

#### **AGENDA ITEM 7.4**

#### TOPIC: **Pharmacy Professionals**

#### Overview

On November 12, 2024, Transition Council reviewed a proposed regulatory exemption for pharmacist members of the Ontario College of Pharmacists.

For more information on this review, please refer to the reference document at the end of this agenda package.

During discussion, Transition Council raised additional questions including larger comments and considerations related to pharmacists issuing renewals of prescriptions.

Transition Council was also informed that the College had only recently received updated information from the Ontario College of Pharmacists related to its thoughts and requests in this area and that they had not been incorporated into the presented material due to timing.

Additional background has now been gathered, and Transition Council is tasked with providing its guidance related to this specific regulatory exemption.

#### Additional Information Gathered Since November 12, 2024

#### **Renewal of Prescriptions by Pharmacists**

In recognition of the questions raised by Transition Council, further information has been gathered related to a pharmacist's ability to provide prescription renewals.

Under the framework established for human health in Ontario<sup>1</sup>, pharmacists are permitted to provide prescription renewals with the following expectations:

- Pharmacists may renew a prescription for the purpose of continuity of care.
- Pharmacists can only renew a quantity of the drug that does not exceed the lesser of:
  - The quantity that was originally prescribed, including any refills that were authorized by the prescriber; or
  - A twelve (12) month supply.

<sup>1</sup> Including the Regulated Health Professionals Act, The Phamacy Act, and the Drug and Pharmacies Regulation Act

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Pharmacists are also required to follow a series of steps before issuing the renewal of a prescription, which is considered a form of prescribing:

- 1. Assess the patient
- 2. Assess their competency
- 3. Assess the environment
- 4. Obtain informed consent to treatment
- 5. Issue the prescription
- 6. Communicate and educate
- 7. Document and notify.

For more detailed information related to these steps, please see the OCP policy "Pharmacist Prescribing: Initiating, Adapting and Renewing Prescriptions" attached to this cover sheet as Appendix **A.** 

While previous prescriptions serve as a source of information in this decision-making, this allowance is tied to the controlled act of prescribing a drug as it requires the pharmacist to make the independent decision to proceed with dispensing a drug.

#### **Continued Conversations with the Ontario College of Pharmacists**

Additional conversations between the College and the Ontario College of Pharmacists have indicated a keen interest in working together to achieve risk-based and evidence-informed approaches to a proposed regulatory exemption for all members of the Ontario College of Pharmacists (hereinafter referred to as pharmacy professionals). In particular, the Ontario College of Pharmacists has shared:

- Commitment to the continued ability for pharmacists to compound, dispense, or sell a drug to an animal or group of animals;
- Confirmation that a pharmacist is viewed as prescribing when they renew a prescription
  and that they are required to inform a prescriber of when they renew but not when they
  deny a request;
- Questions surrounding whether therapeutic substitutions or adaptations include changes in dosage forms;
- Confirmation that a pharmacist is not required to report adverse reactions to a prescriber (though it is encouraged);
- Interest in assuring that regulatory exemption language also extend to pharmacy technicians working within their scope of practice; and
- Confirmation that a pharmacist or pharmacy technician would be expected to adhere to all of standards of practice (including the code of ethics) when practising on animals.



Further, the Ontario College of Pharmacists has confirmed that most pharmacy professionals would not be aware that the Drugs Schedules developed by the National Association of Pharmacy Regulatory Authorities (NAPRA) do not apply to veterinary prescribing in Ontario and that further work would be required related to the differences between human and veterinary pharmacology oversight.

# Early Considerations Related to Policy Development by the Ontario College of Pharmacists

In addition to information gathering, conversations between the College and the Ontario College of Pharmacists resulted in early consideration of whether the Ontario College of Pharmacists would be interested in developing a policy specifically related to animal care.

This consideration came in recognition of the specific policy currently in place at the College of Chiropractors of Ontario and the potential ability to mirror the regulatory exemption language proposed for chiropractors to require pharmacy professionals to adhere to any policies established by the Ontario College of Pharmacists related to animal care.

This proposed approach was presented to the Council of the Ontario College of Pharmacists at its December 9, 2024, meeting. During this meeting, Council members considered the possibility of developing a specific policy and directed their staff to continue to engage with the College in terms of potential policy development.

