

## Section 56 Exemption Communication

In response to the COVID-19 pandemic, Health Canada has issued a [section 56 exemption](#) for all drugs covered under the [Controlled Drugs and Substances Act \(CDSA\)](#). The purpose of the exemption is to reduce regulatory barriers at the federal level to support the health care system to ensure continuity of care for the patients of Saskatchewan. The exemption was effective March 20, 2020 and will expire on the earliest of the following dates:

- September 30, 2021;
- The date that it is replaced by another exemption; or
- The date on which it is revoked.

### What does the exemption cover:

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. A pharmacist may only prescribe, sell, provide or transfer the controlled substance to a patient while that patient is under their professional treatment at a pharmacy. A pharmacist can only prescribe, sell, provide or transfer a controlled substance to a patient in order to extend or renew an existing prescription.

This exemption permits:

1. pharmacists to extend or renew an existing prescription for CDSA drugs to ensure continuity of care,
2. pharmacists to transfer prescriptions for CDSA drugs to other pharmacists within Saskatchewan only,
3. prescribers (for example physicians, RN(NP)'s, dentists) to issue verbal orders to a pharmacist for CDSA drugs to extend or refill a prescription; and
4. pharmacy employees to deliver prescriptions of controlled substances to patient's homes or other locations where they may be (i.e. self-isolating).

### Who has been communicated with:

To implement these exemptions, SCPP has collaborated with Health Canada, the College of Physicians and Surgeons of Saskatchewan (CPSS), the Saskatchewan Registered Nurses Association (SRNA), the Ministry of Health (MoH), Non-Insured Health Benefits (NIHB), the College of Dental Surgeons of Saskatchewan (CDSS) and the Pharmacy Association of Saskatchewan (PAS). We extend a huge thank you to all of our partners for working together to remove as many barriers as possible to ensure the patients of Saskatchewan can rely on the healthcare system to meet their healthcare needs.

### Impact on Prescription Review Program:

In addition, the Ministry of Health and all of the partners of the [Prescription Review Program \(PRP\)](#), have agreed to **temporarily suspend the PRP requirement for a prescription to be in writing in Saskatchewan** until further notice. What does this mean to you? This means that **all prescriptions for [CDSA drugs](#) and those [Schedule I drugs listed in the PRP](#)**

[bylaws](#) can be verbally ordered by an authorized practitioner directly to a licensed pharmacist.

### 1) Transfers of CDSA Drugs to Pharmacies in Saskatchewan:

The section 56 Exemption for CDSA drugs enables pharmacists to transfer CDSA drugs to another pharmacy within Saskatchewan when requested by a patient. As the exemption is specific to pharmacists, it must be a pharmacist that verbally transfers the CDSA drug(s) and must be received by a pharmacist at the accepting pharmacy.

If the host pharmacy is temporarily closed and the pharmacist is unable to transfer the prescription, the pharmacist may prescribe an additional quantity to ensure continuity of care **only**. Pharmacists must follow the **Pharmacists Prescribing/Extending CDSA Drugs requirements outlined below**.

The College expects that members will use their professional judgment in these situations, for example:

- If a pharmacy is closed for the day, then the prescription can be picked up the next business day.
- If the pharmacy is closed for the weekend, the pharmacist can prescribe for the number of days required to support the patient until a proper transfer can occur
- If the pharmacy is closed longer due to COVID-19, then a prescription to bridge that closure will be required.

Pharmacists **MUST** understand that there is RISK if a transfer is done through PIP without contacting the host pharmacy to ensure the original prescription is deactivated in the host pharmacy computer. The College reminds members of this critical risk and that it must be considered in decision making.

#### **Steps required for a proper transfer within the Pharmaceutical Information Program (PIP):**

PIP must be checked when receiving a verbal transfer for all prescriptions and even more importantly for CDSA drugs in order to complete the transfer process correctly as it involves downloading and linking the existing PIP data.

Pharmacy teams must review PIP's [Quality Improvement Program \(QIP\) website](#) for vendor-specific information on how to properly transfer in and review failed transactions to PIP (click on your specific vendor and review "Failed Transaction Report" and "Transfer in Prescriptions Correctly").

#### **Prescription Requirements for Transferring a CDSA Drug to a Pharmacy in Saskatchewan Include:**

- The date and prescription number;
- A copy of the prescription written by the practitioner or the record made in accordance with the verbal prescription;
- Name and address of the patient;
- Name, strength, remaining quantity and if applicable, the specified interval between refills;
- Directions for use;
- Name of prescribing practitioner;

- Date of last refill and a review of past refill history;
- Name of licensed pharmacist and address of pharmacy providing the prescription;
- The name and business address of the pharmacist receiving the prescription transfer; and
- The signature of licensed pharmacist receiving the prescription.
- All [records](#) should be kept in the pharmacy for a period of two years from the date that each record was made.

**Must also meet PRP requirements (excluding the prescription must be in writing requirement):**

- Patient's Health Services Number
- Patient's Date of Birth
- Total prescribed quantity written alphabetically and numerically (only one is required for prescriptions transferred by fax)
- Part-fill quantity if applicable
- Interval between fills

Of note: pharmacy team members may come across barriers if a patient has been restricted to a pharmacy and those will have to be addressed with individual benefit providers.

