received this healing formula on 12 previous occasions, with no reported reactions.

***Specialty compounding pharmacies:***

- *Ensure that the formula's units of measure align with the units of measure displayed by the equipment to be used during compounding; additional conversion calculations should not be required in the process.*
- *Incorporate technology to support patient safety, such as bar coding and scales that print the weight of each item automatically.*
- *Avoid the use of dangerous abbreviations known to lead to medication errors (e.g., "µg" for "micrograms").*

***Complementary care centres:***

- *Ensure the availability of detailed protocols to be followed if an emergency situation occurs, such as a reaction to an intravenous (IV) infusion.*
- *Define the limitations of the complementary care centre and its healthcare providers. Clearly describe clinical circumstances in which patients must be transferred to a conventional, higher level of care (e.g., emergency room).*
- *Use "mcg" to represent "micrograms" in all written documentation.*

However, shortly after initiation of the 13th dose infusion, she became nauseous and diaphoretic. The infusion was stopped, and homeopathic remedies were administered, with no clinical improvement. Over the next several hours, the patient's condition

continued to deteriorate. When the patient began to experience hypotension, shortness of breath to the point of cyanosis, and chest pain, she was transferred to the emergency department of a local hospital, where she later died. The timeline of these events is presented in Figure 1. Postmortem investigations showed that the selenium concentration in the infusion was 1000 times greater than intended, which likely contributed to the patient's death.

## Background

The mineral selenium is an essential trace element in the body that is usually consumed through intake of food and water. It has antioxidant properties and has been studied for use in treating many medical conditions. However, high doses of selenium are toxic, leading to gastrointestinal and cardiovascular complications.[2] Selenium is commercially available in many forms, including as a solution for IV administration.

Tissue- and wound-healing formulations are used in the field of naturopathic medicine as postsurgical support. Naturopathic doctors prepare these complex IV admixtures on site at the CCC, usually from commercially available products. Products that are not commercially available (or that cannot be supplied because of shortages) may be outsourced to compounding pharmacies. Most pharmacies offer some compounding services; however, the scope of such services and the expertise of staff are highly variable. The National Association of Pharmacy Regulatory Authorities (NAPRA) has developed standards for compounding of hazardous and nonhazardous sterile preparations to assist pharmacists and pharmacy technicians in ensuring that the compounding of sterile preparations meets high standards.[3]

## Discussion

This bulletin focuses on 3 key opportunities for improvement (listed in Box 1).

**Box 1.** Key opportunities for improvement

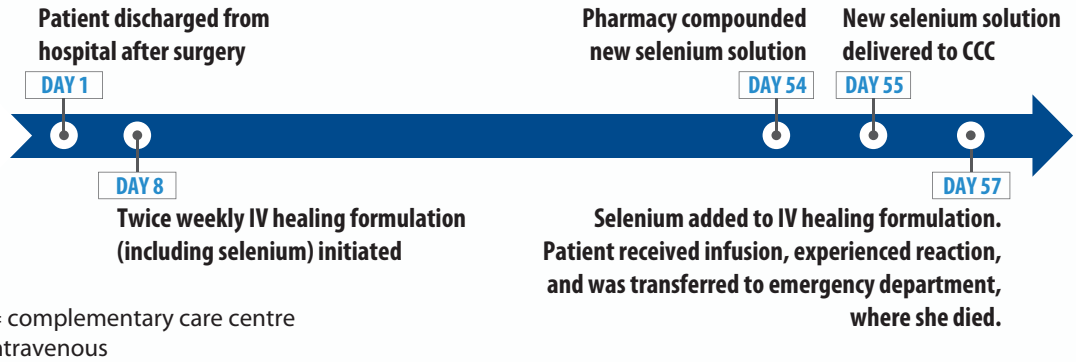
***At the pharmacy***
- Compounding processes

***At the complementary care centre***
- Emergency response
- Preparation, storage, and administration of admixtures

### *Pharmacy: Compounding Processes*

The compounding pharmacy had processes in place to verify calculations and weighing of ingredients, as well as a final product check. Nonetheless, the

**Figure 1.** Timeline of events from the patient's initial hospital discharge until her death




CCC = complementary care centre
IV = intravenous

selenium concentration in the prepared solution was 1000 times what was intended, and this error was not detected at any stage before release of the solution to the CCC. The following factors may have contributed to this undetected error:

- Confirmation bias, which leads individuals to "see" information that confirms their expectations rather than correctly interpreting information that contradicts their expectations, may have played a role.[4] When the amount of selenium powder (in milligrams) required for a 40 mcg/mL solution was weighed and checked, the unit of measure displayed by the scale (grams) may have been incorrectly interpreted as milligrams, with the error in interpretation going unrecognized. Such errors can lead to 1000-fold overdoses.
- The abbreviation "µg" was used for "microgram" in the formula for the selenium solution. This abbreviation is considered dangerous because it is easily confused with "mg" (meaning "milligram"). There have been other medication incident reports where such confusion has led to 1000-fold overdoses.
- Reliance on a visual check of the weighed amount may have contributed to the error. Scales are available that print out the weight of each item to provide a permanent document that can be attached to the compounding record for checking in the final verification step.

***Recommendations***

- Before compounding a sterile product, refer to the Health Canada Drug Product Database to determine whether the product is commercially available.[5]
- Design formulas and worksheets to present information in a logical sequence, with consistent terminology.
- Ensure that the formula's units of measure align with the units of measure displayed by the equipment to be used during compounding; additional conversion calculations should not be required in the process. For example, if the scale displays weight in grams, the formula should express the amount to be weighed and verified in grams, without necessitating any additional conversion calculations.
- Avoid the use of dangerous abbreviations known to lead to medication errors (e.g., "µg" for "microgram").
- Incorporate technology to support patient safety, such as bar coding and scales that print the weight of each item automatically. Alternatively, have pharmacy staff take photographs of the containers used and the weight readings, and attach the photographs to the compounding record.
- Conduct a review of existing processes, including a cognitive walkthrough (a procedure that involves physically walking through the process or task of interest, examining the mental activities required at each step and the challenges experienced[6]), to ensure that compounding processes comply with professional standards (e.g., NAPRA Model Standards for Compounding of Non-Hazardous Sterile Preparations[7]) and medication safety principles.

### *Complementary Care Centre: Emergency Response*

For any patient receiving IV treatments in a naturopathic setting, vital signs should be monitored and recorded regularly. In this case, there did not seem to be a standardized approach to patient assessment and monitoring.

Naturopathic doctors are required to refer patients to receive conventional medical therapy if their condition requires diagnostic procedures, monitoring, or treatment that is beyond the scope of practice of the naturopathic doctor. In this case, the patient was treated with homeopathic remedies. These remedies did not produce any clinical improvement. Available documentation also indicated that there may have been a lack of appropriate supervision by, and timely help from, the naturopathic doctor on the day of the incident, which may have contributed to the delay in transferring the patient to a higher level of care (e.g., emergency room).

***Recommendations***

- Ensure the availability of detailed protocols to be followed in emergency situations, such as reaction to an IV infusion. These protocols should meet the standards of a conventional out-of-hospital facility

providing IV infusion therapy, including the following provisions:
  - designated staff trained in Advanced Cardiac Life Support (e.g., nurse, naturopathic doctor) to oversee the emergency care situation;
  - identification of available emergency/rescue medications and devices, their storage locations, and their indications for use; and
  - appropriate patient monitoring and documentation.
- Define the limitations of the CCC and its healthcare providers. Clearly describe the clinical circumstances in which patients must be transferred to a conventional, higher level of care.

### *Complementary Care Centre: Preparation, Storage, and Administration of Admixtures*

The prepared IV tissue- and wound-healing formulation was a complex admixture of 10 ingredients added to sterile water for injection. There is no uniform standard for the preparation of admixtures in a CCC. From the information available in this case, it appears that handwritten changes to the formula may have been made at each session, and that each solution was prepared individually from bulk ingredients. The sources of components of the final product were unknown, except for the selenium solution, which was obtained from a compounding pharmacy.

#### *Recommendations*

- Review and adhere to compounding guidelines developed by jurisdictional naturopathic regulatory authorities and NAPRA, to ensure compliance with expected standards of practice.
- Use "mcg" to represent "micrograms" in all written documentation. Avoid the use of the dangerous abbreviation "µg", which is known to have contributed to 1000-fold dosing errors.
- Develop preprinted order sets collaboratively with end-users and ensure that these order sets meet the following criteria:
  - present critical information in a logical sequence with consistent terminology;
  - avoid the use of dangerous abbreviations, symbols, and dose designations that may be misinterpreted (see ISMP Canada's Do Not Use list, available from: https://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf);
  - contain only essential information; and
  - undergo regular review.

### Additional Recommendations for Regulatory Agencies

- Consider specific accreditation for facilities that provide specialty compounding services, with criteria to be developed in collaboration with key stakeholders (e.g., NAPRA, Health Canada, and ISMP Canada). The accreditation process should include assessment of compliance with available standards and guidelines.
- Mandate that personnel working in compounding centres have credentials confirming that they have received appropriate training in applicable safe medication preparation and administration practices.

### Conclusion

Sterile compounding of pharmaceuticals is a complex process. Without testing, it is difficult to identify errors in the final prepared product. The incident described here involved a complementary health product; however, a similar error could have occurred with any compounded product. Decisions to compound must consider the potential risks associated with the compounding process. Pharmacies and other facilities preparing sterile pharmaceuticals should carefully consider multiple approaches to reduce risk, including use of commercially prepared products when available and implementation of available technologies.

In settings where IV infusions are to be administered, the importance of establishing emergency protocols, as well as ensuring availability of trained personnel, rescue equipment, medication, and supplies, cannot be overstated. Prompt recognition of symptoms necessitating a higher level of care and access to emergency treatment is critical to mitigate harm.

## Acknowledgements

*ISMP Canada extends appreciation to the 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):* Dana Lyons RPhT, Manager – Technical Practice, Pharmacy Services, Foothills Medical Centre, Calgary, AB; Eric Marsden BSc ND, Clinic Director/Naturopathic Oncology Residency Director, Marsden Centre for Excellence in Integrative Medicine, Concord, ON; Joyce Tsang RPh PharmD BScPhm HBSc, University Health Network – Toronto General Hospital, Toronto, ON.

**References**

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## Stakeholder Consultation on Naming of Biologic Drugs

### January 18 to February 9, 2018

On January 18, 2018, the Institute for Safe Medication Practices Canada (ISMP Canada) will post an online questionnaire to seek input from healthcare providers, consumers, and other interested and affected stakeholders on different approaches to the naming of biologic drugs, including biosimilars, in Canada. The questionnaire is being developed collaboratively with Health Canada. Administration of the questionnaire and analysis of responses will be performed by ISMP Canada.

The objective of the consultation is to gain insight into stakeholder views on the practical impacts of different approaches to the naming of biologic drugs and biosimilars throughout the medication-use process, including prescribing, dispensing, and adverse drug reaction reporting.

Results of the consultation will be used to:

- understand the impact of different approaches to biologic drug naming and the perspectives of healthcare providers, consumers, and other interested and affected stakeholders, and
- inform Health Canada's policy decision on a naming convention for biologic drugs.

For more details on this initiative, click here (https://www.ismp-canada.org/biosimilars/Naming-of-Biologic-Drugs-Consultation-NoticeEN.pdf). Additional details will also be available when the questionnaire is launched on January 18, 2018.

We would appreciate your help to distribute this message to your colleagues, members, or stakeholders to inform them of this initiative and the upcoming consultation. If you have any preliminary questions, please contact us via info@ismp-canada.org

Ontario College of Pharmacists

Putting patients first since 1871

# MEMBERSHIP RENEWAL REMINDER

DUE MARCH 10, 2018

**NOTE: No form will be mailed to you, however email reminders will be sent. If you fail to pay your fees by March 10, a penalty will apply.**

## *Before you begin your renewal you will need:*

- Credit Card
- User ID: This is your OCP number
- Password: If you have forgotten your password, click "**Forgot your Password of User ID?**" A new password will then be emailed to you.

## *Once you're ready:*

- Go to www.ocpinfo.com and click on "**Login to my Account**" and then click on "**My Account**"
- Enter your User ID (your OCP number) and your password
- Once you have successfully logged in, click on "**Annual Renewal**"

## *Health Professional Corporation Renewals*

A reminder that all Pharmacy Health Professional Corporation owners must complete this year's annual renewal on or before March 10, 2018. The renewal application can be found online under the Practice & Education section of the OCP website.

## *Pharmacy Accreditation Renewals*

Pharmacy Accreditation Renewals will be available online the last week of March and must be completed on or before May 10, 2018. Pharmacy owners should watch for future notifications alerting them to when the renewal application becomes available.

# *Safety and Security for Pharmacies:* PREVENTING ROBBERIES

*Reviewed by **Detective Constable Chris Auger** of the OPP Drug Enforcement Unit – Prescription Drug Diversion*

*The College recently published an article on Preventing Drug Diversion, focused on the responsibilities that pharmacies have to prevent opportunities for diversion of controlled substances (narcotics, controlled drugs and targeted substances).*

Pharmacies must also be aware of the potential for robberies, particularly by those in search of narcotics, which may then be trafficked. While there is nothing that can absolutely prevent a robbery, there are measures that pharmacists, pharmacy technicians and pharmacy managers can take to decrease the risk and protect staff and property. Pharmacies are also encouraged to work with their community partners, including police, to assist with deterring offences and contributing to a successful resolution of investigations.

