Tracked Proposed Amendments: *Pharmacy Act Regulations,* O. Reg. 202/94 General

Part VIII.3
Controlled Acts

Interpretation

31. In this Part,

"adapt" means 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;

"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.

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.

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 Table 1 to this Regulation by injection to a patient.

2. Administering a substance specified in Table 2 to this Regulation by inhalation to a patient. O. Reg. 302/12, s. 1.

(2) 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.

(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 Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, ~~is authorized~~ to administer influenza vaccine by injection to a patient who is five years of age or older, if the ~~Part A pharmacist~~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.

34. (5) For the purposes of paragraph 2 of subsection 4(1) of the Act, a Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to administer by injection a vaccine from one of the categories of vaccines listed in Table 3 to this Regulation, 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.

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) 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.

(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, or

iii. have access to the medical record that contains information about the prescription.

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 six 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.

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.

40. Revoked: O. Reg. 451/10, s. 5.

Table 3
Categories of Vaccines
BCG Vaccines
Haemophilus Influenzae type b (Hib) Vaccines
Menningococcal Vaccines • Monovalent (Men-C-C) • Quadrivalent (Men-C-ACYW) • Quanrivalent (Men-P-ACYW-135) • Multicomponent (4CMenB)
Pneumococcal disease Vaccines
Typhoid disease Vaccines
Combined typhoid and hepatitis A Vaccines
Hepatitis A Vaccines
Hepatitis B Vaccines
Hepatitis A and B combined Vaccines
Herpes zoster Vaccines
Human Papillomavirus Vaccines
Japanese Encephalitis Vaccines
Rabies Vaccines
Varicella Virus Vaccines
Yellow Fever Vaccines