

BOARD BRIEFING NOTE

MEETING DATE: JUNE 2023

FOR DECISION

From: Susan James, Director Quality

Topic: Expansion of Scope – Additional vaccine administration, including removal of specific age restriction, Tamiflu prescribing and other related administrative changes.

Issue/Description: The Board is being asked to approve for consultation and subsequent submission to the Ministry, amendments to General Regulation 202/94 under the *Pharmacy Act, 1991*, enabling additional authority for vaccine administration with no age restriction, prescribing of oseltamivir (Tamiflu) and transition of authority for administration of COVID-19 vaccine by pharmacy professionals and prescribing of Nirmatrelvir/ritonavir (Paxlovid) by pharmacists from the *Regulated Health Professions Act (RHPA), Controlled Acts Regulation* (107/96) to the *Pharmacy Act, General Regulation* (202/94).

Public interest rationale:

The Ontario health care system continues to see additional pressure, impacting patient access to care. By expanding the scope of pharmacists and pharmacy technicians to administer additional vaccines and offer appropriate treatment options for COVID-19 and influenza, patients will have improved access to care in the community pharmacy when COVID-19, influenza and respiratory syncytial virus (RSV) may have significant impacts on the health system during the 2023-24 respiratory illness season.

Strategic alignment, regulatory processes, and actions:

The information outlined within this document supports the College's first strategic priority: "enhance system and patient outcomes through collaboration and optimization of current scope of practice" and the regulatory amendments to the controlled acts section of *General Regulation 202/94* under the *Pharmacy Act, 1991*.

Background:

- During the 2022-23 Fall and Winter season, Canadians experienced a surge of respiratory infections due
 to increased infections of influenza, RSV and COVID-19, which resulted in higher than usual
 hospitalizations, intensive care unit admissions and deaths compared to previous seasons. Paediatric
 hospitalizations incidences were persistently above historical peak levels¹.
- Based on insight from multiple health system and pharmacy partners, the 2023-24 Fall and Winter season may experience a similar surge of influenza, RSV and COVID-19 as community-based public health measures, such as masking, have relaxed.
- Pharmacy professionals in Ontario have played a significant role over the past few years immunizing
 patients with the influenza and COVID-19 vaccines, increasing access to care and supporting Ontario's
 influenza and COVID-19 vaccination programs. This role has been supported through the expansion of
 scope of practice of pharmacy professionals by:
 - o enabling pharmacists to administer the influenza vaccine to children as young as 2 years old in December 2020, and enabling pharmacy technicians to do the same in Fall 2021,
 - enabling pharmacists and pharmacy technicians to administer the COVID-19 vaccine through a temporary legislative exemption in regulation 107/96 under the RHPA in early 2021,

¹ https://www.canada.ca/content/dam/phac-aspc/documents/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2023-49/issue-1-january-2023/ccdrv49i01a03-eng.pdf

- In addition, pharmacists have played a significant role in treating COVID-19 patients by prescribing Paxlovid since December 2022. This prescribing authority meant patients had greater access to COVID-19 treatment, when appropriate.
- With the expansion of scope for pharmacy professionals over the last few years, the profession is now positioned to provide access to additional health care services for the public, at a time when the health workforce is under tremendous strain, particularly in some remote communities.
- In preparation for a surge of influenza, RSV and COVID-19 in Fall 2023, there is an opportunity to expand the scope of practice of pharmacy professionals so that community pharmacies can utilize their staff in a more efficient and effective way to meet patient demand and needs.
- Following discussions with the Ministry of Health, the College is proposing the following regulatory amendments that will prepare pharmacy professionals for the upcoming 2023-24 respiratory illness season:
 - Pharmacists and pharmacy technicians to administer the Respiratory syncytial virus (RSV) vaccine,
 - o Pharmacy technicians to administer vaccines from Schedule 3,
 - Pharmacists to prescribe Tamiflu,
 - Removal of age specific age restrictions for administration of influenza and other
 Schedule 3 vaccines by pharmacists and pharmacy technicians; and
 - Transition of authority for pharmacists and pharmacy technicians to administer the COVID-19 vaccine and for pharmacists to prescribe Paxlovid, from the Regulated Health Professions Act (RHPA), Controlled Acts Regulation (107/96) to the Pharmacy Act, General Regulation (202/94).

Analysis:

 Recognizing the influenza season is fast approaching, there is some urgency to enable these scope changes. While the College has initiated consultation with clinical experts and received feedback that supports the proposed expansion of scope, further input will be sought through the consultation process.

Pharmacists prescribing Tamiflu

- Like Paxlovid, increasing access to prescribed influenza treatments, such as Tamiflu, at the community
 pharmacy level can support greater access to influenza treatment options. This would support the
 upcoming 2023-24 respiratory illness season, and divert patients from emergency departments, urgent
 care clinics, and primary care clinics so that health care providers can focus their efforts on higher acuity
 patients.
- Current recommendations for Tamiflu prescribing by the Centre for Disease Control and Prevention (CDC)² provides support for the appropriateness of engaging pharmacists to prescribe for the purpose of treating influenza for select patient populations.

