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**Office of Primary Interest: Office of Primary Health Care within the Population Health and Primary Care Directorate**

**First Nations and Inuit Health Branch**

**POLICY AND PROCEDURES ON**

**CONTROLLED SUBSTANCES**

**FOR FIRST NATIONS HEALTH FACILITIES**

**[where health services and/or pharmacy services are managed by FNIHB]**

08

**Fall**

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# **List of Acronyms**

**ADM** Assistant Deputy Minister

**CCC** Clinical and Client Care

**CS** Controlled Substances

**CDSA** Controlled Drugs and Substances Act

**DNM** Designated Nurse Manager

**FNIHB** First Nations and Inuit Health Branch

**IPS** Interprofessional Practice Support– FNIHB

**NIC** Nurse in Charge

**NIHB** Non-Insured Health Benefits Directorate – FNIHB

**OCS** Office of Controlled Substances - Health Canada

**OPHC** Office of Primary Health Care

**PHCSD** Primary Health Care Systems Division

**PHPCD** Population Health and Primary Care Directorate

**RCSO** Regional Controlled Substances Officer

**RE** Regional Executive

# *Overview*

Controlled substances (CS) provide valuable treatments for many patients. Unfortunately, over the past decade, the rise in the prescribing of CS has contributed to drug dependence, misuse, and diversion particularly with opioids which has emerged as a public health issue. Diversion puts patient safety and public health at risks. Misuse of these medications can cause serious health effects for the user, including a risk of death from an overdose.[[1]](#footnote-1)

To address this opioid crisis faced across Canada, the Canadian Medical Association (CMA) has recommended a comprehensive, multi-pronged strategy. This includes addressing drug safety, monitoring and optimal prescribing, access to pain management and addiction services, as well as public and professional education.

As a quality assurance measure and to promote CS stewardship, the First Nations and Inuit Health Branch (FNIHB) recommends that authorized prescribers and nurses consider minimal CS quantities provided to clients at the health facility. Through collaborative efforts among health care professionals, and patient education we can succeed in promoting appropriate use of CS while minimizing their misuse and diversion in First Nations communities.

# *Overview of Requirements*

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

***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, federal statutes that are administered by the Office of Controlled Substances within Health Canada. Regulations made under the CDSA include the *Narcotic Control Regulations* and the *Benzodiazepines and Other Targeted Substances Regulations*.

***Provincial Regulations***

Provincial 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.

***Professional Standards of Practice***

Every regulated health profession has standards of practice that must be met by those practicing the profession. The provincial 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. Health professionals are encouraged to check with their provincial regulatory body in which they are licensed to practice to verify what functions they may conduct within their scope of practice with controlled substances.

# GENERAL

## 1.0 AUTHORITY

This policy and procedures document is issued under the authority and approval of the Senior FNIHB ADM and the FNIHB Regional Operations ADM.

## DEFINITION OF FIRST NATIONS HEALTH FACILITIES

In this document, First Nations health facilities are defined as a health facility where health services and/or pharmacy services are managed by the First Nations and Inuit Health Branch.[[2]](#footnote-2)

## SCOPE

This policy applies to all nurses providing health services in a First Nations health facility, and to all other personnel involved in the distribution of Controlled Substances (CS) at a First Nations health facility, as defined above.

## PURPOSE

The purpose of this document is to set forth the policies and procedures governing the possession, sale, supply, transport, ordering, storage, prescribing, administration, provision, record-keeping, accounting, wastage, destruction, and security of CS in First Nations health facilities. This document is intended to be consistent with:

* the *Controlled Drugs and Substances Act*;
* the *Narcotic Control Regulations*;
* the *Benzodiazepines and Other Targeted Substances Regulations*;
* Part G of the *Food and Drug Regulations*;
* *Subsection 56 (1) Exemption for Nurses who provide Health Care at a Community Health Facility*;
* *Subsection 56 (1) Exemption for the Person in Charge of a Hospital and/or Pharmacist who Supplies Controlled Substances to a Community Health Facility,* and
* *Provincial pharmacy and nursing Standards of Practice.*

## CONTEXT

In the context of health services delivery at First Nations health facilities, nurses may conduct certain activities with CS in the course of their employment and as directed in this policy and procedures document.

Throughout this document a nurse means:

* an individual who is registered and entitled under the laws of a province to practise nursing (e.g, registered nurse, licensed practical nurse), and
* who is delivering health care in a First Nations facility where the services are managed by the First Nations and Inuit Health Branch, and
* who is permitted by that province authority to administer medications to patients.

This policy and procedure document encompasses the scope of practice of nurses and other regulated health professional such as, licensed practical nurses (LPNs) and pharmacy technicians who have the authority to conduct certain activities with CS as outlined by their provincial regulatory body in which they are licensed to practice.

A nurse practitioner is able to prescribe controlled substances as per the *New Classes of Practitioners Regulation* and as defined by specifications and additional educational requirements of the applicable provincial nurse regulatory body in which they are licensed to practice. Since not all nurse practitioners will proceed with the additional authority the use of the terms “registered nurse” or a “nurse practitioner not authorized to prescribe and/or order CS” will be used throughout this document.

The activities of physicians, dentists, pharmacists, pharmacy clerks/technicians, facility staff, and other persons undertaking activities with CS in these First Nations health facilities are also addressed in this document.

# POLICY

FNIHB requires accountability for CS at three different levels:

* on a regional basis, using the *[Semi-Annual Regional Audit Report (Annex 8)]*,
* on a health facility basis, using the *[CS Signature and Acknowledgment Form (Annex 1)]*, the *[CS Month End Inventory and Usage Report (Annex 3)]*, the *[CS Destruction Request Form (Annex 4)]*, the *[CS Audit Form (Annex 6)]*, and the *[Loss or Theft Report Form for Controlled Substances and Precursors (Annex 7)]*, and
* on an individual patient basis at the time a controlled substance is provided or directly administered to a patient, using the *[CS Register Form (Annex 2A or 2B)]*.

# 3 POLICY DIRECTION

**3.1** Primary responsibility for the implementation of this policy lies with the Senior FNIHB ADM, at national office level, and with the FNIHB Regional Operations ADM at the regional and health facility levels. The ADMs will ensure that policies and procedures are in place to ensure that personnel handling CS follow the requirements set out in this document.

**3.2** For the purpose of administering this policy and related procedures, the Senior FNIHB ADM delegates their authority to the Interprofessional Practice Support Pharmacy Unit of the Population Health and Primary Care Directorate, Office of Primary Health Care, Primary Health Care Systems Division. The IPS Pharmacy Unit will develop and maintain national policies and procedures governing activities with CS, for approval by the Senior FNIHB ADM in consultation with the FNIHB Regional Operations ADM.

**3.3** Every FNIHB Regional Executive (RE) is accountable to the FNIHB Regional Operations ADM for all activities conducted with CS at the First Nations health facilities located within their region. The REs will also take measures to ensure that these substances remain secure, and inform FNIHB National Office (IPS Pharmacy Unit) in addition to the [Compliance and Monitoring Division, Health Canada](mailto:hc.ocs.reporting-rapporter.bsc.sc@canada.ca) whenever a loss or theft is identified.

**3.4** Regional procedures related to CS may be more, but not less, stringent than those set out in this policy and procedures document. Moreover, such regional procedures should be explicit, clearly written, and authorized by the IPS Pharmacy Unit in PHPCD on behalf of the Senior FNIHB ADM.

# 4 OBJECTIVE

The objective of this policy and procedures document is to set out the activities that staff working at a First Nations health facility are authorized to conduct with CS as outlined by their provincial regulatory body in which they are licensed to practice, and to ensure the proper management, record-keeping and security of CS.

# 5 CONTROLLED SUBSTANCE DEFINITIONS

The following definitions have been developed for use in this document. These definitions do not supersede any formal definitions set out in related legislation and regulations.

