



ONTARIO COLLEGE OF PHARMACISTS BOARD OF DIRECTORS MEETING AGENDA

October 27, 2021 Meeting 8:00 a.m. – 9:00 a.m.

Videoconference: Microsoft Teams Link

- 1. Noting Members Present
- 2. Declaration of Conflict
- 3. Approval of Agenda
- 4. For Decision
- 4.1 Briefing Note Pharmacy Technician Administration of Influenza Vaccine and Extension of CDSA Section 56(1) Exemption
- 5. Adjournment



BOARD BRIEFING NOTE MEETING DATE: OCTOBER 2021

FOR DECISION X FOR INFORMATION

INITIATED BY: Susan James, Acting Registrar and Director, Quality

TOPIC: Regulation amendments to enable pharmacy technicians to

administer influenza vaccines and the extension of the *Subsection* 56 (1) class exemption for Controlled Drugs and Substances until

September 2026.

ISSUE: Board approval to submit proposed changes to *General*

Regulation 202/94 under the Pharmacy Act to the Minister of Health which will authorize pharmacy technicians to administer influenza vaccines and enable the extension of the Subsection 56(1) Class Exemption for Patients, Practitioners and Pharmacists Prescribing and Providing Controlled Substances in Canada During the Coronavirus Pandemic. Board approval is also required to waive the requirement for a 60-day open consultation period for

these regulation amendments.

PUBLIC INTEREST RATIONALE:

Pharmacy professionals are playing a critical role to support an effective province-wide response to the coronavirus pandemic. Given that pharmacy technicians have significantly supported COVID-19 vaccination administration across Ontario, and the demands on pharmacies have increased due to ongoing and expanding COVID-19 vaccinations in parallel with influenza vaccinations, there is an opportunity to provide patients with greater access to care, which is in the public interest. Additionally continuing the regulatory authority to permit pharmacists to renew and controlled substances past the current April 7, 2022 exemption expiry will ensure continuity of care for patients that require these medications and helps further minimize public risk by mitigating the spread of the COVID-19 pandemic.

BACKGROUND:

Enabling Pharmacy Technicians to Administer the Influenza Vaccine

On October 25, 2021 the College received a letter from the Assistant Deputy Minister, Strategic Policy, Planning & French Language Services Division (Attachment 1) requesting that the Board of the College include pharmacy technicians in the Universal Influenza Immunization Program, which will require regulation amendments to *General Regulation 202/94* under the *Pharmacy Act, 1991*. The ministry requested the draft amended regulation as soon as possible to enable the additional capacity necessary to support the Roadmap to Reopen. The ministry identified there is an opportunity to provide patients with greater access to care and to improve workflow efficiency within pharmacies by enabling pharmacy technicians to use their knowledge, skills and training more effectively.

Since January 13, 2021, pharmacy technicians were included in the amendments to O. Reg 107/96 for the purpose of exempting them from Section 27(1) of the *Regulated Health Professions Act* (RHPA) which otherwise restricts a person from performing the controlled act of administering a substance by injection unless:

- They have the authority to administer that substance by injection in their scope of practice as conferred by a health discipline Act, or;
- They do so under delegation of authority from another health professional who
 has the scope of practice to administer that substance by injection (see section
 on *Delegation of Authority*)

Currently, outside of this amendment, a pharmacy professional's scope of practice as conferred by the Pharmacy Act and O. Reg. 202/94 does not include the authority to administer COVID-19 vaccine by injection.

This exemption of the RHPA restricted acts enables pharmacy technicians to administer the COVID-19 vaccine, only if and when they have been engaged to do so by an organization or other entity that has an agreement with the Minister of Health (MOH), which has included hospitals, public health units and selected primary care settings and pharmacies throughout the province.

Pharmacy technicians administering the COVID-19 vaccine are expected to adhere to the following expectations outlined in the <u>Guideline – Administering a Substance by Injection or Inhalation</u>:

- Have sufficient knowledge, skill and judgment to safely and effectively administer the vaccine:
 - Successfully complete an OCP-approved injection training course
 - Register their training with the College
 - Valid certification in <u>CPR and First Aid</u> is recommended but not mandated at this time as pharmacy technicians will only administer the vaccine under supervision and in a setting where other health care professionals are required to have this certification
- Ensure the patient has been assessed by a pharmacist or other regulated health professional who has the scope to perform clinical patient assessments and that vaccine administration is appropriate
- Follow recommended infection prevention and control procedures
- Ensure that there are appropriate resources available to safely manage any adverse reactions and that the patient is monitored accordingly
- Document the administration of COVID-19 vaccine as required by the Ministry of Health and/or Public Health

With this exemption, many pharmacy technicians have been involved in the administration of the COVID-19 vaccine. As of Friday October 22, 2021, of the 5,767 registered pharmacy technicians in Ontario, 882 have completed their injection training course and registered their training with the College.

Enabling Extension of the Subsection 56 (1) Class Exemption for Controlled Drugs and Substances

On March 23, 2020, the Board met to review and approve the proposed amendments to General Regulation 202/94 of the Pharmacy Act, 1991, Part VII.3 (Controlled Acts), to enable implementation of the Subsection 56(1) Class Exemption for Patients, Practitioners and Pharmacists Prescribing and Providing Controlled Substances in Canada During the Coronavirus Pandemic, issued by Health Canada on March 19, 2020. The amendment temporarily authorizes pharmacists to renew and adapt existing prescriptions for controlled drugs and substances (CDS) in Ontario. The Ministry of Health went on to approve the amendments to the regulations, which allowed the exemption to remain until April 7, 2022.

