



Health Canada Santé Canada

March 19, 2020

To maintain Canadians' access to controlled substances for medical treatments (e.g., treatment of substance use disorders and chronic pain), while they adhere to social distancing guidance from public health officials or if they need to self-isolate, Health Canada has issued the attached exemptions for prescriptions of controlled substances under the *Controlled Drugs and Substances Act* (CDSA) and its Regulations. If permitted within the applicable provincial/territorial scopes of practice, the exemptions:

- permit pharmacists to extend prescriptions;
- permit pharmacists to transfer prescriptions to other pharmacists;
- permit prescribers to issue verbal orders (i.e., over the phone) to extend or refill a prescription; and
- permit pharmacy employees to deliver prescriptions of controlled substances to patient's homes or other locations where they may be (i.e self isolating).

We strongly encourage all partners to work to implement these exemptions in their jurisdictions and welcome any additional suggestions you may have to maintain Canadians' access to controlled substances for medical reasons during the pandemic.

Further, Health Canada is clarifying, with the attached guidance document, activities that are currently permitted under the CDSA and its Regulations.

We strongly urge Ministries and regulators to conduct a thorough assessment of any barriers to access to medicines that could contravene public health advice for social distancing and self-isolation, when appropriate. This could include, for example, temporarily lifting restrictions on take-home doses ("carries") of opioid agonist treatments, and allowing those with chronic conditions to obtain enough medication to last through a period of self-isolation.

We also recognize that local pandemic precautions may impact the operations of Supervised Consumption Sites (SCS), and are committed to work directly with SCS Operators to assess each individual situation and develop appropriate modifications to their protocols and practices. Operators are encouraged to contact the Office of Controlled Substances' Exemptions Section at hc.exemption.sc@canada.ca.

If you have any questions, please contact Health Canada's Office of Controlled Substances, at: hc.ocs-bsc.sc@canada.ca.

Best Regards,

Michelle Boudreau
Director General
Controlled Substances Directorate
Health Canada



SUBSECTION 56(1) CLASS EXEMPTION FOR PATIENTS, PRACTITIONERS AND PHARMACISTS PRESCRIBING AND PROVIDING CONTROLLED SUBSTANCES IN CANADA DURING THE CORONAVIRUS PANDEMIC

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) A person who is a client of a pharmacist; and
- b) A person who was prescribed a controlled substance prior to March 11, 2020;
- c) A person:
 - i. to whom a pharmacist may prescribe a controlled substance under this exemption ;or,
 - ii. to whom a practitioner may verbally prescribe a controlled substance under this exemption.

Pharmacist means a person:

- a) who is entitled under the laws of a province or territory of Canada to practise as a pharmacist;
- b) who has not been named in a notice under s. 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,
- c) 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:

- a) is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry or veterinary medicine, and includes any other person or class of persons described as a practitioner;
- b) has not been named in a notice under ss. 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,
- c) 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 a prescription by a pharmacist to another pharmacy within the same province or territory, for the purpose of having that prescription filled and picked up by the patient 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:

- 1. Only prescribe, sell, provide or transfer the controlled substance to a patient while that patient is under their professional treatment at a pharmacy;
- 2. Only prescribe, sell, provide or transfer a controlled substance to a patient in order to extend or renew an existing prescription;
- 3. 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;
- 4. 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;
- 5. If not already required pursuant to item 4, keep records of the following:
 - a. the name and address of any patient who is prescribed, sold, or provided a controlled substance under this exemption;
 - b. the name, quantity and form of the controlled substance prescribed;
 - c. the name or initials of the pharmacist who prescribed, sold or provided the controlled substance;
 - d. the date on which the controlled substance was prescribed, sold or provided; and
 - e. the number assigned to the prescription.



6. With respect to the transfer of a prescription, keep records of the following:
 - a. a copy of the prescription written by the practitioner or the record made in accordance with the practitioner's verbal prescription;
 - b. the name and business address of the transferring pharmacist;
 - c. the name and business address of the pharmacist receiving the prescription transfer;
 - d. the number of authorized refills remaining and, if applicable, the specified interval between refills; and
 - e. the date of the last refill.
7. 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:

1. Only prescribe (including verbally prescribe), sell, or provide the controlled substance to a patient while that patient is under their professional treatment;
2. 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;
3. 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

1. Deliver the controlled substance to the individual identified in the prescription (or to a person responsible for that individual's care);
2. 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,
3. 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, 2020;
- 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,

Michelle Boudreau
Director General
Controlled Substances Directorate
Controlled Substances and Cannabis Branch

Effective Date: March 19, 2020



Prescription management by pharmacists with controlled substances under the *Controlled Drugs and Substances Act* and its regulations

CONTEXT

Pharmacists are medication experts and play a significant role in monitoring patients and medication to ensure safe and optimal use while contributing to outcome-focussed patient care. With the goal of supporting better medication management and protecting the health and safety of Canadians, Health Canada has developed the following related to prescribing activities with substances regulated under the *Narcotic Control Regulations* (NCR), the *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR) and the *Food and Drug Regulations – Part G* (FDR - Part G).

SCOPE¹

Information in this document applies to pharmacists who are registered and entitled to practice pharmacy under the laws of their province or territory and are entitled to conduct activities with controlled substances.

While this document does not constitute legal advice as to the scope of the *Controlled Drugs and Substances Act* (CDSA) and its regulations, it is Health Canada's interpretation of the legislation and regulations through which guidance is provided to pharmacists and provincial regulators.

ACTIVITIES PERMITTED

Regulations under the CDSA state that a pharmacist is authorized to sell or provide a controlled substance to a person if they have received a prescription or a written order from a practitioner.

While these regulations do not permit pharmacists to prescribe, other related activities that are included in the meaning of *sell or provide* are permitted as long as the quantity dispensed does not exceed the amount originally authorized. These activities include, but are not limited to:

- **Adjusting the formulation:** adjusting the dosage form in which the drug is prescribed;
 - e.g., change from pill to liquid formulations;
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¹ This policy does not include substances regulated under the *Cannabis Act* and its regulations.



- **Adjusting the dose and regimen:** a structured plan that specifies the frequency in which a dose of medication should be ingested;
 - e.g., change from 20mg per day for 5 weeks to 10mg per day for 10 weeks
- **De-prescribing:** the planned and supervised process of reducing or stopping a medication;
- **Part-filling:** dispensing a quantity of a medication which is less than the total amount of the drug specified by a practitioner;
 - For greater clarity, this includes part-fills requested by a patient, when a pharmacy is dealing with an inventory shortage or other situations where the nature of the part fill is a matter of discussion between the pharmacist and patient.

This information is intended to clarify prescribing-related activities pharmacists are permitted to conduct under the CDSA and its regulations.

Pharmacists conducting any of these activities must ensure that their actions do not restrict patients' access to their needed prescriptions and that they continue to work closely with the prescribing practitioner with a view to optimizing patients' health care.

ADDITIONAL REQUIREMENTS

Please note that there may be additional federal, provincial/territorial and municipal laws, regulations, and scope of practice considerations that must be complied with in addition to those under the CDSA and its regulations.

For any questions, please do not hesitate to contact hc.ocs_regulatorypolicy-bsc_politiquereglementaire.sc@canada.ca.