

Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines on Secure Management and Diversion Prevention



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Introduction

Controlled substances can constitute valuable treatments for patients across the health system, and are therefore commonly used in nearly every type of healthcare facility in Canada. Regrettably, this common usage increases the potential for misuse or diversion by healthcare workers, who have access to these drugs in their work environment. Such diversion puts patient safety, staff safety, and public health at risk.¹

Around the world, healthcare leaders are starting to think differently about diversion of controlled substances from healthcare facilities. Rather than denying or minimizing the problem, they have begun to recognize that it is common, yet often preventable. Some guidelines² now stress the importance of having a dedicated diversion prevention committee—a multidisciplinary group focused on creating policies, educating staff, encouraging reporting, investigating incidents, analyzing trends in the data, and improving the system accordingly.

Lessons can be learned from the fields of medication errors and medication safety, where healthcare workers have moved from a culture of denial, finger-pointing, and individual blame to one of shared responsibility, universal reporting, and system improvement.³

Most health professionals who divert controlled substances do so for personal use. Although it may be true that increased contamination of street drugs has increased the demand for “safer” pharmaceutical-grade opioids diverted from the health system, most health professionals who divert are not doing so for purposes of trafficking. Rather, in most cases, the diverter is suffering from substance use disorder. With this in mind, facilities may want to consider raising awareness and providing education on substance use disorder, as part of an overall strategy to decrease diversion.⁴

This document aims to provide Canadian healthcare facilities with advice and guidance on how to develop a system to prevent, detect, and respond to diversion of controlled substances, and how to continuously improve such a system once it has been established.

These guidelines are being published in fulfillment of one of CSHP’s commitments under the *Joint Statement of Action to Address the Opioid Crisis*.⁵ The guidelines were developed in collaboration with many valued partners who are all responding to what has become an opioid crisis of unprecedented proportions.^{6,7} Across Canada, there is increased attention to the harms of controlled substances, and new clinical practice guidelines recommend limiting the use of opioids.⁸ The concept of opioid stewardship,⁹ involving coordinated interventions to improve the use of opioids, is gaining recognition. Much of this important work is outside the scope of these guidelines, but readers are encouraged to consult the resources cited.

1 Scope

This document provides an update to the 1990 *Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals*, published by Health Canada; however, this is not a Health Canada publication, and adherence to these guidelines is considered **voluntary**.

In general, mandatory requirements set forth in legislation, regulations, professional regulatory authority requirements, or accreditation standards are so noted by use of the term “**shall**”, whereas best practices or recommendations use the term “**should**.”

This document is broader in scope than the previous Health Canada publication, because it aims to provide practical guidance on best practices for all types of healthcare facilities that are embedded within a provincial or territorial health system. Such facilities may include hospitals, ambulatory care clinics, emergency medical services (EMS), long-term care homes, and other institutions and organizations. The guidelines apply to anyone who handles or administers controlled substances in these facilities, including both regulated health professionals and other staff.

Many EMS systems, long-term care homes, and other facilities are managed by municipalities or private corporations. For these facilities, mandatory requirements may differ from those presented here, but [fundamental principles](#) and best practices still apply.

This document does not apply to community pharmacies, outpatient pharmacies, or practitioners’ private offices, which are subject to different regulations.

Above all, this document is intended to complement all relevant legislation (federal, provincial, or territorial), accepted patient safety practices, and each facility’s own policies and procedures. Federal, provincial, and territorial laws supersede any recommendations in these guidelines, and, in the case of conflict, the law takes precedence. These guidelines should not be used as justification to deviate from any practice that is authorized or required by law.

Sections 2 to 4 discuss fundamental principles in the management of controlled substances, including the concept that diversion prevention is a shared responsibility. As such, healthcare organizations should implement a dedicated, multidisciplinary diversion prevention committee. A quality management approach should be taken, and responsibilities and accountabilities across the medication management system should be clearly defined in policy.

Sections 5 to 9 focus on prevention. These sections follow a controlled substance moving through a facility, from procurement to disposal. Strategies to minimize the risk of diversion at each step should be designed so as not to adversely affect drug availability or patient care. [Fundamental principles](#) described in these sections apply to all areas of the facility. Where there are additional considerations for specific areas, these are noted at the end of each section.

Sections 10 and 11 focus on how to identify diversion and how to investigate and report diversion when it does occur. Section 12 gives definitions of common terms and [Appendix A](#) gives common examples of diversion.

2 Overview of Requirements

Everyone concerned with the management of controlled substances should understand the relevant regulatory requirements, professional requirements, and accreditation requirements.

2.1 Federal Regulatory Requirements

Federal regulations define responsibilities and requirements regarding the distribution of controlled substances. Controlled substances are regulated under the *Controlled Drugs and Substances Act* (CDSA) and its regulations,¹⁰ federal statutes that are administered by the Office of Controlled Substances within Health Canada. Regulations made under the CDSA include the *Narcotic Control Regulations*¹¹ and the *Benzodiazepines and Other Targeted Substances Regulations*.¹²

As compared with the narcotic regulations, those for benzodiazepines and other targeted substances are less prescriptive in terms of guidance for storage, distribution, and documentation. However, many decision-makers are choosing to tighten controls on benzodiazepines as well, treating them in the same manner as any other controlled substance. Facility staff should consult with the relevant professional regulatory authorities in their respective jurisdictions as well as facility policies.

Cannabis is regulated separately under the *Cannabis Act*¹³ and is not addressed in this document.

2.2 Provincial and Territorial Regulations

Provincial and territorial regulations govern the delivery of healthcare, including the operation of hospitals, pharmacies, and other healthcare facilities, as well as the services provided by health professionals. These regulations differ across Canada.

2.3 Professional Standards of Practice

Every regulated health profession has standards of practice that must be met by those practising the profession. The provincial or territorial regulatory authority for each profession is responsible for setting that profession's standards of practice and codes of ethics. Regulatory authorities license health professionals and ensure that members of the respective professions meet the standards of practice and any other ongoing requirements

for licensure. In some jurisdictions, the pharmacy regulatory authority also licenses hospital pharmacies.

2.4 Accreditation Standards

Accreditation Canada assesses healthcare facilities across the country against standards developed by Health Standards Organization (HSO). According to HSO's medication management standard, facilities shall have security processes in place for controlled substances, including "monitoring withdrawals, wastage, and administration of controlled substances to identify signs of abuse and diversion, as well as analyzing, documenting, and reporting such situations."¹⁴

3 Organizational Accountability

Within any healthcare facility, no single department holds accountability for controlled substances. Such accountability is a shared responsibility, and all departments should understand their respective roles in managing controlled substances. Nonetheless, federal regulations place final accountability on the "person in charge of a hospital" – in other words, the person at the highest level of the organization is ultimately responsible for preventing and detecting diversion and for taking action when it occurs.

The person in charge of a facility shall have ultimate accountability for controlled substances in 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.

An interdisciplinary committee shall establish policies to oversee the security of all controlled substances.¹⁴ In many facilities, this committee is the Pharmacy and Therapeutics Committee, a medication safety committee, or other body that oversees management of medications within the facility or organization. It is increasingly recognized that each facility or organization should have a comprehensive diversion prevention framework,

with a dedicated diversion prevention committee and at least one staff member who is a diversion prevention specialist.^{2,15,16}

The diversion prevention committee should be responsible for:

- ensuring that the facility complies with all regulations and standards;
- developing and reviewing facility policies to ensure safe handling of controlled substances;
- educating staff about policies, standards, and legislation;
- educating staff about substance use disorder, signs of diversion, and how to report diversion;
- ensuring that incidents can be easily reported at any time;
- regularly reviewing incident reports, to identify data trends and make policy adjustments;
- ensuring that routine audits are conducted and areas of concern identified and addressed;
- ensuring that reporting to Health Canada and the professional regulatory authorities is completed promptly, as described in [Reporting Suspected Diversion](#);
- liaising with local stakeholders such as law enforcement about current diversion trends (e.g., drugs sought for misuse, local forgeries observed, local street prices); and
- promoting a culture of shared responsibility and system improvement.

The diversion prevention committee should be responsible for ensuring the existence of a diversion response team to investigate incidents promptly. The diversion response team may be the committee itself, a subset of the committee, a group of committee members by rotation, the diversion prevention specialist with other assistants as needed, or some other group.

A facility's diversion prevention committee could be part of an existing interdisciplinary committee (such as the Pharmacy and Therapeutics Committee). However, federal regulations place accountability for controlled substances on the person in charge of a hospital. Therefore, the diversion prevention committee should have the support of senior leadership. The committee or its representative should report directly to the person in charge of the facility.

The diversion prevention committee should have broad membership, potentially including staff from some or all of the following departments: pharmacy, nursing, medicine, anesthesia, security, facilities management, human resources, risk management, quality improvement, legal services, information management/technology, employee health, and patient relations.²

An effective program for secure distribution and diversion prevention requires commitment at all levels of the organization. The commitment and accountability of those at the highest levels should be reflected in the policies and procedures established within the facility or organization.

