Expanded Scope Activities

- Initiating Therapy (Smoking Cessation)
- Renewing a Prescription
- Adapting a Prescription
- Performing a Procedure on Tissue below the Dermis
- Administration of Inhalation for Demonstration
- Administration of Injection for Demonstration
- Administration of the Influenza Vaccine within the context of HIP

EXPANDED SCOPE REGULATION NOW IN EFFECT

VARIETY OF RESOURCES AVAILABLE TO SUPPORT UNDERSTANDING AND IMPLEMENTATION
**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 DIRECTIONS:**

1. Optimize the evolving scope of practice of our members for the purpose of achieving positive health outcomes.

2. Promote the use and integration of technology and innovation to improve the quality and safety of patient care, and to achieve operational efficiency.

3. Foster professional collaboration to achieve coordinated patient-centred care and promote health and wellness.

4. Build and enhance relationships with key stakeholders, including the public, the government, our members, and other health care professionals.

5. Apply continuous quality improvement and fiscal responsibility in the fulfilment of our mission.

**COUNCIL MEMBERS**

Council Members for Districts are listed below according to District number. 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.

- H Christine Donaldson
- H Regis Vallencourt
- K Mark Scanlon
- K Esmael Merani
- L Tracy Wiersema
- L Fird Wassef
- L Saheed Rashid
- M Sherif Guergu
- M Tracey Phillips (Vice President)
- M Don Organ
- N Bonnie Hauser
- N Christopher Leung (President)
- N Ken Potvin
- P Rachelle Rocha
- P Jon MacDonald
- T Amber Walker
- TH Tracy Wills
- PM William Cornet
- PM Consan dela Cruz
- PM Babek Ebrahimzadeh
- PM Jim Fyfe
- PM David Hoff
- PM Margaret Irwin
- PM Javaid Khan
- PM Lewis Lederman
- PM Aladdin Mahaghiegh
- PM Gtu Parikh
- PM Lynn Peterson
- PM Shahid Rashdi
- PM Joy Sommerfreund
- U of T Henry Mann
- U of W David Edwards

**Statutory Committees**
- Executive
- Accreditation
- Discipline
- Fitness to Practice
- Inquires Complainants & Reports
- Patient Relations
- Quality Assurance
- Registration

**Standing Committees**
- Communications
- Finance
- Professional Practice

**COLLEGE STAFF**

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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.

Christopher Leung, R.Ph., B.Sc.Phm./MBA
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Marshall Moleschi, R.Ph., B.Sc. (Pharm), MHA
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Our new scope requires . . . a greater level of communication with other members of the health care team, especially with the other prescribers.

Della Croteau, R.Ph., B.S.P., M.C.Ed.
Deputy Registrar/Director of Professional Development

It’s hard to believe we finally have the legislation we have been waiting for, after all those times I said it was just about here! And now the real work begins, implementing the legislation to work collaboratively with other health care providers and benefit patients on a day to day basis.

Although we are excited as pharmacists to be able to exercise more authority with our expanded scope of practice, it’s also important to remember that this legislation is not about us!

It is to allow more collaboration so that we can work with other health care providers to optimize patient care. Thus the requirement for us to notify prescribers of our decisions regarding:

- initiating smoking cessation therapy,
- renewing medication or clinically significant adaptations of prescriptions, is important. It is in the best interest of the patient that we all work together in their care.

The principles of implementing the new scope are stated up front in the Expanded Scope of Practice Orientation Manual and one of those principles states:

The services included within the expanded scope of pharmacy practice are part of ongoing medical care and take place in the context of a collaborative relationship between the pharmacists, the patient, and the patient’s primary health care provider.

Although notification is a legal requirement in the new legislation, notification alone is not enough. It’s important to set up discussions, with prescribers in your area if you are in a community setting or with medical advisory committees if you are in an institutional setting, to talk about how this will work best in your practice environment. It’s in the best interest of our patients that primary care providers understand our new scope and the kinds of communication they will receive from us. Perhaps there are certain areas that should or could be flagged for special attention, and all parties would want to understand that from the beginning.

In addition, the College is working together with the Ontario Pharmacists’ Association (OPA), College of Physicians and Surgeons of Ontario (CPSO) and the Ontario Medical Association (OMA) to clarify practice issues and develop communications for our respective members to enable everyone to move forward collaboratively in the best interest of our patients.

Our new scope requires not only a greater level of decision making on the part of pharmacists, but also a greater level of communication with other members of the health care team, especially with the other prescribers. We will be well served if we keep in mind that it is not about us, but how well we work in a collaborative environment to optimize patient care.
As decision makers . . . we need to appreciate that there is often no single ‘right’ answer.

The presentations are continuously evolving to reflect and address the common issues being raised and where necessary additional resources are being developed to support understanding and implementation of our expanded scope.

An example of this would be the recent production and distribution by the College of the public brochure entitled “Understanding Your Pharmacist’s Expanded Role”. It was identified that although media has been effective in generating public awareness of pharmacists expanded role the messaging was incomplete and patient’s expectations were not aligned with the realities of the pharmacists’ new authority. The brochure is a tool that pharmacists can use to assist them in explaining, to their patients, what their expanded role may mean to them.

Perhaps the biggest observation that I have made however from attending these sessions has been the fact that, as expected with any change initiative, acceptance and competence to embrace our new role varies significantly between individuals. Our expanded scope regulation truly evolves us from dispensers to decision makers and authorizes us to exercise our professional judgement to make independent decisions in the interest of optimizing our patients’ health outcomes. This firmly moves us into the proverbial ‘grey area’ and many pharmacists, as demonstrated by the specific nature of questions asked, are still seeking confirmation of the ‘right’ thing to do.

As decision makers however, we need to appreciate that there is often no single ‘right’ answer. We must each independently take the information that is available to us in any given situation and draw from our own experiences and knowledge to make a decision for action that is in the best interest of our patient. Whether one pharmacist decides, as an example, to renew a prescription for three months and another for six months, another may feel the more appropriate path is to seek authorization from the original prescriber for the renewal. Each of these actions are acceptable options which satisfy our obligation to take care of the patient.

Witnessing individual pharmacists grasp the realization of our new scope is truly invigorating and reaffirms the excitement that I feel for our profession as we continue to safely and effectively enhance our role as integral members of our patient’s health care team. This truly is an evolution, not a revolution, and I too feel cautiously optimistic.
SEPTEMBER 2012
COUNCIL MEETING

THE COLLEGE ELECTS NEW PRESIDENT AND WELCOMES NEW COUNCIL MEMBERS

Council elected Mr. Christopher Leung from District N as President of the College for the new Council year. Also welcomed to the Council table were new members Mr. Regis Vaillancourt, representing District H and Mr. Ken Potvin, representing District N.

For a complete list of Council members, Committee Chairs and appointments, please see page 9, or visit the College’s website, www.ocpinfo.com.

2013 CAPITAL AND OPERATING BUDGET APPROVED

Council reviewed and approved the 2013 budget, which supports the strategic plan approved by Council in March 2012.

In summary, there are no fee increases proposed for 2013 and the unrestricted reserve going into 2013 will be approximately $5.8 million.

As well, Council approved the appointment of Clarke Henning LLP as Auditors for 2012.

RECORD RETENTION, DISCLOSURE AND DISPOSAL GUIDELINE APPROVED

As personal health information custodians, pharmacists are required to collect, use and disclose personal health information as required by by-law and to implement safeguards to protect the information they have collected. Council approved this guideline, which is similar to guidelines in place at other Ontario health professional colleges and pertains specifically to the requirements established in the Personal Health Information Protection Act, 2004 (PHIPA).

The guideline can be viewed on page 31 or on the College’s website, www.ocpinfo.com.

POLICY ON PROTECTING THE COLD CHAIN APPROVED

An increasing number of medications require cold chain protection and it is expected that the number of pharmaceuticals and biologics that require cold-chain monitoring will continue to increase over the next several years. Products that have not been maintained at the appropriate temperature and under the appropriate conditions are considered to be unsafe for use. In addition, in anticipation of amendments being passed
by the government that would authorize members to administer the influenza vaccine to patients five years and older, the Policy on Protecting the Cold Chain (click here) was developed in order to provide members with guidance on their obligations to protect patient safety by ensuring that drugs and biological products which require temperature protection are received, stored and dispensed safely.

The policy can be viewed on page 26 or on the College’s website, www.ocpinfo.com.

APPROVAL OF TECHNOLOGY FOR USE AT A REMOTE DISPENSING LOCATION

In keeping with Council’s position that the College must retain the right of approval for all technology which enables the transmission of paper-based prescriptions through an automated pharmacy system located in a remote dispensing location, and based on results of extensive testing conducted by a technology expert, Council passed a motion approving the technology that is currently acceptable in meeting the expectations set out in sections 40 (4) and 29(d) of the regulations to the Drug and Pharmacies Regulation Act. Certificates of Accreditation that permit the operation of a remote dispensing location by an accredited pharmacy in Ontario will only be issued where the College is satisfied that the technology employed has been approved by Council and that all other standards have been demonstrated to be in place.

COUNCIL MEETING DATES 2012 -2013 TERM

- Monday 10 December 2012
- Monday 18 and Tuesday 19 March 2013
- Monday 10 and Tuesday 11 June 2013
- Monday 9 and Tuesday 10 September 2013

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

ORIENTATION SESSIONS PLANNED FOR 2012/2013

In anticipation of the government passing regulations that will increase Scope of Practice, the College is planning a series of Orientation Sessions over the next few months to assist members in understanding the expectations, requirements and obligations of the expanded scope regulation.

A meeting schedule can be found on page 16 or on the College’s website, www.ocpinfo.com.