**5.1** A ***Controlled Substance*** includes any substance, alone or in combination with other active chemicals, listed in Schedules I through V of the *Controlled Drugs and Substances Act*. Controlled Substances include controlled drugs, narcotics, and targeted substances e.g. benzodiazepines, and their preparations.

**5.2** A***Controlled Drug***includes any substance, alone or in combination with other active chemicals, listed in the Schedule to Part G of the *Food and Drug Regulations*. These drugs are typically amphetamine-like substances, barbiturates or anabolic steroids, e.g., methylphenidate, phenobarbital and testosterone.

**5.3** A ***Narcotic*** includes any substance, alone or in combination with other active chemicals, listed in the Schedule to the *Narcotic Control Regulations*. Many of these substances are used for managing pain, e.g., codeine, meperidine, and morphine.

**5.4** A ***Targeted Substance*** includes any substance, alone or in combination with other active chemicals, listed in Schedule 1 to the *Benzodiazepines and Other Targeted Substances Regulations*. These drugs are typically part of the benzodiazepine family and used as anxiolytics or sedatives, e.g., lorazepam and diazepam.

**Note:** For easy recognition, manufacturers’ labels and the Compendium of Pharmaceutical Specialties (CPS) normally show the following symbols beside the brand name of a drug containing a controlled substance:

* the letter “N” inside a circle for narcotic drugs and their preparations,
* the letter “C” inside a lozenge figure for controlled drugs and their preparations, and
*  the letters “T\C” inside a square for benzodiazepines and other targeted substances.

# PROCEDURES ON CONTROLLED SUBSTANCES FOR FIRST NATIONS HEALTH FACILITIES

## 1. **GENERAL**

**1.1** This document sets forth procedures governing the ordering, transport, possession, storage, prescribing, sale, provision, administration, record-keeping, accounting, wastage, destruction, and security of CS at First Nations health facilities[[3]](#footnote-3). These procedures supplement provincial pharmacy and nursing standards of practice and the preceding *FNIHB Policy on Controlled Substances for First Nations Health Facilities*.

**1.2** Given the variability among and within the regions, FNIHB REs may impose regional procedures that are more restrictiveand more detailed than the national procedures set out in this document. Any regional policies and procedures related to CS must be explicit, clearly written and authorized by the IPS Pharmacy Unit at PHPCD on behalf of the Senior FNIHB ADM. Therefore any proposed changes should be recommended by the FNIHB RE and forwarded to the IPS Pharmacy Unit at PHPCD, FNIHB, for approval.

**1.3** In every health facility where the provision of CS is under the direct responsibility of FNIHB, the Nurse in Charge (NIC) or designate must ensure that a copy of the *FNIHB Policy and Procedures on Controlled Substances for First Nations Health Facilities* is kept with the CS Register. When the region determines that supplementary instructions are required, they should be included in their regional edition of the national FNIHB Policy and Procedures document, with prior approval from the FNIHB IPS Pharmacy Unit.

# 2 RESPONSIBILITIES

**2.1 Senior FNIHB ADM and the FNIHB Regional Operations ADM**

* Approval of the *FNIHB Policy and Procedures on CS for First Nations Health Facilities*
* Overseeing compliance and progress at regional level

**2.2 FNIHB Regional Operations ADM**

* Operational implementation of the procedures detailed in this document
* Auditing of First Nations health facilities3
* Regular reporting to FNIHB National Office on compliance level, in accordance with paragraph 3.2.7

**2.3 IPS Pharmacy Unit - PHPCD**

The IPS Pharmacy Unit is accountable to the ADM of FNIHB through the Director General and Chief Nursing Officer of the Office of Primary Health Care, and responsible for the development and maintenance of a national policy and procedures document, monitoring compliance and progress at regional level, and providing support and advice to the FNIHB Regional Offices and to other stakeholders on matters related to the *FNIHB Policy and Procedures on Controlled Substances* *for First Nations Health Facilities*.

**2.4 Regional Executive (RE) - First Nations and Inuit Health Branch**

**2.4.1 General**

The FNIHB RE is accountable to the FNIHB Regional Operations ADM for the administrative control of CS, where the procurement of CS for First Nations health facilities is under the direct responsibility of the FNIHB Regional Office. The RE is responsible for determining which health facilities are entitled to order and possess CS. The RE is also responsible to determine whether the FNIHB managed First Nations facilities (nursing personnel) in their region will use the FNIHB Drug Classification System[[4]](#footnote-4) in the FNIHB Nursing Station Formulary. The RE may issue additional directives pertaining to the control of CS within the region in accordance with paragraph 1.2, when it is deemed necessary. The appropriate managers will also be informed of the management of CS according to the regional organization structure.

**2.4.2 Appointment of the Regional Controlled Substances Officer (RCSO), the Designated Signing Officer, and their alternate(s)**

The RE is responsible for the appointment of the RCSO and an alternate for the region. The RCSO and the alternate must be a regional pharmacist, registered nurse, physician, dentist or nurse practitioner. If the appointed RCSO is a registered nurse[[5]](#footnote-5) or a nurse practitioner not authorized to prescribe and/or order CS, the RE must also designate a regional pharmacist, physician, dentist, or nurse practitioner[[6]](#footnote-6) and an alternate individual who can legally sign the CS stock requests to replenish health facility stocks and who will be referred to as the Designated Signing Officer. The RE must ensure that the RCSO, the Designated Signing Officer, if different, and the alternate(s) are clearly identified in the organization.

**2.5 Regional Controlled Substances Officer (RCSO)**

**2.5.1** The RCSO is appointed by and accountable to the RE for the management of CS for the region, which includes the following activities:

* ensuring that regional First Nations health facilities adhere to the *FNIHB Policy and Procedures on Controlled Substances*;
* monitoring the utilization of CS by First Nations health facilities;
* approving and signing stock requests to replenish health facility stocks except in situations where the RCSO is a registered nurse or a nurse practitioner not authorized to order CS;
* making recommendations to the RE when improvements are necessary, and
* providing more specific regional directives with RE approval, as required.

**2.5.2** When the appointed RCSO is a registered nurse or a nurse practitioner with the condition indicating not authorized to prescribe and/or order CS, they must submit CS stock requests for the approval of the Designated Signing Officer, for example, an appointed pharmacist, physician, dentist or nurse practitioner. In this case the RCSO (registered nurse or a nurse practitioner with the condition indicating not authorized to prescribe and/or order CS) must bring to the attention of the Designated Signing Officer any unusual utilization of CS by any facility. The RCSO (registered nurse or a nurse practitioner with the condition indicating not authorized to prescribe and/or order CS) must also present the Designated Signing Officer with the applicable *[CS Month* *End Inventory and Usage Reports (Annex 3)]*, or an acceptable roll up of end of month reports, identifying any utilization anomaly. If the nurse practitioner is practising at the health facility they will not be able to act as the RCSO and the RE must designate an alternate.

**2.6 Designated Signing Officer for CS Stock Requests**

**2.6.1** When the RCSO is a registered nurse or a nurse practitioner with the condition indicating not authorized to prescriber and/or order CS, the RE will designate and clearly identify the designated signing officer and an alternate, to sign the orders to replenish the inventories of the health facilities entitled to stock CS as outlined in paragraph 2.5.2.

**2.6.2** Before signing the requests from the health facilities, the Designated Signing Officer must verify with the RCSO (registered nurse or a nurse practitioner with the condition indicating not authorized to prescribe and/or order CS) that the orders are legitimate, and check for utilization anomalies reported by the RCSO as outlined in paragraph 2.5.2.

**2.7 Designated Nurse Manager (DNM) or Equivalent**

The DNM, or equivalent, is accountable to the RCSO and responsible for monitoring the possession, record-keeping, accounting, and security of CS held by First Nations health facilities under their responsibility.

**2.8 Nurse in Charge (NIC) or Designate**

The Nurse in Charge, or designate, is accountable to the DNM or equivalent and is responsible for the possession, record-keeping, accounting and security of CS located at the health facility under their responsibility. The NIC may grant access to the CS kept at the health facility to other nurses, and to pharmacy clerks/technicians employed at the health facility.