4 Fundamental Principles

In the secure management of controlled substances, the following fundamental principles apply to all facilities and departments:

- A continuous quality improvement approach is taken.
- Controlled substances are securely stored and handled throughout the medication management system, from the point of ordering to the time of administration or destruction.
- Accurate and complete records of all transactions involving a controlled substance are maintained in a timely manner. Meeting this requirement entails keeping records at the points of ordering, receiving, prescribing, dispensing or issuing, administration, and destruction.
 - All manual documentation is made in indelible ink.
 - There is a clear chain of signatures showing transfer of responsibility at each transition point.
 - Records can be easily audited.
 - All staff members check for completeness and accuracy of the records for which they are responsible, immediately resolving any discrepancies that are identified.
- Quantities of controlled substances are kept to the minimum needed, according to the patient population and degree of urgency.
- Segregation of duties is implemented for critical functions with significant opportunities for diversion, such as procurement, receiving, and distribution.
- Only authorized staff handle, prescribe, or have access to controlled substances.
- Controlled substances are stored in restricted areas, such as locked rooms, carts, or fridges. All keys are accounted for at all times.
- Systems are set up to ensure that each user is uniquely identified and every transaction can be traced to a user.
- Authorized staff do not share passwords or other means of ordering or accessing a controlled substance. Passwords are changed frequently according to facility policies. Users should log off immediately when systems are not in use.
- All staff inspect the integrity of the controlled substance (as required to safely execute their responsibilities).
- Everyone who orders or handles a controlled substance is responsible for ensuring the safety and security of the system. All staff pay attention to signals, report incidents, and are authorized to “stop the line” (i.e., speak up and immediately halt processes when they see a safety risk).
- Creative compliance (i.e., obeying the letter but not the spirit of the law) is not tolerated.

4.1 Quality Management and Control

Despite best efforts to implement systems designed to prevent, detect, and respond to drug diversion, processes will always be limited by current knowledge and technology. Therefore, it is essential to incorporate continuous quality improvement processes into medication management systems.

Generally, quality control can be exerted at the administrative (and regulatory compliance) level, through organizational processes, and at the provider level.² Change control should also be defined and implemented, to ensure that changes to the system are introduced and managed in a systematic fashion without unwanted or unanticipated consequences.

Key performance indicators (KPIs) related to diversion of controlled substances should be defined by each organization and reported regularly. These indicators may include any of the following:

- results of physical security audits of all areas where controlled substances are stored;
- results of process audits by internal audit services;
- number of unresolved discrepancies involving controlled substances by patient care area;
- completion and accuracy of paper-based documents by patient care area;
- number of loss or theft reports to Health Canada;
- number of instances of confirmed diversion and resulting actions; and
- number of instances of confirmed diversion resulting in patient or staff harm.

Before establishing KPIs and the standard reports to be monitored, the management processes for controlled substances should be mapped.^{17,18} When a risk of diversion or actual diversion is identified, the steps, participants, documentation, and hand-offs should be assessed for weaknesses in the system and auditing plans established. Facilities can conduct a risk assessment based on usage, discrepancies, frequency of staff turnover, and other data from reported incidents.¹⁵ Drug diversion software is available to facilitate the collection and analysis of data for such a risk assessment.

On the basis of established KPIs and the results of associated investigations (and of root cause analyses, where appropriate), relevant changes should be made to the organization's controlled substance management system to address identified gaps.¹⁹

New technologies (e.g., high-resolution cameras, biometrics, tracking software) are constantly emerging, and these should be assessed for feasibility of use within the organization as they become available.

5 Inventory Management

Key principles of successful inventory management include keeping stock secure at all times, maintaining accountability and sign-offs by authorized staff at all transition points, and checking for completeness of an order and integrity of the product at all transition points. To the extent feasible, procurement, receipt, management of back orders, distribution, physical counts, reconciliation, and audits should be conducted by different staff members, but all of these activities should be part of a linked system that allows controlled substances to be easily tracked as they move through the facility.

5.1 Determination of Inventory Requirements

To ensure availability of, and control over, controlled substances, it is important to accurately determine the needs of the healthcare facility and, more specifically, the needs of individual patient care areas. Responsibility for this function rests jointly with pharmacy, the patient care area, the Pharmacy and Therapeutics Committee, and the diversion prevention committee.

Consideration should be given to maintaining the lowest amount of inventory possible while ensuring reasonable and timely access. Unit-of-use packaging should be used whenever possible.

The following factors are to be considered when determining the drug needs of a healthcare facility or a patient care area:

- medical conditions being treated;
- local protocols, pathways, and care maps;
- drug formulary and formulary policies such as automatic substitution;
- utilization and prescribing patterns;
- range of dosing (e.g., pediatric vs adult care; acute vs chronic pain management);
- inventory turnover rate;
- inventory returns from patient care areas;
- destruction of expired or unserviceable (unusable) drugs (e.g., records of specific drugs and quantities destroyed, frequency of destruction);
- availability and capacity of secure storage;
- cost implications (both costs to procure drugs and human resource costs to manage inventory control);
- after-hours access to drugs;
- travel time between receiving department, pharmacy, care units, and other sites; and
- turnaround time between ordering and delivery from suppliers.

There should be consideration for maintaining the lowest quantities of controlled substances that are feasible for each area. Unit-of-use packaging should be used whenever possible.

Once inventory levels are established, drug-use patterns should be periodically reviewed to assess the following:

- minimum and maximum stock levels;
- changes in utilization trends;
- changes in clinical practice or patient mix;
- changes in regulatory requirements (e.g., schedules);
- issues such as medication safety incidents that may shed light on potential for misuse or diversion of controlled substances; and
- the factors previously considered to determine drug needs.

5.2 Procurement

A licensed dealer (e.g., manufacturer or distributor) shall supply a hospital with a controlled substance only if the dealer has first received an order from an individual who is authorized to place orders on behalf of the hospital.^{11,12} The facility should define who may order such drugs and under what circumstances, and should limit the number of individuals designated as such.

Outstanding back orders for controlled substances are a potential source of diversion, especially when there is no separation of duties (i.e., the same person orders and receives drugs). When an ordered item is on back order, the licensed dealer should notify the pharmacist, and the order should be cancelled. If the drug is available in a reduced quantity, a new order should be placed for the amount available. Once the drug is available in the required quantity, the pharmacy should order the drug. Group purchasing organizations can help to establish contractual expectations with licensed dealers, which will help in proactively managing or mitigating a drug shortage.

5.2.1 Manual Procurement Process

Manual processes involve issuing paper-based purchase orders, which are signed by hand, rather than submitting the orders electronically and signing them by means of a digital or electronic signature. Manual ordering should be minimized. When a manual procurement process is used, the forms used to purchase controlled substances should be sequentially prenumbered and closely controlled using a log or other system that monitors:

- orders that are pending or have a back order, for which a procedure for prompt and appropriate follow-up action, taking into consideration the normal or expected turnaround time for each supplier, should be in place.;
- distribution of blank forms; and
- use of forms, including all the information necessary to identify a specific transaction or order.

Under no circumstances should blank purchase orders or requisitions for controlled substances be presigned or left unsecured.

5.2.2 Electronic Procurement Process

According to Health Canada policy, electronic ordering of controlled substances is acceptable as long as the digital signatures used can be authenticated in a manner similar to that used for manual signatures.²⁰ Signing and dating of orders can be done electronically through licensed dealers' online security portals. Each individual authorized to order controlled substances shall have a unique access code. Such access codes shall not be shared or used by others.

Staff responsible for implementing an electronic procurement process shall ensure that the system chosen "will permit them to meet the requirements of the relevant regulations."²⁰

The benefits of electronic ordering systems include security of transactions through individual users' identification, traceability, retention of data, and generation of reports as needed. However, facilities should ensure that they are not relying on outside suppliers for the required record-keeping.

5.3 Receipt

Separation of purchasing and receiving duties is key to strengthening internal inventory controls.

All pharmacy goods and supplies, including controlled substances, should be delivered directly to and received by the pharmacy without intervention of any other department or individual.

When direct delivery to the pharmacy is not feasible, the healthcare facility should have policies and procedures requiring that:

- packages remain unopened by the staff receiving them (with emergency exceptions to be defined in procedures);
- packages are stored securely during those times when both the receiving department and the pharmacy are closed;
- there is a secure storage area reserved for pharmacy goods;
- access to the secure storage area is limited to designated pharmacy and receiving department staff;
- the secure storage area is never left unsecured;
- pharmacy packages are immediately placed in the designated secure storage area and delivered to the pharmacy or picked up by pharmacy staff on a priority basis; and
- as for any movement of drugs through the facility, there is clear accountability, transfer of responsibility, and tracking through a chain of signatures.