BY-LAW REVIEW

Council approved a motion to create a Special Committee of Council to conduct an overall review of the College’s by-law number 2. The review will include proposing to Council suitable amendments and areas recommended for further study, with supporting reasons, and other aspects that this Committee considers appropriate. Interim Reports, as appropriate, will be provided to Council, with a final report no later than September 2013.
## Committee Appointments 2012/2013

### EXECUTIVE
**Elected Members:**
- Chris Leung – President & Chair
- Tracey Phillips - Vice President
- Sherif Guorgui - Past President
- Mark Scanlon

**Public Members:**
- David Hoff
- Lew Lederman
- Aladdin Mohaghegh

**Staff Resource:**
- Marshall Moleschi

### ACCREDITATION
**Elected Members:**
- Bonnie Hauser
- Ken Potvin
- Regis Vaillancourt
- Tracy Wiersema

**Public Members:**
- David Hoff (Chair)
- Margaret Irwin
- Joy Sommerfreund

**NCCM:**
- Timothy Brady
- Lap Chan

**Staff Resource:**
- Tina Perlman

### COMMUNICATIONS
**Elected Members:**
- Christine Donaldson
- Sherif Guorgui
- Bonnie Hauser
- Saheed Rashid (Chair)

**Public Members:**
- David Hoff
- Javad Khan
- Joy Sommerfreund

**NCCM:**
- Gerty Cook

**Staff Resource:**
- Tina Perlman

### FINANCE
**Elected Members:**
- Bonnie Hauser (Chair)
- Esmail Merani
- Tracey Phillips
- Mark Scanlon

**Public Members:**
- David Hoff
- Gitu Parkh

**Staff Resource:**
- Connie Campbell

### DISCIPLINE
**Elected Members:**
- David Edwards
- Sherif Guorgui
- Henry Mann
- Don Organ
- Rachelle Rocha
- Mark Scanlon
- Farid Wassef
- Amber Walker
- Tracy Wills

**Public Members:**
- William Cornet
- Cora dela Cruz
- Bob Ebrahimzadeh (Chair)
- Jim Fyfe
- Javad Khan
- Lew Lederman
- Aladdin Mohaghegh
- Gitu Parkh
- Lynn Peterson
- Shahid Rashid

**NCCM:**
- Larry Boggio
- Erik Botines
- Steve Clement
- Jim Gay
- Tony Huynh
- Sanv Maindrattra
- Toni Niewhof
- Goran Petrovic
- Jeanette Schindler
- Dan Stringer
- Tatjana Sunjc
- Laura Weyland
- David Windross

**Staff Resource:**
- Maryan Gemus

### INQUIRIES, COMPLAINTS AND REPORTS (ICRC)
**Elected Members:**
- Sherif Guorgui
- Ken Potvin
- Saheed Rashid
- Rachelle Rocha
- Mark Scanlon
- Tracy Wiersema (Chair)
- Tracy Wills

**Public Members:**
- William Cornet
- Marg Irwin
- Aladdin Mohaghegh
- Gitu Parkh
- Lynn Peterson
- Shahid Rashid

**NCCM:**
- Elaine Akers
- Kayna Bezhichbnyk-Butler
- Gerry Cook
- Mike Hannahalh
- Gurjit Husson
- Eva Janecek-Rucker
- Elizabeth Kozyra
- Satinder Sanghera
- Beth Sproule

**Staff Resource:**
- Maryan Gemus

### FITNESS TO PRACTISE
**Elected Members:**
- Regis Vaillancourt
- Tracy Wills (Chair)

**Public Members:**
- David Hoff
- Lynn Peterson

**NCCM:**
- Andrea Ball
- Sherry Peister
- Mina Tadrous

**Staff Resource:**
- Tina Perlman

### QUALITY ASSURANCE
**Elected Members:**
- Jon MacDonald
- Sherif Guorgui (Chair)
- Amber Walker
- Farid Wassef

**Public Members:**
- Cora dela Cruz
- Marg Irwin
- Joy Sommerfreund

**NCCM:**
- Steve Clement
- Puja Shanghavi
- Zita Semeniuk

**Staff Resource:**
- Sandra Winkelbauer

### PATIENT RELATIONS
**Elected Members:**
- Christine Donaldson (Chair)
- Bonnie Hauser
- Jon MacDonald
- Tracy Wills

**Public Members:**
- Bob Ebrahimzadeh
- Jim Fyfe
- Aladdin Mohaghegh

**NCCM:**
- James Buttoo
- Doris Nessim
- Dean
- Henry Mann

**Staff Resource:**
- Susan James

**NCCM = Non-Council Committee Member**

### PROFESSIONAL PRACTICE
**Elected Members:**
- Christine Donaldson
- David Edwards
- Esmail Merani (Chair)
- Don Organ
- Tracey Phillips
- Rachelle Rocha
- Amber Walker
Public Members

District K, Mark Scanlon
Peterborough

District K, Esmail Merani
Carleton Place

District L, Farid Wassef
Stouffville

District L,Saheed Rashid
Hamilton

District M, Tracey Phillips
Vice President
Toronto

District M, Don Organ
Toronto

Corazon dela Cruz
Toronto

William Cornet
Ottawa

Babek Ebrahimzadeh
Woodbridge

Jim Fyfe
Niagara Falls

David Hoff
Oakville

Margaret Irwin
Sault Ste. Marie

Javaid Khan
Markham

Lew Lederman
Ottawa

Aladdin Mohaghegh
Toronto

Gitu Parikh
Toronto

Lynn Peterson
Toronto

Faculty of Pharmacy

Henry Mann
Dean
Leslie Dan Faculty of Pharmacy
University of Toronto

David Edwards
Hallman Director
School of Pharmacy
University of Waterloo

Shahid Rashdi
Mississauga

Joy Sommerfreund
London
EXPANDED SCOPE REGULATION NOW IN EFFECT
After much anticipation on October 9th, 2012, in a media event held at the Leslie Dan Faculty of Pharmacy at the University of Toronto, the Ontario government officially announced the expanded scope regulation for pharmacy.

The regulation outlines the parameters under which members of the College are authorized to:

- Prescribe specified drug products for the purpose of smoking cessation;
- Renew and adapt (alter dose, dosage form, regimen, or route of administration) prescriptions;
- Perform a procedure on tissue below the dermis to support patient self-care and chronic disease monitoring;
- Administer, by injection or inhalation, substances listed in the regulation for the purpose of education and demonstration; and

VARIETY OF RESOURCES AVAILABLE TO SUPPORT UNDERSTANDING AND IMPLEMENTATION

Photo at left: Signing of Expanded Scope Regulation by Marshall Moleschi, College Registrar (left) and Sherif Guergui, Past President (right)

EXPECTATION OF THE COLLEGE

The expectation of the College is that prior to exercising any of the expanded scope activities, members will read and understand both the Regulation itself and the information contained in the Expanded Scope of Practice Orientation Manual. On renewal in March 2013, the College will be asking all members to declare that they have met this expectation.
• Administer influenza vaccine to patients five years of age and older in accordance with Ontario’s Universal Influenza Immunization Program (UIIP).

With the exception of additional training required prior to the administration of injections for education, demonstration or flu vaccine, members are now permitted to practice these expanded scope activities once they feel competent to do so.

Given the significance of the new scope however, the College has developed a number of resources to assist members in understanding and applying the new regulation.

In particular, the College has developed an Expanded Scope of Practice Orientation Manual which outlines, in practical terminology, the standards and requirements of each of the expanded scope activities and includes a number of scenarios to illustrate application to practice.

Additionally, in conjunction with the Ontario Pharmacists’ Association (OPA) the College is hosting an extensive schedule of Live Orientation Sessions throughout the province, now through February 2013 (refer to page 16 for remaining schedule). Each session is 1.5 hours long and includes presentations by the College Registrar and Association CEO followed by a question and answer period.

For members who prefer, or who are unable to attend one of the live orientation sessions, an Online Version of the Orientation Session is also available.

Finally, in an effort to support pharmacists in explaining their expanded role to patients, the College has produced a Public Brochure which can be displayed in pharmacies or distributed directly to patients.

All of the resources listed above can be found from the homepage of the College website at www.ocpinfo.com under the heading – Expanded Scope Regulation is Here!

**UNDERLYING PRINCIPLES**

As the practice of pharmacy evolves with the enactment of the expanded scope regulation members are reminded of the underlying principles that guide the implementation of their expanded practice.

1. Members have an obligation to protect and promote the health and well-being of patients;
2. Members are accountable for practicing within their scope of practice, the terms, conditions and limitations on their certificate of registration, if any, and in accordance with their knowledge, skill and judgement;
3. The services included within the expanded scope of pharmacy practice are part of ongoing medical care and take place in the context of a collaborative relationship between the pharmacist, the patient, and the patient’s primary health care provider;
4. Members initiate, adapt and renew prescriptions, administer substances by injection or inhalation only for the benefit of the patient and based on the individual nature of the patient’s need/history and professional judgement exercised accordingly;
5. When initiating, adapting and/or renewing prescriptions, the member assumes full responsibility and liability for that prescription, documents actions as required, and undertakes notifications as appropriate; and
6. Pharmacy services are provided within the context of the legislative requirements, Standards of Practice, and Code of Ethics.
Kicking off to a capacity crowd in St. Catharines on October 17th the Expanded Scope ‘live’ Orientation Sessions, designed to assist pharmacists in understanding and implementing the new expanded scope regulation, continue to be a popular option for members.

With nearly twenty live sessions in ten communities now complete College Registrar Marshall Moleschi and Dennis Darby, CEO of the Ontario Pharmacists’ Association (OPA) are about half way through the extensive schedule that criss-crosses the province. To date, more than 2,000 pharmacists and pharmacy technicians have attended a session.

Each session is 1.5 hours long and begins with a presentation by the College detailing each of the expanded scope activities followed by a presentation by the Association which articulates some of the barriers and opportunities and outlines additional support materials available to pharmacists. The sessions conclude with an engaging and informative question and answer period.

Feedback solicited by participants following each session support the value of attending. Typical comments include: “I have a better understanding and feel more confident in expanding our scope of practice following this session” or “Very informative presentations! The question session afterwards really brought out a lot of practical issues that we would face and how we could potentially solve them”.

With sessions running through to the end of February next year (refer to page 16 for remaining schedule) there is still plenty of opportunity to register to attend a session near you. In most locations both an evening and morning session is offered to best accommodate work schedules.

For members who prefer, or who are unable to attend one of the remaining live orientation sessions, an Online Version of the Orientation Session is available. The online version is an audio-led presentation of the same powerpoint being delivered at the live sessions and is available 24/7 from the comfort and convenience of your own computer.

Registration to a live session and/or access to the online session can be found from the homepage of the College website (www.ocpinfo.com) under the heading – Expanded Scope Regulation is Here!
Live Expanded Scope Orientation Sessions

**REMAINING SCHEDULE**

Note: Space is limited, registration required. Access to registration can be found from the homepage of the College website (www.ocpinfo.com) under the heading – Expanded Scope Regulation is Here!

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<thead>
<tr>
<th>Date</th>
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<tr>
<td><strong>DECEMBER 2012</strong></td>
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<td>Monday, December 3</td>
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<td>Thunder Bay</td>
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<td>London</td>
<td>Best Western Plus Lamplighter Inn &amp; Conference Centre 591 Wellington Road South, London</td>
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<td>Brampton</td>
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<td>Hamilton</td>
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<td>Thursday, January 31</td>
<td>7:00-8:30 PM</td>
<td>Scarborough</td>
<td>Delta Toronto East 2035 Kennedy Road, Toronto</td>
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<td><strong>FEBRUARY 2013</strong></td>
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<td>Holiday Inn Peterborough Waterfront 150 George Street North., Peterborough</td>
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<td>7:00-8:30 PM</td>
<td>Aurora</td>
<td>Howard Johnson 15520 Yonge Street, Aurora</td>
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<tr>
<td>Wednesday, February 13</td>
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Immunization for
Health Care Providers

The Provincial Infectious Diseases Advisory Committee on Infection Prevention and Control (PIDAC-IPC) is a multidisciplinary committee of health care professionals with expertise and experience in Infection Prevention and Control. The committee advises Public Health Ontario on the prevention and control of health care associated infections, considering the entire health care system for protection of both patients and health care providers. The best practices recommended by PIDAC-IPC are evidence-based, to the largest extent possible, to assist health care organizations in improving quality of care and patient safety.