**2.9 Pharmacy Clerks/Technicians**

Pharmacy clerks/technicians are accountable to the NIC, or designate, and provide technical and clerical assistance to the nurses at a First Nations health facility. Pharmacy clerks employed at First Nations health facilities are often trained on the job. The NIC may authorize them to access CS while they are under direct supervision of a registered nurse, in accordance with paragraph 3.1.10.

**2.10 Other Designated Health Facility Staff**

The NIC and/or Health Director may designate one or more members of the health facility staff, e.g., Community Health Representatives (CHRs), clerks, drivers, to transport shipments or medication packages, which may contain CS, between the commercial carrier drop off point (e.g., air strip) and the First Nations health facility, and/or to provide/deliver medication packages to the clients in accordance with the community-based policy and procedures for client-specific medications.

**2.11 Non-Insured Health Benefits (NIHB) Pharmacy Providers (off-site Retail Pharmacists) Client medications.**

The NIHB off-site pharmacy providers are responsible for arranging the delivery of medications to their individual clients. More information on client-specific medications is provided at paragraph 4.3.

In provinces where there are provincial monitoring programs, off-site retail pharmacy providers may require special documentation for the tracking of CS supplied as bulk supply or routine supply to the health facility.

## Licensed dealers*[[7]](#footnote-7)*

Regional offices may make formal agreements with licensed dealers for the bulk supply of CS to health facilities, and/or for the return of CS for destruction. Note: Licensed dealers may supply CS to First Nations health facilities only after receiving stock requests signed by the nurse at the respective First Nations health facility and by either the RCSO or Designated Signing Officer, or by another physician, dentist, nurse practitioner or pharmacist.

# 3 MANAGEMENT OF CONTROLLED SUBSTANCES WITHIN THE FIRST NATIONS HEALTH FACILITIES

## 3.1 Security and Access to CS

**3.1.1** CS must be kept in a locked cupboard or cabinet, which is secured with two locks, as per the most current *FNIHB Pharmacy Room Specifications for First Nations Health Facilities providing Clinical and Client**Care[[8]](#footnote-8)*. Therefore, regional office health facility management must ensure that the CS cupboard/cabinet is:

* securely attached to the wall or floor in a way that it cannot be easily removed,
* located in a room that is not accessible to the public, e.g., the medication or pharmacy room, and
* that room is equipped with a secure and self-closing door which has an automatic locking, heavy duty commercial grade lock (storeroom lock type). An optional combination lock or electronic lock may be added, as per the *FNIHB* *Pharmacy Room Specifications for First Nations Health Facilities providing Clinical and Client Care.*

**3.1.2** Nurses and pharmacy clerks/technicians who have access to the CS cupboard under direct supervision of a registered nurse must ensure the cupboard is locked at all times when it is not being accessed. The pharmacy room door must also be locked at all times when there is no nurse or authorized pharmacy clerk/technician in the room. Maintenance or cleaning personnel must always be accompanied by a nurse, pharmacy clerk, or pharmacy technician, when performing work in the pharmacy room, whether it is done during normal hours of operations or after hours.

**3.1.3** The NIC will ensure that there is only one set of keys to the locked CS cupboard or cabinet in circulation at any time. If a second set of keys is available such as when a new cupboard is received (spare key), the NIC will secure the second set in a locked area that is only accessible to them. It should be kept in a sealed envelope bearing their signature and dated.

**3.1.4** During working hours, a nurse must carry the keys to the CS cupboard and the pharmacy room on them at all times. After hours or when there is no other nurse in the health facility, the NIC or designate must keep the keys in a locked area only accessible to them. When a combination lock is used to access the pharmacy room during working hours, only the nurse will know the combination code. The NIC will ensure the combination code is changed every 6 months or earlier when it is suspected the code is known by an unauthorized person, or when a loss or theft of CS has occurred. If the key(s) to the cupboard or pharmacy room is lost, the NIC or designate will get the lock(s) replaced immediately.

**3.1.5** Only nurses assigned to the health facility, and pharmacy clerks/technicians under the direct supervision of a registered nurse, shall have routine access to the CS cupboard, with the authorization of the NIC. For the purpose of an audit, the RCSO or other FNIHB personnel authorized by the RE may access the CS cupboard in the presence of the NIC or designate.

**3.1.6** Outside hours of operation when there is no nurse in the health facility, the door of the pharmacy room must be locked in a manner that does not allow entry without a key, i.e., any combination or card lock that is used on the pharmacy room door must be disabled so the door can only be opened with a key. If the combination or cardlock cannot be disabled, a deadbolt lock must be installed and kept engaged outside health facility operating hours.

**3.1.7 Storage of Emergency or Refrigerated CS**

The NIC must ensure that refrigerated CS are kept in a refrigerator located in a room which is always locked, such as the pharmacy room, or in a refrigerator equipped with a fixed lockable compartment. CS that may be required in an emergency should be kept in an emergency crash cart, which is locked or equipped with a tamper proof seal. CS kept in a refrigerator or crash cart must be counted at each drug count and recorded on the CS Register. Only nurses assigned to the health facility, and pharmacy clerks/technicians under the direct supervision of a registered nurse, shall have access to the CS kept in the refrigerator or the crash cart.

**3.1.8 Access to CS by Physicians, Dentists, and Paramedics**

CS stored in the CS cupboard, refrigerator and emergency crash cart are under the responsibility of the NIC of the health facility. Direct access to these drugs by dentists, physicians, paramedics, or community based workers is not permitted.

**3.1.9 Access to CS by Dental Therapists**

Dental therapists do not have access to CS. Dental therapists must consult with a dentist, who may be located off-site, when a patient may require a prescription for a CS. If the dentist agrees with this requirement, they must give a verbal prescription to the nurse and forward the written prescription by fax or by mail. The nurse is responsible for providing and/or administering the CS directly to the patient, in accordance with section 3.7.

If a dentist is not available, the dental therapist must consult with a nurse at the First Nations health facility. Under these circumstances, the nurse will assess the patient and decide on appropriate treatment, or determine if consultation with another practitioner is required before initiating treatment.

If CS are required, the nurse is responsible for providing it to the patient and will record the required information in the patient's health record and on the *[CS Register Form (Annex 2A or 2B)]*.

* + 1. **Access to CS by Pharmacy Clerks/Technicians**

NIC is the only person authorized to grant access to the CS kept at the health facility to pharmacy clerks/technicians working in the health facility. Moreover, these personnel may only access CS while they are under the direct supervision of a registered nurse.

In such situations, the role of the pharmacy clerk/technician is restricted to the counting and/or labeling CS to facilitate provision of the CS to a client by a registered nurse, performing drug counts of CS with a registered nurse, and co-signing as a witness in the *[CS Register Form]* when drugs counts are done or when drugs are provided by a registered nurse. Pharmacy clerks cannot act as a witness for the destruction or wastage of CS, whereas a pharmacy technician can. The role of the pharmacy clerk/technician may be further restricted by the NIC or designate or by the registered nurse providing direct supervision, but their role may not be expanded.

**Direct supervision by a registered nurse – definition:**

* the registered nurse providing direct supervision must be authorized to perform the activities they supervise;
* the registered nurse must be authorized by the NIC and/or the Health Director, as applicable, to supervise the performance of the activities relating to CS which are conducted by the pharmacy clerk or technician;
* the registered nurse must be present when the supervised individual (e.g., pharmacy clerk or technician) is performing any activity with CS; and
* the registered nurse must be able to observe and promptly intervene and stop or change the actions of the individual they supervise.

