Ontario College of Pharmacists
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CONTROLLED SUBSTANCES: PRESCRIPTION REGULATION SUMMARY CHART

This is only a summary. Refer to the legislation for detailed information.

Controlled Substance[1]	Prescription Record[2] Requirements	Dispensing (Sales) Record Requirements[3]	Record Retention Requirements

N Narcotics
• Substances listed in Schedule 1 of the *Controlled Substances Regulations*
e.g., buprenorphine, codeine, fentanyl[4], hydromorphone, ketamine, meperidine, methadone[5], morphine, nabilone, oxycodone, tramadol
	Written or verbal[6]:
	• Written prescriptions may be generated and transmitted electronically if the digital signature can be authenticated[7].
	A pharmacy professional receiving a written prescription must record[8]:
	• Their name
	• Date of the prescription
	• Date they received the prescription[9]
	A pharmacy professional receiving a verbal prescription must record[10]:
	• Their name
	• Prescribing practitioner's name and practice address
	• Date the prescription was received
	• Name of controlled substance
	  ○ Brand name and DIN, if applicable
	• Strength and form of controlled substance
	• Quantity
	  ○ Number of containers, and if applicable, units per container[11]
	• If applicable the number of refills, and intervals between refills if specified[12]
	Additional requirements for Narcotics Safety and Awareness Act (NSAA)[13] s10 and O. Reg. 381/11 s5:
	• Patient identification (ID) number and type
	• Prescriber's registration number
		• Pharmacist's name
		• Patient's name and address
		  ○ For animals, also record the name of the animal owner
		• Prescribing practitioner's name and address
		• Prescription identification number
		• Date of dispensing
		• Name of controlled substance
		  ○ Brand name and DIN, if applicable
		• Strength and form of controlled substance
		• Quantity
		  ○ Number of containers, and if applicable, units per container
		• If applicable, number of refills
		  ○ If specified, intervals between refills
		Additional requirements for Drug and Pharmacies Regulation Act (DPRA) s156:
		• Directions for use, as prescribed
		• Drug manufacturer
		• Signature of dispensing pharmacy technician and/or pharmacist,
		  ○ If applicable, signature of the pharmacy professional receiving the verbal prescription
		• Price charged
		Additional requirements for NSAA s11 and O. Reg. 381/11 s5:
		• Patient ID number and type
		• Patient date of birth and gender
		• Prescriber's registration number
		• Days of therapy dispensed
			Sales can be recorded manually in a Narcotic and Controlled Drug Register or electronically.
			Records must:
			• Be kept separately, in sequence as to date and number[14]
			• Use a method that permits an audit of it to be made at any time[15]
			• Be accessible at the pharmacy where the information was recorded[16]
			• Kept for two years after the day it was recorded, or in the case of a prescription or order, after the day it was received[17]
			  ○ Prescriptions and dispensing records are subject to longer retention under the DPRA
			Additional requirements for DPRA s156(2) and O. Reg. 264/16 s2:
			• Prescription records must be retained for not less than ten years[18]
			Additional requirements for O. Reg. 381/11 s7 (under NSAA):
			If an agent receives the patient's prescription, record their:
			• Name and address, as verified
			• ID number and type provided by the agent for verification

C Controlled Drugs • Substances listed in Schedule 2 of the *Controlled Substances Regulations* **Part 1:** Amphetamines, methylphenidate, etc. **Part 2:** Barbiturates (e.g., phenobarbital), butorphanol, nalbuphine **Part 3:** Anabolic steroids (e.g. testosterone)			
C T Targeted Substances • Substances listed in Schedule 3 of the *Controlled Substances Regulations* **Part 1**: flunitrazepam **Part 2:** benzodiazepines (e.g., alprazolam, clobazam, diazepam, lorazepam, midazolam, oxazepam, triazolam), zolpidem			
N Exempted Codeine Products • Codeine phosphate (up to 8 mg/tablet or 20 mg/30 mL), and 2 or 3 medicinal non-narcotic ingredients[19]	May be sold as per NAPRA Schedule II if the pharmacist has reasonable grounds to believe the product will only be used for recognized medical purposes. • If dispensed pursuant to a prescription, refer to requirements for Narcotics above.	The *inner label* and *outer label*[20] must have this conspicuously and legibly printed on it: "This product contains codeine and should not be administered to children except on the advice of a physician, dentist or nurse practitioner."	Not applicable.

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References and resources

[1] ***Controlled substance*** means a substance set out in Schedules I, II, III, IV, or Part 1 of V of the federal *Controlled Drug and Substances Act, 1996*. This resource applies to the substances named in Schedule 1 (narcotics), Schedule 2 (controlled drugs) and Schedule 3 (targeted substances) under the *Controlled Substances Regulations*.

[2] ***Prescription*** means an authorization given by a practitioner that a stated amount of a controlled substance, other than a restricted drug, be sold or provided for the individual named or the animal identified in it. *Controlled Drugs and Substances Act, 1996*, s 1(1)

[3] *Controlled Substances Regulations*, s113

[4] Refer to the Patch-For-Patch Fentanyl Return Program: Fact Sheet for more information.

[5] Refer to the Key Requirements for Methadone Maintenance Treatment (MMT) Fact Sheet before dispensing methadone for opioid agonist treatment (OAT).

[6] *Controlled Substances Regulations*, s98(1)

[7] Refer to the Faxed Transmission of Prescriptions Policy and Authenticity of Prescriptions using Unique Identifiers for Prescribers Position Statement for more information.

[8] *Controlled Substances Regulations*, s116

[9] Prescriptions for controlled substances can only be transferred within 2 years from the date received. Refer to the Prescription Transfers Fact Sheet for more information.

[10] *Controlled Substances Regulations*, s117

[11] ***Container*** means an immediate container of a controlled substance. *Controlled Substances Regulations,* s1(1)

[12] Refer to the Prescription Refills, Part-Fills and Intervals Fact Sheet for more information

[13] The *Narcotics Safety and Awareness Act, 2010, s2* applies to the prescribing and dispensing of a monitored drug (i.e., any controlled substance as defined in the *Controlled Drugs and Substances Act* or any drug product that is an opioid that is not listed under the *Controlled Drugs and Substances Act*).

[14] *Controlled Substances Regulations*, s123(2)

[15] *Controlled Substances Regulations*, s122

[16] *Controlled Substances Regulations*, s124

[17] *Controlled Substances Regulations*, s123(1)

[18] Documents relating to the care of a patient (including original prescriptions and dispensing records) must be maintained for at least 10 years from the last recorded pharmacy service provided to the patient, or until 10 years after the day on which the patient reached (or would have reached) the age of 18 years, whichever is longer. Refer to the Record Retention, Disclosure and Disposal Guideline for more information.

[19] The amount of the two [three] additional medicinal ingredients cannot be less than the regular minimum single dose for one ingredient or one-half [one-third] of the regular minimum single dose for each ingredient; *Controlled Substances Regulations,* s98(2)

[20] Defined in the *Food and Drug Regulations*, A.01.010