PRESCRIPTION REGULATION SUMMARY CHART

Version: March 2025

Portions of this chart are not applicable at this time due to the Subsection 56(1) Class Exemption issued by Health Canada

Health Canada has issued a *Controlled Drugs and Substances Act* (CDSA) subsection 56(1) class exemption for pharmacists from the provisions of:

- 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*.

The exemption expires on **September 30, 2026**, or until it is replaced by another exemption or revoked.

While this exemption is in effect, Part A pharmacists are authorized to:

- Dispense any narcotic pursuant to a written or verbal order from a practitioner
- Transfer prescriptions of narcotics and controlled drugs to another pharmacist in Canada. Prescriptions that have already been transferred may be transferred again to another pharmacist.
- Transfer prescriptions for a benzodiazepine or other targeted substance to another pharmacist. Prescriptions that have already been transferred may be transferred again to another pharmacist in Canada
- Refill prescriptions for a benzodiazepine or other targeted substance if more than one year has elapsed since the date it was issued by the prescriber
- Adapt and/or renew prescriptions for controlled substances for the purposes of facilitating continuation of treatment
    - Provincial regulations under the *Pharmacy Act* have also been amended to enable pharmacists in Ontario to renew and adapt prescriptions (including de-prescribing) for controlled substances (narcotics, controlled drugs and targeted substances).

References:

- Health Canada Subsection 56(1) Class Exemption for Patients, Practitioners and Pharmacists Prescribing and Providing Controlled Substances in Canada
- Prescription management by pharmacists with controlled substances
- Subsection 56(1) Class Exemption– Frequently asked questions

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PRESCRIPTION (Rx) REGULATION SUMMARY CHART

*The activities permitted by the **Health Canada s.56 exemption** are NOT reflected in the chart below.
Please refer to **page 1** for details.

Classification	Description	Rx Requirements[1]		Refills & Transfers[2]		Purchase & Sales Record Requirements[3]	
		Written[1a,b]	Verbal[1a,c]	Refill	Transfer	Purchase Record[3e]	Rx Sales Record[3f]
Narcotic Drugs E.g. buprenorphine, codeine, fentanyl[4], hydromorphone, ketamine, Lomotil®, methadone, meperidine, morphine, nabilone, Novahistex DH®,oxycodone, Percocet®, Teva-Lenoltec No.4, etc.	Drugs listed in the Schedule to the *Narcotic Control Regulations* - All products containing only 1 narcotic ('straight' narcotics) - All narcotics for parenteral use - Narcotic compounds with 1 narcotic and 1 non-narcotic active ingredient - All products containing any of the following 5 narcotics: diacetylmorphine (heroin), hydrocodone, methadone, oxycodone, pentazocine	✓	✗	✗	✗	✓	✓
Narcotic Preparations (Verbal Rx Narcotics) E.g. Dimetane Expectorant C®, Fiorinal® C ¼ & ½, Robitussin AC®, Teva-Lenoltec No.2 & 3, etc.	All combinations for non-parenteral use, containing only 1 narcotic (other than: diacetylmorphine (heroin), hydrocodone, methadone, oxycodone, pentazocine) and 2 or more non-narcotic ingredients in recognized therapeutic doses	✓	✓	✗	✗	✓	✗[3g]
Exempted Codeine Preparations E.g. Mersyndol®, acetaminophen/caffeine/codeine 8mg, etc.	Preparations containing codeine (up to 8 mg/solid oral dosage form, or 20 mg/30mL of liquid) and 2 or more active non-narcotic ingredients	May be sold as per NAPRA Schedule II. If dispensed pursuant to a Rx, follow the requirements for Narcotic Preparations, above.					
Controlled Drugs Part I E.g. amphetamines, dextroamphetamine, methylphenidate, etc.	Drugs listed in Part I of Schedule to Part G of the *Food and Drug Regulations* - All products containing only 1 controlled drug ('straight' controlled drugs) and all combinations containing more than 1 controlled drug	✓	✓	✓, if Rx includes dates for, or intervals between refills ✗, if verbal Rx	✗	✓	✓
Controlled Drugs Part II E.g. butorphanol, *most* barbiturates, nalbuphine, etc.	Drugs listed in Part II of the Schedule to Part G of the *Food and Drug Regulations*	✓	✓	✓, if Rx includes dates for, or intervals between refills	✗	✓	✗[3g]
Controlled Drug Preparations Part II E.g. Tecnal®	All combinations containing 1 controlled drug in Part II and 1 or more non-controlled ingredient(s) in a recognized therapeutic dose						
Controlled Drugs Part III Anabolic steroids and derivatives (e.g. testosterone, etc.)	Drugs listed in Part III of the Schedule to Part G of the *Food and Drug Regulations*	✓	✓	✓, if Rx includes dates for, or intervals between refills	✗	✓	✗[3g]
Benzodiazepines & Other Targeted Substances E.g. chlordiazepoxide, clobazam, clorazepate, diazepam, lorazepam, oxazepam, etc.	Drugs listed in the Schedule to the *Benzodiazepines and Other Targeted Substances Regulations.*	✓	✓	✓, refills valid if <1 year has elapsed since date Rx was issued	✓, but Rx can only be transferred *once*	✓	✗[3g]
Other Prescription Drugs	All drugs listed in the Prescription Drug List (PDL) of the *Food and Drug Regulations* or in Schedule I of NAPRA National Drug Schedules.	✓	✓	✓	✓	✓	✗