The facility should have a procedure for investigating shipments that are lost in transit. However, it is the responsibility of the shipper to report such losses in transit to Health Canada. Refer to Health Canada's guidance document *Reporting of Loss or Theft of Controlled Substances, Precursors and Cannabis*²¹ for further guidance.

5.3.1 Receiving Department

When an individual in the receiving department accepts delivery of packages intended for the pharmacy, that individual assumes responsibility for these goods until they are delivered to and received by the pharmacy department. It is therefore necessary for the receiving department staff to take the following actions:

- confirm that the order is complete (i.e., ensure that the number of packages received is the same as the number recorded on the documents accompanying the shipment); and
- examine the exterior of the package(s) for any signs of tampering or damage.

Any discrepancies, damage, or signs of tampering should be recorded on the waybill at the time of delivery and reported to the pharmacy department as soon as possible.

A separate log for pharmacy deliveries should be maintained in the receiving department or any other area in the facility designated to accept goods for the pharmacy.

The log (manual or electronic) should include:

- date and time received;
- company or supplier that shipped the order;
- number of packages received;
- any identification numbers on the packages;
- carrier;
- name and signature of driver;
- name and signature of individual receiving the goods;
- name and signature of individual delivering the goods to the pharmacy;
- name and signature of pharmacy staff receiving the goods (when delivered);
- date and time delivered to the pharmacy department;
- number of packages delivered to the pharmacy department; and
- comments regarding discrepancies, damage, or signs of tampering.

5.3.2 Pharmacy Department

According to the procedures suggested above, an individual from the receiving department is required to obtain, for documentation in the receiving log, the name and signature of the pharmacy staff member accepting the packages. By signing for the packages, the pharmacy staff member accepts responsibility for the packages and their contents, and the individual from the receiving department is relieved of this responsibility. If problems or discrepancies are noted after this transfer, the pharmacy staff member who signed for the packages is held accountable.

On receiving a package from the receiving department, the pharmacy receiver should:

- ensure that packages are sealed and have not been opened at any time;
- confirm that the order is complete (i.e., the number of packages received is the same as the number noted on the accompanying documentation);
- ensure that there has been no tampering with or damage to the packages;
- record and report any discrepancies or signs of damage on the shipping documents and in the logs of both the receiving department and the pharmacy logs, which are then signed off by both parties; and
- sign the packing slip to document the transfer of responsibility from the receiving department to the pharmacy department.

Packages received in the pharmacy department should be opened as soon as possible after receipt. If doing so is not practical, the packages should be stored in a designated secure area within the pharmacy until they can be processed.

Once the packages are opened, the balance of the information necessary for the receiving log is recorded. The log (whether manual or electronic) should include the following details:

- information required by the Narcotic Control Regulations (name and quantity of any narcotic received, name and address of the person from whom any narcotic was received, date received);
- information already recorded by the receiving department (see bulleted list under [Receiving Department](#));
- invoice number;
- purchase order number;
- drug name (brand and generic), strength, and formulation;
- quantity (number of doses, vials, or other applicable units, which should match those documented on the purchase order);
- lot number;
- expiration date; and
- comments regarding discrepancies or damage.

It is suggested that at the time the original package or container is first opened, the individual responsible visually confirm its contents. It is further suggested that a physical count of solid dosage forms be performed, to ensure that the contents correspond with the expected quantity or volume. Discrepancies should be noted and reported to the director of pharmacy or delegate.

Automated data capture, such as barcode scanning of packages, can help to improve efficiencies and accuracy when ordering and receiving controlled substances. When integrated with the pharmacy information system's database, automated data capture further enables traceability through electronic capture of the drug's lot number and expiry date and other pertinent data.

Problems relating to discrepancies, tampering, or damage should be reported immediately to the director of pharmacy or delegate, as well as to the diversion prevention committee. See [Reporting Suspected Diversion](#) for more guidance.

5.4 Storage in the Pharmacy Department

Controlled substances maintained in the pharmacy department shall be stored in a manner that ensures their physical security, adheres to the recommended storage conditions for the drug, and meets relevant standards (e.g., from accreditation or regulatory authorities).¹⁴

Consideration should be given to the Directive on *Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis (Security Requirements for Licensed Dealers for the Storage of Controlled Substances)* issued by Health Canada's Office of Controlled Substances.²² Although the directive is geared to licensed dealers and research labs, it is cited in the NCR and provides a valuable risk assessment tool that takes into account the following factors:

- the probability of the drug reaching the illicit market, according to
 - location;
 - illicit market value;
 - armed robbery;
- theft; and
 - pilferage.
- the cost to society of the drug reaching the illicit market (diversion); and
- the cost to the organization.

Access to the pharmacy area should be restricted to pharmacy staff. Access to controlled substances or the areas where they are stored should be further limited to designated pharmacy staff. The issue of access and the list of individuals who may enter these areas should be specifically addressed in the facility's policies and procedures.

5.5 Considerations for High-Risk Patient Care Areas

Typically, substantial quantities of controlled substances are used in high-risk patient care areas, such as the operating room and perioperative areas, other anesthesia locations (e.g., interventional radiology suite), labour and delivery area, intensive care unit, and the emergency department. Exercising adequate control over the distribution and use of such drugs in these areas is often complicated by the nature and volume of the work, the demands placed on the staff, and other operational considerations. Nonetheless, the [fundamental principles](#) of responsibility and accountability with respect to the receipt, distribution, and use of controlled substances apply as much to these high-risk areas as they do to other patient care areas and should be followed through policies and procedures for ordering, receipt, storage, access, prescribing, administration, wastage, destruction, and record-keeping. Additional considerations may be required for these areas as a result of operational considerations, the large quantities of drugs used, the nature of these drugs, and access to these areas by a variety of individuals, including patients and the public. As for other areas in the facility, there should be clear documentation that can be readily audited to reconcile the amount of controlled substances dispensed with the amount administered and the amount wasted.

5.5.1 Operating Room, Other Anesthesia Locations, and Labour and Delivery Area

Anesthesiologists are usually solely responsible for preparing, administering, documenting, and monitoring the use of controlled substances, often titrating doses of controlled substances in a time-urgent, high-stress setting. Therefore, the traditional concept of “prescribing”, with the double checks inherent in pharmacy dispensing and nursing administration, does not exist in many of these situations. Given this different paradigm, it may be reasonable for anesthesiologists to follow different procedures with respect to access, prescribing, administration, and record-keeping. However, such procedures are not without risks of diversion,^{23,24,25} and the same [fundamental principles](#) should be adhered to.

Emerging best practices to support appropriate transactions in the operating room and perioperative areas include installing automated anesthesia cabinets or automated dispensing cabinets (ADCs) in each procedure area, adopting disposal and destruction systems to dispose of controlled substance waste, and implementing equipment to test the validity of controlled substances before destruction.

The use of ADCs in the operating room facilitates access to controlled substances while maintaining safe, secure storage. These cabinets also support the documentation of controlled substances used or wasted, and can document a witnessing process when required.

When an anesthesiologist is not in the immediate vicinity (e.g., when the anesthesiologist is accompanying a patient to the recovery room), controlled substances that have been dispensed but not used should be secured in a manner suitable to prevent diversion. Good practice is to use a lock box or hotel safe for this purpose. Where this is not feasible, other suitable options may be considered, such as placing the unused drugs in the care of another health professional during the anesthesiologist’s absence.

As in other patient care areas, the inventory and records for the central operating room stock should be verified at each shift change, at a minimum. The operating room and other anesthesia locations (along with the main pharmacy vault and any other high-use areas) should be recognized as high-risk areas,² and consideration should be given to more security surveillance, more frequent restocking by pharmacy, and more frequent audits in these areas. See also the section on [Physical Counts](#).

5.5.2 Specialty Clinics

Procedures requiring certain controlled substances, including endoscopy, dentistry, and minor surgery, are often performed in specialty clinics within the hospital. Ideally, controlled substances should not be maintained on site when such clinics are not open. Smaller clinics might consider a “narcotic kit”, a mobile locked box or cart that can be moved to the pharmacy or other secure central storage when not needed. When it is not practical to remove drugs from the specialty clinic, physical and procedural security measures

should be implemented to protect them. Staffing limitations often mean that a single person oversees drug ordering, receives the drugs, and stocks them in the clinic. However, separation of ordering, receiving, and stocking duties is considered a best practice to prevent diversion during the procurement process.

5.5.3 Emergency Department

On any given day, a large number of attending physicians, consulting physicians, trainees, and other health professionals will pass through the emergency department. As well, controlled substances are commonly used in the emergency department for sedation or treatment of acute pain. Additional consideration should therefore be given to physical and procedural security measures in this high-traffic, high-usage area.