In August 2012, PIDAC-IPC updated the advice contained in Best Practices for Infection Prevention and Control Programs in Ontario to recommend that annual influenza vaccinations should be a condition of continued employment in health care organizations.

This recommendation builds on the support for this approach by several leading American healthcare organizations which have mandated influenza vaccination among other measures to prevent the spread of influenza for health care personnel and follows the announcement of a similar policy in British Columbia.

In 2005, the Ontario College of Pharmacists published Infection Control for Regulated Professionals: Pharmacists’ Edition. This publication, which was created in collaboration with several Ontario-based health regulatory colleges, also recommends annual influenza immunization as part of the infection prevention strategy for community settings.
Deb Matthews, Minister of Health and Long-Term Care receiving her flu shot on Monday October 22 from pharmacist Carol Wong, Pharmacy Manager, Rexall, First Canadian Place, Toronto
Even though, as specified in the regulation, additional training is required prior to administering injections nearly 2,000 pharmacists have already met this requirement, and with training sessions ongoing more qualified pharmacists are being added to the register every day.

Many of these trained pharmacists are participating in the Universal Influenza Immunization Program (UIIP) which for the first year ever invited pharmacies to fully participate in the program. Nearly 600 pharmacies, from across the province, were successful in meeting the program requirements. Those pharmacies are able to order and store publicly funded flu vaccine and pharmacists are actively administering flu shots to patients.

INJECTION TRAINING

In order to administer injections pharmacists must successfully complete an Ontario College of Pharmacists (OCP) approved injection training course and have and maintain valid certification in CPR and First Aid (equivalent of the Red Cross Standard First Aid with CPR ’C’ + AED Course level). Once these requirements have been met pharmacists must declare this training by registering with the College.

More information on OCP-approved training courses and College registration information is available from the College website (www.ocpinfo.com) under the Continuing Education (CE) tab.

When you add these pharmacies to the list of locations who are also participating in the flu season, by hosting nurse administered flu clinics, access for Ontarians to the flu vaccine has never been greater.

Trained pharmacists are also now able to make a difference in their patient’s care by educating and demonstrating to them, or their care giver, how to self-administer injections to treat conditions such as diabetes.

Whether administering injections as part of participation in the UIIP or teaching patients how to administer their own medications pharmacists are definitely embracing this expanded scope activity and giving it a shot!
Using Professional Judgement, Key to Implementing Expanded Scope

Some of the issues pharmacists are called upon to resolve are straightforward and therefore, the decision to be made is obvious. However pharmacists are expected to use their professional judgement when a decision is not so clear. As members of a self-regulated profession, pharmacists must be able to rationalize the clinical decisions that they make, to their peers and to any person or organization which may be affected by their actions, including individual patients, the public, their employers, and other health care professionals.

The new regulation permitting an expanded scope of practice requires that, more than ever, pharmacists use professional judgement to assess their patient’s health status and make appropriate decisions regarding their medication management. A key principle of practice when pharmacists exercise expanded scope activities is that they do so only for the benefit of the patient based on the individual nature of the patient’s need/history.

The Royal Pharmaceutical Society of Great Britain provides the following advice in their Code of Ethics on the exercise of professional judgement:

The exercise of professional judgement requires identification and evaluation of the risks and benefits associated with possible courses of action. On occasion there may not be a right or wrong answer. Different people may reach different decisions on a single set of circumstances and each may be justifiable.

A decision arrived at through the use of professional judgement is rooted in the problem to be solved and the individual pharmacists’ education, training and experience. Pharmacists already make professional judgement decisions daily, for example, determining whether to:

- Dispense or not dispense a medication for a patient; or
- Acting on or over-riding a drug interaction warning.

When several courses of action are available, the pharmacist applies their expertise and chooses the one that is most appropriate based on an assessment of the patient, the medication-related issue, and the patient’s best interests, documents his or her actions and rationale and if appropriate notifies the primary health care provider.

The Standards of Practice and Code of Ethics are the two most important tools for a pharmacist when faced with using their professional judgement. The key factors that
apply to the exercise of professional judgement are:

1. The best interest of the patient;
2. The pharmacist’s knowledge and expertise;
3. Whether the decision is both reasonable and acceptable; and
4. Documenting the rationale and actions.

1. TAKING ACTIONS IN THE PATIENT’S BEST INTEREST:
Actions and decisions must always be made from the perspective of what is in the best interest of the patient. The patient, or his or her agent, are partners in the decision-making process and must be provided with enough information to understand the options and choices that are available to them in order to provide an informed consent. The role of the pharmacist is to ensure that the patient, and his or her agent, fully understands the situation and the rationale for the recommendations that are being offered.

2. APPLYING KNOWLEDGE AND EXPERTISE:
The pharmacist’s knowledge and expertise is the most complex of the factors involved in patient care decisions because they are based on the range of experience gained through clinical practice in general and through involvement in similar circumstances, if any. The other factors that go into decision-making are based on the pharmacist’s assessment of the patient, including utilizing the information in the patient record, if any, and dialogue with the patient in order to assess the benefits and risks of a proposed approach to therapy.

3. REASONABLE AND ACCEPTABLE:
At times, there may be an opportunity to discuss specific issues with a colleague; however, generally decisions must be made immediately, based on the information at hand. When a decision must be made immediately, it may be helpful to objectively consider whether a peer would make a similar decision, given the circumstances, or whether the rationale that supports the decision would be understood and accepted in a similar practice.

4. DOCUMENTING THE RATIONALE AND ACTIONS:
Documentation is a key element of every health profession’s standard of practice and one of the most basic professional responsibilities. The pharmacist demonstrates accountability and responsibility for their actions, and evidence of the application of their medication and medication therapy management expertise, through documentation. Documentation should be organized in such a manner that all professional actions on behalf of a patient are accurately described. The College’s Documentation Guideline (which can be found on the College’s website, www.ocpinfo.com) provides guidance in this area.

SUMMARY:
Professional judgement is a vital element in everyday practice. The prescribed laws, protocols and policies of our profession can never, nor do they attempt, to provide detailed solutions for every possible situation that a pharmacist might encounter. Rather, they provide a comprehensive set of requirements, standards, and most importantly, intent for pharmacy practice.

Members sometimes seek the College’s “opinion” on a specific situation by asking College staff to interpret applicable professional standards, but the pharmacist is the individual closest to and most aware of the patient’s situation. Interpretations by anyone other than the attending pharmacist would therefore not reflect the judgement of the one person who is responsible and accountable for the decision.

Interpreting the intent and spirit of our profession’s standards can certainly pose difficulties for resolving practice issues, but this ability to interpret is also one of the most valuable contributions that a pharmacist can bring to patient care and practice.
CALL FOR PRECEPTORS

Are you looking for a way to recapture the excitement of practising pharmacy? Consider becoming a Structured Practical Training (SPT) preceptor in 2013 and attend an Orientation Workshop close to home or in Toronto. Please visit www.ocpinfo.com, SPT Overview for more information.

2013 WORKSHOPS

<table>
<thead>
<tr>
<th>DATE</th>
<th>CITY</th>
<th>WORKSHOP &amp; TOPIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wednesday January 9th</td>
<td>Toronto</td>
<td>Orientation</td>
</tr>
<tr>
<td>Tuesday January 29th</td>
<td>Toronto</td>
<td>Orientation</td>
</tr>
<tr>
<td>Tuesday February 12th</td>
<td>Toronto</td>
<td>Advanced (TBA)</td>
</tr>
<tr>
<td>Thursday February 21st</td>
<td>Toronto</td>
<td>Orientation</td>
</tr>
<tr>
<td>Tuesday March 19th</td>
<td>London</td>
<td>Orientation</td>
</tr>
<tr>
<td>Thursday March 21st</td>
<td>London</td>
<td>Advanced (TBA)</td>
</tr>
<tr>
<td>Wednesday March 27th</td>
<td>Toronto</td>
<td>Orientation</td>
</tr>
<tr>
<td>Tuesday April 16th</td>
<td>Ottawa</td>
<td>Orientation</td>
</tr>
<tr>
<td>Wednesday April 17th</td>
<td>Ottawa</td>
<td>Advanced (TBA)</td>
</tr>
<tr>
<td>Thursday April 25th</td>
<td>Toronto</td>
<td>Orientation</td>
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<tr>
<td>Wednesday May 15th</td>
<td>Toronto</td>
<td>Orientation</td>
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<tr>
<td>Thursday May 16th</td>
<td>Toronto</td>
<td>Advanced (TBA)</td>
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<td>Wednesday May 29th</td>
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<td>Orientation</td>
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<tr>
<td>Wednesday June 5th</td>
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<td>Orientation</td>
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<tr>
<td>Tuesday June 18th</td>
<td>Kingston</td>
<td>Orientation</td>
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<tr>
<td>Tuesday June 25th</td>
<td>Toronto</td>
<td>Orientation</td>
</tr>
</tbody>
</table>

September to December 2013 workshop dates will be posted later in the year.

If you wish to attend one of the above workshops, please complete the SPT Preceptor Workshop Application found on the SPT section of the College’s website, www.ocpinfo.com.

The SPT Preceptor Orientation Workshops are now designed to provide pharmacists and pharmacy technicians* with the necessary skills to become preceptors for students, interns and pharmacy technician applicants.

If you wish to become a preceptor for a pharmacy technician applicant you will need to attend a SPT Preceptor Orientation Workshop which addresses the scope for technicians.

*After 1 year of practice, registered pharmacy technicians are eligible to become preceptors for pharmacy technician applicants only.

The Advanced Preceptor Workshops are offered to experienced preceptors with the goal of enhancing their feedback and assessment skills as well as an opportunity to share their precepting experiences with others. Special topics that are relevant to the SPT program are offered throughout the year.

To arrange a workshop in your community, please ask your CE Coordinator to contact Vicky Clayton-Jones at 416-962-4861 or 1-800-220-1921 x 2297 or at regprograms@ocpinfo.com

Please visit our website for regular updates.
The Prescription Regulation Summary chart presented on the following two pages, summarizes the Federal and Provincial Laws Governing Prescription Drug Ordering, Records, Prescription Requirements and Refills.