## 3.2 Accounting

**3.2.1 Signature and Acknowledgment Form**

Prior to being granted access to the CS cupboard/cabinet and making entries in the CS Register, all nurses must sign and initial the *[CS Signature and Acknowledgment Form (Annex 1)]*, in each health facility where they have access to CS. By signing this form, the nurses confirm that they have read and understood the *FNIHB Policy and Procedures on Controlled Substances for First Nations Health Facilities.* The use of this form enables the tracking of all health facility staff that had access to CS over a given period. All pharmacy clerks/technicians must sign and initial the *[CS Signature and Acknowledgement Form (Annex 1)]* to confirm that they have read and understood the *FNIHB Policy and Procedures on Controlled Substances for First Nations Health Facilities.* Personnel must re-sign this form every 2 years.

**3.2.2 CS Register [[9]](#footnote-9)**

A nurse must complete the *[CS Register Form (using Annex 2A- Drug Count Single Drug, or Annex 2B – Drug Count Combined)]*, whenever a CS is received, provided, administered, wasted, lost or stolen, returned to a supplier, or destroyed. The RCSO will provide written directives to the health facilities indicating which *[Register Form (either Annex 2A or 2B)]* should be used in their region. The nurse must complete the headings on the *[Register Form]* as follows: name of health facility, drug name, strength and dosage form, unit of issue (e.g. tablet, ampule, mL), and page number. The rest of the information will be entered at the time of provision, administration or reception, complete with the name of the prescriber or provider, and the nurse’s signature.

All CS *[Register Form]* entries should be complete, legible and written in permanent non-erasable ink. To facilitate audits, the CS counts and receipts will be recorded on the CS *[Register Form]* in RED ink. BLACK or BLUE ink will be used for recording the quantity of CS provided, wasted, lost or stolen, returned to the supplier, or destroyed, and for bringing balances forward.

Completed pages of the CS Register Forms and the current pages of the CS Register Forms must be numbered and kept together in chronological order, in the CS Register.

**3.2.3 CS Drug Counts**

All CS counts must be done by two nurses. In the event that two nurses are not available, a nurse may perform the count with a pharmacy clerk/technician authorized by the NIC. One nurse will witness the other nurse (or pharmacy clerk/technician) doing the count and verify contents, then both people will sign beside the amount of each drug being recorded on the CS *[Register Form]*, after each drug is counted.

The nurses will record each CS count on the *[CS Register Form (Annex 2A or Annex 2B)]*. The nurses are required to count all of the CS stored at the health facility at least once a week, whether CS have been provided/administered or not during that interval. The RCSO, DNM or NIC may determine that more frequent counts are required in their region, zone, or in specific health facilities, at their discretion (i.e., frequent changeover of staff). In health facilities where there is rotational staff, a physical count must be performed on the day of switchover. This should be indicated in writing in the regional edition of the national FNIHB Policy and Procedures document.

**3.2.4 Arrival/Departure of the Nurse in Charge**

Upon arrival at the health facility, the NIC or designate assuming custody of the CS must perform a physical count with the departing NIC and acknowledge receipt of the inventory from them, by signing and dating the stock balance for each CS in the CS Register, confirming that stocks and register balances agree. The departing NIC should then provide the keys to the pharmacy room and the CS cupboard (and refrigerator CS compartment, and crash cart as applicable) to the new NIC.

**3.2.5 Count Discrepancies, Loss or Theft Reports, and Occurrence Reports**

When a nurse or an authorized pharmacy clerk/technician performing a count or making an entry on the *[Controlled Substances Register Form]* discovers a count discrepancy (over or under) they must immediately advise the NIC or designate. If the discrepancy cannot be resolved, the NIC or designate must notify the DNM immediately. The DNM will provide direction to the NIC or designate, after consulting with the RCSO, if necessary.

When there is a loss that cannot be explained or when theft is suspected, the RE must be advised immediately through the RCSO. The disappearance of pages from the CS Register will be treated in the same way as a count discrepancy. If theft or wrongdoing is suspected, the RE will take appropriate measures to investigate the loss/theft as soon as possible.

On the CS *[Register Form]*, where the discrepancy has occurred, the NIC and a second nurse, or another officer authorized by the RE for the purpose of an audit, will correct the count in RED ink and sign, indicating the new count and with a note indicating action taken to resolve the discrepancy.

The NIC and the DNM or other personnel designated by the RE will investigate the loss or theft and complete a [[*Loss or Theft Report Form for Controlled Substances, Precursors and Cannabis*](https://www.canada.ca/content/dam/hc-sc/documents/services/publications/healthy-living/loss-theft-controlled-substances-precursors/loss-theft-report-form-controlled-substances-precursors.pdf) *(see Annex 7)].* This form must be completed whenever a loss or theft has occurred, regardless of whether wrongdoing is suspected, and regardless of the quantity lost or stolen.

The circumstances leading to the preparation of the report must be clearly stated and legibly written in the report. The report must be forwarded within 5 calendar days of the discovery of the loss or theft to the RE through the RCSO. In accordance with the Treasury Board *Policy on Information Management*, the report should be categorized at the proper security level and treated accordingly, if it contains personal or sensitive information (Reference J).

The person completing this form should provide the minimal amount of personal information possible unless the individual’s whose personal information is being recorded in the form has consented to its use.

It is important to note that a Loss or Theft Report is not required when a CS is wasted as part of normal professional practice (see Section 3.8).

The NIC must also complete and submit to their manager a *First Nations and Inuit Health Branch Incident Management Form*, indicating the loss or theft. In addition, the NIC must take other appropriate measures such as consulting with the local law enforcement personnel and notifying the Regional Security Manager: this consultation must be done in accordance with FNIHB's Privacy Standard Operating Procedures (Reference N) before any personal information is provided.

Any disclosures of a completed *[Loss or Theft Report Form]* and/or a completed *FNIHB Incident Management Form* made to a third party (e.g., the police or local law enforcement, Chief and Council, etc.), containing personal information, must be done in accordance with FNIHB's Privacy Standard Operating Procedures (Reference N).

The RCSO will review and complete the *[Loss or Theft Report Form (Annex 7]* as required, indicating his or her licence/permit number, and sign it. The RCSO must fax the completed report form within 10 calendar days of the discovery of the loss or theft to the [Compliance and Monitoring Division, Health Canada in Ottawa](mailto:hc.ocs.reporting-rapporter.bsc.sc@canada.ca), at the fax number indicated on the form. This report should detail the circumstances of the loss/theft, and indicate any follow up action that was or will be initiated to prevent reoccurrence. The report will be completed on an attached page if space is insufficient on Annex 7. The RCSO will also forward a copy of this report to FNIHB National Office attention: [IPS Pharmacy Unit](mailto:beverly.hamilton@canada.ca), PHPCD. IPS Pharmacy Unit will contact and follow up with the region on regional action items outlined on the report to ensure that the actions identified have been resolved and/or implemented. Personal information is not required and should not be provided on this report.

The NIC of the health facility and managers in the line of authority for the region, such as the DNM, RCSO, and RE, must establish necessary measures to prevent similar count discrepancies, losses or thefts of CS in the future, and document the measures taken to prevent reoccurrence.

The RCSO will keep track and document progress on the implementation of any measure that is recommended following the incident.

**3.2.6 CS Month End Inventory and Usage Reports**

The NIC will complete the *[CS Month End Inventory and Usage Report (Annex 3)]* on a monthly basis, or more frequently at the discretion of the DNM or RCSO. The completed report will be forwarded to the RCSO through the DNM within a week following month end. This report will be reviewed by the DNM and the RCSO and kept on file for a minimum period of two (2) years in accordance with paragraph 3.2.9.

The DNM and RCSO must examine unexplained changes in utilization rates at a health facility, or higher rates of utilization compared to other similarly sized communities in their zone or region, and document any action taken.

**3.2.7 Regional reports**

Personal information is not required and should not be provided on these reports.

