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Controlled substances: dispensing and destruction

by Andrew Tolmie, RPh, BScPhm



Learning objectives

Upon successful completion of this lesson, the pharmacy technician will be able to do the following:

- 1. Recognize the importance of and risk associated with controlled substance medication therapy.
- 2. Understand federal legislation describing the requirements associated with controlled drug dispensing and destruction.
- 3. Identify the role of the pharmacy technician in controlled substance dispensing and destruction.

Introduction

Controlled substances (which include narcotics, controlled drugs, and benzodiazepines and other targeted substances) are an important and common part of the care provided to Canadians for a range of medical conditions. Pain management, hormone deficiencies, anxiety disorders, and the treatment of addictions are just a few of the many areas of practice in which practitioners and patients depend upon the safe and effective use of controlled substances as part of their therapeutic plans.

Chronic pain is one of the most common reasons for seeking medical attention in Canada; it is thought to affect between 15%

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TABLE 1 - Number of deaths reported related to opiates in Ontario from January 1 to August 31, 2013 ⁽³⁾				
Opiate	Number of deaths*	Mean Age	Median Age	Age Range
Codeine	14	83	50	21-83
Fentanyl	32	36	37.5	21-63
Heroin	13	34	31	21-53
Hydromorphone	25	51	48	21-70
Methadone	31	37	44	17-64
Morphine	19	53	48	17-83
Oxycodone	37	44	51	22-68

*Where an opiate was indicated to result in death. Data extracted September 2013 is preliminary and subject to change.

TABLE 2 - Federal legislation regulating controlled substances				
Regulation	Federal Act	Controlled substance examples		
Narcotic Control Regulations	Controlled Drugs and Substances	codeine, oxycodone, methadone		
Benzodiazepines and Other Targeted Substances Regulations	Act (CDSA)	alprazolam, temazepam		
Food and Drug Regulations – Schedule G (controlled drugs)	Food and Drugs Act	methylphenidate, testosterone		

and 29% of the Canadian population.⁽¹⁾ Therefore, it is no surprise that the use of narcotic (opioid) pain relievers among the general populations was 15% according to a 2013 Canadian Tobacco, Alcohol and Drugs Survey (CTADS).⁽²⁾ Although narcotic pain relievers, among other controlled substances, have the potential to enhance patient outcomes, they must be managed with a high degree of attentiveness in order to reduce any potential risk to patients and the public.

Canada lacks national-level data with respect to mortality and hospital admission caused by prescription narcotics and other controlled substances. We have a patchwork of provincial data which reinforce the sometimes lethal consequences of inappropriate narcotic treatment and misuse (see Table 1); these alarming figures demonstrate the importance of developing tools to ensure the safe, secure and effective dispensing of all controlled substances.

Pharmacy technicians are often the first point of contact for patients in the dispensing of new or repeat controlled substance prescriptions. They are ideally positioned to assist the pharmacist in identifying concerns related to prescription completeness, signs of misuse, diversion and forgery. In the hospital setting, pharmacy technicians are equally well positioned to contribute to the review of dispensing. Furthermore, pharmacy technicians, as regulated health professionals in several jurisdictions in Canada, now have the legal authority and responsibility for the appropriate storage, distribution and destruction of controlled substances.

Regulatory Framework

In Canada, the prescribing and dispensing of controlled substances is regulated federally and includes three pieces of federal legislation (see Table 2).

In addition to federal legislation, it is important for pharmacy technicians to be aware of any additional provincial legislation and regulatory body policies imposed on the dispensing of controlled substances within one's province of practice. Examples include Ontario's Narcotic Safety and Awareness Act and Manitoba's prescription requirements for exempted codeine products. Pharmacy technicians should consult their provincial regulatory body websites and publications for information and updates.