For your convenience this chart, should you wish to post and reference in your pharmacy, is downloadable in PDF format from the College website www.ocpinfo.com under the Professional Practice, Laws and Regulation tab.
**Prescription Regulation Summary Chart**

<table>
<thead>
<tr>
<th>CLASSIFICATION</th>
<th>DESCRIPTION</th>
<th>PRESCRIPTION REQUIREMENTS</th>
<th>REFILLS &amp; TRANSFERS</th>
<th>PURCHASE &amp; SALES RECORDS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Narcotic Drugs (Schedule N drugs)</strong></td>
<td>All products containing only 1 narcotic (straight narcotic drugs). All narcotics for parenteral use. All narcotic compounds containing more than 1 narcotic drug. All narcotic compounds containing less than 2 other non-narcotic ingredients. All products containing 1 of the following 5 narcotics: heroin, hydrocodone, methadone, oxycodone, pentazocine.</td>
<td>Written or faxed prescription. <strong>Dispensing Requirements:</strong> the record of dispensing for all prescriptions must show: Name and address of patient, Name, strength, quantity and form of drug, Manufacturer of drug, Directions for use, Name and address of prescriber, Identification number, Price Charged, Date of dispensing, Signature of pharmacist and pharmacy technician and when and where the prescription was filled.</td>
<td>Refills are not permitted. All prescriptions must be written or faxed. Narcotics may be prescribed as part-fills and dispensed in divided portions. Part-fills: the total quantity dispensed must be indicated as well as the part-fill quantity. Transfers are not permitted, including part-fills and logged Rx*.</td>
<td>Purchase Records: Products must be recorded in the Narcotic and Controlled Drug Register or invoices filed in chronological order for auditing purposes or other record maintained for such purposes and be readily available on the premises. Sales Records: Record of sales in Narcotic and Controlled Drug Register or in a computer from which a printout may be readily obtained on request or be available on the premises.</td>
</tr>
<tr>
<td><strong>Narcotic Preparations (Verbal Prescription Narcotics)</strong></td>
<td>All combinations containing only 1 narcotic drug (not from the narcotics listed above) and 2 or more non-narcotic ingredients in a recognized therapeutic dose and not intended for parenteral use.</td>
<td>Written, faxed or verbal prescription. Verbal prescriptions may be accepted and recorded by a pharmacist, intern, or registered pharmacy student under the direct supervision of a pharmacist. See above for Dispensing Requirements.</td>
<td>Refills are not permitted. Rx may be written, faxed or verbal. Narcotics may be prescribed as part-fills and dispensed in divided portions. Part-fills: the total quantity dispensed must be indicated as well as the part-fill quantity. Transfers are not permitted, including part-fills and logged Rx.</td>
<td>Purchase Records: Same as Above Sales Records: Not a requirement.</td>
</tr>
<tr>
<td><strong>Exempted Codeine Products:</strong></td>
<td>E.g. Tylenol® No. 1. All combinations containing only 1 narcotic drug (not from the narcotics listed above) and 2 or more non-narcotic ingredients in a recognized therapeutic dose and not intended for parenteral use.</td>
<td>Written or faxed prescription. Written or faxed prescription. Written or faxed prescription. Written or faxed prescription. Written or faxed prescription.</td>
<td>Written Rx: May be refilled if the prescriber has indicated in writing, or faxed, the number of refills and dates for, or intervals between refills. Controlled drugs may be prescribed as part-fills and dispensed in divided portions. Verbal Rx: No refills allowed but part-fills are allowed. Transfers are not permitted, including part-fills and logged Rx.</td>
<td>Purchase Records: Same as Above Sales Records: Record of sales in Narcotic and Controlled Drug Register or in a computer from which a printout may be readily obtained on request or be available on the premises.</td>
</tr>
<tr>
<td><strong>Controlled Drugs Part I (Sch. G) amphetamines and others E.g. methylphenidate, dextroamphetamine, etc.</strong></td>
<td>All straight controlled drugs. All combinations containing more than 1 controlled drug.</td>
<td>Written Rx: May be refilled if the prescriber has indicated in writing, or faxed, the number of refills and dates for, or intervals between refills. Controlled drugs may be prescribed as part-fills and dispensed in divided portions. Verbal Rx: No refills allowed but part-fills are allowed. Transfers are not permitted, including part-fills and logged Rx.</td>
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<td>Purchase Records: Same as Above Sales Records: Record of sales in Narcotic and Controlled Drug Register or in a computer from which a printout may be readily obtained on request or be available on the premises.</td>
</tr>
</tbody>
</table>

1. This is a summary; refer to official legislation for detailed information.
2. Steps to follow when starting to dispense Methadone: [www.ocpinfo.com](http://www.ocpinfo.com), Professional Practice tab, Standards, Policies and Guidelines, “Methadone Maintenance Treatment and Dispensing Policy”.
3. To confirm a methadone prescriber’s exemption for Pain or MMT: Contact Health Canada at 613-946-5139, 1-866-358-0453 or email exemption@hc-sc.gc.ca
4. A logged prescription is a new, unfilled order that is on hold and may be dispensed at a later time.
<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
<th>Prescription Requirements</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Controlled Drugs, Part II | Most benzodiazepines, E.g. diazepam, Oxazepam, lorazepam, etc. | Written, facsimile or signed prescription permitted. Oral order permitted if prescribed by a physician. | Following the Narcotic and Controlled Drug Act of Ontario (NSAA). 
| Controlled Drug Preparations in Part II or IV | All combination containing 1 or more non-controlled ingredients in recognized therapeutic doses. | Written, facsimile or signed prescription permitted. Oral order permitted if prescribed by a physician. | Following the Narcotic and Controlled Drug Act of Ontario (NSAA). 
| Controlled Drugs, Part III | Anabolic steroids and derivatives | Written, facsimile or signed prescription permitted. Oral order permitted if prescribed by a physician. | Following the Narcotic and Controlled Drug Act of Ontario (NSAA). 
| Controlled Drug Preparations in Part III | All combination containing 1 or more non-controlled ingredients in recognized therapeutic doses. | Written, facsimile or signed prescription permitted. Oral order permitted if prescribed by a physician. | Following the Narcotic and Controlled Drug Act of Ontario (NSAA). 
| Brodazepines & Other Targeted Substances | All drugs listed in the schedule of the Benzodiazepines and other Targeted Substances Regulations. | Written, facsimile or signed prescription permitted. Oral order permitted if prescribed by a physician. | Following the Narcotic and Controlled Drug Act of Ontario (NSAA). 
| Opioids & Other Analgesics, E.g. fentanyl, oxycodone, etc. | All drugs listed in Schedule F of the Food and Drugs Regulations. | Written, facsimile or signed prescription permitted. Oral order permitted if prescribed by a physician. | Following the Narcotic and Controlled Drug Act of Ontario (NSAA). 
| Notes: | | | 
| Original Rx must be retained for 2 years as per the DAPA.5.1.2. | 
| Age of patient 18 years or older | 
| Date of dispensing | 
| Signature of pharmacist and pharmacy technician | 
| Name and address of patient | 
| Name, strength, quantity and form of drug | 
| Date and time of dispensing | 
| Name of pharmacist or pharmacy technician |
Protecting the Cold Chain

**Title:** Protecting the Cold Chain  
**Approved:** September 2012  
**Legislative References:** Personal Health Information Protection Act, 2004; Drug and Pharmacies Regulation Act, 1990  
**Additional References:** Ontario Public Health Standards, Vaccine Storage and Handling Protocol, 2010 and the Vaccine Storage and Handling Guidelines  
**College Contact:** Professional Practice

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**PROTECTING THE COLD CHAIN 101**

Protecting the Cold Chain is second nature to pharmacists who provide patients with the temperature-sensitive products that they require. The spotlight has been turned on to this practice with the expanded scope authority for pharmacists, within the context of the UIIP, to administer flu vaccine. The new Policy provides clarity on College expectations in this area.

The policy:

1. Provides essential links to the rules for vaccine storage and handling that are required to be in place in order to participate in Ontario’s publicly funded influenza vaccine program.
2. Clarifies the role of the College inspector in assisting pharmacies to meet the accreditation requirements established in the Drug and Pharmacies Regulation Act.
3. Recommends the equipment necessary to ensure temperature-sensitive products are kept within the appropriate temperature ranges.
4. Outlines the generally accepted practices so that each pharmacy can draft their own policies and procedures.
5. Defines the range of temperatures that fall within the parameters of ‘cool’, ‘cold’ and ‘frozen’.
Protecting the Cold Chain

INTRODUCTION

The cold chain begins with the manufacturer and ends with the patient. Products that have not been handled according to the conditions set by the manufacturer are considered to be unsafe for use as quality and effectiveness may be compromised.

Safe temperature and humidity ranges for products vary according to the conditions required to ensure their continued quality. All temperature-sensitive pharmaceutical and biologic products are at risk of damage if handled improperly. The conditions for the transportation and storage of drug products by wholesalers are set by Health Canada through the Food and Drugs Act and Regulations and storage requirements for publicly funded vaccines are set by the Minister of Health and Long-Term Care according to the requirements set out in the Vaccine Storage and Handling Protocol under the Ontario Public Health Standards, published under the Health Protection and Promotion Act.1,2 The Drug and Pharmacies Regulation Act establishes accreditation requirements for pharmacies in Ontario.3

Note: In addition to these requirements, members storing and handling publicly funded vaccines must meet the Ontario standards specified in the Vaccine Storage and Handling Guidelines. Local public health units will work in collaboration with members to ensure adherence with these provincial policies.

PRINCIPLES

1. Members have an obligation to protect patient safety by ensuring that drugs and biological products requiring temperature protection are received, stored and dispensed according to the manufacturer’s specifications;

All staff members who are responsible for receiving, storing and dispensing products that require cold chain protection are encouraged to read this policy. The local hospital or public health unit is a good source for advice and best practices on how to maintain the cold chain. Additional tips on implementing cold chain protection can also be viewed in the Spring 2012 edition of Pharmacy Connection.

Over the next few months, the College will be developing additional guidance on how to support patients to maintain the cold chain once a product has been dispensed. A review of the pros and cons of purpose-built equipment will also be provided, along with the steps that may be taken when a cold chain breach occurs as there is no ‘once size fits all’ approach.
2. The requirements to protect temperature-sensitive drugs include taking steps to assist patients and their caregivers to protect drugs and biological products once they have been dispensed.

**DEFINITION**

"Cold Chain" A cold chain is a temperature, humidity, and light-controlled supply chain for products that require a specific temperature range during distribution and storage. Specifically, this refers to a supply chain that includes the handling, transportation, and storage of temperature-controlled drug substance or finished drug product.4

**POLICY**

Standard operating policies and procedures must be in place within the pharmacy to ensure that temperature-sensitive products are properly received, stored, and dispensed. These should be reviewed at least yearly and key staff members trained and monitored to ensure cold chain practices are followed.