*Please note that the College cannot offer specific recommendations or directions for pharmacy security. The following are considerations that can be taken into account when assessing security at the pharmacy.*

## PREVENTING ROBBERIES

Look for opportunities to make the pharmacy a less attractive target.

***Consider the overall design of the pharmacy and whether it achieves clear visibility of activities within the pharmacy, including by those outside of the pharmacy (for example, could a bystander see a robbery taking place inside your pharmacy).***

- Does the pharmacy have good visibility? Could someone outside see inside the pharmacy or are the windows covered with products or posters?
- From the dispensary counter, can a pharmacy professional see the rest of the pharmacy, including the doors and/or the windows? If there is another cash location, can the cashier see the dispensary?
- Does the lighting appropriately and evenly illuminate entrances and exits? Are "back of house" areas like the dumpster or delivery area outfitted with motion floodlighting?
- Are deadbolt locks used? Is shatterproof glass used? Are external bars or security gates necessary for pharmacy security?

***Use a quality security system that could alert the management to issues when no one is onsite, alert authorities if a robbery occurs while staff are onsite, and help in identifying a subject should there be a robbery or attempted robbery.***

- Is there high resolution close circuit television (CCTV) recording capabilities (both exterior and interior)? Are all major areas of the pharmacy covered by the CCTV? Are recordings kept for at least seven days? Is the location of the CCTV recordings offsite or hidden? Note that the Office of the Information and Privacy Commissioner of Ontario has published Guidelines for the Use of Video Surveillance.
- Is there an alarm system, motion detectors, door alarms and/or silent alarms? Is there a panic button or trigger code for the alarm? Generally, silent alarms are preferable when

the pharmacy is open and loud alarms are preferable when the pharmacy is closed.

- Is there clear and visible signage that indicates an alarm system is present?

***Ensure good inventory, storage and cash procedures.***

- Is there a safe or other secure storage area?
- Can the controlled substances inventory be kept to a minimum?
- How often are cash deposits made? Try to avoid keeping cash in the pharmacy overnight.

***Establish policies and procedures for staff training and behaviour.***

- Are background checks conducted on staff before hiring, especially those working in the dispensary and/or with cash?
- Are staff clear that they should not discuss pharmacy security procedures with anyone outside of the pharmacy?
- Are staff trained to be alert and aware of suspicious behaviour?
- Do staff know what to do if a robbery occurs?
- Are there adequate staff on hand for evening or late night shifts?

The Windsor-Essex police department has created a checklist of physical and behavioural factors specifically for pharmacies that could impact safety and security. Access the Pharmacy Self Audit Safety Survey Tool.

***If a Robbery Should Occur***

During a robbery, all staff should be trained to:

- Comply with the individual's instructions, stay calm and avoid any sudden movements. Movements that need to be made by staff should be explained.
- Avoid direct eye contact. However, try to gather a description for the police. Make a mental note of the perpetrator's height, weight, gender, clothing, physical features or tattoos. Also, try to take note of any weapon that is used.
- Activate the silent alarm only if it is safe to do so and can be done without the perpetrator noticing. Ensure there is a clear escape route.
- If it is safe to do so, try to get a description of their escape vehicle and direction of travel or get a photo or video.

Following a robbery or the discovery of a break and enter, staff should:

- Call police immediately. Ask for emergency medical services if anyone is injured.
- Secure the pharmacy, including asking customers to stay as they are potential witnesses. Stop all store operations.
- Try to write down any details about the robbery.
- Conduct a narcotic inventory (if narcotics were potentially stolen). Narcotic losses must be reported to Health Canada within 10 days. Review the College's Narcotic Reporting of Forgeries and Losses Fact Sheet.
- Reassess pharmacy security and determine whether any additional actions can be taken to prevent another robbery.

## ASK FOR HELP

Many police departments have programs or contacts that specifically support business owners in preventing robberies from occurring in their establishments. Pharmacy managers should establish a link with them and see if they have any resources to help in protecting the pharmacy and pharmacy staff. They may be willing to come to the pharmacy and provide recommendations on how to enhance the safety of staff and inventory.

Additionally, there are professional security firms and consultants that can be hired to provide specialized recommendations for the pharmacy.

## REFERENCES AND RESOURCES:

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Ontario Pharmacists' Association. Guidelines for Ensuring the Safety and Security of You and Your Staff in the Pharmacy. Copy available from the association (no membership required).

Windsor Police Service. Pharmacy Self Audit Safety Survey Tool. Retrieved December 14, 2017 from: https://www.police.windsor.on.ca/community/services/Crime-Prevention/Documents/CPTED%20checklist%20-%20PHARMACY%20Properties.pdf

# *Innovative Partnerships:* SUPPORTING POSITIVE HEALTH OUTCOMES FOR PATIENTS

The College recognizes the extraordinary opportunity to work with broader health system partners to shape and influence high quality and safe pharmacy care and promote good outcomes for patients throughout the province. Over the past several months, the College has established important collaborative relationships with health system organizations as it leverages its regulatory role and public-protection mandate to fulfill its strategic priorities.

## DEMONSTRATING VALUE AND OUTCOMES: CREATING A DATA FOUNDATION

To help meet its objective to develop, establish and maintain programs and standards of practice to assure the quality of the practice of the profession, the College is moving towards adopting a systems-based focus that is grounded in quality and measurable patient outcomes. The College is forming new partnerships with health system organizations such as Health Quality Ontario (HQO), the provincial advisor on the quality of healthcare, as it leads the development of a set of consistent quality indicators for pharmacy that can help guide improvements, shape quality pharmacy care and better demonstrate the impact and value of College programs. This work builds on progress already being made through initiatives such as the mandatory medication incident reporting which will roll out across the province later in 2018.

## FOCUS ON REGIONAL APPROACHES TO QUALITY

Recognizing that collaboration with the broader health system is required to help achieve the collective goals of quality and safe pharmacy care throughout Ontario, the College is developing valuable new linkages with the province's Local Health Integration Networks (LHINs). For example, this past November the College launched a partnership with the North East LHIN to develop a pharmacy strategy for rural hospitals. This strategy will, through a regional approach aimed at helping area hospitals meet sterile compounding standards, promote quality pharmacy care and support more collaborative approaches to advancing patient safety throughout the province.

## BUILDING BRIDGES BETWEEN PRIMARY CARE AND COMMUNITY PHARMACY

Pharmacy professionals play an important role in a patient's journey throughout the healthcare continuum. To promote better patient care experiences and outcomes, the College has begun to work with the Toronto Central LHIN to identify best practice models that link community pharmacy with primary care and address transitions of care. This is an opportunity to encourage interprofessional collaboration with primary care, create better links between hospital and community, and optimize the scope of pharmacy professionals. It is also expected that these models will identify any policy barriers to this type of collaboration between and across pharmacies in the sub-regions of the LHIN. The College and the Toronto Central LHIN are currently sharing data and identifying existing models and projects from which to build.

# *Compounding:* ARE YOU DOING IT?

College Council adopted NAPRA's *Model Standards for Pharmacy Compounding of Non-Sterile Preparations* at their meeting in December 2017. While an implementation date has yet to be determined, these new standards (once formally published by NAPRA) will require pharmacy professionals to place a renewed focus on the preparation of non-sterile products in pharmacies.

## IS YOUR PHARMACY ENGAGED IN COMPOUNDING?

Health Canada considers compounding to be the following:

> "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. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug's labelling material. [1]

Before compounding a non-sterile preparation, the need for the compounded product should be confirmed by checking for commercially available preparations in the Health Canada's Drug Product Database and contacting manufacturers. [2] To comply with the Health Canada policy on compounding, this confirmation is required in order to validate the lack of product availability and avoid duplicating an approved drug.

Non-sterile preparations can be categorized as simple, moderate or complex [3] (as outlined in *United States Pharmacopeia (USP) Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations*). A number of factors go into determining the type of preparation and level of risk when compounding preparations. Pharmacists and pharmacy technicians who compound non-sterile preparations should evaluate their practice, develop service-related procedures and implement appropriate quality controls for both patients and compounding personnel, with a view to guaranteeing the overall quality and safety of non-sterile preparations.

## HOW TO PREPARE FOR THE STANDARDS

As the College considers an appropriate implementation date, expect additional communication and education related to compliance with the standards.

The standards will be accompanied by a guidance document which will provide pharmacists and technicians who compound non-sterile preparations with the details necessary to evaluate their practice, develop service-related procedures, and implement appropriate quality controls for both the protection of patients and compounding personnel.

In advance of the publication of the standards by NAPRA, pharmacy professionals are encouraged to review current policies and procedures, master formulations and Safety Data Sheets.

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# CHOOSING WISELY:

## *Recommendations for Pharmacists to Help Patients Avoid Unnecessary Medications*

By: **Karen Born**, PhD
*Knowledge Translation Lead, Choosing Wisely Canada & Assistant Professor, Institute of Health Policy, Management & Evaluation*

**ABOUT CHOOSING WISELY**

*Choosing Wisely joined the lexicon of health care just five short years ago with the launch of the campaign in the United States in 2012. Since that time, over 20 countries have created their own national campaigns, including the launch of Choosing Wisely Canada in 2014.*

Choosing Wisely has become synonymous with thinking twice about whether that test, treatment and procedure is necessary. It has also encouraged having conversations with patients and colleagues about why more is not always better when it comes to health care. Unnecessary medical tests, treatments and procedures cause harm to patients, and waste precious resources.

**UNNECESSARY MEDICATIONS CAUSE HARM**

Pharmacists play a critical role in avoiding harms associated with medications. There are ever increasing and powerful medications that pharmacists dispense to patients, which can offer tremendous healing and benefits, but can also lead to significant harm if used inappropriately or unnecessarily. There are also social harms of unnecessary medications.

For example, the problem of antimicrobial resistance is directly tied to unnecessary use of antibiotics. Over 50% of antibiotic prescriptions in Canada are unnecessary, and overuse of these powerful medications makes them less effective when our patients really need them to treat bacterial infections.

Choosing Wisely campaigns offer health care professionals the evidence and information needed to think twice, and question whether that test or treatment is really necessary.

**CHOOSING WISELY CANADA PHARMACIST RECOMMENDATIONS**

In December 2017, the Canadian Pharmacists Association (CPhA) released their list of 'Six Things Pharmacists and Patients Should Question'. This list is the first pharmacy list in the Choosing Wisely Canada campaign, which launched in 2014 in partnership with the Canadian Medical Association. There are over 280 recommendations from medical specialty societies, and a growing number of other clinician societies (such as the Canadian Nurses Association). Recommendations are developed by societies and identify tests and treatments that are commonly used in each specialty, but are not supported by evidence and can expose patients to harm. In addition, Choosing Wisely Canada has materials for patients and the public which explain why more is not always better and offer plain language information about the harms of unnecessary care.

The CPhA list was developed with the input of members, including practicing pharmacists

and pharmacy researchers from coast to coast. This list of six recommendations addresses common problems in pharmacy around unnecessary care and offers an opportunity for pharmacists to question, and engage in conversation with patients and their colleagues.

## RECOMMENDATION 1.

*Don't use a medication to treat the side effects of another medication unless absolutely necessary.*

This recommendation addresses the problem of prescribing cascades, which lead to polypharmacy, which has several associated risks, such as drug interactions, increased frequency or severity of side effects and poor medication adherence. This recommendation reminds pharmacists to question whether a new symptom is an adverse drug reaction, and avoid prescribing additional drug treatment until this possibility has been thoroughly investigated.

## RECOMMENDATION 2.

*Don't recommend the use of over-the-counter medications containing codeine for the management of acute or chronic pain. Counsel patients against their use and recommend safe alternatives.*

There is no evidence to support the use of low-dose codeine pain medication over non-opioid pain relieving medications. In addition, codeine can cause harm as it is an addictive opioid with potential for abuse. Further, harms from high doses of OTC medications with codeine are significant and include liver toxicity, gastric perforation, haemorrhage and peptic ulcer, renal failure, chronic blood loss anaemia and low blood potassium (with potential fatal heart and neurological complications).

## RECOMMENDATION 3.

*Don't start or renew drug therapy unless there is an appropriate indication and reasonable expectation of benefit in the individual patient.*

Data from Canadian Institute of Health Information (CIHI) has found that two-thirds of Canadians over the age of 65 take five or more different medications and more than 40% of seniors 85 and older take 10 or more drugs. As the number of drugs patients take increases, so too do risks for drug reactions. This recommendation is a reminder to clinicians that before adding an additional medication to a patient's regimen, especially an elderly patient, it is wise to ask whether the benefit of this medication outweighs potential harms.

## RECOMMENDATION 4.

*Don't renew long-term proton pump inhibitor (PPI) therapy for gastrointestinal symptoms without an attempt to stop or reduce (taper) therapy at least once per year for most patients.*

This recommendation adds to the Choosing Wisely Canada lists for Gastroenterology which includes a recommendation questioning long-term use of Proton Pump Inhibitors (PPIs) and supporting patients to taper this medication. PPIs are among the most commonly prescribed drugs in Canada and many are becoming available as over-the-counter medications. While generally safe and well-tolerated for short-term use as needed in the treatment of gastro-esophageal reflux disease (GERD), PPIs can cause harm when used for long term, and in older patients.