On September 30, 2021, Health Canada issued an extension to the temporary class exemption, which now expires on September 30, 2026. Health Canada has extended the exemption with the intent to limit unnecessary physical contact during the COVID-19 outbreak and to ensure continuity of care for patients with chronic conditions who require CDS medication if self-isolating and practicing social distancing or whose physician is unavailable due to the pandemic.

To enable this extension in Ontario and to align with Health Canada, the College is proposing to extend the amendment of *O. Reg. 202/94 (General)* made under the *Pharmacy Act, 1991* to continue to temporarily allow pharmacists to renew and adapt prescriptions for CDS until at least September 30, 2026. As the Health Canada exemption may be revoked prior to that date, depending on the status of the current pandemic, the College may have to amend the regulation again at a future date to remain aligned.

ANALYSIS:

Enabling Pharmacy Technicians to Administer the Influenza Vaccine

Throughout the pandemic, the College has maintained its commitment to its public protection mandate and focused its efforts on supporting the profession and collaborating with stakeholders throughout the health system to identify and implement solutions aimed at overcoming unique challenges posed by the pandemic in the delivery of safe, quality pharmacy services.

Since the pandemic was first declared, pharmacy professionals have been on the frontline of the pandemic response while continuing to serve their communities. In addition, pharmacies have also taken on COVID-19 testing of asymptomatic patients, the administration of COVID-19 vaccines as part of the provincial-wide roll out and are once again playing an active role in administering the flu shots in an environment of heightened demand for the flu vaccine. Due to the current and anticipated demands on pharmacies, additional capacity by enabling pharmacy technicians to administer the flu vaccine will provide pharmacy teams the additional support they need to deliver pharmacy services.

In addition to community pharmacies, the College anticipates pharmacy technicians may play a role in administering the flu vaccine in other practice settings, especially in locations where availability of many health care professionals are limited. With the COVID-19 vaccination rollout, pharmacy technicians have been involved administering the vaccine in various practice setting such as mass vaccination clinics and in public health units in northern Ontario, and other rural and remote areas.

Knowledge, skills, judgement and training on the technical administration of the influenza vaccine

As mentioned in the Background, pharmacy technicians are expected to have the knowledge, skills and judgment to safely and effectively administer the flu vaccine given that they are currently administering the COVID-19 vaccine and drawing on the same technical skill set. In addition to successfully completing an injection training course and registering their training with the College, pharmacy technicians must ensure patients have been assessed by a pharmacist or other regulated health professional who has the scope to perform clinical patient assessment and that COVID-19 vaccine administration is appropriate. These same expectations would be made of pharmacy technicians if authorized to administer the flu vaccine.

Pharmacy technicians can provide the technical components for the administration of the flu vaccine, but not the therapeutic components, such as managing informed consent by the patient or their authorized agent, which may involve answering questions related to risks, benefits and concerns related to the flu vaccine. Further, pharmacy technicians will rely on the pharmacist, intern, registered pharmacy student or other regulated health professional to complete an appropriate patient assessment prior to flu vaccine administration.

Similar to the expectations around the administration of the COVID-19 vaccine, pharmacy technicians will also be expected to ensure they administer the vaccine in a clean, safe, private and comfortable environment, and that appropriate infection control procedures are in place. Pharmacy technicians will also be expected to meet the documentation requirements for the administration of the flu vaccine (e.g. name of patient, date of administration, etc.). Pharmacy technicians must also administer the vaccine in accordance with Ontario's Universal Influenza Immunization Program.

A jurisdictional scan of Canadian provinces and territories (Attachment 2) was conducted to determine if this scope of practice is authorized in other jurisdictions. Currently pharmacy technicians in Nova Scotia (NS) and New Brunswick (NB) have the authority to administer the flu vaccine to patients as young as two years old. In NB, pharmacy technicians must be appropriately trained and supervised by a pharmacist who is also authorized to administer injections. Pharmacists must perform the patient assessment and patient counselling prior to the administration of the flu vaccine. In NS, a pharmacist can delegate a pharmacy technician to administer a drug by injection, which includes the flu vaccine. Both the pharmacist and pharmacy technician must hold the relevant permits, which are issued upon meeting the requirements as described in the NS Standards of Practice: Drug Administration.

Administering the flu vaccine to children as young at two years old

Feedback was received from some pharmacist respondents, during open consultation for a previous regulation amendment authorizing pharmacists to administer flu vaccines to children as young as two years old in November 2019, voicing concerns about providing the flu vaccine to children of this age. We anticipate this may be a similar concern from some pharmacy technicians, for similar reasons such as lack of confidence vaccinating young children, need for pain mitigation, and managing parent/guardian expectations, especially if the child is receiving the flu vaccination for the first time.

In response to previous concerns expressed by pharmacists, <u>additional optional courses</u> (referenced on the website) have been created by education providers, to support administration of the vaccine to this age group. These optional courses are also available to pharmacy technicians who wish to equip themselves with these techniques and strategies.