Benzodiazepines may require additional considerations in the emergency department. Across the health system, there is a trend toward tighter controls on targeted substances such as benzodiazepines. However, these substances need to be rapidly available in the emergency department, particularly injectable benzodiazepines for the treatment of status epilepticus. Many emergency departments use ADCs to improve both access and inventory control. Whether or not ADCs are used, staff in patient care areas should work with the pharmacy department and the diversion prevention committee to develop systems that meet local needs. The following options might be considered:

- diversion patterns (e.g., diversion of oral vs injectable benzodiazepines);
- storage requirements (e.g., some injectable formulations require refrigeration);
- simplicity of inventory management (e.g., multiple doses in package with breakable seal may facilitate rapid counting and auditing); and
- usage patterns for specific drugs.

5.5.5 Emergency Medical Services

EMS personnel may be referred to variously as paramedics, emergency medical responders, emergency medical technicians, primary care paramedics, advanced care paramedics, or critical care paramedics. Designations for these personnel and their corresponding scopes of practice vary by jurisdiction.

EMS facilities include vehicles (e.g., ambulance, aircraft), designated EMS areas within hospitals, and EMS stations within the community.

Paramedics administer controlled substances in accordance with medical control protocols or in accordance with case-specific orders from EMS medical directors or independent physicians.

Paramedics document administration and wastage during patient care within the EMS patient care record.

Controlled substances used for EMS stores should be transported from the originating location directly to stations with designated locked storage. Transporting vehicles should have concealed, locked storage compartments that are not located within the patient care area. When multiple stops are made during a trip, the transport vehicle should be locked.

Paramedics often carry controlled substances in a pouch on their belt. Such pouches should be signed out from safes in EMS stations or transferred between paramedics at shift change. Paramedics should ensure that controlled substances are secure on their person or placed in locked storage within the EMS facility. Only paramedics who are assigned to active duty should be allowed to carry controlled substances.

Controlled substances that are locked within EMS facilities, including stations or EMS vehicles, should not be stored within patient care areas within these facilities.

6 Preparation, Dispensing, and Distribution

6.1 In the Pharmacy

Although many departments within a healthcare facility share responsibility for managing controlled substances, pharmacy is generally the central storage, preparation, and distribution point. Retrievable documentation shall be maintained for the storage, manipulation, and distribution of these drugs (including all repackaged, compounded, and unusable drugs) throughout the hospital.¹¹

Pharmacies in large facilities may carry many forms of controlled substances in various types of packaging. For example, solids for oral administration may be received in stock bottles, unit-dose strips, or easy-to-count blister cards. Liquids for oral administration may be received in large stock bottles, injectables in vials or ampoules, and powders in glass bottles. Often, a drug must be repackaged or compounded before it is dispensed to patient care areas. Repackaging and compounding methods should ensure that the controlled substances are easy to secure, tamper evident, and easy to count. Compounding standards shall be followed to ensure that the quality and integrity of the drugs are maintained.^{26,27}

Each formulation and container type should have a separate record within the perpetual inventory. As the drug is manipulated, each “new” type of repackaged or compounded drug requires a new inventory record. For example,

- If 100-count stock bottles of codeine 30 mg tablets are each repackaged into four 25-count blister cards, there will be an inventory record for the stock bottles and a second inventory record for the blister cards.
- If several 5 mL vials of fentanyl are used to compound each 50 mL infusion bag of this drug, there will be separate inventory records for the vials and the infusion bags.

This approach makes all drugs easier to track and assists in investigations of discrepancies.

All repackaging and compounding should be documented on corresponding records or “worksheets”, and it is best practice to store all such records in close proximity to the controlled substances themselves (e.g., in the narcotic vault). Sometimes the original containers received from the manufacturer will contain slightly more or less than the quantity shown on the label. Such unanticipated quantity discrepancies are often identified during repackaging or compounding. Records should be kept for all discrepancies, and losses outside of normal parameters shall be reported to Health Canada within 10 days. Refer to Health Canada’s guidance document on *Reporting of Loss or Theft of Controlled Substances, Precursors and Cannabis*²¹ for further information about what constitutes a reportable loss. Also see [Waste and Disposal of Unusable Drugs](#).

6.2 From Pharmacy to Patient Care Area

The system used to supply or replenish patient care areas with controlled substances varies from one facility to another. Whatever system is used, it is crucial that the movement of these drugs be recorded in a manner that will permit monitoring of the process and ensure responsibility and accountability for all drugs at all times.

An important aspect of the distribution system is written documentation in both the pharmacy and the patient care area. Comparing the documentation between these two areas adds an element of accountability that helps prevent diversion and is also useful for determining and correcting errors.

Typically, distribution of controlled substances within a healthcare facility is conducted by means of a wardstock-based system, with the addition of some patient-specific drugs such as narcotic infusion bags. Pharmacy staff deliver the drugs to the patient care areas according to a delivery schedule. Pharmacy staff assess usage of the drugs within each patient care area, review records in the patient care area for completeness, estimate the quantities required until the next scheduled delivery, select these drugs from the narcotic vault and subtract them from the pharmacy’s perpetual inventory record, and ensure that nursing staff add them to the perpetual inventory record in the patient care area.

The delivery of controlled substances to patient care areas shall be performed using secure methods.¹⁴ Unattended, unsecured pneumatic tubes or dumb waiters are not recommended; pneumatic tubes may be used for delivery only if the product is accessible by security code. Best practice is to have a pharmacy staff member deliver drugs throughout the facility using a closed, opaque container to mask the contents. Travel through nonpublic areas and on service elevators provides the greatest level of safety and security during transport. Consideration should be given to delivering controlled substances at staggered (less predictable) times, if possible.

It must be emphasized that until the drugs are delivered to and accepted by staff in the patient care area, the pharmacy department retains responsibility for them. Before signing for the drugs, both pharmacy staff and patient care area staff should check the drugs, including their strength, dosage form, and the quantity being transferred. Once the nurse or other health professional signs the appropriate record, responsibility and accountability for the drugs is transferred to that individual and to that patient care area.

If additional products or quantities are needed before the next regular delivery, perhaps because of a new order or unanticipated usage, a health professional from the patient care area may pick up the product from the pharmacy. As with delivery, pick-up from the pharmacy by nurses or other health professionals shall be performed using secure methods. Staff from the patient care area should have authorization to pick up controlled substances and should show identification in order to receive the drugs. They should bring the perpetual inventory record with them, so that the drugs picked up can be documented and signed for in the same way as would be done for regular delivery to the care area. Information recorded on the care area record during pick-up should be identical with that required when pharmacy staff deliver controlled substances.

Various documentation methods may be used for tracking the delivery of products. However, the basic principle is that both the pharmacy and the patient care area retain a record at each transition point for a drug. The same principles apply for controlled substances being moved **to** the care area and **from** the care area back to pharmacy (returns). Inventory records should be kept in a secure location for which access is restricted to essential staff only.

For each medication movement, the pharmacy record should include the following information:

- date;
- time of issue;
- patient care area;
- drug name, strength, and dosage form;
- quantity delivered or returned; and
- names and signatures of pharmacy and patient care area staff involved.

For each medication movement, the record in the patient care area should include the following information:

- date;
- time of receipt;
- “Issued by Pharmacy” or “Returned to Pharmacy” (to indicate the direction of movement);
- drug name, strength, and dosage form;
- quantity added or subtracted from inventory in the patient care area;
- “New Balance” (total after the addition or subtraction has been completed); and
- names and signatures of pharmacy and patient care area staff involved.

6.3 In Patient Care Areas

6.3.1 Storage

Facilities that do not have ADCs should use a double or triple lock procedure (e.g., a locked cupboard or cabinet inside a locked medication room, or a locked cupboard inside a locked storage area inside a locked room).¹⁴ The medication room door and the locked cupboard should never have the same lock, so this two-key system is desirable from both security and medication control standpoints. Alternatively, controlled substances may be stored in locked drawers in medication carts used to deliver the drugs to patients. If the cart is ever to be left unattended, it should be secured and locked to the wall or locked in a secure area such as a medication room, and the controlled substance drawer should remain locked at all times.

Whatever container, cupboard, or cabinet is used, it should have secure locks and should be constructed in such a way as to minimize the possibility of undetected forced entry. Consideration should be given to the type of locks and hardware that are used; how they are installed (e.g., with inside hinges); the construction of the container, compartment, or drawer; and the structure into or onto which it is secured or attached. All drug cabinets, drawers, compartments, or other storage areas should be locked when not in use.

6.3.2 Access

Within each healthcare organization, a policy should be established regarding access to drug storage. The policy should describe who has access within each patient care area and the responsibilities associated with such access. The policy should address access for other staff, such as agency nurses or students. The policy should include a procedure to ensure that access privileges are promptly revoked if a staff member is suspended, is terminated, or resigns.