The Role of the Designated Manager

The Designated Manager (DM) is responsible for ensuring that all drugs and biological products purchased by a pharmacy for use or sale are of an acceptable standard and quality.5 The DM is also accountable for ensuring that there are appropriate policies and procedures in place to manage the cold chain once the pharmacy takes custody of the product. Where there is a remote dispensing system operated by the pharmacy, the DM ensures that systems are in place to track the movement of drugs and other medications between and among the pharmacy and its remote dispensing locations. The DM must also ensure that all pharmacy staff members are trained on the protocols necessary to receive, store, and dispense products at the appropriate temperature when these activities are within their duties.

**Accreditation and the Cold Chain**

The accreditation provisions of the Drug and Pharmacies Regulation Act provide the College with the authority to inspect pharmacies and all pharmacies are inspected before opening and then generally once every three years to ensure they continue to meet accreditation standards. Inspections focus on the operational requirements of the pharmacy, to ensure that the operation is safe and the public is protected, and to assist members to comply with legislated requirements. Inspectors are also a resource for the pharmacy and can provide information and advice regarding the pharmacy’s operations.

An inspector will confirm that the refrigerator in the pharmacy meets the temperature requirements and that nothing other than drugs or medications requiring refrigeration are stored in the refrigerator. The inspector will also confirm that the contents are stored appropriately. Where the pharmacy operates a remote dispensing location, the inspector will confirm that the location has an alarm system that provides immediate notification to the DM of any alteration in the temperature of the location outside of the approved standards.

**Recommended Equipment**

- Commercial grade equipment is recommended; however, if a domestic refrigerator is used, a frost-free unit provides more uniform temperatures;
- A separate freezer, or a unit with a separate external freezer door;
- A digital automatic temperature recording and monitoring device that indicates minimum, maximum and current temperatures;
- A data logger (a battery-powered, stand-alone temperature monitor);
- A backup electricity supply;
- A 24/7 temperature alarm system; and
- Insulated containers to store and transport products along with gel/ice packs and packaging as required.
Recommended Cold Chain Practices

Temperature monitoring is critical to ensuring that products are stored within the recommended temperature range. Temperature variations outside of labeled storage conditions for brief periods may be acceptable; however, where a variation has occurred, it must be documented and checked against stability data for that particular substance in order to demonstrate that product quality has not been affected.

General Practices:
- The refrigerator must be well maintained and free from excessive frost build up. Frequent opening of the door can lead to temperature instability, so the door should be opened only when absolutely necessary.
- Very sensitive products should be kept in a separate refrigerator and consideration should be given to storing vaccines separately.
- No vaccines or medications should be stored on the door.

Receiving:
- Protect deliveries from poor weather during unloading and examine containers to ensure there is no damage.
- Follow internal standards of practice (SOPs) for good cold chain receiving:
  - Ensure that temperature-controlled drug products received by or distributed from the pharmacy are suitably packaged in containers that maintain an appropriate environment during extreme weather conditions;
  - Examine delivery documents to ensure product was not subjected to distribution delay;
- Identify products that should not be stored at room temperature on receipt;
- Document information about ordered products that were unusable because they were exposed to temperatures outside the recommended range.
- Transfer the contents of a shipment promptly to the appropriate, environmentally controlled storage area.

Storage:
- Follow internal SOPs for good cold chain storage:
  - Identify products to be stored in a frozen state or those within a specific temperature range;
  - Check freezer sections for drugs that should not be frozen;
  - Check refrigerator and other locations for inappropriately stored drugs;
  - Examine delivery documents to ensure product was not subjected to distribution delay;
  - Ensure products stored temporarily at higher temperature are returned to recommended condition as soon as possible;
  - Document information about ordered products that were unusable because they were exposed to temperatures outside the recommended range.

Cool vs. Cold: What’s the Difference? 11, 12

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>INTERNATIONAL STORAGE AND SHIPPING REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen</td>
<td>Maintained in a place where the temperature is between -10°C and -25°C</td>
</tr>
<tr>
<td>Cold</td>
<td>Any temperature not exceeding +8°C (in Ontario a pharmacy is required to have a refrigerator with a temperature between +2°C to +8°C)</td>
</tr>
<tr>
<td>Cool</td>
<td>Any temperature between +8°C and +15°C</td>
</tr>
<tr>
<td>Controlled Room Temperature</td>
<td>Thermostatically controlled temperature of +20°C to +25°C</td>
</tr>
<tr>
<td>Room temperature</td>
<td>Temperature prevailing in a working area; not thermostatically controlled</td>
</tr>
<tr>
<td>Warm</td>
<td>Any temperature between +30°C and +40°C</td>
</tr>
<tr>
<td>Excessive heat</td>
<td>Any temperature above +40°C</td>
</tr>
</tbody>
</table>
o Store drugs in a manner that does not block air flow within refrigerator;
o Ensure that drug storage refrigerators are dedicated to drugs; and
o Establish schedule to check expiration date and rotation of temperature controlled products.7

Dispensing:
• Educate patients regarding the cold chain and appropriate storage and use of medications:
o Identify temperature-controlled drugs and methods for proper handling and storage in the home and workplace and while traveling;
o Provide written instructions if necessary;
o Instruct patients to avoid unintended exposure of drugs to abnormal temperatures, and
o Instruct patients to avoid exposure and storage in high humidity environments (e.g. bathroom).
• Ensure that the pharmaceutical packaging for home delivery meets the specifications required for the product.8

Vaccines
It is critical to maintain cold chain protection for vaccines, if vaccines are stored or administered at temperatures that are too high or too low, the patient may be inadequately protected or harmed.9 Protection from light and humidity is also a necessary condition for some vaccines. Any loss of vaccine potency is permanent and irreversible. For frozen vaccines the optimum temperature is -15°C or lower and there may be additional restrictions on their use. For example, the Zostavax® vaccine must be maintained at a temperature of -15°C or colder and, once it is reconstituted, must be used within 30 minutes.10

REFERENCES
2. Ontario Ministry of Health and Long-Term Care. Vaccine Storage and Handling Guidelines.
4. Ziance, R. Chandler, C. and Bishara, R. Integration of temperature-controlled requirements into pharmacy practice. Pharmacy Today
5. Ontario College of Pharmacists. Medication Procurement and Inventory Management
6. Ziance, R. Chandler, C. and Bishara, R Integration of temperature-controlled requirements into pharmacy practice. Pharmacy Today
7. Ibid, p. 38
8. Ibid, p. 39
INTRODUCTION

A patient record is the complete account of a patient’s care, comprising personal health information collected or generated by the pharmacy in any form or medium. The patient record includes the patient profile; patient and provider identifying information; data collected; assessment; notes documenting critical thinking and judgement, recommendations, interventions and discussions between members, other health care providers and patients; and prescriptions, records and reports that pertain to the patient’s care. All records and documents generated by members, and through the operation of the pharmacy, must be kept according to the standards of practice, code of ethics, and as required by legislation and regulation.

As a health information custodian, a pharmacy’s record keeping obligations are outlined in multiple acts and regulations. This guideline pertains specifically to the requirements established in the Personal Health Information Protection Act, 2004 (PHIPA), which governs personal health information in the custody and control of health information custodians and their agents. According to the Act, an agent means a person that acts for or on behalf of a health information custodian in respect of the collection,
use, disclosure, retention, or disposal of personal health information. Health information custodians are responsible for the actions of their agents, and should therefore ensure that their agents comply with all of the obligations imposed on the custodian. In the case of a pharmacy, this obligation is shared with the designated manager as outlined in the Drug and Pharmacies Regulation Act, 1990.

**PRINCIPLES**

1. In return for care, patients provide health professionals with personal health information which must be protected from theft, loss and unauthorized use or disclosure;
2. The records and information generated and managed by the pharmacy are both authentic and reliable;
3. The record keeping system ensures that personal health information is protected against theft, loss, and unauthorized use or disclosure;
4. Records are kept in a manner that ensures timely, efficient, and accurate retrieval;
5. Records are retained for the time periods set out in law; and
6. Pharmacies dispose of records securely.

**WHAT IS IN THE RECORD RETENTION, DISCLOSURE**

The guideline outlines the pharmacy’s obligations to create patient records, to keep personal health information safe, and to transfer, store and dispose of records securely. These obligations are established in a number of different laws and regulations, including the Personal Health Information Act and the Drug and Pharmacies Regulation Act. The advent of the expanded scope of practice underlines the importance of ensuring these obligations are understood by members of the College.

The guideline:
1. Describes what a patient record is and what the pharmacy, as the health information custodian, is required to do to meet the record-keeping requirements established in legislation.
2. Establishes principles for the care and keeping of personal health information as required by the Personal Health Information Protection Act.
3. Outlines the rules about patient consent for the collection, use and disclosure of personal health information and links to important resources that can assist the member to work with patients and other health providers providing care.
4. Describes the type of safeguards that need to be in place to protect patient confidentiality and privacy, including physical, administrative and technical safeguards such as encryption where warranted.
GUIDELINE

As health information custodians, pharmacies are required to: 1) collect, use and disclose personal health information according to the rules established by PHIPA; 2) implement physical, administrative, and technical safeguards to protect personal health information; 3) respond to requests to access or correct personal health information and; 4) maintain transparent practices. The pharmacy must protect the confidentiality of personal health information, including with respect to information generated in a remote dispensing location, if any. A pharmacy is required to make and maintain a scanned electronic copy of every written prescription where a drug is dispensed, and of the dispensing information recorded on the prescription. Any records that are not stored in a computer system must be legible, made using non-erasable ink, readily retrievable and stored in an appropriate manner to provide reasonable protection from damage.

Consent to the Collection, Use and Disclosure of Personal Health Information

Pharmacies must obtain individual consent for the collection, use, and disclosure of personal health

AND DISPOSAL GUIDELINE?

5. Includes the actions a pharmacy must take when an individual requests access to his or her personal health information.
6. Contains a section on the responsibility of the pharmacy for transferring health records in the event of a sale.
7. Reiterates the time lines for record retention that were established by the regulation to the Drug and Pharmacies Regulation Act in March 2011.
8. Provides an overview of what needs to happen when a pharmacy disposes of records.
9. Includes lots of links to resources associated with record keeping requirements particularly to those provided by the Information and Privacy Commissioner.
10. Contains appendices with greater detail on important issues like the circle of care, agents appointed by health information custodians and their obligations and selected topics related to access, correction and restriction on the disclosure of patient information.