Staffing, workload and environment pressures

Additional feedback received during the open consultation regarding administration of the flu vaccine to children as young as two years old referred to the challenges and impact of workload demands and limited staffing levels on the practice environment. These concerns may also apply to the proposed amendments for pharmacy technicians to administer the vaccine, especially as pharmacy teams are managing the ongoing pandemic workload in conjunction with flu vaccination efforts.

The College has developed guiding principles of shared accountability through the Community Practice Environment Advisory Group, and is committed to addressing concerns being felt and heard on the front-lines. This work will involve measuring and monitoring the provider experience and understanding how pharmacy professionals are managing their workload given their current practice environment. With various initiatives underway, the College will have the ability to understand where pharmacy technicians are experiencing challenges. While it does not have direct control over individual pharmacy human-resource related matters, the College is fully committed to acting appropriately and effectively through its existing regulatory mechanisms and authorities designed to protect the public. This includes ensuring that owners/operators of pharmacies, including designated managers and those who exert any control over pharmacy operations, understand and are held accountable to their responsibilities and obligations under the Standards of Accreditation and Standards of Operation.

Anticipated stakeholder response

Although health system stakeholder consultation has been limited due to the urgency to enable pharmacy technicians to contribute to the immunization program, profession stakeholders have expressed support. The Ontario Pharmacists Association and Neighborhood Pharmacy Association of Canada did submit a proposal to the Ministry of Health on August 20, 2021, recommending registered pharmacy technicians be authorized to administer publicly funded vaccines. These two pharmacy associations indicated that the comprehensive training, knowledge and experience gained from participation in the COVID-19 vaccine rollout should be leveraged to support increasing vaccination rates, including the flu vaccine. The associations recommend the pharmacy technicians' work under the supervision of a regulated health professional who has the scope to clinically assess the patient to ensure vaccine administration is appropriate. They believe pharmacy technicians can undertake this technical task of vaccine administration to increase capacity and alleviate pressures on other health care providers.

Enabling Extension of the Subsection 56 (1) Class Exemption for Controlled Drugs and Substances

According to data from the Narcotics Monitoring System (NMS), 8000 distinct pharmacists have used this exemption to prescribe 105,862 claims to 41,993 distinct patients. Based on NMS data analyzed by the Ontario Drug Policy Research Network (ODPRN) from March 2020 to March 2021, there was a 2-fold increase in the number of opioid claims and a 9-fold increase in the number of benzodiazepine claims as a result of pharmacist prescribing after the exemptions were enabled. However, the overall proportion of pharmacists prescribing controlled drugs and substances did not exceed 1% of total NMS claims.

Pharmacists have been utilizing this exemption for the purposes of continuity and access to care given the current COVID-19 pandemic. These amendments will also will help to ensure people do not experience disruptions in their prescriptions that may force them to turn to the illegal drug supply to address withdrawal symptoms. Many of the enabling factors of Health Canada exemption, including the transferring of CDS prescriptions between pharmacies to support continuity of care or receiving verbal orders for CDS prescription has supported continued access to care despite the disruptions caused by the pandemic. As a result, it will be important to extend the exemption in *Subsection 56* (1) to align with the Health Canada exemption extension.

Waiving the 60-day circulation period for open consultation

To enable pharmacy technicians to have the authority to administer the flu vaccine during the 2021-22 flu season as well as to extend the exemption in *Subsection 56 (1)*, the amended regulation will need to be approved as soon as possible. As a result, the College is requesting that the Board waive the required 60 day consultation period for the proposed amendments to *General Regulation 202/94* made under the *Pharmacy Act, 1991*. These amendments are intended to immediately contribute to the province's and broader health system's efforts to respond to anticipated challenges associated with the influenza season in the middle of an ongoing public health emergency as well as the evolving and continued focus on COVID-19 vaccination.

Subsection 95 (1.6) of the Health Professions Procedural Code, which is Schedule 2 to the Regulated Health Professions Act, 1991, permits the exemption of a proposed regulation from the requirement that it be circulated for open consultation, or the abridgement of the required 60-day consultation period with the approval of the Ministry of Health.

RECOMMENDATION:

That the Board approve the proposed changes to *General Regulation 202/94* under the *Pharmacy Act*, 1991 (Attachment 3 and 4) to allow for pharmacy technicians to administer the flu vaccine and the extension of the existing regulatory amendments enabling implementation of Health Canada's Subsection 56(1) class exemption for controlled substances.

That the Board seek approval by the Minister of Health to waive or abridge the requirement for a 60-day public consultation period for the proposed regulation changes.

NEXT STEPS:

If approved by the Board, the College will submit the proposed amendments to the Ministry and request expedited approval. Notification of regulatory approval, along with practice guidance will be communicated to all stakeholders immediately thereafter. Given the urgency of the matter, the usual College practice of holding a 60-day public consultation prior to submission will be waived, pending approval.

Ministry of Health Ministry of Long-Term Care

Assistant Deputy Minister Strategic Policy, Planning & French Language Services Division

438 University Avenue, 10th floor Toronto ON M5G 2K8

Tel.: 416 327-8929

October 25, 2021

Ministère de la Santé Ministère des Soins de longue durée

Sous-ministre adjoint Division des politiques et de la planification stratégiques, et des services en français

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Since January 12, 2021 pharmacy technicians have significantly supported COVID-19 vaccination efforts across Ontario with approximately 700 registered pharmacy technicians trained and registered to administer injections.