## RECOMMENDATION 5.

*Question the use of antipsychotics as a first-line intervention to treat primary insomnia in any age group.*

There has been a sharp and alarming increase in the off-label prescribing of atypical antipsychotics for insomnia, especially in young people. This recommendation joins those from Psychiatry which questions this off-label use and suggests to use nonpharmacological measures before a prescription. These include behavioural modifications, and good sleep hygiene as well as short-term use of melatonin.

## RECOMMENDATION 6.

*Don't prescribe or dispense benzodiazepines without building a discontinuation strategy into the patient's treatment plan (except for patients who have a valid indication for long-term use).*

A recent CIHI report found that 1 in 10 Canadian seniors regularly takes a benzodiazepines for anxiety disorders and insomnia. Long-term use of benzodiazepines is harmful. Alternatives should be explored prior to prescribing benzodiazepines, and if determined that they are beneficial, it should be for short term use. It is important to discuss discontinuation or tapering strategies to avoid long-term use.

### CHOOSING WISELY CONVERSATIONS TO AVOID HARM

Pharmacists have joined the Choosing Wisely Canada campaign with the release of the above six recommendations. In addition to using these recommendations in practice, Choosing Wisely means having a conversation with patients and your colleagues about when more is not always better.

Check out all of the Choosing Wisely Canada Recommendations.

# Proper Disposal of **POST-CONSUMER MEDICATION RETURNS**

*By: The Health Products Stewardship Association*

## ONTARIO MEDICATIONS RETURN PROGRAM

The Health Products Stewardship Association (HPSA) would like to remind all pharmacies to follow these simple steps for proper disposal of unused and expired medications returned from the public through the Ontario Medications Return Program:

- All pills should be removed from their original packaging (original and prescription vials) and be loosely disposed of into a medications return collection container. Liquids, creams, inhalers, etc. are the only exceptions to the "no original packaging" rule.

- If a person returns medication in its original packaging, be sure to **remove all personal identification** as well as extra packaging.

- All pharmacies should have a "Take It Back" rack card, which outlines the proper steps of return and disposal. To ensure a member of the public is correctly preparing medications for return, please be sure to provide them with this easy to read information. If you wish to order rack cards, you can do so through HPSA's website: www.healthsteward.ca/collection/Ontario.

## SAFE DISPOSAL OF CONTROLLED SUBSTANCES RETURNED BY A MEMBER OF THE PUBLIC

Please review the College's Destruction of Narcotics, Controlled Drugs and Targeted Substances fact sheet for information on destroying controlled substances.

HPSA would like to remind all Ontario pharmacy staff of their obligations in regards to the responsible management of post-consumer controlled substances:

- Pharmacy staff across Ontario **should not** denature drugs prior to putting them in the collection container. HPSA's programs are not licensed or authorized to handle denatured or altered controlled substances (narcotics, controlled drugs or benzodiazepines).

- The member of the public can combine all unwanted medications, including controlled substances, together for return to a pharmacy registered in HPSA's Medication Returns Program (take-it back programs).

- Controlled substances returned to a pharmacy by the public should be placed into the collection container immediately by pharmacy staff.

- Collection containers must be kept in a secure space in the dispensary during use.

- Once full, the collected container should be sealed and removed from the pharmacy by the HPSA contracted waste management service provider.

- The pharmacist must confirm the pickup service by signing a receipt indicating the number of HPSA containers received, the number of HPSA containers picked-up and the date of service. This information must be kept on file at the pharmacy for two years.

*To learn more about the Ontario Medications Return Program, please visit* http://www.healthsteward.ca/collection/Ontario.

# What We Heard From You: TWO RECENT OPEN CONSULTATIONS

## EXEMPTIONS AND EXCLUSIONS UNDER THE EMPLOYMENT STANDARDS ACT

As previously announced in e-Connect, the Ontario government is seeking public input to help make workplaces fairer for workers in industries that currently have exemptions, special rules or exclusions.

The College, in its capacity as the regulator of pharmacy in the province, was asked to provide the Ministry of Labour with a formal written submission in response to the government's intent to collect input on whether the profession's exemptions from the *Employment Standards Act, 2000* (ESA) should be maintained as they relate to pharmacists. The College took an approach that aligns with our mandate to serve and protect the public interest and conducted an open consultation from November 17 to December 15, 2017.

In total, 382 responses were received via the consultation page.

In addition to feedback from pharmacy professionals, the College also sought feedback from the public and patients through multiple channels.

The College will submit its report to the Ministry of Labour in early 2018.

## AMENDMENTS TO THE PHARMACY ACT ON QUALITY ASSURANCE AND REGISTRATION REGULATIONS

From October 5 to November 20, 2017, the College conducted an open consultation on proposed amendments to the quality assurance and registration regulations that were aimed at implementing an Intern Pharmacy Technician class of registration, incorporating pharmacy technicians into the quality assurance program, eliminating unnecessary steps in registration, and shifting from an hourly reporting of practice to a self-declaration of competency in conjunction with practice assessments.

A total of 41 submissions were received from pharmacy professionals and the public, including a submission from the Ontario Pharmacists Association. The majority of the feedback indicated overall support for the regulation amendments and no further changes were recommended to Council. At its December 2017 meeting, Council received the final report from staff and approved the proposed regulations for submission to the Ministry of Health and Long- Term Care for consideration.

Once received from the College, the Ministry will consider the regulatory changes. Should they be accepted, a date of proclamation will be announced. The College will provide pharmacy professionals with more information on specific timelines and requirements as it becomes available.

# FREQUENTLY ASKED QUESTIONS

*from Pharmacy Practice*

*Note that these answers were current at date of publication and are meant as guidance for pharmacy professionals. The College cannot tell a member what course of action to take, provide legal advice or opinions, or make any decisions for a member.*

## PHARMACY TECHNICIANS

**Q To what degree are pharmacy technicians allowed to work independently in the dispensary? For example, can they check and sign for blister packs independently, or does that still require a pharmacist to cosign the hard copies? Also, are they able to process, fill and sign for a repeat prescription independently or does it have to be cosigned by a pharmacist as well?**

**My assumption is that they would be able to do these things since the original therapeutic check was already done by a pharmacist who checked and signed the original prescription and they would be just refilling it?**

A The legislation (O. Reg 202/94) states "Every certificate of registration as a pharmacy technician is subject to the following terms, conditions and limitations: 1. The member shall only engage in the practice of pharmacy (...) when practising in a pharmacy to which the *Drug and Pharmacies Regulation Act* applies, other than a remote dispensing location, while under the direct supervision of a member holding a certificate of registration as a pharmacist..."

A technician can check any/all prescriptions for **technical** accuracy and completeness. Every prescription – *new and refill, regardless of how they are packaged* – must have both the technical and therapeutic check completed prior to release to the patient. Please refer to the page "Understanding What a Technician Can Do" for more details; note that the term "co-signing" is not used, as each member is performing an independent "check" for different purposes.

A suitable method for documenting both "checks" for a given prescription may be signatures (or some other identifying mechanism) from both members on every hardcopy. However, other methods may be suitable to document the respective actions and associated responsibilities in the dispensing process. As software, workflow, personnel, etc. can vary from pharmacy to pharmacy, the information presented on our website is not meant to be entirely prescriptive for how a pharmacy achieves the desired end result, which is to ensure the patient receives a prescription that is both technically accurate and therapeutically appropriate.

Ultimately, members remain accountable for their respective roles in dispensing a prescription, and documentation on the patient record should reliably demonstrate that every prescription has been reviewed for both technical and therapeutic aspects before it is dispensed. It should be readily retrievable, auditable, and be unambiguous. When and how these functions occur, and what form they take (i.e. operational procedures) are at the discretion of the pharmacist and technician in consultation with the Designated Manager.

**Q Can pharmacy technicians witness MMT doses?**

**A** As outlined in our MMT and Dispensing Policy under the section Administration of Methadone Dose and in the CAMH course, the pharmacist is responsible for patient assessment, witnessing doses as well as the therapeutic check of the prescription. These functions cannot be delegated to a technician. More information can also be found in the CAMH guide Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use.

Registered pharmacy technicians have the independent authority to check the accuracy of the technical components of methadone prescriptions. Pharmacy technicians may also be responsible for other tasks in the workflow that fall under their job descriptions and competencies, such as dose preparation, assisting with documentation and inventory management.

**Q Can pharmacy technicians destroy narcotics?**

**A** As explained in our Fact Sheet on Destruction of Narcotics, Controlled Drugs, and Targeted Substances, registered pharmacy technicians can witness the destruction of narcotics.

## CHANGING THE DOSE OF A CONTROLLED SUBSTANCE

**Q Sometimes I get a prescription for a controlled substance that is not available in the Canadian market (e.g. a prescription for hydromorphone 0.5 mg, 60 tablets, where only hydromorphone 1mg is available). Considering this scenario, am I able to dispense half of the prescriber quantity (e.g. 30 tablets) while breaking the 1mg tablet in half?**

**A** There may be more than one way to dispense a prescription to ensure the patient receives the correct drug, dose and total quantity, such as in the situation you describe. The College cannot provide a specific answer on the action the pharmacist should take; it is the member's responsibility to assess the prescription and decide the best course of action based on all the information at their disposal.

In situations where a specific dose or strength indicated on a prescription does not exist, is unavailable, or is not the most appropriate option for the patient, the pharmacist, in exercising their professional judgment, may choose to use available dosage forms to make up the prescribed strength/dose. Alternatively, the pharmacist may choose to contact the prescriber for clarification — either in writing or verbally — when presented with a prescription that is ambiguous or the intent of the prescriber is not clear.

Depending on the specific scenario, it may be important to ascertain if there was a clinical reason for prescribing a particular strength or dosage form. If there are different options, what does the patient prefer? Or, if the drug does not exist in a given strength, is it possible an error was made in the name of the drug or the dose?

When deciding whether or not it is appropriate to split the tablets prior to dispensing, pharmacy professionals should apply their knowledge to determine whether or not the medication is amenable to splitting (e.g. scored or not, accuracy of resulting dose, stability, tablet integrity) and keep the patient's health outcomes, best interest and safety in mind.

Documentation of one's rationale is important, in addition to documentation of dialogue with the patient, their understanding of the changes, and their informed consent. Pharmacy professionals are encouraged to reach out to their peers for timely guidance with practice-related questions as well, to leverage their practical experience and get advice on how they approach situations like this, assess the prescription, and exercise professional judgement.


"Close-Up on Complaints" explores incidents reported to the College that have occurred in the provision of patient care and which present 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.

# PROTECTING PATIENT PRIVACY

## SUMMARY OF THE INCIDENT

This incident occurred when a patient at a pharmacy noticed that there were documents and medication vials around the pharmacy's dumpster and parking lot. The patient informed the Designated Manager (DM) of the fact that patient information was visible.

The DM accompanied the patient outside to examine the dumpster. He indicated to the patient that he did not own the dumpster and therefore could not do anything about the contents on the ground and stated that the documents were records from the surrounding medical clinics and not his pharmacy.

The patient reported that, other than picking up a few of the documents, the DM did not take any other action that the patient was witness to.

When the patient drove by the pharmacy a few days later, the documents and other items were still there.

## WHY DID THIS HAPPEN?

This incident illustrates a lack of appropriate care with private patient information.

In his interactions with the patient and during the course of the investigation, the DM took little responsibility for a potential patient information privacy breach. He denied that the documents were from the pharmacy, placing blame on the building management for not managing the dumpster and not taking care of picking up documents or other items that were on the ground.

## COMPLAINT OUTCOME

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

In this case, the panel emphasized that photos provided by the patient definitively show that pharmacy documents with identifiable patient information were in the dumpster area. They noted that the DM did not take immediate action when notified of the issue. He continually placed the blame on others for the situation and did not acknowledge that the documents there were related in any way to the pharmacy.

The panel noted that healthcare professionals must take certain actions with respect to privacy breaches. The DM provided no indication that he addressed the privacy breach, particularly notifying any affected patients.

Due to the seriousness of this issue, and the panel's impression that the DM may not understand the importance of protecting patient information and his related obligations as a regulated healthcare professional, the committee issued an oral caution and directed him to engage in additional learning on his obligations under the *Personal Health Information Protection Act* (PHIPA).

**ORAL CAUTIONS**

An oral caution is issued as a remedial measure for serious matters where a referral to the Discipline Committee would not be appropriate. Oral cautions require the pharmacy professional to meet with the ICRC in person for a face-to-face discussion about their practice and the changes they will make that will help avoid a similar incident from occurring in the future.

**REMEDIAL TRAINING (SCERPS)**

A SCERP is ordered when a serious care or conduct concern requiring a pharmacist or pharmacy technician to upgrade his or her skills has been identified. The ICRC orders SCERPs when they believe that remediation is necessary.

## APPROPRIATE CARE WITH PATIENT INFORMATION: LEARNINGS FOR PHARMACY PROFESSIONALS

Pharmacies are considered health information custodians under PHIPA. As custodians, pharmacies must collect, use and disclose personal health information in accordance with the rules established under PHIPA and implement appropriate physical, administrative and technical safeguards to protect personal health information.

In the event of a privacy breach, the responsible health information custodian must notify the individual(s) affected at the first reasonable opportunity. When the custodian notifies a patient of a privacy breach, they must also inform the patient that they can make a complaint about the breach to the Information and Privacy Commissioner of Ontario.