If a manual key is used to access controlled substances, then the use, distribution, and control of keys should be guided by local policy. A key control log is recommended, where nursing staff can sign when they take the key and when they return it. Under no circumstances should a key leave the hospital. If the key has been lost or removed from the hospital, this loss or removal should be reported, and the lock should be changed. Locks should also be changed when a significant loss of drugs is discovered. If a patient care area chooses to maintain more than one key, staff should perform a count of the keys each time the drugs themselves are counted and at every shift change to ensure that the keys are accounted for at all times.

If electronic codes, access cards, or other methods are used to access controlled substances, sharing of such means of access should never be allowed, and passwords should be changed frequently. If an access card is lost, the loss should be reported and the card disabled. Attempts to use disabled cards could also be tracked and reported.

6.3.3 Reconciliation

At each shift change, [physical counts](#) of the controlled substances should be conducted by a health professional coming on duty and a health professional going off duty. In an acute care hospital, counts at shift changes are generally done by two nursing professionals. The same principles apply to health professionals in other settings, such as EMS professionals coming on and off duty in EMS facilities.

If manual access keys are used, responsibility for the key is transferred at this time, and any additional keys are counted. In this way, responsibility for both the key and the drugs is formally transferred to the health professional coming on duty.

6.4 With Automated Dispensing Cabinets

Many facilities have ADCs for storage and management of controlled substances. ADCs should ideally not be placed in high-traffic areas. Rather, these should be located within a locked room, to satisfy the double- or triple lock procedure described under [Storage](#).

Potential advantages of ADCs include shorter delivery time from prescribing to administration, greater inventory control and security measures, and potentially fewer medication errors.²⁸ However, ADCs can create a false sense of security if their use is not supported by rigorous policies and procedures.²⁹

Whenever possible, ADCs should have profiling functionality (i.e., should be linked to the electronic patient profile). With profiled ADCs, the pharmacist reviews new orders before the drugs appear in the patient's profile and are available for the nurse to remove from the ADC. Once a patient-specific drug has been validated by pharmacy staff, it can then be accessed by the nurse for administration. In many facilities, ADCs are part of a closed-loop medication management system that integrates the electronic medical record (EMR), computerized prescriber order entry (CPOE), pharmacist review, and medication administration record (MAR).

In facilities that use ADCs, inventory management and distribution to the patient care area are conducted in the same general manner as for manual systems, with the addition of automated reports on drug-use patterns, which assist with replenishing stock to appropriate levels. Movement of drugs is controlled by unique user identification. User identification is used by pharmacy staff when restocking the ADC and by staff in the patient care area when accessing drugs. With some ADC systems, a witness may not be required during stocking or replenishing of the ADC. When a drug is dispensed, the inventory count is automatically updated. Waste can be witnessed and documented in the system. Controlled substance waste is handled as usual (see [Waste and Disposal of Unusable Drugs](#)). When a witness is required (for stock movement, shift counts, wastage, or any other reason), both parties can enter their user identification to verify the count.

Audits should be conducted frequently, as guided by local policy, and [physical counts](#) should be conducted at least weekly. The updated physical count is entered into the system and variances are flagged. Discrepancies should be addressed immediately and certainly before shift end.

The process of stocking the ADC and conducting physical counts is paperless; however, many reports are available to help in resolving discrepancies and aid in identifying diversion. In many cases, barcode verification of the controlled substance during stock replenishment can also be used as an additional safety feature. Drug diversion software is available that can link transactional data from ADCs with other parts of the medication management system such as EMRs, inventories, or infusion pump data.

6.5 Considerations for High-Risk Patient Care Areas

6.5.1 Operating Room, Other Anesthesia Locations, and Labour and Delivery Area

Controlled substances may be distributed using a per-case method or a daily-supply method.³⁰ The per-case method limits the quantity of controlled substances signed out at one time, but it is more time-consuming. With the daily-supply method, controlled substances are allocated either to a specific operating room or to a specific practitioner. Anesthesiologists may, at the start of the day, access and assume custody of a supply of drugs adequate for anticipated needs that day.

Drugs that have been allocated to a practitioner working in a particular area of the facility who is called to another area should not be removed from the original area where the practitioner was working.

When controlled substances are removed from central stock for use in an operating room or similar location, a record (either manual or electronic) should be created that includes the following information:

- date and time of removal;
- name and signature of the practitioner to whom the controlled substance is allocated;
- destination (e.g., number of the operating room); and
- name and quantity of controlled substance(s).

6.5.2 Specialty Clinics

Clinics, such as those where dentistry, endoscopy, or minor surgical procedures are performed, may be operational only during daytime hours. In these clinics, [physical counts](#) of controlled substances and secure storage of keys and access cards should be undertaken at the end of each business day. These clinics may have minimal staff, so departments should collaborate to ensure that each such count is verified by two regulated health professionals.

7 Prescribing

Prescribers should follow all applicable accreditation standards and the requirements of the provincial or territorial regulatory authority, as well as high-quality clinical practice guidelines. Local policy should dictate who is allowed to prescribe controlled substances, whether verbal or telephone orders are acceptable, and when such orders must be cosigned.¹⁴ Orders for controlled substances to be administered “as needed” should include clear instructions on the frequency of dosing or maximum daily amounts.^{15,32} Practitioners who are the subject of any notice issued under federal regulations shall not be allowed to prescribe, and authorized prescribers shall prescribe controlled substances only for persons who are under their professional treatment.¹¹

In facilities with electronic medical records, prescribers should be able to view their prescribing history, as one method of identifying falsified electronic orders.

7.1 Prescription Pads

Diversion by means of forgery, using prescription pads stolen from hospitals, represents an important means of diversion of controlled substances. Electronic prescribing should therefore be used where the capability exists. The process of electronic prescribing may include the electronic creation of a printed prescription (using CPOE) or the electronic transmission of a prescription to the patient’s pharmacy (commonly called e-prescribing).

In facilities where paper-based prescriptions are used by practitioners in the emergency department and other outpatient areas, security measures are required.

Prescription pads should not be left unattended in any part of the hospital. They should be signed out to individual practitioners from a central distribution point (generally the pharmacy), and a log should be maintained. Pads not in use should be securely stored. Consideration should be given to using tamper-proof prescription pads with a controlled numbering system.

Prescribers shall follow the relevant guidance of their provincial or territorial regulatory authority, as well as the provincial or territorial prescription monitoring program (PMP) where such a program exists. For example, some jurisdictions may require a specific type of form or pad, and may issue these directly to the prescriber.

Missing prescription pads should be reported to the PMP and to local law enforcement as soon as possible. Any signs that a prescriber’s identity has been compromised should also be reported as soon as possible. These occurrences may be part of a larger operation, and timely information may lead to earlier investigation and may limit the ultimate harm done.

8 Administration to the Patient

As controlled substances come under stricter surveillance, there may be increasing risk of diversion at the patient's bedside. Patient harm is possible with any form of diversion, particularly if the patient's caregiver is working under the influence of a controlled substance. In addition, diversion at the point of administration may result in poor pain control for patients, who may receive partial doses, a substitute drug, or no drug at all. Bedside diversion can also pose a significant public health risk if a staff member tampers with injectable drugs.³² See [Examples of Diversion](#).

In general, there are three potential participants in bedside diversion, who may work alone or in collaboration:

- staff member administering the drug;
- patient diverting the administered drug (e.g., a patient “cheeks” an oral medication, and then surreptitiously spits it out); or
- a third party (e.g., family member or patient in a neighbouring bed) diverting an unsecured drug.

When administering a controlled substance:

- verify the order for the controlled substance;
- sign out the controlled substance (i.e., remove it from secure storage) in compliance with the facility's policy;
- confirm the patient's identify using two identifiers;
- before administration, verify the drug order, dose, route, and frequency;
- administer the drug, directly witnessing ingestion;
- document within the MAR as soon as possible after administration; and
- document any wastage as soon as possible after administration (partial doses should not be saved for later use; see [Waste and Disposal of Unusable Drugs](#) for details).

The facility shall establish a list of high-alert drugs for which an independent double check is required.^{14,33} An independent double check involves two regulated health professionals independently confirming the drug order, dose, route, frequency, and patient identity.³⁴

If staff in a patient care area suspect that a patient may be diverting an administered drug, they should share their concerns with the care team, and the prescriber should assess the patient for risk of substance use disorder.

Staff members should be aware that patients with cognitive impairment or aphasia may be unable to communicate a change in pain control, a missing or ineffective dose of medication, or any unusual occurrence at the bedside.

Staff members should not routinely crush tablets (before administration to the patient) to prevent diversion, as doing so may unnecessarily increase workload and may also increase risk of harm (e.g., through accidental crushing of a slow-release opioid tablet).

The facility shall have a policy for handling patients' own medications that are brought to the facility upon admission.¹⁴ The policy should have robust record-keeping requirements and should minimize the risk of diversion and inappropriate use.

8.1 Considerations for Operating Room, Other Anesthesia Locations, and Labour and Delivery Area

An administration record (either manual or electronic) should accompany controlled substances that are removed from central stock, and the practitioner should record the following details:

- date and time of administration;
- name and identification number of patient;
- name and signature of the practitioner;
- name and quantity (in terms of total amount [e.g., mg] and total volume [e.g., mL]) of drug administered; and
- number of the operating room or other location.