Pharmacy professionals administering vaccines with no specific age restriction

Given that pharmacy professionals have the competence and experience administering vaccines to
patients from the age of 6 months and up, different age restrictions based on individual vaccines is
unnecessary and may cause confusion. The assessment of appropriateness to administer a vaccine to
any patient, includes consideration of multiple factors, including age.

² https://www.cdc.gov/flu/professionals/diagnosis/testing-guidance-for-clinicians.htm

Removal of age restrictions is seen in other jurisdictions as well. For example, in the United States, 27 states allow pharmacists to administer all vaccines on the <u>CDC recommended immunization schedule</u> with no age restriction and 19 states allow pharmacists to administer the influenza vaccine with no age restriction³.

Administration of RSV vaccine by pharmacy professionals and Schedule 3 vaccines by pharmacy technicians

- While the RSV vaccine has not yet been approved by Health Canada, an amendment to the regulation is required to allow pharmacy professionals to administer the vaccine, once available. Vaccine administration criteria would be set by the Ministry of Health and communicated to pharmacy professionals so that the expectations of patient population and criteria are clear.
- The same knowledge, skills, and judgment that pharmacy professionals currently use when administering the COVID-19 and influenza vaccines, apply to administration of an RSV vaccine and Schedule 3 vaccines. Training requirements are also the same, as are the expectations outlined in the Guideline Administering a Substance by Injection or Inhalation. In the case of pharmacy technicians, the requirement to ensure patients are first assessed by a pharmacist or other regulated health professional who has the scope to perform a patient assessment and determine vaccine administration is appropriate also remains.

Administrative change to regulatory authority for Administration of COVID-19 vaccine, and prescribing of Paxlovid

By adding COVID-19 vaccine administration by pharmacy professionals and Paxlovid prescribing by
pharmacists to the controlled act section of the regulation under the Pharmacy Act, the temporary
nature of this authority by means of an exemption under regulation 107/96 of the RHPA is removed.
Additionally, the regulatory conditions and expectations associated with these acts becomes
consistent with those set out for other prescribing and vaccine administration authority in regulation
202/94.

Circulation and Submission

- Circulation of the proposed amendments for public review is required for a period of 60 days. During
 this period the College will continue to consult with registrants, clinical experts in pharmacy and other
 health professionals and system partners to plan for and implement this expanded scope in a manner
 that supports patient safety.
- A consultation report, including a summary of feedback and any recommended changes to the
 proposed amendments, will be prepared following circulation. To expedite government approval and
 implementation of the changes in advance of the 2023-24 respiratory illness season, the College will
 submit the proposed amendments to the Ministry, unless the Board Chair determines there are
 substantive changes required following circulation which would necessitate the regulation be brought
 back to the Board for approval.
- If substantive changes are recommended, they will be presented to the Board for consideration at the Sept 2023 meeting with the intent to submit the final regulation amendments to the Minister shortly after.

³ https://naspa.us/wp-content/uploads/2023/04/Pharmacist-Immunization-Authority-April-2023.pdf

Motion: The Board approve the proposed amendments to *Regulation 202/94* of the *Pharmacy Act, 1991* for 60-day public circulation and subsequent submission to the Ministry, unless the Board Chair determines that there are substantive changes required following circulation which would necessitate the regulation be brought back to the Board for approval.

Next Steps:

If approved, the proposed regulations will be posted on the College's consultation page for the mandated 60-day period for circulation and consultation as noted above will continue. A full implementation and communication plan will be developed in collaboration with partners.

Attachments:

- 12.1 Proposed Amendments, O. Reg 202/94
- 12.2 Blackline, Proposed Amendments Reg 202/94

The following is an excerpt of the proposed amendments to <u>General Regulation</u> <u>202/94</u> that pertains to the "Expansion of Scope – Additional vaccine administration, including removal of specific age restriction, Tamiflu prescribing and other related administrative changes". For the entire proposed amended regulation (Attachments 12.1 and 12.2 of the preceding briefing note), please see the <u>Board meeting materials</u> for June 12, 2023, starting on page 101.

- "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); O. Reg. 46/22, s. 1.
 - (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 September 30, 2026, subsection 31 (2) of the Regulation is revoked. (See: O. Reg. 126/20, s. 1 (6) and O. Reg. 766/21, s. 2)

- **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).
 - 3. Administering an influenza vaccine by injection.
 - 4. Administering one of the vaccines specified in Schedule 3 by injection.
 - 5. Administering a coronavirus (COVID-19) vaccine by injection.
 - 6. Administering a Respiratory Syncytial Virus (RSV) vaccine by injection.
- (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 who meets all the requirements in subsection (4) is authorized to perform an act provided for in paragraphs 3 to 6 of subsection (4.11), subject to the terms, conditions and limitations imposed on their his or her certificate of registration. O. Reg. 766/21, s. 1.
- (3) A member <u>referred to in subsection (2)</u> 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,

- 1. Before performing the act, the member must receive an informed consent from the patient or the patient's authorized agent.
 - 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.