The ministry understands that demands on pharmacies have increased due to ongoing and expanding COVID-19 vaccinations and the co-administration of COVID-19 vaccine with other vaccines including influenza.

Based on the success of pharmacy technicians administering COVID-19 vaccines and the need for additional capacity to support Ontario as we move through the Roadmap to Reopen, there is an opportunity to provide patients with greater access to care and improve workflow by enabling pharmacy technicians to use their education and training more effectively. Therefore, we would like to work with the College to include pharmacy technicians in the Universal Influenza Immunization Program. To enable this to occur, we understand that a regulation amendment made under the *Pharmacy Act*, 1991, is necessary.

The ministry is committed to working with the College to bring this work forward for government approval as soon as possible. Ministry staff will reach out to you shortly to work with you and to answer any questions you may have.

Sincerely,

Sean Court

Assistant Deputy Minister

c. Dr. Keiran Moore, Chief Medical Officer of Health

Jurisdiction	Techs Administering Influenza Vaccine	Comments	References
АВ	No		https://abpharmacy.ca/sites/default/files/StandardsofPractice.pdf Standard 17
ВС	No		5099- HPA Bylaws Drug Administration Injection Intranasal.pdf (bcpharmacists.org)
МВ	No		https://cphm.ca/wp-content/uploads/Resource- Library/Practice-Directions-Standards/Practice-Direction- Standard-5-administration-of-injections.pdf
NB	Yes* (New as of 2021)	Under routine supervision by a pharmacist. Pharmacy technician can do technical aspect, pharmacist must do clinical aspect.	Policy: Administration of Injections, Supplemental Standards of Practice: Administration of Injections FAQ - Pharmacy Technicians and Administration of Injections *See details below
NL	No		https://nlpb.ca/media/SOPP-Administration-of-Drug- Therapy-by-Inhalation-or-Injection-Mar2021.pdf

NS	Yes*	Both pharmacist & technician need permit, and pharmacist needs to delegate.	*See details below
PEI	No		https://www.princeedwardisland.ca/sites/default/files/legis lation/r10-1-07- regulated health professions act pharmacist and pharm acy technician regulations.pdf
SK	No		In SK, ss. 23(3) of The Pharmacy and Pharmacy Disciplines Act (https://saskpharm.ca/document/3530/The Pharmacy and Pharmacy Disciplines Act.pdf) prevents Pharmacy Technicians from administering the flu (or other) vaccines (only licensed Pharmacists are authorized via that Act to administer vaccines As per page 4: of the following document (https://saskpharm.ca/document/7292/REF_COVID- 19 Immunizers FAQs.pdf) the SK provincial government provided emergency authorization via The Disease Control (COVID-19) Amendment Regulations, 2021 for Pharmacy Technicians to inject COVID-19 vaccines
CF	No	The Canadian Forces do not regulated pharmacy technicians	

NWT	No	Northwest Territories does not regulate pharmacy technicians	
NU	No	A review of the <i>Pharmacy</i> Act and its regulations (including the Drug Schedules Regulations) did not reveal any relevant details on the regulation of pharmacy technicians	
QC	Not Yet, but likely before 2024	The department at OPQ and the Office des professions (Quebec's Health Professions Regulatory Advisory Council) have been working on a proposed regulation allowing for the delegation of certain acts to properly trained personnel. Administering medication by various routes, including vaccines, is one of the actvities that will be allowed for delegation under regulation to properly trained pharmacy assistants and pharmacy techs.	

Υυ	No	A review of the <i>Pharmacy</i> Act and its regulations did not reveal any relevant details on the regulation of pharmacy technicians.	
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*NOVA SCOTIA

- The Pharmacy Act and its regulations authorize a pharmacist to delegate a pharmacy technician to administer a drug by injection.
- This pharmacy technician must hold a **NSCP Drug Administration by Injection Technical Permit** and the pharmacist delegating must hold a **NSCP Drug Administration by Injection Permit**
 - Permits:
 - Tech:
 - Drug Administration by Injection Technical Permit = a permit issued upon meeting the requirements as described in the Standards of Practice: Drug Administration that qualifies them to accept a delegation to administer a drug by injection to a patient from a pharmacist.
 - More details can be found in Standards of Practice, Appendix D
 - Pharmacist:
 - Drug Administration by Injection Permit = a perit issued upon meeting the requirements in the Standards of Practice: Drug Administration that qualifies them to administer drugs by injection to patients
 - More details can be found in <u>Standards of Practice</u>, Appendix C

*NEW BRUNSWICK

- Pharmacy Technicians on the Active: Direct Client Care register may administer injections under the routine supervision of a pharmacist on the Direct Client Care register (with authorization to administer injections) via IM or SC routes in accordance with Regulations (22.3-22.5), the Model Standards of Practice for Canadian Pharmacy Technicians, the Supplemental Standards of Practice: Administration of Injections and the Policy: Administration of Injections

Pharmacy Act, 1991 Loi de 1991 sur les pharmaciens

ONTARIO REGULATION 202/94 GENERAL

Consolidation Period: From March 12, 2021 to the e-Laws currency date.