Prescription Requirements

As outlined in the National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards of Practice for Canadian Pharmacy Technicians, pharmacy technicians are expected to review prescriptions to confirm that they are complete, authentic and meet all current laws, regulations and policies.⁽⁴⁾ To assist pharmacy technicians in meeting this obligation, provincial pharmacy regulatory authorities have developed regulation summary tools describing specific requirements depending on the classification of drug (see example in Table 3).

Dispensing Considerations

Ensuring that prescriptions directing the dispensing of controlled substances meet all legal requirements (federal and provincial) is an important duty for pharmacy technicians. However, the role of the pharmacy technician extends beyond the prescription, in supporting the pharmacist in assessing the patient and appropriateness of the therapy prescribed. Pharmacy technicians should remain aware of and identify:

- Patterns of late or early prescription refills/ part-fills
- Unusual patient behaviour (e.g., nervousness, lack of eye contact, aggressiveness)
- Changes to a patient's customary appearance or demeanour
- Instances of multiple controlled substances from different prescribers
- Alerts from provincial (or other third-party) controlled substance monitoring systems

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TABLE 3 - Controlled substance federal regulation summary* Observice interview				
Classification (examples)	Description	Prescription Requirements	Refills & Transfers	Purchase & Sales Records
Narcotic Drugs (Schedule N drugs) (e.g., buprenorphine, codeine, fentanyl, hydromorphone, ketamine, methadone [prescriber exemption required], morphine, etc.)	All products containing only 1 narcotic (straight narcotic drugs). All narcotics for parenteral use. All narcotic compounds containing more than 1 narcotic drug. All narcotic compounds containing less than 2 other non-narcotic ingredients. All products containing 1 of the following 4 narcotics: hydrocodone, methadone, oxycodone, pentazocine	Written or faxed prescription.	Refills are not permitted. All prescriptions must be written or faxed. Transfers are not permitted.	Purchase Records: Purchases must be recorded in the Narcotic and Controlled Drug Register. Sales Records: Record of sales in Narcotic and Controlled Drug Register.
Narcotic Preparations (Verbal Prescription Narcotics) Schedule N preparations (e.g., Fiorinal-C1/4, Fiorinal®-C1/2, Tylenol No.2, Tylenol No.3, Robitussin AC, Dimetane Expectorant C, 282, 292, etc.) Exempted Codeine Products: (e.g., acetaminophen w/ codeine & caffeine)	All combinations containing only 1 narcotic drug (not from the 4 narcotics listed above) and 2 or more non-narcotic ingredients in a recognized therapeutic dose and not intended for parenteral use. Exempted codeine products: Contain codeine up to 8 mg/solid dosage form or 20 mg/30 mL liquid and 2 or more active non- narcotic ingredients.	Written, faxed or verbal prescription permitted.	Refills are not permitted. Transfers are not permitted.	Purchase Records: Purchases must be recorded in the Narcotic and Controlled Drug Register. Sales Records: Not a requirement
Controlled Drugs, Part I (Sch. G) (amphetamines and others e.g., methylphenidate, dextroamphetamine, etc.)	All straight controlled drugs. All combinations containing more than 1 controlled drug.	Written, faxed or verbal prescription permitted.	Written Rx: May be refilled if the prescriber has indicated in writing, or faxed, the number of refills and dates for, or intervals between refills. Verbal Rx: No refills allowed. Transfers are not permitted.	Purchase Records: Purchases must be recorded in the Narcotic and Controlled Drug Register. Sales Records: Record of sales in Narcotic and Controlled Drug Register.
Controlled Drugs, Part II (Sch. G) (butorphanol and barbiturates, e.g., phenobarbital) Controlled Drug Preparations Part II (Sch. G) (e.g., Bellergal Spacetabs, etc.) Controlled Drugs, Part III (Sch. G) (e.g., testosterone etc.)	Most barbiturates and others All combinations containing 1 controlled drug in Part II and 1 or more non-controlled ingredients in recognized therapeutic dose. Anabolic steroids and derivatives	-	Refills permitted for written or verbal Rx if the prescriber has authorized (at the time of issuance) the number of refills and dates for, or intervals between refills. Transfers are not permitted.	Purchase Records: Purchases must be recorded in the Narcotic and Controlled Drug Register. Sales Records: Not a requirement
Benzodiazepines & Other Targeted Substances (e.g., alprazolam, diazepam, flurazepam, lorazepam, chlordiazepoxide, clobazam, clorazepate, midazolam, oxazepam, temazepam, triazolam, etc.)	All drugs listed in the schedule to the Benzodiazepines and other Targeted Substances Regulations.	Written, faxed or verbal prescription permitted.	Refills are permitted via written, faxed or verbal prescriptions. Transfer of Rx permitted except for an Rx that has already been transferred. Note: prescriptions for benzodiazepines and other targeted substances are valid for 1 year from the date prescribed.	Purchase Records: Purchases must be recorded in the Narcotic and Controlled Drug Register. Sales Records: Not a requirement