**2) Verbal Orders for CDSA Drugs:**

The section 56 Exemption enables pharmacists to accept verbal orders for [CDSA drugs](#). In order to enable the exemption, the PRP requirement for a written prescription has been suspended for the duration of the exemption. All other PRP requirements will remain in effect as outlined above. The temporary exemption from Health Canada permits prescriptions for [CDSA drugs](#) and the temporary suspension of the written PRP requirement enables those Schedule I drugs listed in the [PRP Bylaws](#) to be ordered verbally to a licensed pharmacist by an [authorized provider](#).

Verbal prescriptions can increase the risk of errors and diversion therefore pharmacists should take steps necessary to authenticate the source of verbal prescriptions, while providers should be prepared to provide their unique license number assigned to them by their College as a form of authenticity. SCPP has collaborated with CPSS, SRNA and CDSS to ensure providers are prepared to give their unique license number when giving a verbal prescription for a CDSA drug(s). Pharmacists must validate the license number by using [PIP's provider search](#) found under the reference tab to ensure every effort is being made to prevent diversion and protect the public.

SCPP recommends documenting the words section 56 exemption or S(56) on the transcribed verbal prescription for future Health Canada audits.

Verbal orders facilitate and support isolation and social distancing practices for the public during the COVID-19 pandemic. Providers are able to conduct virtual and telephone consultations and at times may not have access to prescribing electronically through PIP or faxes. SCPP reminds pharmacists of the requirement to check PIP prior to filling any [CDSA drug](#) and drugs listed in the [PRP bylaws](#).

### 3) Pharmacists Prescribing/Extending CDSA Drugs

Under the exemption, pharmacists can prescribe (extend/renew) prescriptions for patients who are currently on existing CDSA therapies (including methadone and Suboxone®) when the patient is unable to obtain a new prescription from their usual provider. Efforts must be made to transfer an existing prescription if there are part fills remaining or obtain a prescription from the patient's prescriber prior to prescribing a CDSA drug. The intention of this exemption is to ensure continuity of care and support self-isolation; therefore, pharmacists must prescribe at the same dose and duration, and cannot make therapeutic substitutions or initiate a new therapy. Pharmacists must have the skills, knowledge and competencies prior to prescribing for CDSA drugs and must have read and have a clear understanding of the section 56 exemption as provided in the [letter from Health Canada](#).

As per SPP Bylaws, Part K(2), pharmacists must utilize the [Pharmacist Assessment Record \(PAR\)](#) created by medSask, and fax the completed PAR to the patient's provider so they are informed of the prescription for their office records. Specific PARs can be found for [methadone](#), [Suboxone®](#) and a [generic PAR](#) for all other CDSA drugs.

The patient's medication history must be reviewed in the PIP, and applicable lab values and or urine screens in the eHealth viewer prior to prescribing and dispensing. Pharmacists must ensure there are no transmission errors to the PIP by [reviewing the Failed Transaction Report](#) daily. Failure to do so could lead to missing critical information in the PIP.

If the pharmacy did not fill the most recent prescription, every effort must be made to contact the pharmacy and obtain and confirm the dose and directions and any other pertinent information in the notes.

While every effort should be made for the patient to see their usual provider, if that is not possible due to social isolating and distancing policies or the provider is in quarantine and a pharmacist has already prescribed once for the patient, it is acceptable for a pharmacist to prescribe consecutively (does not have to be the same pharmacist). Ideally, a patient should be followed up by their usual provider after a pharmacist prescribes, however during these uncertain times there may be a requirement to prescribe more than once until it is safe for the patient to receive an assessment by their usual provider. This is permissible under the exemption and the Drug Plan and Extended Benefits Branch (DPEBB) is aware this may occur.

### 4) Delivery of CDSA Drugs:

Pharmacy staff members delivering CDSA drugs must ensure practices are in place to validate the identity of the individual receiving the medication. The pharmacy staff must verify with the patient prior to delivery if they, or an agent will be receiving the medication, and the name of that individual should be provided to the person delivering to ensure the correct individual receives the medication. Further guidance will be provided in a separate communication for methadone and Suboxone® with respect to carries, daily witnessing and deliveries. SPP strongly encourages pharmacy managers to have procedures in place to ensure the safety of the delivery personnel and the safe delivery of CDSA drugs.

- Pharmacy staff who deliver controlled substances must adhere to the requirements of social distancing.

- Pharmacy staff who deliver prescriptions **must ensure** they:
  - can confirm the identity of the patient or the person responsible for that individual's care,
  - can ensure the security and integrity of the controlled substances provided to the patient,
  - can ensure the privacy and confidentiality of the patient is maintained at all times,
  - 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. Further clarification from Health Canada indicates that this note can be inside the delivery bag for the patient and the employee making the delivery must have a way to contact the pharmacist and must return all undelivered items to the pharmacy before the end of the day, and
  - have a copy of the above note as well as a copy of the Health Canada Exemption while effecting the delivery.

Please continue to check SCPPs website on a daily basis as things are changing quickly at <https://saskpharm.ca/site/coronavirus-information>.

If you have any questions about the section 56 exemption, please contact Lori Postnikoff, Deputy Registrar, at [lori.postnikoff@saskpharm.ca](mailto:lori.postnikoff@saskpharm.ca).