Last amendment: 187/21.

Legislative History: 750/94, 539/95, 280/96, 121/97, 98/98, 642/98, 548/99, 270/04, 451/10, 59/11, 302/12, 154/13, 225/13, 452/16, 126/20, 742/20, 187/21.

This Regulation is CONTROLLED ACTS made in English

only.

PART VII.3

 Interpretation
 31-32

 Controlled Acts
 33-40

PART VII.3 CONTROLLED ACTS

INTERPRETATION

31. (1) In this Part,

"adapt" means, subject to subsection (2), to change a patient's prescription respecting,

- (a) the dose of the prescribed drug,
- (b) the dosage form of the prescribed drug,
- (c) the directions for use of the prescribed drug, or
- (d) the route of administration for taking the prescribed drug,

but does not include therapeutic substitution;

Note: On April 7, 2022, the definition of "adapt" in section 31 of the Regulation is amended by striking out "subject to subsection (2)" in the portion before clause (a). (See: O. Reg. 126/20, s. 1 (2))

"coronavirus exemption" means the exemption issued by the Minister of Health for Canada on March 19, 2020 under subsection 56 (1) of the *Controlled Drugs and Substances Act* (Canada) entitled "Subsection 56(1) Class Exemption for Patients, Practitioners and Pharmacists Prescribing and Providing Controlled Substances in Canada During the Coronavirus Pandemic", available on a website of the Government of Ontario, including any renewal or replacement of the exemption;

Note: On April 7, 2022, the definition of "coronavirus exemption" in section 31 of the Regulation is revoked. (See: O. Reg. 126/20, s. 1 (4))

- "Part A pharmacist" means a member who holds a certificate of registration as a pharmacist and who is listed in Part A of the register;
- "prescriber" means a person who is authorized under the laws of a province or territory of Canada to give a prescription within the scope of his or her practice of a health profession;
- "prescription" means a direction from a prescriber directing the dispensing of a drug or mixture of drugs for a specific patient;
- "renew" means to provide a patient with a prescription that repeats a prescription previously provided to that patient;

- "therapeutic substitution" means the substitution of a drug that contains chemically different active ingredients that are considered to be therapeutically equivalent. O. Reg. 302/12, s. 1; O. Reg. 126/20, s. 1 (1, 3).
 - (2) While the coronavirus exemption is in effect, in this Part,
- "adapt", in relation to the adaptation of a prescription for a controlled substance under the *Controlled Drugs and Substances Act* (Canada), means to change the prescription respecting,
 - (a) the dose and regime of the prescribed drug,
 - (b) the dosage form of the prescribed drug,
 - (c) the de-prescribing of the prescribed drug, or
 - (d) the part-filling of the prescription,

but does not include therapeutic substitution. O. Reg. 126/20, s. 1 (5)

Note: On April 7, 2022, subsection 31 (2) of the Regulation is revoked. (See: O. Reg. 126/20, s. 1 (6))

- **32.** (1) Where the provisions of this Part are inconsistent with a law of Canada respecting prescriptions, including those related to a targeted substance, the law of Canada shall prevail and the provisions of this Part to the extent they are inconsistent with that law shall not apply. O. Reg. 302/12, s. 1.
- (2) Where the provisions of this Part are inconsistent with the provisions of the *Narcotics Safety and Awareness Act*, 2010, the provisions of that Act shall prevail and the provisions of this Part, to the extent they are inconsistent with that Act, shall not apply. O. Reg. 302/12, s. 1.
 - (3) In this Part,
 - (a) a reference to a part A pharmacist includes a member who holds a certificate of registration as a pharmacist (emergency assignment); and
 - (b) a reference to a pharmacy technician includes a member who holds a certificate of registration as a pharmacy technician (emergency assignment). O. Reg. 187/21, s. 9.

CONTROLLED ACTS

- **33.** A member shall not perform a controlled act under paragraph 2, 3, 4 or 5 of subsection 4 (1) of the Act except in accordance with this Part. O. Reg. 302/12, s. 1.
- **34.** (1) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (3) is authorized to perform the following acts:
 - 1. Administering a substance specified in Schedule 1 by injection to a patient.
 - 2. Administering a substance specified in Schedule 2 by inhalation to a patient. O. Reg. 452/16, s. 1 (1).
- (2) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform an act provided for in subsections (1), (4) and (5), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1; O. Reg. 452/16, s. 1 (2).
- (2.1) A pharmacy technician is authorized to perform an act provided for in subsection (4.1), subject to the terms, conditions and limitations imposed on his or her certificate of registration.
 - (3) A member may only perform an act provided for in subsection (1) if he or she complies with the following:
 - 1. The member may only perform the act for the purpose of patient education and demonstration, and before performing the act.
 - i. must explain that purpose to the patient or his or her authorized agent, and
 - ii. must receive an informed consent from the patient or his or her authorized agent.
 - 2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.
 - 3. The member shall ensure that appropriate infection control procedures are in place.
 - 4. The member must possess sufficient knowledge, skill and judgment respecting the substance to be administered, and sufficient understanding of the condition of the patient, to be able to administer the substance safely.
 - 5. The member must consider whether administering a substance by injection or inhalation to the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances.
 - 6. The member must maintain a patient record that includes,
 - i. the name and address of the patient,