*Table 3 is adapted from the Ontario College of Pharmacists Prescription Regulation Summary Chart.⁽⁶⁾ This summary is intended to capture federal legislation only. Always refer to official legislation and additional provincial regulations.

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TABLE 4 - Oral opioid analgesic conversion table* ⁽⁶⁾				
	Equivalence to oral morphine 30 mg:	To convert to oral morphine equivalent, multiply by:	To convert from oral morphine, multiply by:	
Morphine	30 mg	1	1	
Codeine	200 mg	0.15	6.67	
Oxycodone	20 mg	1.5	0.667	
Hydromorphone	6 mg	5	0.2	
Meperidine	300 mg	0.1	10	
Methadone and tramadol	Morphine dose equivalence not reliably established			

*table is based on oral dosing for chronic non-cancer pain

• Narcotic prescriptions for doses greater than 200 mg of morphine or equivalent per day (Table 4)

All of these may be indicative of less than optimal drug therapy, or in some instances medication misuse or diversion. Such scenarios and observations should be documented by the pharmacy technician and discussed with the pharmacist. An intervention or change in therapy may be warranted, in collaboration with the pharmacist, the prescriber and the patient.

Destruction of Controlled Substances

Standards of practice require that pharmacy technicians, when distributing drugs, demonstrate a responsibility for ensuring that inventory management and distribution of scheduled drugs and controlled substances is completed in accordance with required applicable laws, regulations and policies.⁽⁴⁾ This includes adhering to established regulations in the destruction of narcotics, controlled drugs and targeted substances. It is important to note that the documentation and authorization process for the destruction of controlled substances varies by classification.

Narcotics and Controlled Drugs

Prior to the destruction of any damaged, expired and unusable narcotic or controlled drugs in a pharmacy's inventory, authorization had to be received from Health Canada's Office of Controlled Substances (OCS). Destruction requests had to specify the name, strength and quantity of drug to be destroyed, as well as the pharmacist's signature with his or her regulatory body license number.

As of July 2016, pharmacies are no longer required to request and receive prior authorization for local destruction of unserviceable narcotics and controlled drugs from Health Canada. However, all other requirements, including documentation, remain in place.

Methods of destruction can vary; however, what is critical is that the drugs are altered or denatured to render consumption improbable or impossible. An example includes using soapy water as a vehicle to create a paste or slurry before disposal by a licensed waste management company. Such disposal must be done in accordance with federal, provincial and any municipal environmental legislation. Pharmacy teams should collaborate with waste management companies in ensuring compliance with all applicable legislation.

It is important to note that two healthcare professionals are required to witness the destruction of narcotics and controlled drugs, of which only one can be a pharmacy technician. For example, this may include two pharmacists or a pharmacist and a pharmacy technician. Two pharmacy technicians cannot witness and destroy narcotics. The name of the pharmacist and witness must be recorded along with signatures.