## Type and frequency of reports from regions to national office (FNIHB/PHPCD)

**For every occurrence[[10]](#footnote-10):**

***[Loss and Theft Reports (Annex 7)].***

* In addition to the copy sent to [Compliance and Monitoring Division, Health Canada](mailto:hc.ocs.reporting-rapporter.bsc.sc@canada.ca), the regions will send a duplicate copy to FNIHB [IPS Pharmacy Unit](mailto:beverly.hamilton@canada.ca) (within 10 days of occurrence). Reports should be clearly written and indicate action taken (e.g. any actions initiated, circumstances of the loss, and recommendations of the RCSO, etc.
* When action is still pending at the time the loss or theft report is submitted, the region will report on any final actions taken to close the file and prevent re-occurrence/mitigate risk, or any implementation issue (within 30 days of occurrence).

**For every occurrence:**

Any other CS-related issue that requires national office’s attention.

**Every six months:**

***[Semi-annual regional audit reports (Annex 8)]*** to be submitted **by May 15th**(for the preceding 6-month period ending on April 30th) and **by November 15th** (for the preceding 6-month period ending on October 31st)

**Part 1:** These semi-annual regional roll up reports will indicate the names of the health facilities audited in the preceding 6 months and the dates upon which the audits were conducted. When it is the case, the report will also indicate in the third column the objective(s) not fully met for the second consecutive time, with an explanation and expected date of compliance.

**Part 2:** These reports will also indicate the names of the health facilities which have not been audited in the last year, with the date of the next scheduled audit.

**3.2.8 Filing system**

The IPS Pharmacy Unit, regional, and zone offices must maintain a specific file for all CS-related correspondence and reports, that can be accessed easily for auditing purposes. The CS documents should preferably be filed together. These documents include stock requests and receipt documents, audit reports, loss/theft reports, requests for destruction and authorizations, regional reports described above at paragraph 3.2.7, etc. Any disclosure of personal information must comply with FNIHB's Privacy Standard Operating Procedures (Reference N).

**3.2.9 Retention of CS records and documents**

All records and correspondence pertaining to CS, which are required under these procedures, must be kept for a minimum period of two (2) years. Records can only be destroyed after the 2-year period and when an on-site audit has been completed. This will ensure that all records are available from one audit to the next and that the two-year minimum retention time requirement is met.

At the health facility level, CS-related documents must be kept in a manner that will enable an audit at any time. These documents include the CS Register Forms, stock requests and receipt documents, destruction requests, return authorizations, etc. All documents that can be disposed of after the minimum two-year period may be shredded or otherwise securely destroyed with the permission of the NIC and the DNM. Stock requests and receipt documents can be kept on file at either health facility or regional level, based on directives from the RCSO, as the same documents (duplicates) do not need to be kept at both places.

## 3.3 CS Audits and Inspections

**3.3.1** All CS records and inventory are subject to inspection by inspectors[[11]](#footnote-11) and audit by officers authorized by the FNIHB RE. The NIC is responsible for ensuring that all records, including prescriptions for CS, the CS Register and CS Register Forms are accessible and kept in an organized manner to enable an efficient and effective audit or inspection.

**3.3.2** On-site audits will be conducted by the DNM (or regional representative if a DNM is not available) twice a year. Audits will be conducted more often when deemed necessary by the RCSO. The person performing the audit must verify the CS Register entries against the prescription information written in the health records, the receipt and destruction documents, and then must verify all stock balances. At least 10 charts of patients to whom CS were provided/administered must be reviewed at each audit, or all charts if CS were provided/administered to less than 10 patients since the last audit. The *[CS Verification Tool (Annex 5)]* may be used when performing the audit. The person performing the audit will make appropriate entries of the stock balance in the CS Register with verification of a stock balance. If all CS cannot be accounted for during the audit, it will be treated as a count discrepancy (see paragraph 3.2.5).

**3.3.3** The person performing the audit must complete the *[Controlled Substances Audit Form (Annex 6)]* with appropriate recommendations, as necessary. The DNM will provide timely verbal and written reports to the NIC, the RCSO, the Designated Signing Officer if applicable, and other health staff as appropriate after completion of the audit, within 30 days of the audit. The RCSO will ensure that anomalies or gaps are documented on the audit form and that an action plan is initiated to address them. The RCSO will monitor the action plan and keep track of progress until all measures are implemented.

## 3.4 CS Stock Requests

**3.4.1 Routine stock requests**

The NIC of the health facility will sign all CS stock requests for replenishing the inventory from a supplier (i.e., licensed dealer). The NIC will submit the requests to the DNM for verification of entitlement and quantities. The DNM may recommend the requests as such or with changes and forward them to the Regional Office for approval. The RCSO will verify and approve appropriate requests, and forward them to the supplier by e-mail, by fax, by mail, or in the manner stipulated by the supplier. If the RCSO is a registered nurse or a nurse practitioner not authorized to order CS, requests must be approved and signed by the Designated Signing Officer before they are forwarded to the supplier.

* + 1. **Emergency stock request**

When a nurse at a health facility has identified an emergency need for CS listed in the *FNIHB Nursing Station Formulary* that cannot be met through the routine stock supply chain, due to either product shortage or time-line issues, and an alternate product is not available, the NIC will advise the DNM. The DNM will assume responsibility for identifying an alternate supplier in a timely manner. The stock request must be approved and signed by a physician, dentist, pharmacist, or nurse practitioner involved with the emergency request. All tracking and accounting procedures continue as per routine stock requests. It may be possible to get an emergency supply of a CS from a hospital and/or off-site retail pharmacist, with an appropriate request signed by a physician, dentist, pharmacist, or nurse practitioner.

**3.4.3 Type and Quantity of CS to keep in inventory**

Nurses at First Nations health facilities may only order and stock CS in accordance with the *FNIHB Nursing Station Formulary[[12]](#footnote-12)*. The RCSO and DNMs are collectively responsible for establishing the minimum and maximum levels of each CS to be stored in inventory at each health facility, in consultation with the NIC. The NIC will ensure the maximum level of each CS is indicated in the CS Register, and that the CS quantities are within these parameters.

**3.4.4 Utilization monitoring**

The DNM is responsible for examining any request that falls outside normal parameters, e.g., sudden increases or larger utilization compared to other health facilities. When any nurse, pharmacist, physician or dentist, either on-site or in the chain of approval, notices a change in the utilization pattern or any anomaly that cannot be justified, this individual is responsible for ensuring that the RE is advised as soon as possible, through the line of responsibility when possible. The RE and/or the RCSO will take appropriate measures after assessment of the situation with the staff involved, the DNM and/or the NIC.

## 3.5 Delivery / Receipt of Controlled Substances

**3.5.1 Order tracking**

There must be a method in place to track routine and emergency stock orders of CS while in-transit between the supplier (e.g., licensed dealer, hospital, Drug Distribution Centre, etc.) and the nurse at the health facility, i.e., use of a commercial carrier and chain of signatures. The supplier should also include a packing slip with each shipment in order to enable nurses to verify its contents.

**3.5.2 Normal Receipt of Controlled Substances in Good Condition**

Upon receipt of a shipment containing CS in good condition, the nurse receiving the shipment will sign the receipt voucher of the purchase order provided by the supplier and return a copy to the supplier. The content of the shipment must be verified and recorded by two nurses. In the event that two nurses are not available, a nurse may open the shipment and perform the recording with a pharmacy clerk/technician authorized by the NIC immediately after reception on the *[CS Register Form (Annex 2A or 2B])*, in RED ink, as follows: the date received (year, month written out, date), time, name of supplier, quantity received, new balance, and signature of the nurse receiving/recording the receipt of the CS. If *[Register Form Annex 2B]* is used, the nurse will list each drug of a different strength or unit of issue in a separate column. A copy of the receipt voucher will be kept with the CS Register, or at the regional office as directed by the RCSO. In the event where there is only one nurse at the health facility (after hours), the nurse will ensure that the shipment is kept in a secure place until there are two authorized staff available.