Information regarding scanning requirements can be found by visiting the College website, www.ocpinfo.com, and doing a search using the terms ‘Scanning Technology’.
information. Consent must satisfy the following conditions: it must be the consent of the individual; it must be knowledgeable; it must relate to the personal health information; and it must not be obtained through deception or coercion. Consent may be express or implied, unless PHIPA stipulates that express consent be obtained; for example, if a custodian makes the disclosure to a person that is outside of the ‘Circle of Care’, express consent is generally required. When a patient presents a prescription to be filled, a pharmacy can rely on his or her implied consent to fill that prescription and for the purposes of providing healthcare to that patient. (See Appendix 1 for more information on consent and the circle of care).

An individual may withdraw their consent at any time by providing oral or written notice of withdrawal to the pharmacy. The withdrawal is not retroactive and would not impact information that has already been disclosed to other custodians.

Security of Personal Health Information

Pharmacies are accountable for taking reasonable steps to protect personal health information and to keep it secure. This obligation extends to employees, as well as to agents and service providers, including accountants, lawyers, and records management services who act on behalf of the pharmacy. (See Appendix 2 for additional detail on agents and their obligations).

All records are to be maintained in a manner that protects patient confidentiality and privacy through the use of physical, administrative, and technical safeguards.

Physical Safeguards: physical restrictions, including controlling access to areas where records are stored and taking steps to protect records from fire, flooding, and other hazards.

Administrative Safeguards: the maintenance of security protocols such as the development of policies and procedures, training staff on their obligations, and executing written confidentiality agreements with staff and other agents. Pharmacies must inform agents of their responsibilities under PHIPA.

Technical Safeguards: including the implementation of password protection, firewalls, and back-up and recovery systems to protect information maintained in an electronic format, and maintaining a copy of a digital back-up off-site or in a fire-proof or theft-resistant safe.

At times it may be necessary to keep personal health information on a mobile device to support the delivery of care outside the workplace. In these cases only the minimum necessary data should be transported and the pharmacy must ensure that the information is encrypted in order to safeguard it against theft, loss or unauthorized use or disclosure, and to ensure the records are protected against unauthorized copying, modification or disposal. Unless the pharmacy has access to a secure e-mail service offering strong encryption, the use of e-mail to communicate personal health information should be avoided.

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.

Access and Correction of Personal Health Information

The pharmacy will support and enable individual access to personal health information, subject to the requirements of PHIPA. Subject to the limitations discussed below and set out in PHIPA, if an individual submits a written request for access to his or her personal health information, the pharmacy has 30 days to consider the request, conduct a reasonable search for records that are responsive to the request, and provide a written response to the requesting individual. In responding, the pharmacy must either:

(a) Make the record (or a copy of the record) available to the individual, and, if reasonably practical, an explanation of any term, code or abbreviation used in the record, or
(b) Indicate that no record exists, provided that, if a responsive record is later found, the pharmacy must inform the patient that a record was located; or

c) Indicate that access is denied either in whole or in part, provided that the denial is pursuant to a specific section of PHIPA, and the response explains the reason for the denial of access along with information about making a complaint to the Information and Privacy Commissioner.

An individual may also request a correction to his or her personal health information if he or she believes that a record is inaccurate or incomplete. The individual must demonstrate that the record is incomplete or inaccurate and he or she must provide the information necessary to correct the record.

(More detail on access and correction of personal health information is included at Appendix 3.)

Transferring Health Records in the Event of a Sale

Pharmacies remain responsible for records of personal health information until complete custody and control of these records is transferred to another legally authorized person. This means that when a store is sold, the pharmacy remains responsible for the secure retention, transfer and disposal of records until custody and control of those records is transferred to the purchaser. Pharmacies are encouraged to review their obligations in the event of a change in practice that impacts personal health information.

Patients must continue to be able to access their personal health information in the event of a transfer of records. Pharmacies are required to take reasonable efforts to give notice to the individuals to whom the records relate before transferring the records or, if that is not reasonably possible, as soon as possible thereafter. If it is not reasonable to contact each individual, multiple means of providing notice should be adopted including placing a notice on the pharmacy’s website, leaving a message at the pharmacy’s telephone number, and/or posting a notice where members of the public can readily view it.

Secure Storage/Transfer of Health Records in the Event of Permanent Store Closure

In the event of a permanent store closure, the pharmacy retains all obligations with respect to health information until responsibility is transferred to another legally authorized person. Patients must continue to have access to their records and the pharmacy must make appropriate arrangements for the secure retention or transfer of patient records. The member must notify the Ontario College Pharmacists of the disposition of the records.

Record Retention: Time Frames

The pharmacy will ensure that appropriate record retention schedules are in place:

- The entire patient record must be retained as a whole.
- Scanned electronic copies must be created through scanning an original document with software that does not permit the data in the resulting electronic document to be edited or extracted.
- All original prescriber generated prescriptions will be readily retrievable for a period of at least two years.
- All records and documents relating to the care of a patient, other than original written prescriptions, shall be maintained for a period of at least 10 years from the last recorded professional pharmacy service provided to the patient, or until 10 years after the day on which the patient reached, or would have reached, the age of 18 years, whichever is longer.

The pharmacy must retain records for longer than the general retention period if a request for access to personal health information has been received until such time as the record may no longer be required to respond to that request for access. (Legislative excerpts of the Drug and Pharmacies Regulation Act and Regulation that address record retention time frames are included at Appendix 4.)
Disposal of Records

The pharmacy should ensure that records marked for disposal are physically segregated from other records in a secure area, and clearly marked for disposal. In the event that a third party is engaged to dispose of records, the pharmacy must transfer the records securely and document the transfer. A third party retained by the pharmacy to dispose of records is an agent of the pharmacy and the pharmacy must ensure that the agent complies with PHIPA. It is recommended that the pharmacy enters into a written contract with the third party that specifies roles and responsibilities to ensure that all parties fully understand their respective roles and responsibilities.

APPENDIX 1: CONSENT AND THE CIRCLE OF CARE

The information in this appendix is based upon a publication of the Information and Privacy Commissioner “Circle of Care: Sharing Personal Health Information for Health-Care Purposes”.

Express consent from the individual or their substitute decision-maker, if any, is required to disclose personal health information to a person who is not a health information custodian, or when the disclosure to another health information custodian is not for the purposes of providing health care or assisting in providing health care. In circumstances where express consent is required, all the elements of consent must be fulfilled: it must be a consent of the individual, or their substitute decision maker, if any; it must be knowledgeable; it must relate to the personal health information, and it must not be obtained through deception or coercion.

Implied consent is a form of consent which is not expressly granted by a person, but rather inferred from a person’s actions and the facts and circumstances of a particular situation (or in some cases, by a person’s silence or inaction).

The term ‘circle of care’ is not defined in law; however, it is a term used to describe the ability of health information custodians, including pharmacies, to assume an individual’s implied consent to collect, use and disclose personal health information for the purpose of providing health care in circumstances defined by the PHIPA.

All of the following conditions must be met in order to assume implied consent within the circle of care:

• The health information custodian must fall within a category of health information custodians that are entitled to rely on assumed implied consent;
• The personal health information to be collected, used or disclosed by the pharmacy must have been received from the individual, his or her substitute decision-maker or another health information custodian;
• The pharmacy must have received the personal health information that is being collected, used or disclosed for the purpose of providing or assisting in the provision of health care to the individual;
• The purpose of the collection use or disclosure of personal health information by the pharmacy must be for the provision of health care or assisting in the provision of health care to the individual;
• In the context of the disclosure, the disclosure of personal health information by the pharmacy must be to another health information custodian; and
• The health information custodian that receives the personal health information must not be aware that the individual has expressly withheld or withdrawn his or her consent to the collection, use or disclosure.

APPENDIX 2: AGENTS AND THEIR OBLIGATIONS

An agent of a health information custodian is anyone who is authorized to do anything on behalf of the custodian with respect to personal health information. A person can be an agent of a health information
custodian whether or not they are being paid, whether or not they are employed by the health information custodian or whether or not they have the power to enter into agreements on behalf of the health information custodian. Agents of a health information custodian include, for example, employees, persons contracted to provide services where the person has access to personal health information such as copying or shredding services or records management services and volunteers or students who have any access to personal health information.

An agent may collect, use, disclose, retain, or dispose of personal health information as permitted by the health information custodian or as permitted in the regulations under PHIPA.

A health information custodian may permit its agents to collect, use, disclose, retain, or dispose of personal health information on the custodian’s behalf only if:

- The custodian is authorized by PHIPA to handle the personal health information, and
- The collection, use, disclosure, retention or disposition of the personal health information is in the course of the agent’s duties.

If another law permits or requires the agent to collect, use, disclose, retain or dispose of personal health information, the agent does not need the authorization of the custodian. An example is where the agent is an employee who is a health practitioner and who is required to make a report under the provisions of another Act, such as the Child and Family Services Act.

APPENDIX 3: ACCESS, CORRECTION, AND RESTRICTIONS ON THE DISCLOSURE OF PERSONAL HEALTH INFORMATION

Access

Generally speaking, all information in a record must be released to a patient upon request.

A request for access to health information can be made informally or formally. A health information custodian can communicate with a requester and provide access to requested personal health information even when the individual does not make a formal access request, and can also communicate with the individual’s authorized substitute decision-maker about a record if the individual has a right of access to the record.

A formal request is one that is made in writing. The request must contain sufficient detail to enable the custodian to identify and locate the record with reasonable efforts. If the request is not sufficiently detailed, the health information custodian must offer assistance to the requester in reformulating the request. A formal access request triggers the time frames in the act and the rights of complaint and appeal.

Correction

If the health information custodian refuses to correct the record, the reasons for the refusal must be provided to the requester. The custodian must inform the requester of their right to prepare a statement of disagreement setting out the correction the health information custodian refused to make, and that the requester can require the custodian to attach the statement to the records and disclose it along with the personal health information related to the disagreement.

Restriction

The individual has the authority to restrict disclosures of their personal health information including:

- A particular item of information (i.e. a diagnosis);
- The entire record;
- A particular health information custodian, agent of a health information custodian, or class of custodians or agents; or
- A direction that a particular health information custodian, agent or class of custodians or agents cannot use their personal health information.
Where an individual wishes to restrict the disclosure of information, or give conditional consent, their instructions should be set out in writing.

APPENDIX 4: LEGISLATIVE EXCERPTS - RECORD RETENTION

DRUG AND PHARMACIES REGULATION ACT

Records of pharmacy

153. The designated manager of every pharmacy shall keep or cause to be kept a record of every purchase and sale of a drug referred to in the Schedules to the Controlled Drugs and Substances Act (Canada) or the Schedule to the Narcotic Control Regulations (Canada) in such form or manner as the regulations may prescribe. 2007, c. 10, Sched. L, s. 17.