CONTACT INFORMATION FOR OFFICE OF CONTROLLED SUBSTANCES Office of Controlled Substances Health Canada 150 Tunney's Pasture Driveway Tunney's Pasture AL 0300B Ottawa ON K1A 0K9

Phone: 613-954-1541 Fax: 613-957-0110 E-mail: national_compliance_section@ hc-sc.gc.ca

Benzodiazepine and Targeted Substances Unlike narcotics and controlled drugs, benzodiazepines and targeted substances do not require approval by the OCS prior to destruction. However, this class of controlled substance does still require a record of destruction including the drug name, strength, quantity of the targeted substance, and the date of destruction.

Record Keeping

As per federal regulations, records for narcotics, controlled drugs, benzodiazepines and targeted substances are to be maintained for a period of two years. Authorizations to destroy and records of such destruction may be kept with the narcotic and controlled drug purchase records. Pharmacists and pharmacy technicians should also be aware of any additional federal legislation (e.g., Revenue Canada) or provincial requirements when considering record-keeping practices.

Special Considerations for Fentanyl Patches

Fentanyl is a narcotic drug that is primarily used to treat severe pain. It is available as an injection, and as a transdermal patch that slowly releases the medication so it can be absorbed through the skin. When prescribed and administered appropriately, fentanyl can be an effective treatment for patients with severe pain. However, a consequence of its high potency, is that when used incorrectly, fentanyl can result in severe health risks and even death.

The Canadian Centre on Substance Abuse estimates that between 2009 and 2014, at least 655 deaths in Canada were caused by fentanyl or fentanyl was a contributing cause.⁽⁷⁾ Fueling these numbers is the high prevalence of fentanyl patch diversion and abuse within the illicit drug market. In an effort to curb this trend many jurisdictions, by way of pharmacy-level policy or regional ini-

tiatives in collaboration with law enforcement. have instituted fentanyl "patch for patch" return programs. Although programs may vary by province or region, the overriding theme is that patients (or their agent) must return used fentanyl patches to the pharmacy before new fentanyl patches are dispensed. In Ontario, this concept has taken the shape of formal legislation via Bill 33 - Safeguarding our Communities Act (Patch for Patch Return Policy).⁽⁸⁾ It is anticipated that regulations supporting this Act will be developed by the government and communicated to Ontario pharmacies in 2016. Regardless of the context in which the patch for patch program takes place (legal or local initiative), pharmacy technicians have contributed and will continue to contribute to the safe and appropriate return of used fentanyl patches and the dispensing of new doses.

Conclusion

Pharmacy technicians, in both hospital and

community settings, play an important role in the safe distribution of controlled substances—including the authority to witness and destroy any damaged, expired and unusable medications (alongside a pharmacist). In doing so, pharmacy technicians must follow standards of practice, are responsible for their own actions, and at all times remain accountable to the public.

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BIOGRAPHY

Pharmacist Andrew Tolmie is Experiential Coordinator, Patient Care Rotation at the University of Waterloo's School of Pharmacy. His areas of clinical interest include opioid agonist maintenance treatment and diabetes education. He has completed the Opioid Dependence Treatment Certificate Program delivered by the Centre for Addiction and Mental Health, and regularly contributes to addiction treatment publications and education for professionals.

QUESTIONS

- 1. Narcotics and benzodiazepines are regulated under what federal Act?
- a) Federal Narcotics Act
- b) Controlled Drugs and Substances Act
- c) Food and Drugs Act
- d) Narcotic and Benzodiazepine Control Act

2. According to a 2013 Canadian Tobacco, Alcohol, and Drugs Survey (CTADS) approximately what percentage of Canadians use opioid pain relievers? a) 15% b) 60%

- c) 5% d) 25%
- 3. What percentage of the Canadian population is affected by chronic pain?
- a) 70% to 80%
- b) 10% to 25%
- c) 50% to 60%
- d) 15% to 29%

4. As described by federal legislation, testosterone is an example of which class of drug?

- a) Controlled drug
- b) Narcotic
- c) Benzodiazepine
- d) Cannabinoid

Please select the best answer for each question and answer online at www.CanadianHealthcareNetwork.ca for instant results.