The Standards of Practice require that pharmacists protect patients' privacy when collecting and using relevant information. Pharmacists must also ensure that the confidentiality of patient information is maintained at all times. This means that from collection of the information to its storage, its use, and its destruction, the information must not be disclosed without an authorized purpose.

Under the *Drugs and Pharmacies Regulation Act* (DPRA), every pharmacy must have procedures in place to protect the confidentiality of all personal information maintained by the pharmacy and to protect the privacy of persons who receive pharmacy services there.

The pharmacy is responsible for the safety and security of patient records even if the storage or disposal of those records is contracted out to a service provider. It does not matter whether the dumpster in this case really belonged to the pharmacy or not – what was important is that the patient information was in the care and control of the pharmacy. If the established system for disposing of records is not adequate, then that is the pharmacy's responsibility to manage.

**VIEW THE COLLEGE'S**

Guideline on Record Retention, Disclosure and Disposal

Designated Managers should provide the appropriate supports to ensure that policies and procedures are followed, including confidentiality agreements for staff, agents and any external contractors hired to dispose of patient records. Staff should be appropriately trained on how to prevent unauthorized or accidental disclosures of patient information and how to respond to any incidents that may occur.

The Code of Ethics requires pharmacy professionals to assume responsibility for all decisions and actions they undertake in their practice, including a failure to make a decision. In this case, the DM did not take action when presented with a clear issue in his pharmacy's practice and processes. When presented with issues in practice by a patient, pharmacy professionals should listen to their concerns, evaluate them and respond to them appropriately, with the goal of maintaining patient trust and upholding their obligations as healthcare professionals.

## CONCLUSION

When patients provide confidential personal health information to their pharmacy they are doing so with the understanding that their information will be protected and used appropriately. A careless disregard for patient privacy through the improper disposal of records is not acceptable practice. Pharmacy professionals and Designated Managers should regularly review their processes for complying with legislation related to patient health information. Patient concerns raised in this regard should be dealt with appropriately and quickly, keeping in mind their rights under PHIPA.

# Did you know?

The College provides a listing of ***continuing education resources*** for pharmacists and pharmacy technicians?


**Check it out at:**
http://www.ocpinfo.com/practice-education/continuing-education/

# GROWING THE PACE PROGRAM

After the successful launch of PACE for international pharmacy graduates on January 18, 2017, the College launched PACE for interns on January 18, 2018. This encompasses those who graduated from a Canadian-accredited pharmacy degree program (CCAPP) in a province other than Ontario and graduates from American-accredited pharmacy degree programs (ACPE). Graduates from the University of Toronto and University of Waterloo entry-level PharmD programs will continue to complete their practice based assessment within their individual programs, using the universal rating tool, the Ontario Pharmacy Patient Care Assessment Tool (OPPCAT).

The College continues to recruit pharmacists as PACE assessors, particularly in the Greater Toronto Area and Windsor. Assessors are supported by ongoing education and training. If you are interested in learning more about PACE or becoming an assessor, please contact regprograms@ocpinfo.com or visit Information for Assessors.

## Thank you to our 2017 PACE Assessors!

Their commitment was integral to the program's success and continued growth.

### BARRIE
D'Souza, Stanley ..... Drugstore Pharmacy

### BRAMPTON
Bansal, Viney..... Shoppers Drug Mart
Hanna, Rania..... Shoppers Drug Mart
Khan, Carolyn..... Queen-Lynch Pharmacy
Singh, Parvinder.....Bramcentre Pharmacy

### BRANTFORD
Mimar, Rana..... Remedy's Rx

### BURLINGTON
Salama, Heba ..... Shoppers Drug Mart
Serafine, Nesrine.. Brant Lakeshore Pharmacy
Youssef, Peter..... The Medicine Shoppe

### CAMBRIDGE
Butt, Shahzad ..... Shoppers Drug Mart
Roodbaraki, Poorang .... Shoppers Drug Mart

### DOWNSVIEW
Ismail, Fatima..... Nor-Arm Pharmacy
Kherani, Alym ..... Shoppers Drug Mart

### DUNDAS
Tashfin, Asif .....Rexall

### ETOBICOKE
Salamath,
Mohammud Shakeel..... Loblaw Pharmacy
Sundaramoorthy,
Ragavan ..... Shoppers Drug Mart

### EXETER
Jose, Tijo ..... Loblaw Pharmacy

### GUELPH
Daniels, Gary..... Shoppers Drug Mart

### HAMILTON
Alam, Intekhab .....HD Pharmacy
Rana, Ayesha..... Shoppers Drug Mart

### KINGSTON
Akinwumi, Olumide.....Rexall
Doyle, Adam ..... Shoppers Drug Mart
McReelis, Brenden .....Rexall Pharma Plus
Vaghela, Krina..... Shoppers Drug Mart

### KITCHENER
Naidoo,
Abilashen ..... Health Care Centre Pharmacy

### LONDON
Bhalodia, Mitul ..... MedicalRx Pharmacy
Neilson, Andrea ..... Shoppers Drug Mart
Rankin, John..... Shoppers Drug Mart
Saleemi, Zan .....London Care Pharmacy
Suleiman, Munir..... Shoppers Drug Mart
Tan, Ludmila..... Shoppers Drug Mart

### MISSISSAUGA
Benegal, Suraj..... City Centre Remedy's Rx
Esguerra, Monaliza ..... Shoppers Drug Mart
Rajput, Jasbir ..... City Centre Remedy's Rx

### NORTH YORK
Cheng, Albert..... Pharma Plus

### OAKVILLE
Nazmy, Gehan .....St. Mark's Pharmacy

### ORLEANS
Thabet, Essame ..... Shoppers Drug Mart

### OTTAWA
Abdalla, Amira..... Shoppers Drug Mart
Badawy, Tamer .....First Care Pharmacy
Hanna, Nabil ..... Shoppers Drug Mart
Ibrahim, Najlaa ..... Shoppers Drug Mart
Walsh, Cibele .....Carlingwood Pharmacy

### REXDALE
Ratti, Gaurav ..... Shoppers Drug Mart

### RICHMOND HIL
Li, Kwan Ting..... Shoppers Drug Mart
Lo, Fai ..... Shoppers Drug Mart
Morgan, Faddy ..... PharmAssist

### RIDGEWAY
Edwards, Donald
... Boggio & Edwards Ridgeway IDA Pharmacy

### SCARBOROUGH
Kabigting, Ana Marie .....Rexall
Mok, Timothy .....Guildview Pharmacy
Patel, Rajvi .....Rexall Pharma Plus

### TORONTO
Anand, Shalini..... Shoppers Drug Mart
Chan, Anita ..... Shoppers Drug Mart
Fanous, Kirillos ..... Cloud Pharmacy
Francis, Baher..... Allcures Pharmacy
Maseh, Kyrollos .....Pharmasave
Pardal, Sapna..... Shoppers Drug Mart
Remtulla, Nadeem..... Shoppers Drug Mart
Wang, Wei..... Shoppers Drug Mart
Wong, Serina ..... Shoppers Drug Mart

### UXBRIDGE
Singh, Uday Pratap ..... Shoppers Drug Mart

### WALLACEBURG
Ali, Shadi..... Pharma Plus

### WINDSOR
Francis, Nathalee..... Shoppers Drug Mart
Hijazi, Amal ..... Windsor Clinical Pharmacy

### WOODBRIDGE
Pandit Pautra, Akhil..... Costco Pharmacy
Valela, Anna.....Rexall Pharma Plus

# *Medication Incidents Associated with Patient Harm in Community Pharmacy:* A Multi-Incident Analysis

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**Jim H. Kong,**
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[3] School of Pharmacy, University of Waterloo

## BACKGROUND

Although pharmacy professionals and pharmacy organizations aim to provide error-free patient care, medication incidents are inevitable. Medication incidents are defined as any preventable events that may cause inappropriate medication use or patient harm while the medication is in the control of the healthcare professional or patient; these events occur when vulnerable medication-use systems and/or human factors affect prescribing, transcribing, dispensing, administration, and monitoring practices. [1,2]

Community pharmacies in Canada dispense over 600 million prescriptions annually, [3] but only a fraction of medication incidents will reach the patient and an even smaller proportion will result in harm. However, these incidents are associated with significant costs to patients and the healthcare system. In particular, they may lead to negative business implications for community pharmacies as a result of direct legal and financial costs, tarnished reputations, and decreased customer loyalty. On the other hand, these incidents often reveal broader system flaws, and thus, represent excellent opportunities for incident analysis and shared learning.

In an effort to identify and address factors that lead to harmful medication incidents, pharmacy organizations have developed and implemented incident reporting systems. At the local level, reporting systems are frequently an integral part of continuous quality improvement (CQI) programs, and as such,

are associated with long-term improvements in organizational learning and patient safety culture. [4] At the national level, reporting systems provide representative data for large-scale aggregate analysis, enabling healthcare stakeholders to better understand contributing factors that may have led to medication incidents, and aiding practitioners, pharmacies, and regulatory authorities in developing and sharing strategies to prevent recurrence. A multi-incident analysis is one form of aggregate analysis that is used to qualitatively analyze reported incident data to extract contributing factors and develop safety measures to prevent the incidents from re-occurring. By organizing and reviewing narrative incident data with common themes based on composition or origin, a multi-incident analysis can offer system-based learning that cannot be obtained through other analysis methodology.

The Institute for Safe Medication Practices Canada (ISMP Canada) established a national incident data repository for community pharmacies through its community pharmacy incident reporting (CPhIR) program. This article explores a multi-incident analysis conducted on harm-related medication incidents reported to CPhIR. The following sections contain an overview of the reported medication incidents and results from the analysis. Specific examples of reported incidents are also provided for reflection and to aid in developing strategies that can be customized to any practice setting. By systematically examining such incidents, root causes can be identified and process changes can be made to reduce the likelihood of similar errors from occurring again.

## METHODS

A total of 971 medication incidents associated with patient harm were extracted from the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program (http://www.cphir.ca) from 2009 to 2017. Sixty-two incidents were excluded due to insufficient narrative incident description for analysis. A total of 909 incidents were included for the multi-incident analysis, which was conducted by two independent ISMP Canada analysts. Themes, sub-themes, contributing factors, and recommendations to address patient safety gaps corresponding to harm-related incidents were then derived from this analysis.

## RESULTS

Three main themes were identified: (1) High Risk Processes in the Pharmacy; (2) Communication Gaps; and (3) Preventable Adverse Drug Reactions (Table 1). Subsequent sub-themes were then derived from these three main themes accordingly (Table 1). Incident examples, contributing factors and recommendations based on the hierarchy of effectiveness for CQI solution development (Figure 1) are also provided below (Tables 2, 3, and 4).

**Table 1: Main Themes and Subthemes Derived from the Multi-Incident Analysis of Medication Incidents Associated with Patient Harm**

| Main Themes | Subthemes |
|---|---|
| High Risk Processes in the Pharmacy | Methadone Maintenance Therapy (MMT)<br>Compliance Packs<br>Compounding |
| Communication Gaps | Patient-Provider Engagement<br>Interprofessional Collaboration |
| Preventable Adverse Drug Reactions | Drug-Drug Interaction<br>Documented Drug Allergy |

**Figure 1: Designing Effective Recommendations Using the Hierarchy of Effectiveness**

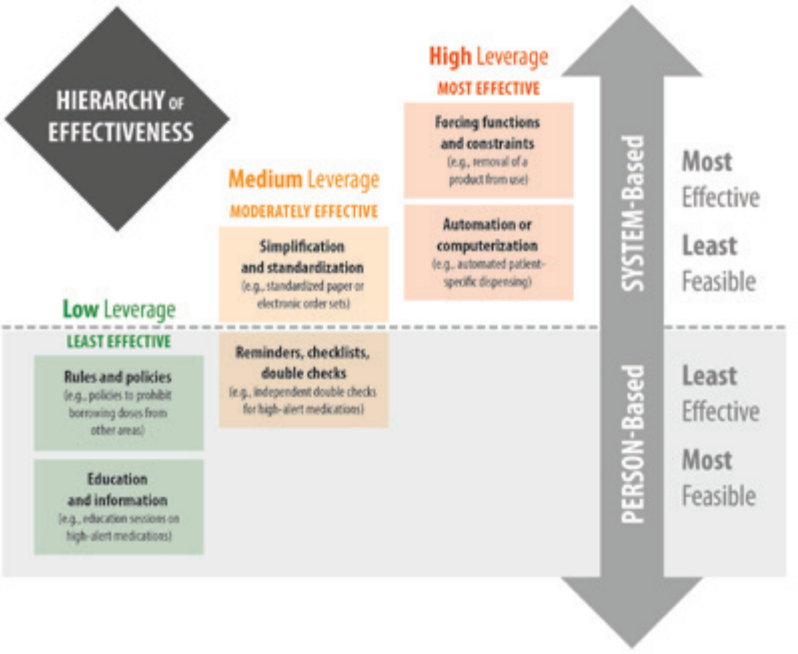


**Table 2: Theme 1 – High Risk Processes in the Pharmacy**

| Methadone Maintenance Therapy | | Recommendations | More Effective / Less Feasible |
|---|---|---|---|
| **Incident Example** | **Contributing Factors** | 1. Implement barcode scanning to ensure correct selection of medication [5] [Automation and Computerization]. | |
| *A patient was mistakenly given another patient's dose of methadone. The dose given was significantly higher than the patient's normal dose. Both patients had similar names and the incident was discovered when the second patient arrived for his dose, but it could not be found.* | • Pre-pouring of daily methadone doses.<br>• Lack of a standardized process to verify patient identification. | 2. Develop standardized procedures and documentation for high-risk processes [Simplification and Standardization]. | |
| **Compliance Packs** | | 3. Perform independent double checks throughout all steps of a high-risk process [5,6,7] [Reminders, Checklists, Double Checks]. | |
| **Incident Example** | **Contributing Factors** | 4. Only designated staff members are allowed to perform high-risk processes [Rules and Policies]. | |
| *A patient was prescribed hydrochlorothiazide and her blister packs were repackaged to include the medication. When the following month's blister packs were made, hydrochlorothiazide was omitted. The patient experienced higher than normal blood pressure as a result.* | • Change of drug regimens in the middle of a pack.<br>• Lack of a standardized process for documentation of medication regimen changes.<br>• Preparing of blister packs weeks in advance of pick-up. | 5. Ensure designated staff members are adequately trained and equipped [7] [Education and Information]. | |
| **Compounding** | | | |
| **Incident Example** | **Contributing Factors** | | |
| *A patient reported that the menthol and hydrocortisone cream compound she had received caused burning, which did not happen previously. The technician who prepared it did not get another staff member to double check the amount measured and initial for it. The compound was re-made and the patient reported no burning.* | • Lack of standardized compounding process.<br>• Inadequate training of personnel. | | Less Effective / More Feasible |