Prescription information

156. (1) Every person who dispenses a drug pursuant to a prescription shall ensure that the following information is recorded on the prescription,

(a) the name and address of the person for whom the drug is prescribed;
(b) the name, strength (where applicable) and quantity of the prescribed drug;
(c) the directions for use, as prescribed;
(d) the name and address of the prescriber;
(e) the identity of the manufacturer of the drug dispensed;
(f) an identification number or other designation;
(g) the signature of the person dispensing the drug and, where different, also the signature of the person receiving a verbal prescription;
(h) the date on which the drug is dispensed;
(i) the price charged. R.S.O. 1990, c. H.4, s. 156 (1).

Retention of records

(2) The records required under subsection (1) shall be retained for not less than two years. R.S.O. 1990, c. H.4, s. 156 (2);

ONTARIO REGULATION 58/11

GENERAL

PART X - RECORDKEEPING

Recordkeeping

54. (1) A pharmacy shall,

(a) maintain the records and documents required under the Act and its regulations, in the required manner;
(b) maintain the records and documents required to be made by members under the Pharmacy Act, 1991 and its regulations and to meet the standards of practice of the profession, in the required manner;
(c) maintain the records and documents required to be made by the pharmacy or members practising at the pharmacy under any federal legislation governing the purchase or sale of drugs in the required manner;
(d) make and maintain a scanned electronic copy of every original written prescription pursuant to which a drug is dispensed as well as a copy of the information required by subsection 156 (1) of the Act and retain those copies as part of the patient record;
(e) make the original prescriptions and other records referred to in clause (a), (b), (c) or (d) available for inspection by an inspector of the College; and
(f) assist the inspector to make or obtain copies of any records or documents referred to in clause (a), (b), (c) or (d), if requested by the inspector. O. Reg. 58/11, s. 54 (1).

(2) The requirements of clause (1) (d) do not apply to a pharmacy until May 11, 2012, if a certificate of accreditation was issued in respect of the pharmacy before
that clause came into force. O. Reg. 58/11, s. 54 (2).

(3) A pharmacy shall maintain the records and documents referred to in subsection (1) in a computer system where possible and, where that is not possible, shall maintain them in a systematic manner that allows for their easy retrieval. O. Reg. 58/11, s. 54 (3).

Length of retention

55. (1) Subject to subsection (3), records and other documents relating to the care of a patient, other than original written prescriptions, shall be maintained for a period of at least 10 years from the last recorded professional pharmacy service provided to the patient or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer. O. Reg. 58/11, s. 55 (1).

(2) All prescription records required to be maintained by the Act shall be maintained for the period specified in the Act or if no period is specified in the Act, for the period set out in subsection (1). O. Reg. 58/11, s. 55 (2).

(3) While an audit or inspection is being performed by or on behalf of the College in respect of the pharmacy or in respect of a member who is practising at the pharmacy, no record or document shall be destroyed until the audit or inspection is completed, except with the written approval of the Registrar. O. Reg. 58/11, s. 55 (3).

REFERENCES

1. Drug and Pharmacies Regulation Act, General O Reg 58/11 s54(1)(d)
2. Drug and Pharmacies Regulation Act RSO 1990, c H.4, s156(1)
3. Implied consent is a form of consent which is not expressly granted by a person, but rather inferred from a person’s actions and the facts and circumstances of a particular situation (or in some cases, by a person’s silence or inaction)
4. Circle of Care is a term commonly used to describe the ability of certain health information custodians to assume an individual’s implied consent to collect, use or disclose personal health information for the purpose of providing health care, in circumstances defined in PHIPA. More information on the term and guidance on access to patient information, is outlined in the document created by Ontario’s Information and Privacy Commissioner: Circle of Care: Sharing Personal Health Information for Health-Care Purposes
5. Information and Privacy Commissioner: Fact Sheet 1: Safeguarding Personal Health Information
6. Information and Privacy Commissioner: Fact Sheet 12: Encrypting Personal Health Information on Mobile Devices
7. Cavoukian, A. & Rossos, P., Personal Health Information: A Practical Tool for Physicians Transitioning from Paper-Based Records to Electronic Health Records
8. Information and Privacy Commissioner: Fact Sheet: Health-Care Requirement for Strong Encryption
10. Information and Privacy Commissioner: Personal Health Information Protection Act REPORT, FILE NO. HR 10 -18, p6
12. Information and Privacy Commissioner: Checklist for Health Information Custodians in the Event of a Planned or Unforeseen Change in Practice
14. For sample contractual clauses, please refer to the document Get rid of it Securely to keep it Private: Best Practices for the Secure Destruction of Personal Health Information
15. Information and Privacy Commissioner: Circular: How to Avoid Abandoned Records: Guidelines on the Treatment of Personal Health Information, in the Event of a Change in Practice
17. Ibid. p. 11
18. Ministry of Health and Long-Term Care: Personal Health Information Protection Act, 2004: An Overview for Health Information Custodians, p.27 August 2004
19. Information and Privacy Commissioner: Lock-box Fact Sheet. 2005
A prescription for a patient who had been discharged from hospital was received by fax at a community pharmacy (Figure 1).

Heparin was dispensed, and the patient received 2 doses. When the hospital sent a request to the pharmacy to provide syringes and alcohol swabs for the duration of the “dalteparin” therapy, the community pharmacy recognized that an error had occurred. Further investigation revealed that the hospital had in fact sent a prescription for “dalteparin 15 000 U” (see Figure 2), but during fax transmission, the first 2 letters of the drug name, “da”, were cut off, which resulted in the appearance shown in Figure 1. The hospital’s fax transmission log indicated that the fax had been sent correctly, giving no indication of any problem.

The following are some recommendations to help minimize transmission errors when prescriptions are sent electronically (e.g., by fax):

- Educate all users about potential errors that can occur with faxes, scanners, and other technology and how to identify such errors.
- Review all transmitted prescriptions for quality issues (e.g., truncation of a prescription header, extraneous marks in the prescription area), in addition to legibility of the prescription itself. In this case, the names of the prescriber and of the hospital, which appeared in the upper left-hand corner of the original prescription, were cut off during receipt of the faxed prescription.
- When sending a prescription by electronic means, ensure the presence of suitable margins, and avoid writing in the margin or borders of prescriptions.
- Whenever possible, include both the generic and brand names of the intended medication, to provide an additional opportunity for verification. For example, integrate this information into computerized prescribing systems.
- Avoid using dangerous abbreviations (e.g., U for units).
- If using a fax machine or scanner, ensure that only original prescriptions are transmitted or scanned; do not transmit NCR (i.e., no-carbon-required) copies of prescriptions.
- Implement a process to establish when a prescription has been scanned (e.g., use a “Faxed” stamp, with time and date of transmission).
- Schedule regular maintenance and cleaning of fax machines and other equipment to ensure optimal transmission of medication-related information.
- Engage and educate patients.
throughout the medication-use process, especially at transition points (e.g., discharge). Provide patients with a list of their medications, including dose, frequency, and other information. Patients can and do identify discrepancies and errors and are in an ideal position to improve the safe use of their medications.

- Whenever possible, provide patients with a copy of any electronically transmitted prescriptions (clearly distinguished from the original) to give to the community pharmacist, as an additional opportunity for verification during dispensing.

- As another way of identifying potential errors, always consider the appropriateness of various aspects of the prescription in relation to the specified drug dosing (e.g., dose, frequency, route, indication). In the case described above, for example, unfractionated heparin for subcutaneous administration is to be given every 8 or 12 hours.

### REFERENCES


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**BEWARE OF MIX-UPS BETWEEN CYCLOSPORINE AND CYCLOPHOSPHAMIDE**

SafeMedicationUse.ca has received a report from a consumer who identified a potentially harmful mix-up between cycloSPORINE and cyclophosphamide. The consumer was discharged from hospital with a prescription for cyclophosphamide for the treatment of an autoimmune disease, but cycloSPORINE was dispensed in error by a community pharmacy. Fortunately, the consumer recognized the mistake and did not take the cycloSPORINE. It appears that thorough education about new medications before discharge from hospital was a factor in allowing the consumer to identify this incident.


A previous mix-up between cycloSPORINE and cyclophosphamide was described by the Institute for Safe Medication Practices in the United States. An in error by a community pharmacy. Fortunately, the consumer recognized the mistake and did not take the cycloSPORINE. It appears that thorough education about new medications before discharge from hospital was a factor in allowing the consumer to identify this incident.


In 2010, a Canada-wide survey of oncology practitioners was conducted as part of a joint initiative on TALLman lettering of drugs used in oncology. As a result of the survey, cycloSPORINE and cyclophosphamide were recognized as a drug name pair with the potential to cause harm. CycloSPORINE is now included on the list of TALLman lettering for look-alike/sound-alike drug names in oncology developed and recommended by ISMP Canada and the Canadian Association of Provincial Cancer Agencies. Use of TALLman lettering (for example, within pharmacy information systems and on storage bins within pharmacies, including community pharmacies) could help to prevent incidents due to drug name mix-ups.

This near-miss report also highlights the role that consumers can play in preventing harmful medication incidents. Healthcare practitioners are reminded of the importance of providing patients with the necessary information and education to support this role.

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**REFERENCES**

Recommendations for Prevention of Narcotic Medication Errors

**INTRODUCTION**

The Patient Safety and Review Committee (PSRC) assists the Office of the Chief Coroner in the investigation, review and development of recommendations towards the prevention of future deaths relating to healthcare-related cases where systems-based errors appear to be a major factor. The Committee also assists coroners in improving the investigation of deaths within, or arising from, the healthcare system in which system based errors appear to have occurred.

A relatively recent case concerned a dispensing error of slow release morphine (Sandoz M-Eslon) resulting in an overdose of the drug in a palliative cancer patient. This was brought to the College’s attention in a report from the Office of the Chief Coroner. Consequently, the PSRC has made recommendations for OCP and other colleges to implement in order to address issues related to narcotic medication errors.

**EDITOR’S NOTE:** Below is a summary of the case and recommendations for pharmacists and pharmacy technicians to be aware of in order to prevent similar errors in the future.

**CASE**

**DATE OF DEATH**
August 18, 2010, 1800-1900 hours

**AGE**
82 years

**PATIENT OVERVIEW**
Patient undergoing treatment for advanced breast cancer. One week prior to death, assessed and prescribed medications including M-Eslon for pain. Moved from hospital to a palliative care home one day prior to death.

**AUGUST 11, 2010**
Patient’s condition deteriorated, as noted by her daughter who notified the oncologist that she was “considerably weaker.”

**AUGUST 12, 2010**
Patient referred to home palliative care service. Palliative Performance Scale (PPS) score was observed to be 60% with a prognosis of death in approximately three months.