Following this direction, the College further connected with the staff at the Ontario College of Pharmacists and confirmed their commitment to develop an animal-specific policy that would apply to both pharmacists and pharmacy technicians. As part of this conversation, the College communicated a desire to ensure that the policy reflected that:

- Pharmacy professionals should only be selling, dispensing, or compounding a drug for an animal based on a veterinary prescription;
- That pharmacy professionals should make no therapeutic substitutions for a veterinary prescription;
- That the pharmacy professional should make no adaptations to a veterinary prescription;
   and
- That the pharmacy professional should provide no information or education relating to drug use in animals where the provision of the information requires therapeutic knowledge, clinical analysis, or clinical assessment unless they have specific knowledge, skill, and/or training in veterinary pharmacology.

Staff at the Ontario College of Pharmacists expressed their early understanding and support for these parameters and committed to continuing to connect with the College to ensure that a policy would be in place prior to the full implementation of the *Veterinary Professionals Act*, 2024.



# Amended Proposal Related to a Regulatory Exemption for Pharmacists

Based on this additional information, the following two (2) updated proposals pertaining to a regulatory exemption for pharmacy have been developed for Transition Council's consideration and guidance related to next steps.

These updated proposals contain:

- Recognition of both pharmacists and pharmacy technicians as members of the Ontario College of Pharmacists who would qualify under the regulatory exemption;
- General language referencing expected adherence to any Ontario College of Pharmacists professional policies, including those specific to animal care<sup>2</sup>; and
- Removal of proposed ability to renew prescriptions as it would require allowances related to independent prescribing including the ability to assess an animal.

#### Regulatory Exemption for Members of the Ontario College of Pharmacists

It is proposed that a regulatory exemption be developed for members of the Ontario College of Pharmacists for the following reasons:

- 1. Section 9 (5) 2 of the *Veterinary Professionals Act, 2024* clearly states that regulation language may be developed to allow for "a person who, under the *Pharmacy Act, 1991*, is a member of the Ontario College of Pharmacists" to carry out any such authorized activities as may be prescribed in accordance with any prescribed guidelines, processes, terms, conditions, limitations, or prohibitions;
- 2. The College's risk-based research and analysis in the area has indicated that certain members of the Ontario College of Pharmacists possess the skills, knowledge, and judgement to safely perform specific authorized activities; and
- The Ontario College of Pharmacists recognizes their members' ability to practice on animals and is supportive of a regulatory exemption that ties said exemption to their licensing model.

This exemption would apply for both pharmacists and pharmacy technicians who are duly registered with the Ontario College of Pharmacists in the Part A Class and would be subject to any terms, conditions, or limitations that may exist on their licence (including relevant scopes of

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<sup>&</sup>lt;sup>2</sup> This is the same approach proposed for members of the College of Chiropractors of Ontario.



practice). It would also require both pharmacists and pharmacy technicians to comply with all policies of the Ontario College of Pharmacists including any specific to animal care.

Should the College become aware of a pharmacy professional who is offering authorized activities to the public who may not meet these requirements, the College would have the ability to investigate these concerns including requesting proof of eligibility and adherence and to pursue further action including reporting of a pharmacy professional to the Ontario College of Pharmacists as well as its own ability to investigate under either unauthorized practice and/or the risk of harm clause if warranted.

# Authorized Activities Permitted to be Performed By Pharmacy Professionals under Regulatory Exemption

It is proposed that a regulatory exemption permit the following authorized activities (or components of) to be performed in the course of engaging in the practice of pharmacy on animals:

Authorized Activity	Reasoning
Compounding, dispensing, or selling a drug.	Pharmacy professionals are currently able to provide these authorized activities, and would be expected to adhere to the Ontario College of Pharmacists policies.

#### **Discussion**

A proposed regulatory exemption related to pharmacy is now being presented to Transition Council for its review and discussion related to next steps. To aid in this discussion, Transition Council is encouraged to consider the following questions:

- Is there anything unclear or missing?
- Does the proposal seem logical?
- Does the proposal raise any concerns?
- Does the proposal raise any thoughts or considerations related to unintended consequences?

#### Attachments:

1. Appendix A – OCP Policy: "Pharmacist Prescribing: Initiating, Adapting and Renewing Prescriptions"

# Pharmacist Prescribing: Initiating, Adapting and Renewing Prescriptions

## Purpose:

This guideline outlines legislative requirements and expectations for pharmacists prescribing a drug as authorized by the <u>Pharmacy Act</u> and <u>O. Reg. 256/24</u>. It is meant to be used alongside the <u>Standards of Practice</u>, <u>Standards of Operation</u>, and <u>Code of Ethics</u>.