**Table 3: Theme 2 – Communication Gaps**

| Patient-Provider Engagement | | Recommendations | More Effective / Less Feasible |
|---|---|---|---|
| **Incident Example** | **Contributing Factors** | 1. Implement Electronic Health Records and E-prescribing in pharmacy practice [Automation and Computerization]. | |
| *A patient experiencing cough was given a new prescription for valsartan to replace ramipril. The patient discontinued metoprolol instead of ramipril and brought the metoprolol back for destruction. The incident was discovered when the patient called for a refill of his ramipril.* | • Complicated medication directions.<br>• Inadequate verification of patient understanding. | 2. Have standardized documentation for follow-up of problematic orders and hand off between health care professionals [8] [Simplification and Standardization]. | |
| **Interprofessional Collaboration** | | 3. Use "show and tell" and "teach back" technique to ensure understanding during counselling [Reminders, Checklists, Double Checks]. | |
| **Incident Example** | **Contributing Factors** | 4. Require staff to offer medication reviews to eligible patients annually to identify drug therapy problems [9,10] [Rules and Policies]. | |
| *The nursing home contacted the pharmacy for a refill of a patient's prescription for Arthrotec® (diclofenac/ misoprostol). There was no record of Arthrotec® on the patient file, but there was a prescription for diclofenac. It was discovered that, in addition to receiving diclofenac, the patient was taking a sample of Arthrotec® that he received from the doctor.* | • Limited sharing of medical information between providers.<br>• Lack of an up-to-date medication list. | 5. Encourage patients to carry an updated medication list when interacting with health care professionals [Education and information]. | Less Effective / More Feasible |

**Table 4: Theme 3 – Preventable Adverse Drug Reactions**

| Drug-Drug Interaction | | Recommendations | More Effective / Less Feasible |
|---|---|---|---|
| **Incident Example** | **Contributing Factors** | 1. Clinical decision support systems (CDSS) for prescribers and pharmacists should have the functionality to detect drug-drug interactions/drug allergies and be updated regularly to prevent "alert fatigue". [11] [Automation and Computerization]. | |
| *A patient was started on lithium carbonate and was prescribed metronidazole 7 days later without cautioning about the interaction. The patient called the pharmacy reporting side effects consistent with lithium overdose.* | • Knowledge deficit of the practitioner.<br>• Too many insignificant alerts resulting in "alert fatigue". | 2. Develop standardized procedures and documentation when a drug interaction or drug allergy is identified [Simplification and Standardization]. | |
| **Documented Drug Allergy** | | 3. Double check allergy status at order entry and pick-up [Reminders, Checklists, and Double Checks]. | |
| **Incident Example** | **Contributing Factors** | 4. Require documentation when a drug interaction or allergy override occurs, and audit regularly (i.e. monthly) [11] [Rules and Policies]. | |
| *A patient complained of tight throat over several days. He/she went to emergency and was diagnosed with an allergic reaction to moxifloxacin. The pharmacist had missed the allergy caution when dispensing.* | • Inadequate alert to indicate drug allergy.<br>• Bypassing entry of allergy information.<br>• Free-form entry of allergies. | 5. Subscribe to a drug information service and post information on known dangerous drug interactions [Education and Information]. | Less Effective / More Feasible |

## CONCLUSION

Medication incidents associated with patient harm present an opportunity for learning and improvement of the medication-use system in community pharmacy. This multi-incident analysis revealed that high risk processes, communication gaps, and preventable adverse drug reactions were the most common themes for reported medication incidents associated with patient harm.

When designing safety solutions using the hierarchy of effectiveness (Figure 1), we have provided different recommendations that can be implemented in your practice based on feasibility and effectiveness. In particular, implementing independent double checks is a feasible strategy for preventing incidents associated with high-risk processes. Furthermore, developing standardized communication and documentation is necessary to ensure safe and effective medication use within the circle of care. Finally, improving the effectiveness of clinical decision support systems utilized by health care practitioners will help mitigate the potential for preventable adverse drug reactions. We hope our findings from this multi-incident analysis help improve medication safety by providing a platform for reflection and shared learning.

## ACKNOWLEDGEMENT

ISMP Canada would like to acknowledge support from the Ontario Ministry of Health and Long-Term Care for the development of the Community Pharmacy Incident Reporting (CPhIR) Program (http://www.cphir.ca). The CPhIR Program contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (https://www.ismp-canada.org/cmirps/index.htm). A goal of CMIRPS is to analyze medication incident reports and develop recommendations for enhancing medication safety in all healthcare settings. The incidents anonymously reported by community pharmacy practitioners to CPhIR were extremely helpful in the preparation of this article.

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# DISCIPLINE DECISIONS

**Abdul Baqi, R.Ph.** (OCP #214965)

At a hearing on October 12, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Baqi 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 certain identified drugs and/or products, from on or about November 1, 2013 to on or about June 30, 2014.

- That he falsified pharmacy records relating to his practice in relation to the dispensing of and/or claims made to the Ontario Drug Benefit program for one or more certain identified drugs and/or products, from on or about November 1, 2013 to on or about June 30, 2014.

- That he failed to ensure that the Pharmacy complied with all legal requirements, including but not limited to, requirements regarding record keeping, documentation, and billing the Ontario Drug Benefit Plan; and/or

- 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, professional supervision of pharmacy personnel and billing

In particular, the Panel found that he

- Failed to maintain a standard of practice of the profession

- 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, 6 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

- Permitted, consented to or approved, either expressly or by implication, the contravention of 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, 6 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

- 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

2. a 12 month suspension of the Member's certificate of registration, with 1 month of the suspension to be remitted on condition that the Member

complete the remedial training specified below. The suspension shall commence on October 12, 2017, and shall run without interruption until September 11, 2018, inclusive. If the Member is required to serve the balance of the suspension, then the remitted portion shall commence on September 12, 2018, and shall run without interruption until October 13, 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. the Member must successfully complete, with an unconditional pass, at his own expense and within 11 months of the date the Order is imposed, the ProBE Program on professional / problem-based ethics for health care professionals offered by the Centre for Personalized Education for Physicians.

   The Registrar is empowered, in her discretion, to grant a request for an extension of time to complete the remedial training set out in paragraph 3(a) and/ or to make any related necessary adjustments to the dates upon which the Member is to serve the remitted portion of his suspension set out in paragraph 2, if the Registrar is of the view that it is in the interests of fairness to do so and that it is not contrary to the College's mandate to serve and protect the public interest;

   ii. The Member shall be prohibited from having any proprietary interest in a pharmacy of any kind and/or receiving remuneration for his work as a pharmacist other than remuneration based on hourly, or weekly rates only, provided that this term, condition and limitation may be removed by an Order of a panel of the Discipline Committee, upon application by the Member, such application not to be made sooner than four (4) years from the date the Order is imposed;

   iii. For a period of four (4) years from the date the Order is imposed, the Member shall be prohibited from acting as a Designated Manager in any pharmacy;

   iv. For a period of four (4) years from the date the Order is imposed , the Member shall be required to notify the College in writing of the names(s), address(s) and telephone numbers(s) of all employer(s) within fourteen (14) days of commencing employment in a pharmacy;

   v. For a period of four (4) years from the date the Order is imposed, the Member shall provide his pharmacy employer with a copy of the Discipline Committee Panel's decision in this matter and its Order; and

   vi. For a period of four (4) years from the date the Order is imposed, the Member shall only engage in the practice of pharmacy for an employer who agrees to write to the College within fourteen (14) days of the Member's commencing employment, confirming that it has received a copy of the required documents identified above, and confirming the nature of the Member's remuneration.

   vii. For a period of four (4) years from the date the Order is imposed, the Member shall not work at nor be employed by any pharmacy in which a family member has a proprietary interest.

4. Costs to the College in the amount of $12,500.

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

The Panel expressed its disappointment with the Member's actions. The Panel pointed out that the Ontario Drug Benefit Program is publically funded and operates on an honour system, and that submitting claims that were false or misleading shows a lack of integrity.

The Panel suggested that the Member's acts were unbecoming of a pharmacist. The Panel expressed its expectation that the Member has learned from this process, that he will improve his practice of pharmacy, and that he will work hard to regain the trust he has lost through his actions.

The Panel indicated its expectation that the Member will never again appear before a panel of the Discipline Committee.

### Allen Kula, R.Ph. (OCP #28479) and W.J. Gagne Drugs Limited, c.o.b. as Romana Pharmacy (#303221)

At a hearing on October 26, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Kula with respect to the following incidents, in that he:

- Charged excessive dispensing fees and/or co-payments for dispensing less than the full quantity of the drugs

prescribed for the patient, [Patient], without agreement of the patient or other valid authorization, in or about August–November 2013

In particular, the Panel found that he

- Failed to maintain the standards of practice of the profession
- Dispensed or sold drugs for an improper purpose
- Charged a fee that is excessive in relation to the service provided
- 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, including sections 4, 5, 6 and/or 15 of the Ontario Drug Benefits Act, R.S.O. 1990, Ch. O.10, as amended; sections 18 and/or 20.2 of O.Reg. 201/96, as amended; and/or section 9 of Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c.P.23, 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

At the same hearing on October 26, 2017, the Panel made findings of professional misconduct against Mr. Kula with respect to the following incidents, in that he:

- Dispensed and/or billed prescription and non-prescription medications, without authorization, for certain identified patients, in or about February-August 2014
- Failed to keep records of prescriptions dispensed for certain identified patients, in or about April-September 2014
- Failed to document renewals of prescriptions by a pharmacist for certain identified patients, in or about May-September 2014;
- Dispensed and/or billed prescription and non-prescription medications, without authorization, by relying on "blanket authorizations" from Dr. [Name] to renew prescriptions for certain identified patients, on or about May 27-28, 2014;
- Failed to keep records as required regarding current prescriptions but instead "piggybacking" on old prescriptions for certain identified patients, in or about June-November 2014;
- Falsified claims for medications dispensed to patients at less frequent intervals than claimed for billing purposes for certain identified patients, in or about January-November 2014;
- Dispensed lesser quantities of medications than prescribed without the written agreement of the patients, or failed to keep records of any such agreements, for certain identified patients, in or about January-November 2014;
- Billed and/or dispensed quantities of medications in excess of the quantities required for certain identified patients, in or about April-July 2014;
- Billed and/or dispensed medications for certain identified patients, after the Pharmacy had been advised that the patients were deceased, in or about June-August 2014;
- Failed to provide prescription receipts for medications dispensed for certain identified patients, on or about August 7, 2014;
- Billed for MedsCheck Reviews without justification, or without documenting any such justification, for certain identified patients, on or about January 22, 2014;
- Dispensed medications to patients other than the specific medications identified in the prescription records, including ferrous gluconate and/or risperidone, in or about January-August 2014;
- Failed to sign prescription hardcopies by a pharmacist for as many as 1,115 dispensing or billing transactions for up to 116 patients, in or about April-November 2014;
- Failed to maintain prescription records in a readily-retrievable manner, including the records for certain identified prescriptions;
- Failed to maintain records regarding authorizations for medications dispensed to patients in retirement homes, and/or prescription hardcopies signed by a pharmacist for such transactions, in or about July-August 2014;
- Permitted non-pharmacist staff, [Staff Person 1] and/or [Staff Person 2], to process claims outside the Pharmacy for medications for certain identified patients, in or about April-July 2014

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 a record 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
- Charged a fee that was excessive in relation to the service provided
- 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 4 of the Pharmacy Act, 1991 S.O. 1991, c. 36, as amended; sections 36, 37 and/or 38 of O.Reg. 202/94, as amended; sections 150, 155 and/or 156 of the Drug and Pharmacies Regulation Act , R.S.O. 1990, c. H-4 as amended; and/or sections 54, 55, 56 and/or 57 of O.Reg.58/11, as amended
- Contravened, while in 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 9 of the Food and Drugs Act, R.S.C. 1985, c.F-27, as amended; section C.01.041 of the Food and Drug Regulations, C.R.C., c. 870, as amended; sections 9 and/or 10 of the Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c.P.23, as amended; section 4 of Ontario Regulation 936, as amended; and/or sections 5, 6 and/or 15 of the Ontario Drug Benefit Act, R.S.O. 1990, c.O.10, as amended; and/or sections 27 and/or 29 of O.Reg. 201/96, as amended
- 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 he was a director
- 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

