From Policy to Practice: A Joint Webinar



on Narcotic Accountability

with the College of Pharmacists of Manitoba and Health Canada

Questions and Answers

Inventory management and Reporting

Q: Where can I find resources on controlled substance inventory management and loss/theft reporting?

A: Applicable Health Canada (HC) guidelines and resources include:

- Health Canada's Loss or theft reporting webpage
- Guidance on reporting loss or theft of controlled substances and precursors
- <u>Controlled substances guidance for community pharmacists: security, inventory reconciliation and record-keeping</u>

Applicable College of Pharmacists of Manitoba (CPhM) practice directions, guidelines and resources include:

- Drug Distribution and Storage Practice Direction
- Pharmacy Facilities Practice Direction
- <u>Narcotic and Controlled Drugs Accountability Guidelines</u>
- <u>CPhM Loss, Theft, or Forgery of Controlled Substances webpage</u>

Q: If I open a new bottle of a targeted substance and it is missing one tablet and I double counted and reported it to the manufacture, do I still have to send a report to Health Canada?

A: As long as you document this count and the missing tablet, you can adjust your inventory with this reasoning. Since it does not involve an unexplained loss or theft, there is no need to report it to HC. More information, including how to manage larger manufacture shortages, can be found in HC's <u>Guidance on</u> reporting loss or theft of controlled substances and precursors.

Q: Am I required to report all losses of controlled substances? Even if I am only missing 1 tablet?

A: Yes. Any quantity of unexplained loss or theft of a controlled substance must be reported to HC and CPhM even if it is one single tablet. This is a requirement of section 2.3.2.5 of the CPhM <u>Drug Distribution and Storage Practice</u> <u>Direction</u>. Small quantities of loss can accumulate overtime, for accountability purposes it is important that these losses are still reported. If the loss can be explained by regular business practices it does not need to be reported, however this explanation must be definite and supported by documentation. If you only suspect or think a loss is explained, it must be reported as it is still unexplained. For further guidance on reporting please see HC's <u>Guidance on reporting loss or theft of controlled substances and precursors</u>.

Q: When there is a pharmacy manager change and the outgoing pharmacy manager is not willing to do a count concurrently with the incoming pharmacy manager, what advice would you give to the incoming pharmacy manager to manage this situation?

A: As the incoming pharmacy manager, it is important that you:

- complete a full inventory count yourself,
- thoroughly document the count, including any necessary investigations,

- report all losses to HC and CPhM,
- make any required adjustments to the inventory with the proper explanations and documents filed, and
- effectively manage the inventory moving forward.

Even if the outgoing pharmacy manager conducts an inventory count on their own prior to leaving, the new pharmacy manager should still complete an independent count. It is important that this count occurs as soon as possible. It is recommended the incoming Pharmacy Manager reviews all existing controlled substance policies and procedures and makes appropriate changes to ensure accountability.

Q: Can we enter a narcotic order coming from the supplier into our computer system manually?

A: Yes. Depending on the software used at the pharmacy, manual entry of controlled substance purchases may be the preferred method. The method of entry is not specified in the regulations. However, as with any manual adjustment, the reason for the adjustment should be clearly documented in an auditable manner so that the adjustment can be traced back to the specific order/invoice number.

Q: Are narcotics allowed in automation (counting machines, packaging machines etc.)?

A: The regulations do not prohibit the use of counting machines or automated packaging machines; however, these tools must be used with caution. These tools are known to impact the accuracy of counts and lead to increased losses that you are required to report. Counting machines should be checked for accuracy and the use of double counting is recommended with the second count being done manually.

Packaging machines can increase the risk of losses due to the machines mechanics but can also be prone to pilferage. Many machines are loaded with large quantities and may not be kept secure. The contents would need to be relocated to your safe at the end of each day. Packaging machines are also known to drop and break tablets which you would need to keep track of on a log in order to adjust your inventory levels or account for them in loss and theft reports submitted to HC and CPhM.

Destruction

Q: Where can I find resources on controlled substance destruction?

A: Applicable HC guidelines and resources include:

- <u>Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals: Handling and</u> <u>Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs or Targeted Substances</u>
- <u>Guidance Document: Handling and destruction of post-consumer returns containing controlled</u>
 <u>substances</u>

Applicable CPhM practice directions, guidelines and resources include:

- Drug Distribution and Storage Practice Direction
- <u>Narcotic and Controlled Drugs Accountability Guidelines</u>
- Destruction and Return of Narcotic, Controlled and Targeted Drugs Forms

Q: If I have a complete liquid narcotic bottle, should I open it to add alcohol for destruction in spite of the fact there is no more space to add alcohol?

A: When conducting local destruction of a controlled substance, the controlled substance must be denatured to the point where consumption is impossible or highly improbable. The pharmacist destroying the substance must ensure this requirement is met.

A narcotic cannot be considered destroyed in its original state. If the original packaging is not large enough to complete the destruction, it is recommended to transfer the substance to a larger container suitable for the destruction procedure.

CPhM and HC cannot endorse a particular destruction method as the specific process of destruction may vary between different substances. However, it is generally advised to consider a change of state (e.g., from liquid to solid) as a recommended approach.

Also note that simply adding water is not the most effective way to denature controlled substances. The addition of some soap is a more effective way to ensure the controlled substance is denatured and its consumption is improbable.

Q: How do you recommend that fentanyl patches are denatured? Is cutting fentanyl patches and then putting in slurry appropriate for destruction?

A: HC and the CPhM do not have procedures for destruction methods. CPhM and HC cannot endorse a particular destruction method as the specific process of destruction may vary between different substances. However, it is generally advised to consider a change of state (e.g., from liquid to solid) as a recommended approach.