The administration form should be completed as soon as possible after the drug is administered, and it is the responsibility of the practitioner who administered the drug to complete this record. It is inappropriate and unacceptable to call upon operating room staff to complete such records on behalf of the practitioner.

9 Waste and Disposal of Unusable Drugs

On occasion, it is necessary to dispose of a small volume of drug when the supplied formulation is greater than the required dose. The volume of drug not used is called a "partial" or a partial dose, and this partial dose is "wasted" or becomes "wastage." Normal practice under these circumstances is to destroy the wastage in the presence of a witness (a health professional who is entitled by law to perform this function), although wastage may also be placed in a tamper-proof container for destruction at a later time if necessary. The manner in which wastage is to be completed should be defined or specified in policy and procedures established by the facility.

General principles in developing an organizational policy for wastage of controlled substances include the following:

- Consideration should be given to having a policy inclusive of all pharmaceutical waste, with wastage of controlled substances being one part of this policy.
- Wastage of all controlled substances should be witnessed and documented by two independent regulated health professionals.

- Wastage should be disposed of safely and securely (in a manner that protects the public, healthcare providers, and the environment) only in designated pharmaceutical waste containers.
- All pharmaceutical waste containers shall be secured and, where possible, tethered to prevent unauthorized removal.
- Preparation and disposal of controlled substances should occur in an open or observable area specifically designated for the preparation of drugs.
- For administration of a single dose, excess drug that must be discarded should be wasted before administration of the dose at the patient's bedside.
- If controlled substances are stored in ADCs, wastage should be documented in the device from which the substance was removed.
- When witnessing wastage, the witness should
 - verify the drug label;
 - confirm that the amount wasted and the actual drug matches the documentation; and
 - observe disposal of the drug into the appropriate waste container.
- New technologies are emerging and these should be assessed for feasibility as they become available.

Similarly, when a controlled substance or its container is damaged in the patient care area (e.g., a vial is broken, a tablet is dropped on the floor), it should be destroyed in the presence of a witness, with documentation by two regulated health professionals.

A controlled substance may become unserviceable for various other reasons. Health Canada defines unserviceable stock as products that are unusable, expired, or that cannot be dispensed.

In practice, this definition includes the following:

- expired or recalled drugs;
- drugs that have been “poured” (opened or otherwise made ready for administration) but have been discontinued, refused by the patient, or otherwise not administered;
- overfill in vials;
- partial doses (e.g., partial tablets, or drug remaining in vials or ampules);
- drug remaining in infusion bags, syringes, or cassettes;
- drug remaining in transdermal delivery systems;
- drugs that were specially compounded and cannot be used for a different patient;
- drugs from outside of the facility (e.g., patient's own medications for which disposal has been requested); and
- other unusable drugs (e.g., drugs that have fallen on the floor, were spit out by the patient, or were prepared for the wrong patient).

Unserviceable stock that is not witnessed and destroyed in the patient care area may sometimes be returned to pharmacy. If the drugs have never been removed from the facility, drugs that have been returned to the pharmacy from patient care areas are not automatically defined as unusable. However, local policy should guide the re-use of such drugs, taking into account the requirements of the relevant professional regulatory authority, storage requirements (e.g., cold chain), and best practices for infection control. Such guidance would apply to all drugs (not only controlled substances) and is beyond the scope of this document. Controlled substances that are being returned to the pharmacy for re-use should be signed back into inventory following procedures similar to but reversed from the procedures used when the drugs were signed out [from pharmacy to patient care area](#). All records maintained in the patient care area should be modified to reflect this transfer of stock.

A separate log should be maintained in the pharmacy for drugs that are no longer usable and have been designated for destruction. This log should include the following details:

- date removed from inventory;
- name, strength, and dosage form;
- quantity;
- reason for removal from inventory; and
- name and signature of pharmacy staff member responsible.

Drugs that have been designated for destruction should be stored in a tamper-resistant container and kept secure until the container is removed from the facility or destroyed. Removal or destruction should occur in a timely manner, because a large amount of unusable stock can be a target for diversion.

Unusable controlled substances shall be destroyed in accordance with Health Canada guidance,³⁵ and the process of destruction shall respect all applicable environmental laws. Such drugs shall either be sent to a licensed dealer for destruction or be destroyed locally.

Principles of local destruction include the following:³⁵

- The controlled substance shall be “altered or denatured to such an extent that its consumption [is] rendered impossible or improbable.”
- The method of destruction should be guided by local policy. Methods of destruction, in order of preference, are incineration (ideal), chemical denaturation, and physical destruction. Incineration or chemical denaturation is generally done by a licensed dealer with the appropriate equipment; this entails sending the controlled substances to the dealer. The use of chlorine bleach is not recommended for local destruction, because the use of bleach can result in an exothermic reaction. Local destruction often involves physical destruction to the point of rendering the product unusable (e.g., emptying vials of liquid drug into gauze or paper towel). However, pharmaceutical disposal systems for local destruction are increasingly available. These systems destroy controlled

substances in a tamper-proof container, rendering them unusable and irretrievable.

- Local destruction shall be carried out by a pharmacist or a person in charge of a hospital, “except where the unserviceable stock represents any partial or unusable doses, and the unserviceable drug is already outside the pharmacy, e.g., on a ward. In this case, local destruction can be carried out by a licensed health professional, at the discretion of the person in charge of a hospital.”
- All local destructions shall be witnessed by a practitioner, a pharmacist, a pharmacy intern, a pharmacy technician, or a Health Canada inspector.

9.1 Considerations for Operating Room, Other Anesthesia Locations, and Labour and Delivery Area

Wastage by anesthesiologists may require special consideration, but should nonetheless follow [fundamental principles](#), such as ensuring that records are accurate and complete, ensuring that related records are reconciled (e.g., records of stock dispensed, administered, wasted, and returned), and conducting periodic audits.

The desired outcome is to prevent diversion of controlled substances by ensuring that each movement of a controlled substance can be easily audited, while supporting patient safety, staff safety, and optimal patient care. Facilities should define the specific policy and procedure that will be used to meet the desired outcome, and may consider the following:

- It is good practice for wastage to be witnessed by a second health professional.^{31,36,37,38,39}
- The sharing of partial vials between patients is poor practice and should be avoided.^{37,40,41,42} Therefore, wastage should ideally be case-specific.
- Technology such as ADCs may be helpful for tracking controlled substances and for documenting waste. When implementing such technology, consider how it will be integrated into existing workflows.
- Several pharmaceutical waste disposal systems are commercially available. These systems destroy or denature controlled substances at the point of wastage, rendering them unusable. This option conveniently combines wastage and destruction in one step, but would need to meet the requirements for local destruction.
- Wastage can be returned to the pharmacy for disposal.³⁰ However, wasting at the point of use may be better practice for workflow and patient safety.⁴³

Destruction of unserviceable stock should occur in the same manner as in other patient care areas. Unusable controlled substances shall be destroyed in accordance with Health Canada guidance.³⁵

10 Identifying Diversion

Diversion and the risk of diversion can take many forms and can occur anywhere in the medication management system, including procurement, preparation, dispensing, product selection/removal from storage, administration, or waste disposal. Reducing diversion requires a thorough knowledge of how controlled substances enter the system, how and where they are stored and used (and by whom), and how stock exits the system.

Controls can take the form of physical security measures (e.g., no access to the vault through the ventilation system or ceiling) or administrative measures (e.g., policies and procedures, forcing functions in technology, locks on doors). Automation can allow for improved tracking and identification of potential diversion incidents. Diversion software is available that can compile and analyze large amounts of data to produce easily customized reports. These technologies are powerful tools, but diversion is often multifactorial, and automation alone cannot prevent it. Detection often relies on staff awareness and timely reporting. It also relies on dedicated resources to receive and review reports in a timely manner and to proactively look for unusual trends in usage or diversion reports.

See [Examples of Diversion](#) for common methods and signs of diversion.

Timely identification of a potential diversion event relies on the following:

- **Physical counts.** Verify the amount of stock on hand at regular and frequent intervals.
- **Rigorous record-keeping.** Document the transaction every time a controlled substance changes hands or moves through the facility.
- **Reconciliation.** Ensure that all records across the facility are in agreement (e.g., amount procured, amount dispensed, and stock on hand; amount dispensed by pharmacy and amount received by patient care area; amount assigned to a clinic or department, amount administered, wasted, and returned by that department, and amount on hand in that department).
- **Audits.** Verify all of the above with frequent and random checks in different parts of the facility.

10.1 Record-Keeping and Audits

10.1.1 Pharmacy

[Physical counts](#) and reconciliation of specific products should occur whenever new stock is received, issued to a patient care area, or dispensed. Full reconciliation of all controlled substances stored in pharmacy, including those being held for destruction, shall occur at frequent and regular intervals, in accordance with the standards of the relevant provincial or territorial regulatory authority and facility policy.