At the same hearing on October 26, 2017, the Panel made findings of proprietary misconduct against Allen Kula, as director of W.J. Gagne Drugs Limited, c.o.b. as Romana Pharmacy, and/or Designated Manager of Romana Pharmacy in Keswick, Ontario with respect to the following incidents, in that he:

- Failed to keep records of prescriptions dispensed for certain identified patients, in or about April-September 2014
- Failed to keep records as required regarding current prescriptions but instead "piggybacking" on old prescriptions for certain identified patients, in or about June-November 2014
- Dispensed medications to patients other than the specific medications identified in the prescription records, including ferrous gluconate and/or risperidone, in or about January-August 2014
- Failed to sign prescription hardcopies by a pharmacist for as many as 1,115 dispensing or billing transactions for up to 116 patients, in or about April-November 2014
- Failed to maintain certain identified prescription records in a readily-retrievable manner
- Failed to maintain records regarding authorizations for medications dispensed to patients in retirement homes, and/or prescription hardcopies signed by a pharmacist for such transactions, in or about July-August 2014.
- Dispensed and/or billed prescription and non-prescription medications, without authorization, for certain identified patients, in or about February-August 2014
- Falsified claims for medications dispensed to patients at less frequent intervals than claimed for billing purposes for certain identified patients, in or about January-November 2014
- Dispensed lesser quantities of medications than prescribed without the written agreement of the patients, or failed to keep records of any such agreements, for certain identified patients, in or about January-November 2014;
- Dispensed and/or billed prescription and non-prescription medications, without authorization, by relying on "blanket authorizations" from Dr. [Name] to renew prescriptions for certain identified patients, on or about May 27-28, 2014

In particular, the Panel found that Mr. Kula and W.J. Gagne Drugs Limited, as holder of Certificate of Accreditation #303221 for Romana Pharmacy in Keswick, Ontario,

- Failed to keep records required to be kept by the pharmacy respecting the patients and the practice of the pharmacy

- Falsified a record of the pharmacy

- Signed or issued a document that contained a false or misleading statement

- Submitted an account or charge which was false or misleading

- Charged a fee or an amount that was excessive in relation to the service or product provided

- Contravened the Act or the regulations made under the Act, and in particular, sections 150, 155 and/or 156 of the Act, and/or sections 54, 55, 56 and/or 57 of O.Reg. 58/11

- 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, section 9 of the Food and Drugs Act, R.S.C. 1985, c.F-27, as amended; section C.01.041 of the Food and Drug Regulations, C.R.C., c. 870, as amended; sections 9 and/or 10 of the Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c.P.23, as amended; sections 5, 6 and/or 15 of the Ontario Drug Benefit Act, R.S.O. 1990, C.O.10, as amended, and/or sections 27 and/or 29 of O.Reg.201/96, as amended

- Engaged in conduct or performed an act relevant to the business of a pharmacy that would reasonably be regarded by members as disgraceful

The Panel imposed an Order which included as follows:

1. A reprimand, to be scheduled within six months of the date of the Order.

2. Directing the Registrar to impose specified terms, conditions or limitations on the Member's Certificate of Registration requiring:

   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 Registrar is empowered, in her discretion, to grant a request for an extension of time to complete the remedial steps set out in subparagraph 2(a), if the Registrar is of the view that it would be in the interests of fairness to do so and that it would not be contrary to the College's mandate to serve and protect the public interest; and

   c. that the Member shall be prohibited from acting as the Designated Manager at any pharmacy for a period of two (2) years from the date of this Order.

3. Directing the Registrar to impose specified terms, conditions or limitations on the Certificate of Accreditation for Romana Pharmacy requiring that the practice of pharmacy and related business activities at Romana Pharmacy be monitored by the College for a period of two (2) years from the date of this Order by means of inspections of a representative of the College at such times as the College may determine. The monitoring inspections 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. Pharmacy staff shall cooperate fully with the College during the inspections. The Pharmacy shall pay to the College in respect of such monitoring the amount of $1,000.00 per inspection, such amount to be paid immediately after each inspection, with the total number of inspections for which the Pharmacy is required to pay, not to exceed four (4) regardless of the number of inspections.

4. 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 condition the Member complete the remedial training program as specified in subparagraph 2(a) above. The suspension shall commence on November 2, 2017 and continue without interruption until January 1, 2018, inclusive. If the remitted portion of the suspension has to be served, the further suspension shall commence on October 27, 2018 and continue without interruption until November 26, 2018, inclusive, unless the time for completing the remedial steps in subparagraph 2(a) above is extended by the Registrar, in which case, the date on which the remitted portion of the suspension shall commence, if required, shall be adjusted accordingly.

5. Costs to the College in the amount of $20,000.00.

At the time of publication, the reprimand in this matter remains outstanding.

## George Politis, R.Ph. (OCP #68632)

At a hearing on November 6, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Politis with respect to the following incidents:

- On November 17, 2015, he attended a shiatsu massage spa with [Name], an employee of the Pharmacy, during work hours, in circumstances where he ought to have known that doing so would make [Name] uncomfortable.

In particular, the Panel found that he:

- Failed to maintain the standards of the profession
- 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 impose the following conditions on the Member's certificate of registration:

   a. that the Member successfully complete, within twelve (12) months of the date of this Order, 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; 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, and maximum of 3;

      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. Successful completion of the course will include completion of an essay, acceptable to the Registrar, addressing the objectives of professional regulation and the importance to the public interest of maintaining professional conduct towards colleagues;

      iv. The essay shall be at least 1000 words in length. The Member shall be responsible for the cost of review by the consultant to assist the Registrar to determine whether the essay is acceptable, up to a maximum of $500;

      v. the Member shall be responsible for the cost of the course;

      vi. the Member will request a report from the consultant confirming that the Member has completed the course to the satisfaction of the consultant, and the Member will provide a copy of the report to the College within twelve (12) months of the date of this Order;

   b. the Registrar is empowered, in her discretion, to grant a request for an extension of time to complete the remedial steps set out in subparagraph 2(a) if the Registrar is of the view that it would be in the interests of fairness to do so and that it would not be contrary to the College's mandate to serve and protect the public interest;

   c. that the Member be prohibited from acting as a Designated Manager for any pharmacy, from December 1, 2017 until he has completed the remedial training specified in subparagraph 2(a), as confirmed by the consultant;

3. Directing the Registrar to suspend the Member's Certificate of Registration for a period of 2 months, 1 month of which shall be remitted upon the Member successfully completing the remedial training as specified in subparagraph 2(a) above. The suspension shall commence on December 1, 2017, and run until December 31, 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 specified in subparagraph 2(a) above within the time specified, the remainder of the suspension shall commence on November 6, 2018, and continue until December 5, 2018, inclusive unless the time for completing the remedial steps in subparagraph 2(a), above, is extended by the Registrar, in which case, the date the remitted portion of the suspension shall commence, if required, shall be adjusted accordingly;

4. Costs to the College in the amount of $10,000.00.

In its reprimand, the Panel noted that, as a member of this profession, the Member is held in high regard by the public, and that he has a moral obligation to conduct himself in a manner that is professional, ethical, and serves the public interest.

The Panel indicated that pharmacists are expected to demonstrate personal and professional integrity and to maintain professional boundaries at all times. These boundaries are based on trust, respect, and the appropriate use of power.

The Panel expressed its hope that the Member has had a chance to reflect on his conduct and that he understands its impact on his colleagues, the profession, and the public. The Panel indicated its expectation that the ethics course ordered will serve as an opportunity for remediation and that it will provide the Member with insight into personal and professional boundaries.

### **Mamdouh Soliman** (OCP #114278)

At a hearing on November 17, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Soliman with respect to the following incidents:

- He made making unwelcome comments of a sexual nature towards his co-worker and patient, [Name]; and/or
- He verbally abused, swore at and/or yelled at his co-worker and patient, [Name]; and/or
- On one or more occasions, he touched inappropriately or attempted to touch inappropriately his co-worker and patient, [Name]; and/or
- In or about December 2014, he wrote his co-worker and patient, [Name], a note in which he said "fuck you" or words to that effect.

In particular, the Panel found that he

- Sexually abused a patient
- 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 and unprofessional

The Panel imposed an Order which included as follows:

- A reprimand

In its reprimand, the Panel observed that members of the public hold pharmacists in high regard. Pharmacists have a moral obligation to conduct themselves in a manner that is professional and maintains public confidence.

The Panel indicated that pharmacists are expected to demonstrate personal and professional integrity and to maintain professional boundaries at all times. These boundaries are based on trust, respect, and the appropriate use of power. These standards are high.

The Panel explained that, had Mr. Soliman not resigned from practice for the other matters that were drawn to their attention, the Panel would likely have accepted other elements of an order, such as a term of suspension, remediation coursework, costs, and perhaps other components.

The Panel related that, given Mr. Soliman's signed acknowledgement and undertaking, which irrevocably surrendered his certificate of registration, it accepted the Agreed Statement of Facts, his admission of misconduct, and the Joint Submission on Order.

### **Niloofar Saiy** (OCP #608704)

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

- She inappropriately provided pharmaceutical treatment to herself and certain identified family members, contrary to the College's Policy on Treating Self and Family Members
- She dispensed prescription medications without valid authorization in respect of certain identified patients and transactions
- She falsified pharmacy records in respect certain identified prescription transactions
- She failed to keep records as required in respect of certain identified patients

In particular, the Panel found that she

- Failed to maintain the standards of practice of the profession
- Failed to keep records as required
- Falsified a record relating to her practice
- Signed or issued, in her professional capacity, a document that she knew contained a false or misleading statement

- 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

- 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 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, and within 12 months of the date the Order is imposed, the ProBE Program on Professional / Problem-based Ethics for Health Care Professionals offered by the Center for Personalized Education for Physicians; and,

   b. that the Member complete successfully, at her own expense and within 12 months of the date of this Order, the Ontario College of Pharmacists' Jurisprudence Exam;

   c. that the Registrar is empowered, in her discretion, to grant a request for an extension of time to complete the remedial steps set out in subparagraphs 2(a) and/or 2(b), if the Registrar is of the view that it would be in the interests of fairness to do so and that it would not be contrary to the College's mandate to serve and protect the public interest;

3. That the Registrar suspend the Member's Certificate of Registration for a period of three months, with one month of the suspension to be remitted on condition that the Member complete the remedial training as specified in paragraph 2. The suspension shall commence on November 26, 2017, and shall continue until January 25, 2018, inclusive. If the remitted portion of the suspension is required to be served by the Member because she fails to complete the remedial training as specified in paragraph 2, that portion of the suspension shall commence on November 21, 2018, and shall continue until December 20, 2018, inclusive, unless the time for completing the remedial steps in subparagraphs 2(a) and/or 2(b), above is extended by the Registrar, in which case, the date on which the remitted portion of the suspension shall commence, if required, shall be adjusted accordingly.

4. Costs to the College in the amount of $6,000.

In its reprimand, the Panel noted that through this professional misconduct, the Member failed in her obligations to adhere to the standards of practice. The Panel pointed out that the Member knowingly breached the public's trust and, in doing so, let down the profession of pharmacy.

The Panel related that the standards of practice demand that pharmacists practice to a very high standard, and that this type of conduct can cause the public to mistrust and lose confidence in the profession, and is a risk to the privilege of being a self-regulated profession.

The Panel expressed its trust that the Member has learned from this experience, that she will appropriately change her practice standards, and that she will never again appear before a panel of the Discipline Committee.

## **Safaa Eskander** (OCP #116661)

At a hearing on November 27, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Ms. Eskander with respect to the following incidents:

- That she submitted accounts or charges for services that she knew were false or misleading to the Ontario Drug Benefit program for:

  o one or more of certain identified drugs and/or products, from on or about July 1, 2010 to on or about June 30, 2012,

  o Ventolin HFA, from on or about July 1, 2010 to on or about June 30, 2012, in circumstances where interchangeable products were dispensed; and/or

  o one or more of the drugs and/or products transferred from Wilson Medical Pharmacy between on or about February 22, 2012 and on or about August 1, 2014;

- That she falsified pharmacy records relating to her practice in relation to the dispensing of and/or claims made to the Ontario Drug Benefit program for:

  o one or more of certain identified drugs and/or products, from on or about July 1, 2010 to on or about June 30, 2012,

- Ventolin HFA, from on or about July 1, 2010 to on or about June 30, 2012, in circumstances where interchangeable products were dispensed; and/or

- drugs and/or products transferred from Wilson Medical Pharmacy between on or about February 22, 2012 and on or about August 1, 2014;

- That she failed to ensure that the Pharmacy complied with all legal requirements, including but not limited to, requirements regarding record keeping, documentation, and billing the Ontario Drug Benefit Plan; and/or

- That she 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, professional supervision of pharmacy personnel and billing.