#### **Definitions:**

**Pharmacy professional:** Pharmacy professional refers to a pharmacist and/or a pharmacy technician. For the purposes of this guideline, where the term 'pharmacist' is used, it means a Part A pharmacist and is inclusive of pharmacy interns and students, and subject to any terms, conditions and limitations on their certificates of registration. Where this is not the case, it will be clearly identified.

**Minor Ailment:** Health conditions that can be managed with minimal treatment and/or self-care strategies. Additional criteria include: usually a short-term condition; lab tests are not usually required; low risk of treatment masking underlying conditions; medications and medical histories can reliably differentiate more serious conditions; and, only minimal or short-term follow up is required. Minor ailments approved for pharmacist prescribing are listed in Schedule 4 of O. Reg. 256/24.

#### Guideline:

Pharmacists have the authority to initiate, adapt or renew a prescription in accordance with the regulations if:

- They possess sufficient knowledge and skills respecting the drug and the patient's condition to do so safely and effectively.
- It is in the best interest of the patient and appropriate, given the known risks and benefits of prescribing the drug.

  Initiating a Prescription<sup>[1]</sup>

Pharmacists are authorized to prescribe the following:

- Varenicline tartrate and/or bupropion hydrochloride for smoking cessation.
- A drug listed in Column 3 of <u>Schedule 4</u> to O. Reg. 256/24 for the associated minor ailment in Column 1.
- Publicly funded minor ailment services must be provided in accordance with Ministry of Health requirements.
   Only Part A pharmacists, and not interns, are authorized to prescribe the following:
- Oseltamivir for treating influenza.
- Nirmatrelvir/ritonavir for treating COVID-19.
- Do not prescribe nirmatrelvir/ritonavir if the patient is at risk of any drug interactions that are contraindications or that cannot be properly managed.
- Publicly funded nirmatrelvir/ritonavir must be prescribed in accordance with Ministry of Health requirements.

# Adapting or Renewing a Prescription<sup>[2]</sup>

The pharmacist must be in possession of the prescription to be adapted or renewed, or

- Obtain a copy of the prescription directly from the dispensing pharmacy.
- Have verbal confirmation about the prescription from a pharmacist at the dispensing pharmacy.
- Have access to the medical record that contains information about the prescription.
   Pharmacists do not have the authority to renew or adapt a prescription for a controlled substance (narcotic, controlled drug and/or targeted substance) or a drug designated as a monitored drug by the regulations under the Narcotics Safety and Awareness Act, 2010.
- Refer to <u>Appendix A</u> for information on Health Canada's <u>Controlled Drugs and Substances Act (CDSA) subsection 56(1) class exemption</u>, **in effect until September 2026. Adapting**
- Pharmacists may adapt a prescription based upon the individual circumstances of the patient by altering **the dose, dosage form, regimen or route of administration** to address the patient's unique needs and circumstances.
- Adapting a prescription does not include therapeutic substitution; refer to <u>Appendix B</u> for more information. **Renewing**
- Pharmacists may renew a prescription for the purpose of continuity of care.

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- Pharmacists can only renew a quantity of the drug that does not exceed the lesser of:
- The quantity that was originally prescribed, including any refills that were authorized by the prescriber; or
- A twelve (12) month supply.

#### Before prescribing, pharmacists must:

#### 1. Assess the patient

The pharmacist determines that the therapy is safe and appropriate by evaluating the risks and benefits, considering the patient's health status and unique circumstances.

To inform their decision-making, the pharmacist should gather the available and relevant information necessary for this assessment, including (but not limited to):

- Patient records (e.g., pharmacy profile, electronic health records).
- Past medical history (e.g., medical conditions, medications or natural health products, allergies, intolerances).
- Current medical history (e.g., indication/diagnosis, medications, signs and symptoms).
- Physical characteristics (e.g., age, weight, height, pregnancy, lactation status).
- Results of physical assessment, laboratory, point-of-care, or other tests.
- Lifestyle (e.g., nutrition, exercise, substance use) and socioeconomic factors.
- Anything reasonable to identify possible drug therapy problems, contraindications, or precautions.
- For more information, please refer to the <u>Patient Assessment Practice Tool</u>.
   Community pharmacies are strongly encouraged to enrol in one of the provincial clinical viewers (ConnectingOntario or ClinicalConnect) at no cost through Ontario Health.
- Viewers provide a dynamic, near real-time view of patient's health information (e.g., laboratory test results, dispensed medications covered by Ontario Drug Benefit, a history of publicly funded professional services) to enhance clinical decision making.