* + 1. **Receipt of CS in damaged condition**

If a shipment containing CS is received in damaged condition (which may include breakage or a shipment compromised by lack of temperature control), the NIC or designate will ensure that the receipt of the damaged CS is appropriately recorded on the CS Register, and that the CS are kept in a secure place until they can be returned to the supplier or destroyed, in accordance with section 3.9. Breakage must be reported immediately to the DNM who will advise the regional office, by means of or followed by a completed *FNIHB Incident Management Form*. The DNM is responsible for providing disposal instructions to the Nurse in Charge as soon as possible.

If possible, the DNM or the RCSO will arrange for the return of the CS to the supplier for credit. The DNM or RCSO will obtain written or email authorization from the supplier prior to returning any CS to the supplier, and forward it to the NIC. The NIC must retain both the return authorization and the shipment voucher in the CS Register, as proof of the item being returned. When CS are returned to a supplier, the shipment must be made through a traceable carrier. If the DNM is requiring that the CS shipment or part thereof be destroyed instead of being returned, the instructions given must be in accordance with section 3.9 of this document (Destruction).

Liquid or injectable forms of CS received in damaged condition, when the liquid cannot be recovered, should be wasted in accordance with paragraph 3.8.3, once damage reported to the DNM as outlined above.

As with serviceable stocks, all receipts, returns, wastage or destruction of CS received in damaged condition must be entered on the appropriate *[CS Register Form]* and must be completed by two (2) authorized staff members at the health facility as defined in section 3.5.2.

**3.5.4 Discrepancy in receipt of CS**

## Upon receipt of a shipment containing a CS where there is a discrepancy (e.g., wrong quantity, incorrect stock received etc.), the NIC or designate will ensure that the discrepancy in shipment is appropriately recorded on the CS Register, and that the CS are kept in a secure place until they can be returned to the supplier. Discrepancies must be reported immediately to the DNM who will advise the regional office, by means of or followed by a completed FNIHB Incident Management Form. The DNM is responsible for providing instructions to the NIC as soon as possible, when applicable.

If possible, the DNM or the RCSO will arrange for the return of the CS to the supplier for correcting the shipment as per the original order for possible credit as required. The DNM or RCSO will obtain written or email authorization from the supplier prior to returning any CS to the supplier whether the CS shipment or part of be returned, and forward it to the NIC.

The NIC must retain both the return authorization and the shipment voucher in the CS Register, as proof of the item being returned.

When CS are returned to a supplier, the shipment must be made through a traceable carrier.

As with serviceable stocks, all receipts and returns of CS received with a discrepancy must be entered on the appropriate *[CS Register Form]* and must be completed by two (2) authorized staff members at the health facility as defined in section 3.5.2.

## 3.6 Prescribing Controlled Substances

**3.6.1 Authority**

Only physicians, dentists and nurse practitioners[[13]](#footnote-13) are authorized to prescribe controlled substances.

**3.6.2 Written prescriptions**

When present at the health facility, the authorized prescriber must record all their prescriptions for CS in the patient health record by specifying the date of the prescription, the name, form and strength of the drug, the quantity to be provided, and direction for use, followed by their name and signature. When a separate prescription form is written by the authorized prescriber (in addition to the health record entry) and not remitted to the patient at that time, the nurse, physician or dentist will attach the prescription form to the patient's health record until the drug can be provided. Once the nurse provided the drug to the patient, they must file the prescription in the CS prescription file in the pharmacy room, as applicable.

**3.6.3 Verbal prescriptions and use of fax machines**

When there is an emergency and there is no authorized prescriber at the health facility, the nurse should consult an authorized prescriber located off-site before providing or administering a CS to a patient. If the authorized prescriber deems it is necessary to prescribe a CS, they must give a verbal prescription to the nurse. The nurse accepting a verbal prescription from an authorized prescriber must record it in the patient health record, with the date of the prescription, the name, form and strength of the drug, the quantity to be provided, direction for use, name of prescriber, followed by the name and signature of the nurse receiving the prescription.

The authorized prescriber should also fax a written copy in accordance with section 3.6.4, confirming the verbal prescription as soon as possible, instead of mailing the original signed copy. If the authorized prescriber is scheduled to visit the health facility within the next month, the nurse may offer the prescriber to sign the prescription at that time instead of sending a copy by fax, if this is more efficient.

**3.6.4 Fax prescriptions**

Following a verbal prescription for CS, an authorized prescriber must transmit a CS prescription by fax from their office or health facility to the appropriate nurse in the First Nations health facility. The elements of the fax prescription must be met (See Annex 9).

The authorized prescriber providing the CS prescription by fax must keep the original on file for at least two years from the date of making the prescription, while the nurse at the First Nations health facility is required to keep the fax prescription on the respective patient file for the same length of time.

In addition, an authorized prescriber located at the First Nations health facility may fax a signed CS prescription to an off-site pharmacist for dispensing, in a manner that respects the elements set out in the *[Fax Model Prescription Form (Annex 9)].* In these cases, the First Nations health facility must keep the original prescription on the respective patient file for at least two years of making the prescription.

**NOTE:** Nurses cannot fax a CS prescription received by fax from an off-site authorized prescriber to an off-site pharmacist for dispensing. Instead, the authorized prescriber must fax their prescription directly to the off-site pharmacist.

**3.6.5 Chronic medication sheet**

When the CS are prescribed by an authorized prescriber for a chronic condition, the nurse may also be required to record the prescription information on a separate chronic medication sheet in addition to the treatment/progress notes, in accordance with regional procedures. Alternatively, the nurse may request a copy of the medication profile from the off-site pharmacy dispensing the chronic medications, and/or keep a copy of the prescriptions that were sent to the off-site pharmacy for dispensing.

**3.6.6 Correction of recording errors**

If an error is made when the prescription is recorded in the patient health record, a single line should be drawn through the error, the word "error" should be written above the line and the prescriber or the nurse recording a verbal prescription should sign it. The reason for the error should be noted (e.g., wrong patient chart). Correction fluid or tape shall never be used to correct an entry error.

**3.6.7** In all cases, prescriptions and health records must be organized, searchable and accessible to enable an audit/inspection.

## 3.7 Provision and Administration of Controlled Substances

**3.7.1 Authority**

Only nurses working at the health facility are authorized to provide CS from the health facility’s CS inventory. Physicians, dentists, dental therapists, or paramedics should not have access to the CS cupboard. CS stored at the health facility are under the responsibility of the NIC of the health facility.

**3.7.2** Nurses may provide or administer CS to patients at the health facility based on a written or verbal prescription (confirmed by fax) from an authorized prescriber. In an emergency situation where it is not possible to consult with an authorized prescriber, nurses or a nurse practitioner not authorized to order CS may provide/administer one dose of a CS in accordance with the most recent *FNIHB Clinical Practice Guidelines,* *FNIHB Nursing Station Formulary and Drug Classification System.* The prerequisites for providing/administering CS in accordance with the Drug Classification System are listed in the *FNIHB Nursing Station Formulary* and CS Annex 10. In regions where the Drug Classification System is not used, nurses or a nurse practitioner not authorized to order CS must always obtain a prescription (written or verbal prescription confirmed by fax) from an authorized prescriber prior to providing/administering any controlled substance.

3**.7.3 Recording the Provision/Administration of CS**

The nurse will record the provision or administration of the CS in the patient's health record. In some regions the nurse may have to underline or highlight this entry in the patient’s health record, in accordance with RCSO’s instructions, to facilitate retrieval during subsequent CS count reconciliations or audits[[14]](#footnote-14). The nurse will also make the appropriate entry on the *[CS Register Form (Annex 2A, 2B)]* in BLACK or BLUE ink, at the time the CS is provided or administered. The following information must be recorded: date (year, month written out, date), time, patient's full name, patient date of birth or unique identifier, quantity issued, amount wasted if any (on next line), new balance, prescriber's or provider’s name as applicable (first initial and full last name), and signature of the nurse providing/administering the medication with the professional designation.

If a signature is illegible, the signee’s name must be printed below.