- ii. the name and address of the member,
- iii. the date the act was performed,
- iv. the name, strength (where applicable) and quantity of the substance that the member administered to the patient,
- v. the circumstances relating to the administration of the substance to the patient and any adverse reaction experienced by the patient, and
- vi. confirmation that an informed consent was given by the patient or his or her authorized agent. O. Reg. 302/12, s. 1.
- (4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer influenza vaccine by injection to a patient who is two years of age or older, if the member,
 - (a) administers the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website;
 - (b) receives an informed consent from the patient or his or her authorized agent; and
 - (c) meets all the requirements in paragraphs 2 to 6 of subsection (3). O. Reg. 302/12, s. 1; O. Reg. 452/16, s. 1 (3); O. Reg. 742/20, s. 1.
- (4.1) For the purpose of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2.1) is authorized to administer influenza vaccine by injection to a patient who is two years of age or older, if the member,
 - (a) administers the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website;
 - (b) possesses sufficient knowledge, skill and judgment to be able to administer the influenza vaccine safely;
 - (c) meets all the requirements in paragraphs 2, 3 and 6 of subsection (3); and
 - (d) has confirmed that a member referred to in subsection (2), or another regulated health professional authorized to administer the influenza vaccine by injection:
 - (i) has received an informed consent from the patient or his or her authorized agent;
 - (ii) has a sufficient understanding of the influenza vaccine and condition of the patient for the influenza vaccine to be administered safely; and
 - (iii) has considered whether administering the influenza vaccine by injection to the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances.
- (5) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer a vaccine from one of the vaccines specified in Schedule 3 by injection to a patient who is five years of age or older, if the member,
 - (a) receives an informed consent from the patient or his or her authorized agent;
 - (b) meets all the requirements in paragraphs 2 to 6 of subsection (3); and
 - (c) notifies the patient's primary care provider (if any) within a reasonable time that the member administered a vaccine to the patient and provides details respecting the administration. O. Reg. 452/16, s. 1 (4).
- **35.** (1) For the purposes of paragraph 3 of subsection 4 (1) of the Act, a member referred to in subsection (3) who complies with the other requirements of this section is authorized to prescribe the following specified drugs:
 - 1. Varenicline Tartrate.
 - 2. Bupropion Hydrochloride. O. Reg. 302/12, s. 1.
- (2) A drug mentioned in subsection (1) may only be prescribed by a member for the sole purpose of smoking cessation. O. Reg. 302/12, s. 1.
- (3) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform the act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1.
 - (4) A member may only prescribe a drug under this section if he or she,
 - (a) possesses sufficient knowledge, skill and judgment respecting the drug and the patient's condition to prescribe the drug for the patient;
 - (b) has considered whether prescribing the drug for the patient is appropriate, given the known risks and benefits of prescribing the drug for the patient and other relevant factors respecting the patient;
 - (c) gives the prescription to the patient or his or her authorized agent;

- (d) advises the patient or his or her authorized agent, at the time of giving the prescription, that he or she may elect to take it to a pharmacy of his or her choosing for dispensing;
- (e) notifies the patient's primary care provider (if any) within a reasonable time, that the member prescribed a drug for the patient and provides details respecting the prescription; and
- (f) complies with the additional requirements under sections 37 and 38. O. Reg. 302/12, s. 1.
- **36.** (1) For the purposes of paragraph 4 of subsection 4 (1) of the Act, a member referred to in subsection (3) who complies with the other provisions of this section is authorized to perform the following acts:
 - 1. Adapting a patient's prescription.
 - 2. Renewing a patient's prescription for the purpose of continuity of care. O. Reg. 302/12, s. 1.
- (2) Subject to subsection (2.1), subsection (1) does not authorize a member referred to in subsection (3) to adapt or renew a prescription for a controlled substance as defined in the *Controlled Drugs and Substances Act* (Canada) or a drug designated as a monitored drug by the regulations under the *Narcotics Safety and Awareness Act*, 2010. O. Reg. 302/12, s. 1; O. Reg. 126/20, s. 2 (1).

Note: On April 7, 2022, subsection 36 (2) of the Regulation is amended by striking out "Subject to subsection (2.1)" at the beginning. (See: O. Reg. 126/20, s. 2 (2))

(2.1) During the period of time in which the coronavirus exemption is in effect, subsection (2) does not apply to the extent that the coronavirus exemption or the *Controlled Drugs and Substances Act* (Canada) authorizes the member to adapt or renew a prescription for a controlled substance under that Act. O. Reg. 126/20, s. 2 (3).

Note: On April 7, 2022, subsection 36 (2.1) of the Regulation is revoked. (See: O. Reg. 126/20, s. 2 (4))

- (3) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform an act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12. s. 1.
 - (4) A member may only perform an act provided for in subsection (1) if he or she complies with the following:
 - 1. The member must either possess the patient's prescription to be adapted or renewed or,
 - i. receive a copy of the prescription directly from the pharmacy where the prescription was dispensed to the patient,
 - ii. be satisfied based on verbal confirmation from a pharmacist at the pharmacy where the prescription was dispensed to the patient as to the existence and details of the prescription,
 - iii. have access to the medical record that contains information about the prescription, or
 - iv. during the period of time in which the coronavirus exemption is in effect, if the criteria set out in subparagraphs i, ii and iii cannot be met, be satisfied as to the existence and details of the prescription from an alternative source, including, but not limited to, the prescription label, the prescription receipt with medication history, a photograph of the prescription or a facsimile of the prescription.