In particular, the Panel found that the Member

- Failed to maintain a standard of practice of the profession;

- Falsified records relating to her practice;

- Signed or issued, in her professional capacity, a document that she knew contained a false or misleading statement;

- Failed to keep records as required respecting her patients;

- Submitted accounts or charges for services that she knew to be false or misleading;

- Contravened the Pharmacy Act,1991 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, in connection with prescription information and container identification markings;

- 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, 6 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 with respect to submitting claims for payment to the Ontario Drug Benefit program where no payment was required, and/or that she knew or reasonably ought to have known were false, inaccurate or misleading claims;

  - Sections 155 and 156 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H-4, as amended, in connection with prescription information and container identification markings;

  - Sections 8, 10 and 11 of the Narcotics Safety and Awareness Act, 2010 SO 2010, c 22, with respect to making disclosures to the Narcotic Monitoring System between on or about May 14, 2012 to on or about July 23, 2013 which did not contain the required information regarding the prescriber of the drug dispensed;

- Permitted, consented to or approved, either expressly or by implication, the contravention of 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, 6 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 with respect to submitting claims for payment to the Ontario Drug Benefit program where no payment was required, and/or that she knew or reasonably ought to have known were false, inaccurate or misleading claims;

  - Sections 155 and 156 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H-4, as amended, in connection with prescription information and container identification markings;

  - Sections 8, 10 and 11 of the Narcotics Safety and Awareness Act, 2010 SO 2010, c 22, with respect to making disclosures to the Narcotic Monitoring System between on or about May 14, 2012 to on or about July 23, 2013 which did not contain the required information regarding the prescriber of the drug dispensed;

- 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:

(i) A reprimand;

(ii) A 14 month suspension of the Member's certificate of registration, with 2 months of the suspension to be remitted on condition that the Member complete the remedial training specified below ;

(iii) An Order directing the Registrar to impose specified terms, conditions or limitations on the Member's certificate of registration as follows:

i. the Member must successfully complete with an unconditional pass, at her own expense and within 12 months of the date the Order is imposed, the ProBE Program on professional / problem-based ethics for health care professionals offered by the Centre for Personalized Education for Physicians;

ii. for a period of three (3) years the Member shall be prohibited from having a proprietary interest of any kind in a pharmacy, and the Member shall have 60 days from the date of this Order to divest herself of any such proprietary interests, at which time the three year period shall commence;

iii. following the expiry of the three-year period referred to in subparagraph (b) above, the Member's practice and all activities at any pharmacies in which the Member has a proprietary interest of any kind shall be monitored for a period of two (2) years by the College, by means of practice assessments by a representative or representatives of the College in such number and at such time or times as the College may determine. 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 $1000.00 per assessment, such amount to be paid immediately after completion of each of the assessments, with the total amount paid by the member not to exceed $10,000.00, regardless of the number of assessments;

iv. for a period of five years from the date the Order is imposed, the Member shall be prohibited from:

1. acting as a Designated Manager in any pharmacy; and,

2. receiving any remuneration for her work as a pharmacist other than remuneration based on hourly or weekly rates only or (subject to paragraph (b) above) by reason of having a proprietary interest in a pharmacy;

v. for a period of five 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) within fourteen days of commencing employment in a pharmacy;

vi. for a period of five years from the date the Order is imposed, the Member shall provide her pharmacy employer with a copy of the Discipline Committee Panel's decision in this matter and its Order; and

vii. for a period of five years from the date the Order is imposed, the Member shall only engage in the practice of pharmacy for an employer who agrees to write to the College within fourteen days of the Member's commencing employment, confirming that it has received a copy of the required documents identified above, and confirming the nature of the Member's remuneration;

(iv) Costs to the College in the amount of $15,000.

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. The Panel indicated that the volume of unsubstantiated claims over a two-year period of time, which amounted to $162,000, is an example of her disregard for the trust that has been placed in her by the public and the profession.

The Panel pointed out that the Member billed claims on behalf of another pharmacy, falsified pharmacy records, and failed as designated manager to participate in the day to day management of the pharmacy, and related that these actions are not acceptable for a member of this profession.

The Panel explained that pharmacy is a self-regulated profession and that pharmacists bear the responsibility to ensure that they maintain the trust of the public and of members. The Panel noted that the practice of pharmacy is a privilege and comes with significant obligations to the public, the profession, and oneself.

The Panel expressed its expectation that, in the future, 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 further expectation that, in doing so, she will change the way she practices and will not appear again before a panel of the Discipline Committee.

## **John Shenouda** (OCP #218737)

At a hearing on December 5, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Shenouda with respect to the following incidents:

- He disclosed personal health information of the Pharmacy's patients by posting prescriptions on Facebook, without consent or other authorization, in respect of:

  i. [Patient 1], in or about February, 2016;

  ii. [Patient 2], on or about February 20, 2015; and/or

  iii. [Patient 3], on or about March 31, 2016;

- He inappropriately consulted on Facebook about prescriptions for the Pharmacy's patients, instead of with the physicians and other appropriate resources, in respect of:

  i. [Patient 1], in or about February, 2016;

  ii. [Patient 2], on or about February 20, 2015; and/or

  iii. [Patient 3], on or about March 31, 2016; and/or

- On or before May 11, 2016, the Pharmacy's website made the following offers:

  i. "Transfer your prescription today and get your gift"; and/or

  ii. "Thursday Special – Hollandview Pharmacy waives the dispensing fee for all patients who do not have drug plans."

In particular, the Panel found that he

- Failed to maintain a standard of practice of the profession

- Offered or distributed, directly or indirectly, a gift, rebate, bonus or other inducement with respect to a prescription or prescription services

- 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 dishonourable and 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 confidentiality of personal health information; 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 at least 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, if and when available; and

   (v) the Member will request a report from the consultant confirming that the Member has completed the course to the satisfaction of the consultant, and the Member will provide a copy of the report to the College within six (6) months of the date of this Order;

   (b) that the Member:

(i) retain, at the Member's expense, a practice mentor acceptable to the College, within three (3) months of the date of this Order;

(ii) meet at least three (3) times with the practice mentor, at the Member's place of practice, for the purpose of observing him interacting with patients during the dispensing process and to assess his clinical knowledge and judgment, and to identify areas in the Member's practice with respect to these issues that require remediation;

(iii) the Member shall provide the practice mentor the following documents in advance of the meetings, to facilitate the design of a learning plan:

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, if and when available;

(iv) develop a learning plan, together with the mentor, to address the areas requiring remediation;

(v) demonstrate to the practice mentor that the Member has achieved success in meeting the goals established in the learning plan; and

(vi) request a report from the practice mentor to report the results of the mentorship meetings to the Manager, Investigations and Resolutions at the College, after their completion, which shall be no later than twelve (12) months from the date of this Order;

(c) that the Registrar is empowered, in her discretion, to grant a request for an extension of time to complete the remedial steps set out in subparagraphs 2(a) and 2(b) if the Registrar is of the view that it would be in the interests of fairness to do so and that it would not be contrary to the College's mandate to serve and protect the public interest.

3. Directing the Registrar to suspend the Member's Certificate of Registration for a period of three (3) months, with two (2) months of the suspension to be remitted on condition the Member complete the ethics course and mentorship program as specified in subparagraphs 2(a) and 2(b) above. The suspension shall commence on January 4, 2018 and continue without interruption until February 3, 2018. If the remitted portion of the suspension has to be served because the Member fails to complete the course specified in paragraph 2(a) as required, then the further suspension shall commence on June 5, 2018 and shall continue to run without interruption until August 4, 2018, inclusive. If the remitted portion of the suspension has to be served because the Member fails to complete the mentorship specified in paragraph 2(b) as required, then the further suspension shall commence on December 5, 2018 and shall continue to run without interruption until February 4, 2019, inclusive. In either case, if the time for completing the remedial steps in subparagraphs 2(a) and 2(b) above is extended by the Registrar, the date on which the remitted portion of the suspension shall commence, if required, shall be adjusted accordingly.

4. Costs to the College in the amount of $5,000.

In its reprimand, the Panel noted that pharmacy is a self regulated profession, which bears the responsibility to ensure that the trust of members is maintained and the public served. The practice of pharmacy is a privilege, which carries with it significant obligations to the public, the profession, and to oneself.

The Panel expressed its view that the misconduct to which the Member admitted is unacceptable to the public and to his fellow pharmacy professionals. Of particular concern to the Panel was the fact that the Member's misconduct involved patient privacy breaches and the offering of inducements for the purpose of soliciting patients. The Panel indicated that Facebook is not a private forum. Facebook, and other online forums, should never take the place of proper consultation with other healthcare professionals within the circle of care.

The Panel expressed its trust that the Member now realizes the importance of this responsibility as a member of this College and that he will benefit from the remediation in which he has agreed to participate. The Panel voiced its confidence that the Member will return to the profession with more honour and integrity, and that he will not appear before of a panel of the Discipline Committee again.

### **Jayant Patel** (OCP #96288)

At a hearing on November 1, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Patel with respect to the following incidents, in that he:

- Failed to comply with the decision of the Inquiries, Complaints and Reports Committee dated September 16, 2015 ("ICRC decision") requiring him to complete a specified continuing education or remediation program ("SCERP") by September 16, 2016;

- Failed to access and read encrypted email communications sent to him by the College regarding the ICRC decision and SCERP on September 16, 2015; October 20, 2015; March 15, 2016; and/or October 7, 2016;

- Failed to respond to the College's inquiries to him regarding the ICRC decision and SCERP by telephone messages left for him on May 4, May 10, October 4, October 5 and/or October 6, 2016; and/or

- Failed to comply with the commitment he communicated to the College by email on September 29, 2016 that he would ensure he completed the SCERP as soon as possible and provide confirmation to the College that he had.

In particular, the Panel found that he

- 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 as disgraceful, dishonourable and unprofessional

After further arguments with respect to the Order to be made which were heard on December 14, 2017, the Panel imposed an Order which included as follows:

1. A reprimand

2. Directing the Registrar to suspend the Member's Certificate of Registration for a period of twelve (12) months or until such time as the Member successfully completes the remedial components set out in paragraphs 3(a), 3(b), and 3(c), below, whichever is later. The suspension shall commence on the date this Order becomes final.

3. Directing the Registrar to impose the following specified terms, conditions or limitations on the Member's Certificate of Registration:

   a. the Member shall complete successfully, within twelve (12) months from the date this Order becomes final, a remedial program with Gail E. Siskind Consulting Services or another professional ethics consultant to be chosen by the College ("the Consultant"), to be designed by the consultant, regarding the issues raised by the facts and findings of professional misconduct in this case; 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 three (3) meetings.

      ii. the manner of attendance at the sessions shall be in person.

      iii. the Member shall be responsible for the cost of the program.

      iv. the Member shall provide to the Consultant the following documents, in advance of the program, to facilitate the design of the program:

         1. the Notice of Hearing;

         2. the Agreed Statement of Facts; and

         3. the Panel's Decision and Reasons, if and when available; and

      v. the Member will request a report from the Consultant confirming that the Member has completed the course to the satisfaction of the Consultant, and the Member will provide a copy of the report to the College within twelve (12) months of the date this Order becomes final;

   b. the Member shall complete successfully, at his own expense, within twelve (12) months of the date this Order becomes final, the ProBE Program on Professional/Problem Based Ethics for Healthcare Professionals by the Center for Personalized Education for Physicians, with an unconditional pass, and the Member shall provide the College with confirmation of such within twelve (12) months of the date this Order becomes final.

   c. the Member shall complete successfully, at his own expense, the Jurisprudence exam offered by the College within twelve (12) months of the date this Order becomes final.

   d. the Member shall complete successfully the Medication System Safety Review for a Community Pharmacist On-Site Assessment program offered by the Institute for Safe Medication Practices Canada, at his own expense, within twelve (12) months

following the end of the suspension referred to in paragraph two (2), above.

e. the Member shall be prohibited, for a period of twenty-four (24) months following the end of the suspension referred to in paragraph two (2), above, from acting as a Designated Manager in any pharmacy.

f. the Member's practice shall be monitored by the College by means of practice reviews for a period of twenty-four (24) months following the end of the suspension referred to in paragraph two (2), above. The practice reviews shall be conducted by a representative(s) of the College at such time(s) as the College may determine, to a maximum of four (4) reviews. The Member shall cooperate with the College and its representative(s) during the practice reviews, which shall be at the Member's expense, up to a maximum of one thousand dollars ($1,000.00), per review to be paid immediately after the completion of each practice review. The Member shall complete any reassessments, learning plans or other follow-up steps arising from the practice review, as required, and within the timelines required by the practice review.

g. the Registrar is empowered, in her discretion, to grant a request for an extension of time, of up to twelve (12) months, to complete the remedial steps set out in paragraphs 3(a), 3(b) and 3(c), if the Registrar is of the view that it would be in the interest of fairness to do so and that it would not be contrary to the College's mandate to serve and protect the public interest. If the Registrar grants such an extension, the Member's certificate of registration will remain suspended in the manner described in paragraph two (2), above.

4. Costs to the College in the amount of twenty thousand dollars ($20,000.00).

In its reprimand, the Panel noted that integrity, trust, and professional conduct are the core of the practice of pharmacy and the delivery of care to the public, and that, in return, the profession is held in high regard by the people of Ontario. The Panel indicated that pharmacy is a self-regulated profession and, as such, it bears the responsibility to ensure that it maintains the trust of its members and the public it serves.

The Panel expressed its view that the Member's conduct showed persistent disregard to the College, which may put the public at risk. It is a fundamental expectation that all members respond to enquiries of the College in a timely manner.

The Panel voiced its expectation that when a member of the profession indicates to their regulator that they will comply with an order made by their regulator, that they will do so. The Panel pointed out that the Member has clearly failed to do so, and has let the profession down.