#### 2. Assess their competency

The pharmacist must only prescribe when they can do so competently and safely by:

- Possessing sufficient knowledge, skill and judgment respecting the drug1.
- Having sufficient understanding of the condition of the patient 1.
- Having the resources necessary to meet their professional obligations and standards of practice.
- Being of sound physical, emotional and mental capacity.
- Addressing gaps or learning opportunities, identified through self- and/or peer-assessment, with continuing education and/or additional training.

Prior to prescribing for a minor ailment, the pharmacist must complete the mandatory OCP <u>Orientation for Minor Ailments</u> <u>Prescribing e-Learning module</u> and is expected to critically **evaluate information from relevant, evidence-based sources to inform their clinical decision-making.** 

#### 3. Assess the environment

Physical assessments must take place in an environment that is clean, safe, private, and comfortable for the patient, in a way that protects their confidentiality and dignity.

The Standards of Operation require pharmacy premises, facilities, and layout – along with equipment, technology and staffing – to support practice, to mitigate risks associated with the delivery of services, and to safeguard the health, safety and wellbeing of patients.

Community pharmacy owners and Designated Managers are expected to implement the <u>Guiding Principles for Shared</u>
<u>Accountability</u> to support a suitable practice environment, which includes the physical working space as well as the practice culture, operating procedures, workflow, and resources available.

# 4. Obtain informed consent to treatment[3]

Prior to initiating a prescription, the pharmacist must receive informed consent from the patient or their authorized agent.

Under the <u>Health Care Consent Act</u>, consent to treatment is informed if, before giving it, the person received:

- Information about the nature, expected benefit, potential risks or side effects of the proposed treatment.
- Information about other options and consequences of not having the treatment.
- Any information that a reasonable person in the same circumstances would require to make a decision about the treatment.
- Responses to their request for additional information.

https://www.ocpinfo.com/regulations-standards/practice-policies-guidelines/adaptations-renewing-prescriptions/

The information provided to patients to make informed decisions about their healthcare should be consistent with the best available clinical evidence.

- Consent is contingent on an individual's capacity to understand why and for what the consent is being sought.
- There is no minimum age of consent in Ontario.
- Consent may be express or implied.
- o Express consent may be provided by the patient in writing or provided verbally and documented by the pharmacist.
- The pharmacist may determine that implied consent is provided, based on the patient's action(s) or inaction in the circumstances at hand.

#### After deciding to prescribe, pharmacists must:

#### 5. Issue the Prescription

The following information must be recorded on the prescription [4]:

- Name and address of the patient.
- Name, strength (where applicable), and quantity of the prescribed drug.
- Directions for the use of the drug, including dose, frequency, route of administration, and any special instructions.
- Name, address, telephone number, and College registration number of the pharmacist issuing the prescription.
- Date the prescription was issued.
- Number of refills authorized, if applicable.

#### 6. Communicate & Educate

At the time of initiating, adapting or renewing a prescription, the pharmacist must advise the patient or their authorized agent that they are entitled to the prescription and may take it to a pharmacy of their choice for dispensing<sup>2</sup>.

Effective communication with patients and their healthcare team supports continuity of care and positive treatment outcomes. Pharmacists are expected to:

- Communicate the rationale for their decision(s) (to prescribe, to refer, etc.).
- Educate the patient on their treatment plan including any monitoring and/or follow-up required.
- Collaborate with colleagues and other health care professionals to facilitate quality patient care.

#### 7. Document & Notify

#### **Document**

When prescribing, the pharmacist must document in the patient record:

- If applicable, reference to, or a copy of, the original prescription being renewed or adapted including the name and contact information of the prescriber<sup>[5]</sup>.
- A copy of the prescription taken by the patient or their authorized agent<sup>5</sup>, if applicable.
- The rationale for the decision to initiate, adapt or renew the prescription (patient assessment, clinical guidelines consulted, etc.).
- Results of any laboratory or other tests considered<sup>5</sup>.
- Confirmation that informed consent was received.
- Follow-up and monitoring plan.
- Any other relevant details and/or recommendations.
- The date that the original prescriber (and primary care provider if different) were notified, if applicable, and the method by which the notification occurred<sup>5</sup>.

Pharmacists are expected to adhere to the College's Documentation Guideline. which describes how to meet the Standards of Practice for documentation (e.g., patient assessment, monitoring, follow up).