**AUGUST 13, 2010**
Patient assessed by palliative care nurse.

**AUGUST 17, 2010**
Patient referred to palliative care physician for “severe pain and deterioration” and a PPS score of 30%. Patient bedbound, and sleeping twenty hours a day. End of life (EoL) goals reported as patient “wants to die.” Orders include do not resuscitate (“DNR”), “NO” transfer to hospital, and patient to receive comfort care only.
Patient to receive M-Eslon 10mg orally every twelve hours (60) with morphine solution 5mg/mL- ½ - 1mL administered every two hours as needed. Flagyl cream topically bid for breast lesions, increased nursing care (to daily) and personal support worker (PSW) hours.

AUGUST 18, 2010
~1715 HOURS
Daughter who was with patient, reported her to be non-responsive and exhibiting a rattling respiratory rate. Following consultation, physician suggested emergency admission to treat potentially reversible condition. The patient’s daughter declined.

~1800 HOURS
The physician reassessment noted condition unchanged and that blood sugar was approximately 16.9 (very high).

1942-2041 HOURS
Physician informed of patient’s death and went to home to declare death. Physician noted discrepancy between 10mg of M-Eslon prescribed and 100mg found at home of patient and given to patient at 1030 hours. Noted that patient was entering actively dying phase prior to administration.

POST-MORTEM FINDINGS
Post Mortem Toxicology (femoral Blood):
• Morphine: 160ng/mL
• Codeine: < 0.50 mg/L

The pathologist noted that these levels are consistent with end of life care; the morphine is lower than the concentration seen in fatalities and the codeine is within the therapeutic index.

DISCUSSION
Though it was found that the levels of morphine and codeine are consistent with end of life care, it should be noted that the patient’s previous narcotic consumption was minimal with only small amounts of Tylenol #2 and Tylenol #3 administered. It was also noted that the patient’s levels of morphine and codeine were therapeutically valid and “consistent with end of life care.”

However, because the patient was relatively opiate naïve, she had little tolerance to the effects of morphine. This fact is more important than the patient’s actual blood levels. According to the CPS, the potency 100mg of morphine is roughly equivalent to eleven times 60mg of codeine, the equivalent dose of two Tylenol #3 tablets. In this context, the 100mg dose and the patient’s blood levels are very high and constitute an inadvertent overdose. It is improbable that this overdose caused the patient’s death but likely that it contributed to it.

It is therefore important to consider the cause of the medication error and the resulting overdose. A cause suggested by the coroner is a misinterpretation of the dose on the handwritten prescription as 100mg instead of 10mg. On examination of the prescription, this could be true.

However, there are several red flags that indicate that the prescription for M-Eslon 100mg should not have been dispensed and the prescription should have raised major concerns for the dispensing pharmacist. Firstly, as the patient was relatively opiate naïve as seen in the pharmacy records, the prescribed amount represented a steep increase in dose to 100mg of morphine. Secondly, the dosing schedule of M-Eslon of 100mg every twelve hours does not correspond with the “as needed” (PRN) dose of the morphine solution. The combination of these factors should have prompted the dispensing pharmacist to clarify the dose on the prescription with the prescribing physician.

Members are reminded of the criticality of reviewing a patient’s medication history to ensure the appropriateness of the medication and dose before dispensing new narcotic medications as per standards. It is also recommended that high alert medications such as narcotics are given an additional review prior to dispensing as well as an independent check.
Pharmacists must be aware of the potential for product selection errors due to the availability of more than one concentration or strength of some non-prescription products. Similarity in product appearance can also increase the potential for error as the following cases demonstrate.

**CASE 1**

The father of a five year old child approached a pharmacy assistant at the dispensary counter and requested a bottle of Kwellada® for the treatment of head lice. In error, the pharmacy assistant selected a bottle of Kwellada®-P Lotion which is indicated for the treatment of scabies instead of Kwellada®-P Crème Rinse which is indicated for the treatment of head lice. The incorrect product was given to the parent and the pharmacist summoned for counseling. Upon seeing the bottle of Kwellada®-P Lotion, the pharmacist began to counsel the father on the use of Kwellada®-P Lotion for the treatment of scabies. Surprised at the pharmacist’s statements, the father exclaimed “my child does not have scabies!” The pharmacist apologized and provided the correct product and information.

### POSSIBLE CONTRIBUTING FACTORS:

- The pharmacy assistant selected the incorrect product and may have been unaware of the differences between the two products.
- The pharmacist did not take the time to gather the necessary information before providing information.
- The two products are similar in appearance and are stored next to each other. (See photograph).

**CASE 2**

A seven year old child was taken to a walk in clinic for treatment of an allergic skin reaction. The physician provided a written note to the child’s mother with the instructions to give one teaspoonful of “Benadryl®” every four to six hours. The mother went to the local
pharmacy and bought a bottle of Children’s Liquid Benadryl® which contains 6.25mg diphenhydramine hydrochloride per five milliliters. The child was given one teaspoonful per dose as recommended by the physician.

A few days later on returning to the pharmacy to purchase a second bottle, the mother noticed that there were two different strengths of Benadryl® oral liquid available and questioned the pharmacist regarding the appropriate product selection and dosage. On investigation, the pharmacist confirmed that the physician had intended that the child be given 12.5mg diphenhydramine hydrochloride or five milliliters of the Benadryl® Elixir. The child had therefore received only half of the intended dosage.

POSSIBLE CONTRIBUTING FACTORS:

- The parent was unaware that Benadryl® oral liquid was available in two different strengths.
- The two products are similar in appearance. (See photograph).
- The packaging of both products include dosing instructions for a seven year old child.

RECOMMENDATIONS:

- Educate all pharmacy team members of the potential for error when selecting these and other similar products.
- The pharmacist must gather all the necessary information including the identity and age of the patient before providing information.
- Always double check pediatric dosages for appropriateness.

Please continue to send reports of medication errors in confidence to Ian Stewart at: ian.stewart2@rogers.com.
CONTINUING EDUCATION

Visit the College’s website: www.ocpinfo.com for a complete listing of upcoming events and/or available resources. A number of the programs may also be suitable for pharmacy technicians.

For local live CE events in your area, contact your regional CE coordinator by going to www.ocpinfo.com and searching on “Regional Coordinators”.

GTA AND REGIONS

Introductory Psychopharmacology for Clinicians
February 23 – 24, 2013,
April 20 - 21, 2013
Leslie Dan Faculty of Pharmacy, University of Toronto
http://www.pharmacy.utoronto.ca/cpd/psychopharmacology/registration
To register, contact Ryan Keay at 416-978-7562

Psychiatric Patient Care Program
November 30 – December 2, 2012
Ontario Pharmacists Association
http://www.opatoday.com/
Contact: education@dirc.ca

Tobacco Interventions for Patients with Mental Health and/or Addictive Diseases
February 28 – March 1, 2013
TEACH Specialty Course
Contact: teach@camh.net

Immunizations and Injections Training Courses
Various dates and locations – contact course providers
Ontario Pharmacists Association
http://www.opatoday.com/
RxBriefcase, CPS and PHAC
Pear Health
University of Toronto
http://www.pharmacy.utoronto.ca/cpd

ON-LINE/ WEBINARS/ BLENDED CE

Canadian Pharmacists Association
Home Study Online education programs accredited by the Canadian Council on Continuing Education in Pharmacy (CCCEP), including the ADAPT Patient Skills Development certificate program, Diabetes Strategy for Pharmacists, Micronutrients, QUIT: Quit Using & Inhaling Tobacco and Respiratory care
http://www.pharmacists.ca/index.cfm/education-practice-resources/professional-development/adapt/

Canadian Society of Hospital Pharmacists (CSHP)
Online education program accredited by CCCEP
www.cshp.ca

Canadian Healthcare Network
On-line CE Lessons
www.canadianhealthcarenetwork.ca

Centre for Addiction and Mental Health (CAMH)
On-line courses with live workshops in subjects including mental health, safe and effective use of opioids, opioid dependence treatment core course (with additional elective courses), motivational interviewing, interactions between psychiatric medications and substances of abuse.

Clinical Tobacco Interventions for Health Care Professionals
Online CE
www.opacti.org

Communimed
A Practical Guide to Successful Therapeutic Drug Monitoring and Management (TDM & M) in Community Pharmacy: Focus on Levothyroxine
www.tdm-levothyroxine.ca

Visit the College’s website: www.ocpinfo.com for a complete listing of upcoming events and/or available resources. A number of the programs may also be suitable for pharmacy technicians.

For local live CE events in your area, contact your regional CE coordinator by going to www.ocpinfo.com and searching on “Regional Coordinators”.

GTA AND REGIONS

Introductory Psychopharmacology for Clinicians
February 23 – 24, 2013,
April 20 - 21, 2013
Leslie Dan Faculty of Pharmacy, University of Toronto
http://www.pharmacy.utoronto.ca/cpd/psychopharmacology/registration
To register, contact Ryan Keay at 416-978-7562

Psychiatric Patient Care Program
November 30 – December 2, 2012
Ontario Pharmacists Association
http://www.opatoday.com/
Contact: education@dirc.ca

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www.tdm-levothyroxine.ca
Interested in expanding your network and giving back to the profession?

OCP is looking for regional CE coordinators

OCP is looking for regional CE coordinators in regions 4 (Pembroke and area), 9 (Lindsay area), 10 (North Bay area), 25 (Sault Ste. Marie area), 27 (Timmins area). See complete list of CE regions by town/city on our the College’s website at www.ocpinfo.com.

As a Regional CE Coordinator, you will help identify CE needs of local pharmacists in your region and organize CE events with fellow team members. Interested pharmacists should submit their resume to rovais@ocpinfo.com

Continuous Professional Development - Leslie Den Faculty of Pharmacy, University of Toronto
Infectious Diseases Online Video Lectures and Slides, Influenza DVD
http://www.pharmacy.utoronto.ca/cpd/

Ontario Pharmacists Association (OPA)
Online certificate programs in therapeutic areas including Pain and Palliative care and Diabetes level 1.
Complimentary online programs in therapeutic areas including the Common cold and Flu, Methadone, Smoking Cessation, Ulcerative colitis and Vitamin D in osteoporosis.
Contact: onlinelearning@opatoday.com

RxBriefcase
On-line CE Lessons (Clinical and Collaborative care series) and the Immunization Competencies Education Program (ICEP)
www.rxbriefcase.com
REMINDER:

ONLINE MEMBERSHIP RENEWAL BEGINS IN JANUARY 2013
WATCH FOR MORE INFORMATION ON DEADLINES AND ENSURE WE HAVE YOUR UPDATED E-MAIL ADDRESS AS MEMBERSHIP RENEWAL IS OFFERED ONLINE