Random verification of purchase orders placed, orders received, and entries into the perpetual inventory system in the pharmacy should be undertaken on a frequent basis by a member of the diversion prevention committee or other designated staff. Audits and verifications should be conducted more frequently when there are staffing changes, when concerns exist, or when there is a high volume of drug turnover.

The audit should include the monitoring or verification of:

- stock on hand;
- purchase orders that have been issued;
- purchase orders that are pending;
- back orders;
- records of receipt (pharmacy receiving log);
- records of distribution (items issued, received, returned, outstanding); and
- records of drugs to be destroyed.

In a paper-based system, purchase orders should be tested for serial continuity to ensure that all forms are accounted for. An inventory should be kept of all uniquely numbered logs for controlled substances issued to patient care areas and completed logs returned. Returned logs should be reviewed by pharmacy staff for completeness of entries (including page number verification) and returned, within two working days of receipt, to leaders in the patient care area for resolution of discrepancies, if required. Logs should be firmly bound and sorted by consecutively numbered pages. Logs not returned within 30 days should be retrieved and reconciled. Frequent discrepancies require follow-up with leaders in the patient care area.

Multifacility health systems should maintain a consolidated list of all reported losses from all sites, to help identify trends in control problems and to track staff working at various sites who may be involved in diversion.

10.1.2 Patient Care Area

In facilities that use paper-based systems, a perpetual inventory log of controlled substances should be maintained wherever these substances are stored in patient care areas. All issues to patients, wastage, receipts from pharmacy, and returns should be documented. The log should include:

- date and time;
- patient name;
- names and signatures of staff involved;
- new balance on hand; and
- drug name, dose, wastage (if applicable), strength, and number of units (e.g., tablets, vials, syringes) removed or returned.

Verification and cosignature by a second health professional should be required for:

- receipt of stock from pharmacy or another unit;
- return of stock to pharmacy or transfer to another unit;
- broken or contaminated products;
- copying forward of balances to a new page of the log or to a new log book;
- wastage of a partial dose; and
- [physical counts](#).

When a log book has been completed, it should be reviewed by the manager of the patient care area for completeness and accuracy of entries before it is returned to pharmacy.

In facilities with ADCs in patient care areas, a blind count-back should be conducted each time a controlled substance is removed for a specific patient. Discrepancies should be addressed immediately and certainly before shift end. Audits of physical inventory of controlled substances should be conducted at least weekly on each ADC.

Whether a facility is using paper-based or ADC distribution of controlled substances, random audits of doses removed versus doses administered should be conducted frequently; such audits should be based on 24 hours of usage of a randomly chosen product. Audits may be conducted by members of the diversion prevention committee or other designated staff. Audits should include a review of the MAR as well as confirmation that:

- a valid prescriber's order was present for the particular drug for the particular patient;
- dose removed was documented as administered;
- dose administered was the dose ordered or was within the dose range ordered;
- dose administered plus amount wasted was equivalent to the amount removed;
- date and time of removal coincided reasonably with the date and time of administration;
- dose was removed and administered by a health professional who was on shift at the time; and
- documentation of patient response was completed.

In facilities using electronic MARs as well as ADCs, this process can be automated, and reviews can be conducted more frequently. Similar processes and reporting can be undertaken where anesthesia workstations are in use. Additional information that is available from automated systems to support detection of diversion and that should be reviewed regularly may include:

- reports of anomalous usage;
- reports of temporary user access (to identify who was granted access, by whom, and when, and what drugs were removed);
- occurrences of overrides for controlled substances, including frequency of such overrides among specific users;
- occurrences of the same two health professionals repeatedly cosigning each other's wastage (such occurrences may be legitimate in care areas with low staffing levels); and
- frequent cabinet access without record of drug removal.

10.2 Physical Counts

Physical counts of all controlled substances in all areas of the facility shall occur at frequent and regular intervals, in accordance with the standards of the relevant provincial or territorial regulatory authority and facility policy.

The longer the interval between counts, the more difficult it will be to reconcile any discrepancies, because of the volume of transactions to be reviewed and the declining recollection of events that may have contributed to the discrepancy. Longer intervals also delay the ability to take action and implement corrective measures when problems arise.

In patient care areas, physical counts should occur with each shift change.

Random, unannounced counts should be conducted in all areas of the facility. Such random counts should be conducted in the same manner throughout the facility.

The physical count should be performed by two staff members authorized by the facility, preferably regulated health professionals. These two staff members should not always be the same people.

To perform the count, one staff member should count the products on the shelf or in the ADC and read the quantities on hand to the other staff member, who records the quantity in the perpetual inventory record or confirms that the count matches the inventory amount displayed in the ADC. The count should be a blind count, whereby the person recording does not express to the person counting the number that should be on hand. The person counting can then verify the entries of the person recording. Both staff members should verify balance totals that are brought forward to the next page.

Blind count: How many oxycodone tablets are there?
Confirm count (or verify count): Are there 10 oxycodone tablets?

The person counting need not count the contents of bottles or vials with the original manufacturer's seal still intact. However, such products should be examined to ensure that no tampering has taken place. The person counting should check that seals are intact, that packaging is not damaged, that rubber stoppers have not been punctured, and so on.

If the physical count does not match the documented amount on hand, the discrepancy should be investigated immediately and resolved before the end of the shift. Differences that cannot be reconciled shall be reported to Health Canada within 10 days. Refer to Health Canada's guidance document *Reporting of Loss or Theft of Controlled Substances, Precursors and Cannabis*²¹ for further information.

11 Investigating Diversion

The facility should have a process for responding to discrepancies identified through physical counts or audits and for responding to reports of diversion incidents. These processes should be the responsibility of the multidisciplinary diversion prevention committee (described in the section on [Organizational Accountability](#)), which should ensure that policies are in place, staff education is routinely conducted, and diversion incidents are promptly investigated.

11.1 Reporting Suspected Diversion

Any theft or unexplained loss shall be reported to Health Canada within 10 days of discovery (or less, where required by the provincial or territorial regulatory authority). It is not necessary to complete the full investigation by the time the initial report is filed; an amendment to the report can be filed at a later date if appropriate. Health Canada defines a reportable loss as an unexplained incident in which there is a possibility that a controlled substance has been diverted. Incidents such as spillage, breakage, and known dispensing errors are not reportable losses. Refer to Health Canada's guidance document *Reporting of Loss or Theft of Controlled Substances, Precursors and Cannabis*²¹ for further guidance.

Incidents should also be reported to the facility's diversion prevention committee. Facilities should define in policy when reporting is required, who is responsible for reporting, who should receive the reports, and who is responsible for acting on the reports.

All staff members should receive education about signs of diversion. Desired competencies for staff should include the ability:

- to identify activity suspicious of diversion;
- to describe how to report suspicious activity; and
- to describe how to respond to reports of suspicious activity.

Consideration may be given to creating a system for confidential reporting by staff members, such as a designated telephone line.

11.2 Conducting a Diversion Investigation

The facility should have a process for investigating suspected diversions. The facility should consider having procedures related to such investigations reviewed by legal counsel in advance of a diversion event.

The diversion prevention committee should oversee diversion investigations and response, and may appoint a lead staff member for each investigation.

Although the supervisor or manager in the area where diversion is suspected will assist in conducting the investigation, those external to the area should also be involved, to ensure that biases do not influence the investigation.

It is essential that the individuals involved accurately record their observations and any other relevant details or information for consideration by the investigator. The diversion prevention committee may choose to develop a standardized form for use during an investigation, which can be reviewed in advance by legal counsel and local law enforcement. The form can help to ensure that the investigator understands the authority under which the investigation is taking place; it may also be a useful communication tool if the investigation needs to be turned over to law enforcement.

It is important to maintain objectivity at all times and to recognize and examine all points within the system where diversion may have taken place.¹⁹

It is probable that attempts have been or will be made to conceal the diversion and to divert attention or suspicion from the individual responsible. As such, it is important to avoid allegations or accusations until the investigation is concluded. Review and verification of all records, forms, and charts associated with the receipt and release of the drugs will help to track the transfer of responsibility and to focus the investigation. Detailed notes about the nature of the records examined (e.g., inventory log books vs patients' private medical records) may be helpful if search warrants are required later.

Other elements of the investigation should include:

- checking for administration of drugs just before discharge or transfer of patient;
- verification that previous balances were carried forward correctly;
- verification of physical counts conducted at shift changes;
- examination of usage patterns;
- signs that record entries (names, dates, quantities, signatures) have been altered;
- laboratory analysis of any samples, as permitted by regulations;
- errors in charting or signing out doses;
- examination of drug waste and destruction (including frequency, patterns, and individuals involved);
- verification that all records and forms are available;
- observation over a period of time;
- consideration of patient complaints, such as continuing pain;
- examination of packages for signs of tampering or substitution;

- behaviour of staff:
 - signs of physical impairment;
 - work habits;
- work history; and
 - complaints from patients, family members, or other staff members.

