Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada

Pursuant to subsection 56(1) of the *Controlled Drugs and Substances Act* (CDSA), and subject to the terms and conditions herein, practitioners and pharmacists, authorized within their scope of practice, are hereby exempted from the following provisions of the CDSA and its regulations when prescribing, selling, or providing a controlled substance to a patient or transferring a prescription for a controlled substance to a pharmacist in Canada:

- Section 5 of the CDSA;
- Subsection 31(1), and section 37 of the Narcotic Control Regulations (NCR);
- Sections G.03.002 and G.03.006 of Part G of the Food and Drug Regulations (FDR);
- Paragraphs 52 (c) and (d), subsection 54(1) of the Benzodiazepines and Other Targeted Substances Regulations (BOTSR).

Individuals delivering a controlled substance on behalf of a pharmacist are exempt from section 5 of the CDSA.

Patients who receive a controlled substance from a pharmacist

pursuant to this exemption, are exempt from subsection 4(1) of the CDSA with respect to that controlled substance.

Except as provided below, the terms used in this exemption have the same meaning as those provided in the CDSA and its regulations:

Patient means:

- a person who is a client of a pharmacist;
- a person who was prescribed a controlled substance; and
- a person:
- to whom a pharmacist may prescribe a controlled substance under this exemption; or,
- to whom a practitioner may verbally prescribe a controlled substance under this exemption.

Pharmacist means a person:

- who is entitled under the laws of a province or territory of Canada to practise as a pharmacist;
- who has not been named in a notice under section 48(1) of the NCR, G.03.017.2 of the FDR or section 79 of the BOTSR unless a notice of retraction has been issued under the respective regulations; and
- whose scope of practice of pharmacy includes prescribing of

drugs including controlled substances as authorized under this exemption and, in a manner consistent with any applicable provincial or territorial pharmacy legislation and any applicable policies of a provincial or territorial licensing authority.

Practitioner means a person who:

- is registered and entitled under the laws of a province or territory to practise in that province or territory the profession of medicine, dentistry, or veterinary medicine, and includes any other person or class of persons described as a practitioner;
- has not been named in a notice under subsection 59(1) of the NCR,G.04.004.2(1) of the FDR, or 79 of the BOTSR unless a notice of retraction has been issued under the respective regulations; and,
- whose scope of practice of medicine, dentistry, or veterinary medicine includes prescribing drugs, including controlled substances as authorized under the relevant provincial or territorial pharmacy legislation and consistent with any applicable policies of any provincial or territorial body responsible for the regulation of practitioners.

Transfer of prescription means the sending of a prescription by a pharmacist to another pharmacy within the same province or territory, for the purpose of having that prescription filled at that pharmacy.

This exemption provides practitioners with the authority to

issue a verbal prescription for controlled substances.

- This exemption provides pharmacists with the authority to transfer a prescription for a controlled substance, and to prescribe, sell, or provide a controlled substance to patients subject to the terms and conditions of this exemption.
- The exemption is only applicable if the following conditions are met.

(A) Pharmacists acting under the authority of this exemption must:

- Only prescribe, sell, provide or transfer the controlled substance to a patient while that patient is under their professional treatment;
- Only prescribe, sell, provide or transfer a controlled substance to a patient in order to extend or renew an existing prescription;
- Only prescribe a controlled substance to a patient in accordance with any policies and/or guidelines established by the provincial or territorial government and by any relevant provincial or territorial licensing authorities;
- Comply with a record keeping obligations established by the provincial or territorial government and any relevant provincial or territorial licensing authority regarding all transactions involving controlled substances;
- If not already required pursuant to item 4, keep records of the following:

- the name and address of any patient who is prescribed, sold, or provided a controlled substance under this exemption;
- the name, quantity, and form of the controlled substance prescribed;
- the name or initials of the pharmacist who prescribed, sold, or provided the controlled substance;
- the date on which the controlled substance was prescribed, sold, or provided; and
- the number assigned to the prescription.
- With respect to the transfer of a prescription, keep records of the following:
- a copy of the prescription written by the practitioner or the record made in accordance with the practitioner's verbal prescription;
- the name and business address of the transferring pharmacist;
- the name and business address of the pharmacist receiving the prescription transfer;
- the number of authorized refills remaining and, if applicable, the specified interval between refills; and
- the date of the last refill.

 All records should be kept in the pharmacy for a period of two years from the date that each record is made.

(B) Practitioners must:

- Only prescribe (including verbally prescribe), sell, or provide the controlled substance to a patient while that patient is under their professional treatment;
- Only prescribe (including verbally prescribe), a controlled substance to a patient in accordance with any policies or guidelines established by the provincial or territorial government or any relevant provincial or territorial licensing authority; and
- Comply with record keeping obligations established by the provincial or territorial government and relevant provincial or territorial licensing authorities regarding all transactions involving controlled substances.

(C) Any individual who delivers a controlled substance on behalf of a pharmacist must

- Deliver the controlled substance to the individual identified in the prescription (or to a person designated to accept the delivery on behalf of that individual);
- Obtain in writing a note from the pharmacist identifying the name of the individual effecting the delivery, the name and quantity of the controlled substance to be delivered, and the place of delivery; and,

- Have the above note as well as a copy of this exemption while effecting the delivery.
- (D) Any controlled substance prescribed, sold, provided or transferred under the authority of this exemption must be for the purpose of facilitating continuation of treatment that the patient was already receiving.

This exemption expires on the earliest of the following dates:

- September 30, 2026;
- The date that it is replaced by another exemption; or
- The date on which it is revoked.

Failure to comply with the terms and conditions of this exemption may, among other things, result in immediate suspension of this exemption, and ultimately, in its revocation.

This exemption may be suspended without prior notice if the Minister deems that such suspension is necessary to protect public health, safety or security. If necessary, the Minister may change the terms and conditions of this exemption. Should this be the case, you will be informed in writing and reasons for the changes will be provided.

Notwithstanding the conditions above on the ability to suspend, the Minister may suspend or revoke the exemption if she believes that it is no longer necessary. Signed for and on the behalf of the Minister of Health,

Jennifer Saxe
Director General
Controlled Substances Directorate
Health Canada

Effective Date: October 1, 2020