**3.7.4 Correcting recording errors**

The same procedure used for correcting errors in patient health records (paragraph 3.6.6) should be used for correcting errors in the *[CS Register Form].*

**3.7.5 Initial amount provided immediately by a nurse on-site and additional amount dispensed later by an off-site retail pharmacist (NIHB pharmacy provider).**

When CS are prescribed for a patient to take home, the nurse may immediately provide the complete quantity of medication to the patient, or may send the prescription to the off-site NIHB pharmacy provider for dispensing by an off-site pharmacist, based on the nurse's judgment of the urgency of the situation, the CS inventory available at the health facility, and the patient’s health and security. This function may be restricted for some nurses based on their provincial regulatory body in which they are licensed to practice.

If the nurse provides a part of the medication to the patient immediately and an additional amount is to be dispensed later by an off-site pharmacist, the authorized prescriber must write two separate prescriptions, one for the quantity provided on site by the nurse, and the other for sending to the off-site pharmacy provider for dispensing.

* + 1. **Partial-fills for CS dispensed by retail pharmacies**

Individuals requiring CS for the treatment of chronic conditions and/or palliative care may require larger quantities of CS on a continuing basis. These CS should be dispensed by an off-site retail pharmacist (NIHB Provider). If the nurse is concerned about a large quantity of CS being dispensed to a client all at once, they should notify the authorized prescriber and/or off-site retail pharmacist to arrange for part-fills, i.e., the dispensing of the CS by the off-site pharmacist in smaller amounts, at fixed minimum intervals and delivered from the off-site pharmacy directly to the client as per the client specific prescription delivery process.

Should there be an exceptional client need, as agreed upon by the nurse and authorized prescriber**,** which requires the health facility to hold at the health facility any amount of client-specific CS coming from an off-site pharmacy for re-distributing in smaller quantities at a time to this client, *or for bridging therapy,*the nurse will initiate a separate *[CS Register Form (Annex 2A or 2B)]* for this client’s controlled substances, to be kept with the health facility CS Register. These smaller quantities should come from the off-site pharmacy in the appropriate packaging with the appropriate amount of medication in each package. The nurse will make a note on the patient health record and on the *[CS Register Form]* each time the medication is provided to this client, and amounts remaining must be verified in the weekly CS counts and reported as "patient specific medications" on the *[Annex 3 Month End Inventory and Usage Report].* These are the only situations in which CS sold or dispensed by an off-site retail pharmacist for individual clients may be kept in the CS cupboard with the health facility’s CS inventory.

**3.7.7 Provincial monitoring programs**

In provinces where there are provincial monitoring programs, such as triplicate prescription programs, for the tracking of CS prescribed or dispensed to clients, the authorized prescribers and off-site pharmacists (NIHB providers) have to follow applicable provincial regulations. The RCSO must ensure that regional arrangements are made as necessary, if there are provincial monitoring programs which require reporting of CS dispensed/provided to clients from health facility stock.

## 3.8 Wastage of Controlled Substances

**3.8.1** A nurse is authorized to destroy immediately an unserviceable, injectable CS, in quantities that represent a partial dose from an ampoule. In this case, the nurse must register the quantity wasted on the *[CS Register Form]* under the wastage column, sign it, and get the note co-signed by another nurse, physician, regional pharmacist, or pharmacy technician who witnessed the wastage. A separate line entry is used to clearly document wastage. The healthcare professional witnessing the wastage should indicate whether they are witnessing all the circumstances leading up to and including the wastage, or only the wastage. In situations where only one nurse is present in the health facility, they may enter only their signature on the *[CS Register Form]*, subject to prior written direction provided by the DNM or RCSO. When possible, alternate authorized healthcare professional may co-sign the wastage in the CS Register.

**3.8.2** If a nurse spills a liquid, drops and loses a pill, or breaks an ampoule accidentally, the nurse will make an entry on the *[CS Register Form]* to adjust the new stock balance, make a note stating the circumstances of the loss, and get the entry co-signed by another nurse. The nurse witnessing the wastage should indicate if they are witnessing the whole process or only the wastage of the CS.

**3.8.3** Liquid or injectable forms of CS received in damaged condition from the supplier (broken bottles or ampoules) that cannot be recuperated should be treated as wastage, after reporting the damaged shipment to the DNM as outlined in paragraph 3.5.3. The wastage should be documented and witnessed, in accordance with paragraph 3.8.1.

**3.8.4** In any other circumstance, the nurse must keep unserviceable/unusable doses of CS in the CS cupboard, ensuring that they are clearly marked as “unusable - for destruction” and kept separate from usable stock, until they can be destroyed in accordance with Section 3.9 below.

**3.8.5** Oral liquid CS can often be marginally out due to small but repeated errors in the measuring and checking process or as a result of some of the liquid remaining in the measuring device (e.g., syringe or cylinder) after the dose was removed. This overage/underage quantity is considered and managed as a discrepancy. The nurse will make an entry on the *[CS Register Form]* to adjust the new stock balance, make a note stating the circumstances of the overage/underage, and get the entry co-signed by another nurse. The overage/underage of over 5% must be reported to the DNM who will advise the RCSO.

## 3.9 Destruction of Controlled Substances

**3.9.1** The destruction of CS must not be confused with wastage described in section 3.8.

**3.9.2** Until the CS are destroyed, nurses must count them as part of the regular CS inventory. However, in order to avoid accidental use, the unserviceable/unusable stock must be clearly marked as “unusable - for destruction”, and there must be clear stock separation between usable and unusable stock in the CS cupboard.

**3.9.3** The NIC must initiate a*[CS Destruction Request Form (Annex 4)]* listing the inventory of all drugs to be destroyed, which includes the drug name(s), unit of issue, strength, quantity, expiry date, and reason for destruction. A copy of the Request Form should be kept in the CS Register.

**3.9.4** The NIC will forward all the *[CS Destruction Request Form]* to the RCSO, through the DNM. The RCSO[[15]](#footnote-15) will review the *[CS Destruction Request Form]* for Targeted Substances (Benzodiazepines), Narcotics and Controlled Drugs and sign the *[CS Destruction Request Form].*

**3.9.5** The RCSO will return the signed *[CS Destruction Request Form]* to the NIC through the DNM, and keep a copy in the regional office CS files.

These destruction documents will indicate the following:

* only the medications listed in the destruction request may be destroyed; and
* the CS must be destroyed within 60 days from the date on the signed *[CS Destruction Request Form].*

**3.9.6** After receipt of the signed *[CS Destruction Request Form (Annex 4)]* listing the inventory of items for destruction (Annex 4), the NIC will perform the destruction. In the case of an on-site destruction, the NIC will destroy the CS in the presence of another nurse, regional pharmacist, pharmacy technician, or a Health Canada inspector. The destruction will be recorded on the appropriate *[CS Register Form]* and the balance adjusted accordingly. Both healthcare professionals will sign the entry on the *[CS Register Form],* as well as sign and print their names on a joint statement on the inventory list of items destroyed, indicating that they witnessed the destruction and that the CS destroyed have been altered or denatured to such an extent that its consumption has been rendered impossible or improbable. The NIC is responsible for ensuring that the destruction is carried out using an appropriate method[[16]](#footnote-16) and in compliance with all applicable municipal, provincial and federal environmental legislation.

**3.9.7** The NIC must ensure that the signed *[CS Destruction Request Form (Annex 4)]* is kept on file in the CS Register at the facility. The document must be kept for a minimum period of two (2) years in accordance with paragraph 3.2.9.

**3.9.8** **Destruction of Controlled Substances by a Licensed Dealer**

Regional Offices may make formal arrangements with a licensed dealer to destroy unserviceable/unusable CS.

Where such arrangements are in place, the NIC, DNM or RCSO (in accordance with directives from the RCSO) will obtain written or email authorization from the licensed dealer to return the CS to be destroyed, each time CS have to be destroyed. The NIC will retain both the authorization to return and the shipment voucher in the CS Register, as proof of item being returned. In this case, the licensed dealer receiving the shipment will be responsible for the destruction of the narcotics and/or controlled drugs. When CS are returned to a licensed dealer to carry out destruction, the shipment must go through a commercial carrier with a tracking system.