Note: On July 1, 2023, subsection 34 (3) of the Regulation is amended by adding the following paragraphs: (See: O. Reg. 95/23, s. 1 (2))

- 7. Where administering a substance specified in Schedule 1 by injection to a patient through an established central or peripheral venous access device, the member must only do so in collaboration with a member of the College of Nurses of Ontario who is a registered nurse in the extended class or a member of the College of Physicians and Surgeons of Ontario.
- 8. Where the act is performed for a purpose other than that of patient education or demonstration the member must, within a reasonable time after performing the act, notify the following persons that the member performed the act, and provide details respecting the act:
 - i. The prescriber, if any, of the substance that was administered.
 - ii. The patient's primary care provider, where the member knows that the patient has such a care provider other than the prescriber.
- 9. Where administering an influenza vaccine by injection, the member must administer the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website.
- 10. Where administering a coronavirus (COVID-19) vaccine by injection, the member must administer the vaccine in accordance with [Ministry guidance TBD].
- 11. Where administering a Respiratory Syncytial Virus (RSV) vaccine by injection, the member must administer the vaccine in accordance with [Ministry guidance TBD].

Note: On July 1, 2023, subsection 34 (3) of the Regulation is amended by adding the following subsection: (See: O. Reg. 95/23, s. 1 (3))

- (3.1) Where a limitation or a route of administration is indicated with respect to a substance listed in Schedule 1, a member shall only administer the substance in compliance with the limitation and in accordance with the route of administration specified. O. Reg. 95/23, s. 1 (3).
- (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 2.1) may only perform an act provided for in paragraphs 3 to 6 of subsection (1) if he or she,
 - (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;
- (ba) possesses sufficient knowledge, skill and judgment to be able to administer the influenza vaccine safely;
- (eb) meets all the requirements in paragraphs 2, 3, and 6 of subsection (3); and
- (c) meets the requirements in paragraphs 9, 10 or 11 of subsection (3), as applicable; 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, has,
 - (i) received an informed consent from the patient or the patient's authorized agent,
 - (ii) a sufficient understanding of the influenza vaccine and condition of the patient for the influenza vaccine to be administered safely, and
 - (iii) 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 and any other relevant circumstances. O. Reg. 766/21, s. 1.
- (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
 - (e) 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 meets all the requirements of this section in subsection (4) is authorized to prescribe the following drugs:
 - 1. For the sole purpose of smoking cessation, the following specified drugs:
 - i. Varenicline Tartrate.
 - ii. Bupropion Hydrochloride.
 - 2. For the sole purpose of treating a minor ailment listed in Column 1 of the Table to Schedule 4; a drug in a class of drugs listed opposite the minor ailment in Column 2 of that Table. O. Reg. 460/22, s. 1 (1).
 - 3. For the sole purpose of treating COVID-19: Nirmatrelvir/ritonavir.
 - 4. For the sole purpose of treating influenza: Oseltamivir.
 - (2) REVOKED: O. Reg. 460/22, s. 1 (2).
- (3) A Part A pharmacist 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.
- (3) A Part A pharmacist, an3.1) An intern or a registered pharmacy student who meets all the requirements in subsection (4) is authorized to perform thean act provided for in paragraphs 1, 2 and 4 of 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;
 - (f) complies with the additional requirements under sections 37 and 38; and

- (g) in the case of a drug referred to in paragraph 2 of subsection (1), has determined, through a therapeutic assessment, that the drug is the most appropriate treatment for the patient's minor ailment condition. O. Reg. 302/12, s. 1; O. Reg. 460/22, s. 1 (3).
- **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 September 30, 2026, 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) and O. Reg. 766/21, s. 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 September 30, 2026, subsection 36 (2.1) of the Regulation is revoked. (See: O. Reg. 126/20, s. 2 (4) and O. Reg. 766/21, s. 2)

- (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 September 30, 2026, 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) and O. Reg. 766/21, s. 2)

- 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 clause 35 (4) (d) or 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; O. Reg. 460/22, s. 2.
- **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;
 - (b) the pharmacy technician is under the direction of a Part A pharmacist at the time when the pharmacy technician performs the act; and
 - (c) if the act is performed to administer a point-of-care test, a Part A pharmacist interprets the results of the test and makes any professional decision arising from those results. O. Reg. 302/12, s. 1; O. Reg. 46/22, s. 2 (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, unless the act is performed to administer a point-of-care test.
 - 1.1 The member may only perform the act to administer a point-of-care test if the test is listed in subsection 28 (2) of Ontario Regulation 45/22 and if it is administered for the purpose of assisting patients with the management of their medication to treat chronic disease.
 - 1.2 Before performing an act described in paragraphs 1 or 1.1, the member must,
 - i. explain the purpose to the patient or his or her authorized agent, and
 - ii. 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.