A person who is diverting controlled substances may not exhibit poor work habits or work history. In fact, the person may volunteer for extra shifts, arrive at work early, stay late, or come in on days off.

11.3 Interviewing a Suspected Diverter

The facility should establish a procedure for interviewing a person suspected of diversion. The procedure should define who will lead the interview, who else should be present, at what point in the investigation the interview should take place, and under what criteria legal counsel or local law enforcement should be consulted. During the information-gathering phase, of which the interview forms one aspect, there should be a focus on impartiality. The investigator should have appropriate training and skill in various interview techniques.

11.4 Responding to Confirmed Diversion

Once diversion has been confirmed, the facility must assess whether to terminate or suspend the staff member, transfer the person to a lower-risk area, take other action (e.g., remove access to controlled substances), or undertake other sanctions. Any such action should be in accordance with established local policy and professional regulatory requirements, as applicable.

The facility should establish guidelines for engaging others external to the organization, such as local law enforcement. It is helpful to have a collaborative relationship with law enforcement in place before a diversion event occurs. The law enforcement agency can thus be familiar with the facility's procedures and offer advice when needed.

The facility's policy will dictate what further action will be taken with respect to the individual within the organization. If the individual is found to have a substance use disorder, it is appropriate to recommend treatment, rehabilitation, and support, through an employee assistance program or similar organization.

In the case of regulated health professionals, it is important to advise the relevant provincial or territorial regulatory authority. A cursory internet search will yield many examples of harm done by health professionals who were known to have diverted controlled substances but were not reported to the relevant regulatory authority and were therefore able to continue working at another facility.

The regulatory authority may take into consideration the motivation behind the diversion (e.g., personal substance use disorder vs trafficking). However, the regulatory authority must ultimately assess the person's fitness to practise. In many provinces and territories, regulated health professionals are legally obligated to file a report when they suspect that another health professional (e.g., a colleague) may be working while impaired.

Glossary

Controlled substance

Any drug or substance found in Schedules I, II, III, or IV of the *Controlled Drugs and Substances Act*,¹⁰ including narcotics, amphetamines, methylphenidate, barbiturates, benzodiazepines, anabolic steroids, and other such drugs. These substances “can alter mental processes” and “may produce harm to an individual or to society when diverted to an illicit market.”⁴²

A facility may choose to designate and treat additional substances as controlled substances for the purposes of its local policies and procedures.

Creative compliance

The practice of finding ways to accomplish compliance with the letter of the law (or policy, or guideline) while undermining the spirit or the intent behind the words.

Destruction

The process of altering or denaturing a controlled substance to such an extent that consumption is rendered impossible or improbable.

Diversion

The transfer of a controlled substance from a lawful to an unlawful use.

Emergency medical services (EMS)

Urgent medical response service; also known as ambulance services or paramedic services. In this document, EMS facilities include vehicles (e.g., ambulance, aircraft), designated EMS areas within hospitals, EMS stations within the community, and controlled substances in the paramedic’s possession (e.g., stored in a secure pouch on their person).

Healthcare facility	A place where healthcare is delivered. In this document, such facilities include hospitals, clinics, emergency medical services (EMS) facilities, long-term care homes, and other settings embedded within the provincial or territorial health system. In this document, the term “healthcare facility” does not refer to community pharmacies or practitioners’ private offices, which are subject to different regulations.
Healthcare organization	An institution that encompasses multiple healthcare facilities, such as a health authority or a multisite hospital system.
Investigation	A comprehensive and systematic analysis, designed to study the circumstances surrounding an incident and to identify its underlying causes; not a criminal investigation.
Narcotic	Any drug listed in the Schedule of the <i>Narcotic Control Regulations</i> . Used colloquially to describe any addictive drug that can reduce pain and cause stupor.
Opioid	Any drug resembling opium in its physiological effects. Examples include natural opiates, such as morphine and codeine, semisynthetic opioids such as oxycodone and hydromorphone, and synthetic opioids, such as fentanyl.
Pharmacy and Therapeutics Committee	A committee within a healthcare facility or organization that is composed of representatives from the pharmacy service, medicine, nursing, administration, and other disciplines, which serves as a policy-recommending body on all matters relating to the use of medications in the facility or organization. May be known by another name (e.g., pharmacology committee, pharmacotherapy committee).

Pharmacy staff	Members of staff in the pharmacy of a healthcare facility. May include pharmacy professionals (pharmacists and regulated pharmacy technicians), pharmacy assistants, pharmacy students, and pharmacy technician students. Consideration should be given to limiting the management of controlled substances to pharmacy professionals.
Practitioner	A physician, dentist, veterinarian, midwife, nurse practitioner, or podiatrist, as defined by the <i>Controlled Drugs and Substances Act</i> ¹⁰ or the <i>New Classes of Practitioners Regulations</i> . ⁴⁴
Shall	Describes a mandatory requirement found in legislation, regulations, professional regulatory authority requirements, or accreditation standards.
Should	Describes a recommendation, something that is advised but not mandatory.
Unserviceable stock	Any drug product in the pharmacy inventory that is unusable, expired, or that cannot be dispensed. In the hospital setting, this term does not apply to partial or unusable doses outside of the pharmacy. ^{35,45}
Unusable drugs	The combined total of unserviceable stock (in pharmacy inventory) and any drugs outside the pharmacy that cannot be administered to a patient. This may encompass partial doses, as well as other forms of wastage.
Wastage	Medication left over when the supplied formulation is greater than the required dose. Also called a “partial” or a partial dose, such drugs should be disposed of (or “wasted”) and not saved for later use.

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Appendix A

Examples of Diversion

Common methods of diversion include:

- entering a quantity of drugs into perpetual inventory (in the pharmacy or a patient care area) that is different from the quantity actually received;
- “borrowing” stock between patient care units;
- tampering with the inventory control record (changing quantities, removing pages);
- pilfering a noncontrolled substance and reporting a missing dose;
- replacing package contents with a look-alike drug;
- replacing prepared syringe contents with saline;
- removing controlled substances without an order;
- falsifying a verbal or electronic order;
- documenting administration of drugs without having administered the drugs;
- removing a full dose and documenting its administration, but administering a partial dose;
- removing a larger dose than ordered and not wasting the excess;
- removing a controlled substance, pilfering it, and administering a less potent analgesic;
- removing a controlled substance, pilfering it, and administering a drug that will mimic the side effects of the controlled substance (e.g., drowsiness from diphenhydramine, dimenhydrinate, or haloperidol);
- tampering with an infusion pump or other device to remove drug at the bedside;
- prematurely replacing infusion bags or infusion devices;
- pilfering partial infusion bags or infusion devices when a treatment is discontinued;
- pilfering from drug waste, sharps containers, or patches that have been removed from patients;
- pilfering patient-supplied drugs or not returning such drugs at discharge; and
- removing drugs for a discharged or nonexistent patient.

Appendix A

Examples of Diversion Continued...

Common signs of diversion include:

- missing purchase order or packing slip;
- compromised packaging (watch for excessive “accidents”, and check rubber stoppers for punctures);
- verbal orders created but not verified by prescriber
- numerous unresolved discrepancies;
- numerous corrected transactions;
- removal of drugs for more patients than are generally assigned to a single health professional;
- removal of drugs for patients assigned to another health professional (beyond that required for coverage of breaks or a team-based approach among nurses within a patient care area);
- staff member frequently volunteering to pick up controlled substances from the pharmacy between scheduled deliveries;
- failure to document wastage;
- failure to discard wastage or render it unusable;
- frequent or excessive wastage through selection of a larger product size or dosage form than required;
- frequent breakage or wastage of entire doses;
- regular choice of the same witness for wastage;
- delay in witnessing or documenting wastage (to facilitate substitution);
- bulk entry of wastage at end of shift;
- disposal of controlled substances in regular trash;
- staff member frequently volunteering to take out the trash;
- staff member frequently offering to administer doses for colleagues, arriving early, staying late, or coming to work on days off;
- staff member frequently volunteering to hold the keys to the storage area for controlled substances;
- complaints (from patient or family) of inadequate pain management;
- variation in patient’s pain control (e.g., well-controlled on one shift but poorly controlled on another shift); and
- substantial differences in patient’s pain control for similar procedures or surgeries.

Appendix A

Examples of Diversion Continued...

Methods and signs of potential diversion that are unique to automated dispensing cabinets include:

- frequent setup of temporary users or temporary patients;
- frequent medication overrides;
- frequent access of the unit without removal of a drug;
- removal of drugs under a colleague's sign-on credentials;
- removal of more doses than documented; and
- removal of duplicate doses from the same or different cabinets.

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**Controlled Drugs and
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