Note: On April 7, 2022, paragraph 1 of subsection 36 (4) of the Regulation is amended by adding "or" at the end of subparagraph ii, by striking out "or" at the end of subparagraph iii and by revoking subparagraph iv. (See: O. Reg. 126/20, s. 2 (6))

- 2. If the member is renewing a prescription, he or she must not prescribe a quantity of the drug that exceeds the lesser of,
 - i. the quantity that was originally prescribed, including any refills that were authorized by the prescriber, and
 - ii. a 12 months' supply.
- 3. The member must, within a reasonable time, notify the prescriber identified on the prescription adapted or renewed by the member, as well as the patient's primary care provider if the member knows that the patient has such a care provider other than the prescriber, providing details about the patient's prescription, when the member,
 - i. renews a patient's prescription, or
 - ii. adapts a patient's prescription, if, in the member's opinion,
 - A. adapting the prescription is clinically significant in relation to the patient, or
 - B. the notification is necessary to support the patient's care.
- 4. At the time that the member adapts or renews the patient's prescription, the member must advise the patient or his or her authorized agent,
 - i. that he or she is entitled to the prescription, and
 - ii. that he or she may take the prescription to a pharmacy of his or her choosing for dispensing.
- 5. The member must comply with the additional requirements under sections 37 and 38. O. Reg. 302/12, s. 1; O. Reg. 126/20, s. 2 (5); O. Reg. 742/20, s. 2.

- **37.** A member who performs an act provided for in section 35 or 36 must ensure that the following information is recorded on the prescription:
 - 1. The name and address of the patient for whom the drug is prescribed.
 - 2. The name, strength (where applicable) and quantity of the prescribed drug.
 - 3. Directions for the use of the drug, including its dose, frequency, route of administration and any special instructions.
 - 4. The name, address, telephone number and College registration number of the member issuing the prescription.
 - 5. The date the prescription was issued by the member.
 - 6. If applicable, reference to the prescription that the member adapted or renewed, including the name and contact details of the original prescriber.
 - 7. The number of refills that the member authorized, if applicable.
 - 8. Any other information required by law. O. Reg. 302/12, s. 1.
- **38.** A member who performs an act under section 35 or 36 must maintain a patient record that includes details of the member's rationale for his or her decision to act under section 35 or 36 and the following information, if applicable:
 - 1. Reference to, or a copy of, the patient's prescription that the member renewed or adapted, including the name and contact information of the prescriber.
 - 2. A copy of the prescription that the member gave to the patient or his or her authorized agent under clause 35 (4) (c) or that the member gave to the patient or his or her authorized agent to take to a pharmacy of their choosing under paragraph 4 of subsection 36 (4).
 - 3. A record of the results of laboratory or other tests that the member considered in making the decision to act under section 35 or 36.
 - 4. The date on which the member notified the following persons, as applicable, and the method by which the notification occurred:
 - i. The patient's primary care provider notified under clause 35 (4) (e) or paragraph 3 of subsection 36 (4).
 - ii. The patient's prescriber notified under paragraph 3 of subsection 36 (4). O. Reg. 302/12, s. 1.
- **39.** (1) For the purposes of paragraph 5 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (4) is authorized to perform the act of piercing a patient's dermis with a lancet-type device to obtain blood. O. Reg. 302/12, s. 1.
- (2) A member who is a Part A pharmacist, an intern, a registered pharmacy student or a pharmacy technician is authorized to perform the act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1.
 - (3) A pharmacy technician shall not perform the act provided for in subsection (1) unless,
 - (a) a Part A pharmacist is physically present on the premises at the time when the pharmacy technician performs the act; and
 - (b) the pharmacy technician is under the direction of a Part A pharmacist at the time when the pharmacy technician performs the act. O. Reg. 302/12, s. 1.
 - (4) A member may only perform the act provided for in subsection (1) if he or she complies with the following:
 - 1. The member may only perform the act for the purpose of demonstrating the appropriate use of lancet-type devices for the patient's self care and education or for the patient's self monitoring of his or her chronic disease, and before performing the act,
 - i. shall explain that purpose to the patient or his or her authorized agent, and
 - ii. shall receive an informed consent from the patient or his or her authorized agent.
 - 2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.
 - 3. The member shall ensure that appropriate infection control procedures are in place.
 - 4. The member must possess the knowledge, skill and judgment respecting the performance of the act and understand the condition of the patient, to perform it safely and effectively.
 - 5. The member must consider whether performing the act on the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome and any other relevant circumstances.
 - 6. The member must maintain a patient record that includes,

- i. the name and address of the patient and the member,
- ii. the date the act was performed, and
- iii. confirmation that an informed consent was given by the patient or his or her authorized agent. O. Reg. 302/12, s. 1.