This is a summary. Refer to legislation for detailed information. Additional resources are available on www.ocpinfo.com.

PRESCRIPTION (Rx) REGULATION SUMMARY CHART

*The activities permitted by the **Health Canada s.56 exemption** are NOT reflected in the chart below.
Please refer to **page 1** for details.

[1] Prescription and Dispensing Record Requirements are set out in the federal *Controlled Drugs and Substances Act* (CDSA) and the *Food and Drugs Act* (FDA), and the provincial *Drug & Pharmacies Regulation Act* (DPRA), the *Narcotics Safety & Awareness Act* (NSAA), the *Safeguarding our Communities Act (Patch for Patch Return Policy)* and their respective regulations

[a] **Dispensing Record Requirements:**

- Name and address of patient
- Name, strength, quantity and form of drug
- Manufacturer of drug
- Directions for use
- Identification number of prescription
- Date of dispensing
- Signature (authorization) of dispensing pharmacist (RPh) and pharmacy technician (RPhT) (if applicable)
- Price charged
- Name and address of prescriber
- Prescriber's registration number*
- Patient identification (ID) number and type*

[b] Written prescriptions may be transmitted electronically (e.g., by fax, electronic ("e-") prescribing software, etc.)

[c] Additional Verbal Prescription Record Requirements: The signature (authorization) of the pharmacy professional receiving the verbal prescription, where different from the pharmacy professional dispensing the prescription

* Per the NSAA, prescriber registration number and patient identification number/type requirements apply to monitored drugs as defined by the Ministry of Health, including all controlled substances and opioids

[2] Where a transfer is not permitted, this includes transfers of part-fills and "logged" prescriptions

- A logged prescription is a new, unfilled prescription that is entered into the patient record ('on hold') and may be dispensed at a later time
- A part-fill is described as dispensing a quantity less than the total amount of drug specified by the prescriber. Any prescription can be written to direct the dispensing of part-fills and may be used in cases where refills are not permitted (i.e. narcotic prescriptions).

[3] Purchase and Prescription (Rx) Sales Record requirements are set out in the federal CDSA and FDA, the provincial *Drug Interchangeability and Dispensing Fee Act* (DIDFA) and their respective regulations

[e] **Purchase Record Requirements** - Maintain in the Narcotic and Controlled Drug Register, as invoices filed in chronological order, or in other record for such purposes; must be readily available for auditing purposes for at least 2 years.

[f] **Prescription Sales Record Requirements** - Maintain in the Narcotic and Controlled Drug Register or in a computer from which a printout must be readily available for auditing purposes for at least 2 years.

[g] Prescription sales records are not required, however, emergency sales to other pharmacists require a sales record as per *Narcotic Control Regulations* s45(1)(b), *Food and Drug Regulations* subsection G.03.014(b), *Benzodiazepines and Other Targeted Substances Regulations* s55(1)(b)(ii)

[4] Fentanyl patches must be dispensed according to the provincial *Safeguarding our Communities Act (Patch for Patch Return Policy)* and its regulations

Notes:

- Scanned original prescriptions and dispensing records must be retained for at least 10 years after the patient's last recorded pharmacy service or at least 10 years after the day on which the patient reached/would have reached the 18 years of age, whichever is longer (DPRA; O. Reg. 264/16)
- Report an unexplained loss, theft or forged prescription (if dispensed) of a controlled substance within 10 days to the Office of Controlled Substances. See Health Canada's website for additional information: Loss or Theft

This is a summary. Refer to legislation for detailed information. Additional resources are available on www.ocpinfo.com.

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