- 5. Which of the following methods are permitted for prescriptions for narcotic drugs (i.e., schedule N drugs)?
- a) Written only
- b) Written or faxed
- c) Written, faxed or verbal
- d) None of the above

According to the Narcotic Control Regulations, which statement best describes prescription refills for narcotics?

- a) Permitted but are not best practice
- b) Permitted if the prescriber has indicated the number of refills and dates for, or intervals between refills
- c) Not permitted
- d) Permitted but for only one refill of the initial quantity prescribed

7. Which of the following statements is correct with respect to the "transfer" of benzodiazepine prescriptions between pharmacies?

- a) Are permitted with no restrictions
- b) Are not permitted
- c) Are permitted only in "emergencies"
- d) Are permitted except if the prescription has been already transferred

- 8. As per the NAPRA Model Standards of Practice for Canadian Pharmacy Technicians, pharmacy technicians are expected to?
- Review prescriptions to confirm they are authentic
- b) Review prescriptions to confirm they are complete
- c) Review prescriptions to confirm they meet all current laws, regulations and policies
- d) All of the above

9. Which of the following is an example of provincial legislation governing narcotic prescriptions and dispensing?

- a) British Columbia Codeine Control Act
- b) Ontario's Narcotic Strategy Act
- c) Ontario's Narcotic Safety and Awareness Act
- d) None of the above
- 10. When dispensing a prescription for a controlled substance, which of the following may be indicative of suboptimal drug therapy or medication misuse?
- a) Multiple controlled substances from different prescribers
- b) Unusual patient behaviour (e.g., nervousness, lack of eye contact,

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aggressiveness)

- c) Patterns of late or early prescription refills/ part-fills
- d) All of the above

11. What must be specified on requests for permission sent to Health Canada (Office of Controlled Substances) to destroy narcotic or controlled drugs?

- a) The name, strength and quantity of drug to be destroyed, as well as the pharmacist's signature with his or her regulatory body license number
- b) The name, colour and cost of drug to be destroyed, as well as the pharmacist's signature with his or her regulatory body license number
- c) The name, strength and quantity of drug to be destroyed, as well as any pharmacy staff member's signature and date
- d) Pharmacies are no longer required to request and receive pre-authorization for local destruction of unserviceable narcotics and controlled drugs from Health Canada.
- 12. What is a pharmacy required to do when destroying an expired bottle of lorazepam

from pharmacy inventory?

- a) Receive authorization first from Health Canada's Office of Controlled Substances prior to destroying the expired lorazepam
- b) Maintain a record of destruction including the drug name, strength, quantity of the targeted substance, and the date of destruction
- c) A and B
- d) None of the above

13. Which combination of pharmacy staff may destroy and witness narcotics and controlled drugs?

- a) Two pharmacists or a pharmacist and a pharmacy technician
- b) Two pharmacists, two pharmacy technicians, or a pharmacist and a pharmacy technician
- c) A pharmacist and any full-time employee of the pharmacy
- d) Only pharmacists are permitted to destroy and witness narcotics and controlled drugs
- 14. What method(s) is(are) preferred for destroving damaged, expired and unusable controlled substances?

- a) Flushing all controlled drug products down the toilet to ensure they cannot be misused
- b) Using a method that ensures the drugs are altered or denatured to render consumption improbable or impossible
- c) Disposing of controlled drug products at home instead of the pharmacy to prevent diversion
- d) All of the above

15. Which of the following is correct with respect to pharmacy-based fentanyl patch return programs?

- a) Patient return of used/unused fentanyl patches is required by law across all provinces
- b) The objective of pharmacy-based fentanyl patch return programs is to reduce misuse and diversion
- c) Collaboration with physicians who prescribe fentanyl is neither required nor relevant
- d) None of the above

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Controlled Substances: Dispensing and Destruction

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