The Panel expressed its hope that the Member has learned from these experiences, and that he will take this opportunity to reflect on his actions and complete the required remediation. In doing so, the Panel expects that the Member will change the way he relates and responds to his regulator.

The Panel noted its expectation that the Member will not appear again before a panel of the discipline committee.

### **Zoltan Wighardt** (OCP #101036)

At a hearing on January 5, 2018, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Wighardt with respect to the following incidents:

- In or about the summer of 2008, after having sexual intercourse with an employee of the Pharmacy, he provided her with Plan B (levonorgestrel), an emergency contraceptive, and directed her to take it;
- He contributed to an uncomfortable work environment for employees of the Pharmacy, including, from time to time, intimidating and harassing them, and engaging in a violent outburst on or about December 2, 2015;
- From time to time he brought weapons into the Pharmacy, including a rifle, handguns and machetes; and
- On more than one occasion he removed a handgun from its case while on the premises of the Pharmacy, in the presence of staff of the Pharmacy.

In particular, the Panel found that he

- Failed to maintain the standards of practice of the profession; 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 disgraceful, dishonourable and unprofessional.

The Panel imposed an Order which included as follows:

1. A reprimand

2. That the Registrar be directed to impose the following conditions on the Member's certificate of registration:

   a. that the Member shall successfully complete, with an unconditional pass, 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 and any related evaluations offered by the Centre for Personalized Education for Physicians;

   b. that the Member shall successfully complete, within twenty-four 24 months of the date of this Order, a course with Gail E. Siskind Consulting Services, or another professional ethics consultant chosen by the College, to be designed by the consultant, but with the general aim of addressing the professional conduct issues raised by the facts of this case. The following terms shall apply to the 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 provide to the consultant his evaluation from the ProBE course, and any essay he completed as part of that course, and discuss with the consultant the issues arising from that course.

      iv. The Member shall be responsible for the cost of the course.

      v. the Member will request a report from the consultant confirming that the Member has completed the course to the satisfaction of the consultant, and the Member will provide a copy of the report to the College within twenty-four (24) months of the date of this Order.

   c. that the Member shall successfully complete, at his own expense, and within twenty-six (26) months of the date of this Order, the ProBE Plus Program on Ethics for Healthcare Professionals;

   d. that the Member shall be prohibited, for a period of three (3) years from the date the Order is imposed, from acting as a Designated Manager in any pharmacy, and from acting as sole proprietor of a pharmacy, a partner in a partnership that owns a pharmacy, or a director of a corporation that owns a pharmacy.

   e. for a period of two (2) years commencing on June 6, 2018:

      i. the Member shall notify the College in writing of any employment in a pharmacy, which notification shall include the name and address of the employer and the date on which he began or is to begin employment, within seven (7) days of commencing such employment;

      ii. he shall only work for an employer in a pharmacy who provides confirmation in writing from the Designated Manager of the pharmacy to the College, within seven (7) days of him commencing employment at the pharmacy, that the Designated Manager received and reviewed a copy of the panel's decision and reasons in this matter before he commenced employment;

      iii. the terms in clauses 2(f)(i) and (ii) shall apply even if the Member's employment in the pharmacy is as a relief pharmacist;

3. Directing the Registrar to suspend the Member's Certificate of Registration for a period of six (6) months of which one (1) month shall be remitted upon the Member successfully completing the remedial training as specified in subparagraphs 2(a), (b) and (c) above. The suspension shall commence on January 6, 2018, and run until June 5, 2018, inclusive. If the remitted portion of the suspension is required to be served by the Member because he fails to complete the remedial training specified in subparagraph 2(a), the remainder of the suspension shall commence on January 6, 2019, and continue until February 5, 2019, inclusive. If the remitted portion of the suspension is required to be served by the Member because he fails to complete the remedial training specified in subparagraph 2(b), the remainder of the suspension shall commence on January 6, 2020, and continue until February 5, 2020, inclusive. If the remitted portion of the suspension is required to be served by the Member because he fails to complete the remedial training specified in subparagraph 2(c), the remainder of the suspension shall commence on March 6, 2020, and continue until April 5, 2020, inclusive.

In its reprimand, the Panel noted that the Member is part of the honourable profession of Pharmacy. Integrity,

trust, and professional conduct are at the core of the practice of pharmacy and the delivery of care to the public. Pharmacists bear the responsibility to ensure that they maintain the trust of the members and the public they serve.

The Panel expressed the expectation that all pharmacists treat colleagues with respect and act as a positive role model. The Panel related that the Member's conduct with his colleague, who was in a vulnerable position, was reprehensible and breached professional boundaries, both as a manager and as a pharmacy professional.

The Panel found it highly disturbing that the Member would bring weapons to the pharmacy, where the provision of healthcare to the public takes place, with total disregard for the effects this may have on his staff. This also created an unsafe work environment for his pharmacy staff and for the patients he serves.

The Panel pointed out that, although this was his first appearance before a panel of the Discipline Committee, these actions cannot be condoned. The Panel expressed its expectation that the Member has learned from the experience, will complete the remedial courses, and will return to the profession with an understanding of professional boundaries and conduct that would be expected of a member of this College.

### **Wieslawa (Vivian) Lewna** (OCP #204360)

At a hearing on October 19, 2017, a Panel of the Discipline Committee made findings of professional misconduct against Ms. Lewna with respect to the following incidents:

- On or about October 15, 2015, she dispensed a prescription for Oxycodone CR 80mg in doses and/or quantities that were clinically questionable, without taking and/or documenting any steps to assess the propriety of the prescription;

- On or about October 15, 2015, she dispensed a prescription for four benzodiazepines in doses and/or quantities and/or combinations that were clinically questionable, without taking and/or documenting any steps to assess the propriety of the prescription;

- Between about January 19, 2016 and May 10, 2016, she dispensed drugs pursuant to a prescription for client [Patient A] in smaller quantities than prescribed, without written authorization from the person presenting the prescription, contrary to s. 9(1) of the Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c. P.23;

- On or about May 24, 2016, she performed the controlled act of prescribing a drug in circumstances where she was not authorized by a health profession act to do so and was otherwise without authorization to do so, with respect to her prescribing of four benzodiazepines;

- On or about May 24, 2016, she performed the controlled act of prescribing a drug without doing the following, which she was required to do:

o Notifying the patient's prescriber that she renewed the patient's prescription, and/or recording in the patient's record the date on which she notified the patient's prescriber;

o Recording all of the information on the prescription and/or the patient record required by ss. 37 and 38 of O. Reg. 202/94 made under the Pharmacy Act, 1991, S.O. 1991, c. 36

In particular, the Panel found 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, ss. 36, 37, and 38 of O. Reg. 202/94, as amended, made under the Act, and/or s. 27 of the Regulated Health Professions Act, 1991, and/or s. 4(2) of the 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, s. 9(1) of the Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c. P.23, and s. 51(1) of the Benzodiazepines and Other Targeted Substances Regulations, SOR/2000-217, made under the Controlled Drugs and Substances Act, S.C. 1996, c. 19

- 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

On January 8, 2018, the Panel imposed an Order which included as follows:

1. A reprimand.

2. The Registrar impose specified terms, conditions or limitations on the Member's Certificate of Registration, and in particular:

   a) that the Member complete successfully, within twelve months of the date of this Order, a program with Gail Siskind, an expert in ethical issues for regulated health care professionals, or such other expert as is acceptable to the College, to be designed by the expert, regarding the issues raised by the facts and findings of professional misconduct in this case, including the role of pharmacists in monitoring, advising on, and recommending changes to, patients' medication therapy; and the following terms shall apply to the course:

      i) the number of sessions shall be at the discretion of the expert, 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 expert, but shall ultimately be at the discretion of the expert;

      iii) the Member shall be responsible for the cost of the course;

      iv) the Member shall provide to the expert the following documents, in advance of the course, to facilitate the design of the course:

         i. the Notice of Hearing;

         ii. the Agreed Statement of Facts;

         iii. this Joint Submission on Order; and

         iv. the Panel's Decision and Reasons, if and when available; and

      v) the Member will request a report from the expert confirming that the Member has successfully completed the program requirements to the satisfaction of the expert, and the Member will provide a copy of the report to the College within twelve (12) months of the date of this Order.

   b) that the Member complete successfully, at her own expense, within twelve months of the date of this Order, the following course and evaluations: Safe and Effective Use of Opioids for Chronic Non-cancer Pain, offered by the Centre for Addiction and Mental Health;

   c) that the Member undergo a Practice Review performed by a Community Practice Assessor employed by the College; the initial Practice Review assessment shall be performed within six months of the date of this Order; the Member shall complete any re-assessments, learning plans, or other follow-up steps arising from the Practice Review as required and within the times required as part of the Practice Review;

3. The Registrar suspend the Member's Certificate of Registration for a period of 1 month, with the suspension to be fully remitted on condition that the Member complete the remedial training as specified in subparagraphs 2(a), and (b) above.

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

In its reprimand, the Panel noted that pharmacy is an honorable and self-regulated profession, and that pharmacists bear the responsibility of following the standards of practice and accompanying laws and recommendations for detailed record keeping and documentation.

The Panel observed that pharmacists are called upon every day to make decisions and communicate with prescribers. But, in doing so, they must always stay within their scope of practice and understand those limits.

The Panel noted that, in the changing practice climate in which pharmacists find themselves, clinical acumen is paramount in keeping patients safe, especially when it comes to potentially addictive, high risk, and over prescribed medications.

The Panel expressed its hope that this Order and the discipline process will deter similar conduct in the future.

**The full text of these decisions is available at www.canlii.org**
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# FOCUS ON ERROR PREVENTION

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

## CALCULATION ERRORS

Pediatric patients often require individualized doses of medications based on the child's age, weight, the indication for use and the recommended dosage regimen of the medication.

The determination of individualized doses usually requires the use of calculations which introduces an additional source of error and an increased risk of patient harm.

Pharmacists must therefore use extra care when assessing and calculating the appropriate dosages in high risk populations such as pediatric patients.

**1) Amox S 250 mg/5 mL powder for reconstitution**
Take **2.50** mL(s) PO **BID** for 10 Days **Dispense:** 50mL(s)

**Instructions:** Wt: 12kg
Dose: 80mg/kg/day
80mg x 12kg=960mg
960mg x 5 ml= 4800mg/ml
4800/250= 5ml
= 5ml/day
= 2.5ml BID

### CASE:

The above preprinted prescription was given to the mother of a one year-old child with acute otitis media. The prescription was taken to a local community pharmacy for processing.

The pharmacy assistant entered the prescription into the computer as printed and prepared the amoxicillin suspension for checking by the pharmacist.

Upon checking the prescription, the pharmacist correctly confirmed the child's weight, the indication for use and the recommended dosage. The correct dose was calculated to be 480mg twice daily or 9.6mls of the 250mg/5mls concentration to be given twice daily. The printed dose was therefore only approximately one-quarter of the intended dosage.

Upon contacting the prescriber regarding the calculation error, she apologized and thanked the pharmacist for catching the error.

### RECOMMENDATIONS:

- When dispensing medications for pediatric patients, always use the child's age, weight, the indication for use and the recommended dosage regimen of the medication to ensure that the appropriate drug and dosage is being dispensed.
- Always use a calculator or another computing device to check the results for accuracy.
- Always double check pediatric doses for appropriateness as these patients are at an increased risk of experiencing harm due to the incomplete development of their defense systems.
- Wherever possible, a second individual should independently complete the calculation without prior knowledge of the results of the first calculation.
- Use standardized drug concentrations wherever possible.
- Though computer generated prescriptions can minimize medication errors due to illegible handwriting, be aware that new types of errors may be introduced.
- When similar errors involving computerized prescriptions are encountered, educate the prescriber regarding the apparent error in computer logic. Suggest that the software vendor be contacted as soon as possible to prevent future errors.
- Be aware of the following types of calculation errors which have been reported:

  1. Interchange of pounds and kilograms. Many patients report their weight in pounds. However, doses are usually provided in terms of kilograms (e.g. mg/kg).

  2. Calculating the total daily dose as a single dose. The dose of a specific drug may be listed as 10mg/kg q12h or 10mg/kg/**day** to be given at twelve hour intervals.

3. Performing the incorrect mathematical operation. For example, multiplying by two instead of dividing by two. Or, dividing the denominator by the numerator instead of dividing the numerator by the denominator.

4. Ten-fold errors due to the misplacement of a decimal point.

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

# REMINDER:
## REQUIREMENTS FOR PHARMACY PRACTICE MANAGEMENT SYSTEMS

Pharmacy computer systems must support the good delivery of patient care and meet certain national minimum requirements, which have been developed in compliance with Canadian regulations and standards. Set out in NAPRA's Pharmacy Practice Management Systems (PPMS), these functional and administrative requirements are designed to ensure the safety and efficacy of e-prescriptions and related electronic pharmacy records. They are also supported by a supplementary document, Pharmacy Practice Management Systems Supplemental Requirements on Traceability and Bulk Preparation Labelling. Pharmacy professionals can also access NAPRA's Frequently Asked Questions on the PPMS standards.

The effective date for these requirements was **January 1, 2016**.

Additionally, computer systems must have sufficient speed and capacity to enable efficient and effective practice by pharmacy professionals and ensure that there are deliberate and auditable procedures required before any information can be purged from the system.

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