- Documentation sent to other HCPs should be concise and include pertinent details respecting the pharmacist's initiation, renewal or, if appropriate, adaptation of the prescription to ensure that the patient record is complete in all locations.
- Documentation requirements for the provision of publicly funded services are established by the Ministry of Health.

  Patients who do not have a primary care provider should be advised that they, or another health professional providing care to them in the future, are entitled to access this information at any time. Patients may also wish to have a copy of the documentation from their record for this purpose.

#### Notify

The pharmacist must notify the primary care provider or prescriber within a reasonable time after initiating<sup>1</sup> or renewing a prescription<sup>2</sup>.

- Notification of the prescriber is also required if a pharmacist has adapted a prescription in a manner that is clinically significant in the individual circumstances of the patient, or necessary to support the patient's care <sup>2</sup>.
- If the patient's primary health care provider is different from the original prescriber, they should also be notified in a reasonable time to ensure continuity of care<sup>2</sup>.
- Notification requirements for the provision of publicly funded services are established by the Ministry of Health.

## Legislative References:

- Pharmacy Act
- PART VII.3, O. Reg. 256/24
- Health Care Consent Act

#### **Additional References:**

- Minor Ailments Resources
- Policy <u>Medical Directives and the Delegation of Controlled Acts</u>
- Patient Assessment Practice Tool
- Pharmacy Connection article <u>5 Things Pharmacy Professionals Should Know About Informed Consent</u>

#### **External References:**

- Clinical viewers: ConnectingOntario and ClinicalConnect
- Ministry of Health Executive Officer Notices
- Ontario Health <u>Access to COVID-19 antiviral treatment (Paxlovid™)</u>
- Ontario COVID-19 Science Advisory Table
- o COVID-19 Drug Interactions Checker
- Centre for Effective Practice (CEP)
- o COVID-19: Clinical Guidance for Primary Care Providers
- Public Health Ontario Influenza Resources

# **Implementation**

Published: October 1, 2024

**Version #:** 7.00

College Contact: Pharmacy Practice

## **Revision History**

VERSION #	DATE	ACTION	
1.00	October 2012	Expanded Scope of Practice Orientation Manual.	
2.00	February 2018	Guideline extracted from manual.	
3.00	December 2020	Review, reformatting and inclusion of scope changes from O. Reg 202/94.	
4.00	December 2022	Revised to include prescribing exemption for Paxlovid™ in O. Reg. 107/96.	
5.00	January 2023	Revised to include prescribing for minor ailments.	
6.00	December 2023	Addition of 'pharmacist prescribing' to title; addition of prescribing nirmatrelvir/ritonavir and oseltamivir to O. Reg. 202/94; minor content revisions.	
7.00	October 2024	Removed definition of 'pharmacy professional' and replaced with 'pharmacist'. Student removed from definition of pharmacist.	
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#### APPENDIX A: Controlled Drugs and Substances Act (CDSA) Exemption

Health Canada has issued a <u>Controlled Drugs and Substances Act (CDSA) subsection 56(1) class exemption</u> to permit pharmacists to <u>adapt and/or renew prescriptions</u> for <u>controlled substances</u> for the purposes of facilitating continuation of treatment. The quantity prescribed/dispensed cannot exceed the amount originally authorized. Pharmacy interns and registered pharmacy students are not named in this exemption.

Appendix A
Please refer to the College's Guidance – <u>Providing a Prescription for Controlled Substances during the Coronavirus Pandemic</u> for further information.

Additional Resource: <u>E-learning module – Application in Practice: The Controlled Drugs and Substances Act Subsection 56(1)</u>
<u>Class Exemption</u>

#### **Appendix B: Therapeutic Substitution**

Therapeutic substitution is defined in O. Reg. 256/24 as "the substitution of a drug that contains chemically different active ingredients that are considered to be therapeutically equivalent." Therefore, the drug prescribed cannot be changed.

Pharmacists should exercise caution when changing the route of administration; an adaptation should not alter the pharmacokinetics or pharmacodynamics of the prescribed treatment if it leads to a clinically significant change of its therapeutic effect.

- 1. O. Reg. 256/24, s51 ↑
- 2. O. Reg. 256/24, s52 ↑
- 3. Health Care Consent Act, PART II 1
- 4. O. Reg. 256/24, s53 ↑
- 5. O. Reg. 256/24 s54 ↑



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