DRAFT General Regulation 202/94 Clause by Clause Comparison

Existing Clause	Proposed New Clause	Rationale
PART VII.3 CONTROLLED ACTS	PART VII.3 CONTROLLED ACTS	
 34. (1) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (3) is authorized to perform the following acts: 1. Administering a substance specified in Schedule 1 by injection to a patient. 	34. (1) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (3) is authorized to perform the following acts: 1. Administering a substance specified in Schedule 1 by injection to a patient. 2. Administering a substance specified in Schedule 2 by	
inhalation to a patient. O. Reg. 452/16, s. 1 (1). (2) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform an act provided for in subsections (1), (4) and (5), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1; O. Reg. 452/16, s. 1 (2).	inhalation to a patient. O. Reg. 452/16, s. 1 (1). (2) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform an act provided for in subsections (1), (4) and (5), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1; O. Reg. 452/16, s. 1 (2). (2.1) A pharmacy technician is authorized to perform an act provided for in subsection (4.1), subject to the terms, conditions and limitations imposed on his or her certificate of registration.	Indicates the inclusion of pharmacy technicians for the specific section of the regulation dealing with administration of the flu vaccine. Also references the additional requirements associated with performing this act.
(3) A member may only perform an act provided for in subsection (1) if he or she complies with the following:1. The member may only perform the act for the purpose of patient education and demonstration, and before performing the act,	(3) A member may only perform an act provided for in subsection (1) if he or she complies with the following: 1. The member may only perform the act for the purpose of patient education and demonstration, and before performing the act,	

Existing Clause	Proposed New Clause	Rationale
i. must explain that purpose to the patient or his or her	i. must explain that purpose to the patient or his or her	
authorized agent, and	authorized agent, and	
ii. must receive an informed consent from the patient or	ii. must receive an informed consent from the patient or	
his or her authorized agent.	his or her authorized agent.	
2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.	2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.	
3. The member shall ensure that appropriate infection control procedures are in place.	3. The member shall ensure that appropriate infection control procedures are in place.	
4. The member must possess sufficient knowledge, skill and judgment respecting the substance to be administered, and sufficient understanding of the condition of the patient, to be able to administer the substance safely.	4. The member must possess sufficient knowledge, skill and judgment respecting the substance to be administered, and sufficient understanding of the condition of the patient, to be able to administer the substance safely.	
5. The member must consider whether administering a substance by injection or inhalation to the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances.	5. The member must consider whether administering a substance by injection or inhalation to the patient is appropriate, given theknown risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances.	
6. The member must maintain a patient record that includes,i. the name and address of the patient,ii. the name and address of the member,iii. the date the act was performed,	6. The member must maintain a patient record that includes, i. the name and address of the patient, ii. the name and address of the member, iii. the date the act was performed,	

Existing Clause	Proposed New Clause	Rationale
iv. the name, strength (where applicable) and quantity of the substance that the member administered to the patient, v. the circumstances relating to the administration of the substance to the patient and any adverse reaction experienced by the patient, and vi. confirmation that an informed consent was given by the patient or his or her authorized agent. O. Reg. 302/12, s. 1. (4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer influenza vaccine by injection to a patient who is two years of age or older, if the member, (a) administers the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website; (b) receives an informed consent from the patient or his or her authorized agent; and (c) meets all the requirements in paragraphs 2 to 6 of subsection (3). O. Reg. 302/12, s. 1; O. Reg. 452/16, s. 1 (3); O. Reg. 742/20, s. 1.	iv. the name, strength (where applicable) and quantity of the substance that the member administered to the patient, v. the circumstances relating to the administration of the substance to the patient and any adverse reaction experienced by the patient, and vi. confirmation that an informed consent was given by the patient or his or her authorized agent. O. Reg. 302/12, s. 1. (4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer influenza vaccine by injection to a patient who is two years of age or older, if the member, (a) administers the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website; (b) receives an informed consent from the patient or his or her authorized agent; and (c) meets all the requirements in paragraphs 2 to 6 of subsection (3). O. Reg. 302/12, s. 1; O. Reg. 452/16, s. 1 (3); O. Reg. 742/20, s. 1. (4.1) For the purpose of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2.1) is authorized to administer influenza vaccine by injection to a patient who is two years of age or older, if the member, (a) administers the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website; (b) possesses sufficient knowledge, skill and judgment to be able to administer the influenza vaccine safely;	As referenced in (2.1) above this section defines the expectations associated with administration of this act. The authority is consistent with the criteria set out for pharmacists where the pharmacy technician posses the knowledge, skills and judgement necessary to meet the same requirements as a pharmacist. This is the case for (a), (b), (c).

Existing Clause	Proposed New Clause	Rationale
Existing Clause	(c) meets all the requirements in paragraphs 2, 3 and 6 of subsection (3); and (d) has confirmed that a member referred to in subsection (2), or another regulated health professional authorized to administer the influenza vaccine by injection: (i) has received an informed consent from the patient or his or her authorized agent; (ii) has a sufficient understanding of the influenza vaccine and condition of the patient for the influenza vaccine to be administered safely; and (iii) has considered whether administering the influenza vaccine by injection to the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances.	(d) identifies the components of the act that fall outside the scope of a pharmacy technician. The pharmacy technician must therefore confirm that these aspects of the act have been completed by another authorized pharmacy professional or other regulated health professional with authority to administer the flu vaccine under the Universal Influenza Immunization Program prior to administering the vaccine to a patient.