Federal regulations require you to keep track of all controlled substances waiting for destruction and always ensure their security. Under provincial requirements, controlled substances waiting for destruction must be logged and counted every three months and secured in the safe until they are destroyed.

HC removed the requirement for pharmacists to request permission to destroy controlled substances to allow this process to happen more quickly, so these items are not held for extended periods of time. The best practice is to denature as much as possible and then ensure these items are sent for incineration as soon as possible. For safety reasons pharmacists are advised to avoid directly touching returned fentanyl patches. When handling returned patches gloves are recommended to prevent accidental drug exposure.

Q: In Manitoba pharmacy technicians are not licensed. Does that mean pharmacy technicians cannot be a witness for the destruction of controlled substances in Manitoba?

A: Manitoban pharmacy technicians can witness the destruction of Controlled Substances.

HC allows a pharmacy technician to act as a witness for controlled substance destruction. HC defines a pharmacy technician as a person who works in a pharmacy or dispensary and meets any applicable provincial or professional requirements in order to work as a pharmacy technician or equivalent designation.

In Manitoba, the Pharmaceutical Act defines a Pharmacy Technician as a person who has the qualifications, experience and other requirements set out in the regulations. The title "pharmacy technician" is restricted to those who meet the legislated criteria under section 60(2) of the Pharmaceutical Regulation. The College maintains a list of all qualified pharmacy technicians.

Under the HC definition of a pharmacy technician and provincial legislation, a pharmacy technician listed by CPhM can act as a witness for controlled substance destruction.

Please note a pharmacy assistant cannot act as a witness.

Q: What about a licensed nurse? Can they be a witness?

A: No. A licensed nurse cannot act as a witness. Only a nurse practitioner as defined in the <u>New Classes</u> <u>Practitioners Regulations (justice.gc.ca)</u> can be a witness to the destruction of Controlled Substances.

Q: What if there is no other pharmacist or registered pharmacy technician working in the same pharmacy? How do you witness a controlled substance destruction?

A: All local destructions must be witnessed on site by a practitioner, pharmacist, a pharmacy intern, or a pharmacy technician. A HC inspector may also serve as a witness should they be present.

If only a single pharmacist works at the pharmacy an appropriate witness must be arranged prior to destruction. The person does not have to be employed by the site, but they must be an approved practitioner, pharmacist or pharmacy technician.

Hospital Practice

Q: Where can I find resources on managing controlled substances in a hospital setting?

A: The Canadian Society of Hospital Pharmacists has developed a <u>guideline</u> to prevent diversion and support the management of controlled drugs and substances in Hospitals and Health Care Facilities. Q: I would like to know about discrepancies of controlled substances in the ward stock of the hospital. Do we need to report these discrepancies?

A: If an unexplained discrepancy is found, it must be reported. The individual in a facility who holds the position of authority is ultimately responsible for the controlled substances within that facility. For facilities meeting the federal definition of a hospital, this accountability is defined in federal legislation, whereby the "person in charge of a hospital" is responsible for ensuring that regulatory requirements are met. Specific responsibilities may be delegated to others at an operational level. The level of delegation, the specified areas of responsibility, and the principles upon which procedures are developed should be defined in the facility's formal policies. In practice, this means that although the pharmacy department generally has responsibility for procurement, receipt, initial storage, and distribution of controlled substances to patient care areas, the management of controlled substances extends far beyond the pharmacy department. As such, it is important that responsibility and accountability of all persons with access to controlled substances be clearly articulated in organizational policy.

Q: Is a nurse at certain unit in a hospital allowed to borrow a narcotic drug from another unit at the same hospital?

A: Yes. As long as the narcotic remains in the same hospital, the inventory remains accounted for, hospital policy is followed, and the drug remains under the responsibility and oversight of the person in charge of the hospital. Hospitals should have their own detailed policies outlining what is acceptable within the hospital and what procedures must be followed.

Q: Is the Health Canada inspection process the same in hospitals?

A: Currently HC does not have an inspection program for hospital pharmacies, but the <u>Controlled Drugs and</u> <u>Substances Act</u> and the associated regulations apply. Federally the responsible party is the person in charge of the hospital.

Other Questions

Q: Can you clarify needing the Registrar to approve offsite record storage?

A: Section 79(3) of the <u>Pharmaceutical Regulation</u> states records do not need to be stored in the pharmacy if they

are stored in a secure location that is satisfactory to the Registrar. This is applied to all records listed in section 79(2) of the Pharmaceutical Regulation and is not limited to narcotic records.

If document storage is delegated to a third-party, section 2.9 of the <u>Records and Information Practice Direction</u> further clarifies that the company must be bonded, and the pharmacy must enter into a service agreement with the storage company that is compliant with the Personal Health Information Act.

The pharmacy retains responsibility for the safety and security of records even if the storage is contracted out to a third party. All records, including those stored off site, must be readily accessible and open to regulatory review. Prior to transferring records to offsite storage, the pharmacy should direct correspondence to CPhM (info@cphm.ca) and seek approval of the location of the off-site storage of records.

Q: Should we file prescriptions for benzodiazepines and targeted drugs with narcotic prescriptions or with regular prescriptions?

A: Prescriptions for benzodiazepines and targeted drugs are not required to be filed in the special file with narcotic and controlled prescriptions. The requirement for the special file is part of the <u>narcotic</u> and <u>controlled</u> drug regulations. The special file is not a requirement of the <u>Benzodiazepines and Other Targeted Substances</u> <u>Regulations</u>.