# ADDITIONAL INFORMATION

## 4.1 Transportation and Security of Controlled Substances during Health Facility Closure or during an Emergency Evacuation

The following procedures should be implemented to maintain security of the First Nations health facility CS inventory during a health facility closure. However at no time should the NIC or other First Nations health facility staff compromise their personal security in order to secure or transport the First Nations health facility CS inventory.

**4.1.1** **Closure for an indeterminate period**

A First Nations health facility may be closed for an indeterminate period of time due to various reasons including the lack of nursing personnel, security risks to personnel (other than emergency evacuations described below), or a change in mandate of the health facility. When CS are stocked at the health facility, the NIC or designate must advise the RCSO through the DNM. The RCSO must inform the [Office of Legislative and Regulatory Affairs, Health Canada](mailto:hc.ocs.reporting-rapporter.bsc.sc@canada.ca) within 10 calendar days of the closure. The CS should be returned to the supplier or destroyed, following the procedures for returns or destruction found in section 3.9 of this document.

The CS stock may also be transferred or relocated to another First Nations health facility, community pharmacy or hospital pharmacy, after obtaining appropriate authorizations from the receiving party. The RCSO must notify the [Office of Legislative and Regulatory Affairs, Health Canada](mailto:hc.ocs.reporting-rapporter.bsc.sc@canada.ca) as to where the CS will be relocated, prior to the relocation or no later than 10 calendar days after the relocation.

The NIC or designate will transfer the CS stock and the CS register to the approved location in a carrying case or a container that can be locked, performing a drug count upon departure with another nurse, pharmacy clerk/technician, physician, dentist or pharmacist acting as a witness. If time permits, the CS may also be shipped to destination via a commercial carrier providing a signature tracking system.

When the CS arrive at destination, whether the CS have been hand carried or commercially shipped, the NIC and another health professional will perform another drug count to confirm that the CS stock balances and CS Register balances agree, to ensure there are no discrepancies. The NIC will then inform the DNM and Office of Legislative and Regulatory Affairs, Health Canada (through the RCSO) of the completed relocation and the quantity of CS relocated.

**4.1.2 Closure for a limited period/emergency evacuation**

A First Nations health facility may need to be closed for a limited time, as part of the emergency evacuation of a community when there is a significant threat posed to a specific area or to an entire community. Causes of an evacuation could include natural, accidental, or human-caused disasters, such as a flood or forest fire. In such a situation, the NIC or designate is authorized to leave the CS at the health facility, ensuring that the CS are left in a locked cabinet, in a locked pharmacy room and in the locked First Nations health facility, accessible only to personnel normally authorized access outside regular hours of operation. These measures are additional to normal security and policing measures put in place by local authorities during an evacuation.

**4.1.3** **CS management when time permits a count before an evacuation without jeopardizing the personal safety of nursing personnel**

The NIC or designate accompanied by a nurse, pharmacy clerk/technician, physician, dentist, or pharmacist, must perform a drug count of all CS in the First Nations health facility inventory, upon departure. Before leaving the premises, the NIC must send a copy by fax to the RCSO of the most recent register page for each CS kept in their inventory, and take a copy of these pages with him or her to the temporary personal relocation place. These CS must be counted upon return to the First Nations health facility and balanced against the register sheets. Any discrepancy must be reported as per approved procedure.

**4.1.4** **CS management when time does not permit a drug count before an evacuation without jeopardizing the personal safety of nursing personnel**

The NIC or designate should take the complete (current) CS Register with them (or the most recent sheet for each CS), and fax a copy of these sheets to the RCSO as soon as possible from another location. The NIC or designate will maintain custody of the register sheets at all times and secure them until return to the First Nations health facility.

## 4.2 Transportation and security of Controlled Substances to support treatment provided from an alternate location outside of the First Nations Health Facility

When a nurse is required to transport CS to other locations, e.g., for medical evacuations or satellite visits, the CS must be signed out of the *[CS Register Form]* as a quantity issued (in blue or black ink), and signed back in as a quantity received (in red ink). The names of patients provided with a CS during the outside visit must also be recorded by the nurse in the CS Register (in blue or black ink) upon return to the health facility.

## 4.3 Delivery of Controlled Substances sold or provided by off-site retail pharmacists/NIHB Pharmacy Providers to their clients living in remote areas (client-specific medications)

**4.3.1** **Definition**

Client-specific medication means a medication dispensed by an off-site pharmacist (NIHB pharmacy provider) pursuant to a prescription, for a specific client.Client-specific medication is the personal property and responsibility of the client and/or family. Client-specific medication packages delivered through First Nations health facilities should not be opened by facility personnel. Therefore all medication packages should be treated as potentially containing CS.

**4.3.2** **Direct delivery to clients**

The off-site retail pharmacists are responsible for the dispensing of the medications they sell or provide to their clients, including provision of patient counselling. Off-site retail pharmacists should make arrangements with their remote clients for the delivery of their medications without using the health facility as their drop off point. It is the responsibility of the off-site retail pharmacist to collaborate with the client and/or Health Director to set up a routine system for the delivery of client-specific medications which does not use the health facility as an intermediary. This delivery arrangement does not remove the off-site pharmacists’ responsibility to comply with their provincial regulations for the dispensing and delivery of medications to their clients.

* + 1. **Delivery to clients through a First Nations Health Facility**

When there is no other alternative, the Health Director may designate a person at the health facility, to accept medication packages from off-site pharmacists to be provided to the pharmacists’ clients by way of the First Nations health facility, thus accepting responsibility for their safeguarding and delivery to the clients. Regional Offices may collaborate with the Health Director in the development of community-based Client-Specific Medication policy and procedures to ensure compliance with federal and provincial legislation, and provincial pharmacy and nursing standards of practice for the management of client-specific medications delivered through the health facility. Nurses’ involvement with client-specific medications delivered through the health facility should be limited to partial-fills for CS as defined in section 3.7.6. In Regions where FNIHB staff are involved in the oversight of client-specific medications delivered through the health facility, the staff must comply with regional policy and procedures for client-specific medications.

REFERENCES

1. *Controlled Drugs and Substances Act (*1996, c.19), and Regulations under the Act
2. *Food and Drugs Act*, (R.S. 1985, c. F-27), and Regulations under the Act.
3. *Benzodiazepines and Other Targeted Substances Regulations: Guidance Document for Hospitals* (2000). Health Canada, Healthy Environments and Consumer Safety Branch.
4. *First Nations and Inuit Health Branch Nursing Station Formulary.* (June 2019). Indigenous Services Canada, FNIHB
5. CPS - *Compendium of Pharmaceuticals and Specialties*. Canadian Pharmacists Association.
6. *FNIHB Pharmacy Room Specifications for First Nations Health Facilities providing Clinical and Client Care* (February 2012). Indigenous Services Canada, FNIHB.
7. *Policy on Information Management* (July 2007) - Treasury Board of Canada. Available on the Treasury Board of Canada Secretariat website. See also *Guideline for Employees of the Government of Canada: Information Management (IM) Basics/* *Safeguard and Protect Information*, on same website.
8. *FNIHB Clinical Practice Guidelines for Nurses in Primary Care.*
9. *FNIHB Pediatric Clinical Practice Guidelines for Nurses in Primary Care.*
10. *Fax Prescription Model Policy* (Rev. November 2001) - National Association of Pharmacy Regulatory Authorities. As accessed on NAPRA.org website March 31st, 2010.
11. [*FNIHB Privacy Standard Operating Procedures*](http://intranet-sac-isc/eng/1535553340758/1535553371899)*.* Available on the – ISC FNIHB intranet website. (as accessed on October 2019).
12. [*Narcotic Control Regulations*](http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/) (C.R.C., c.1041) 2019
13. [*New Classes of Practitioner Regulations*](http://laws-lois.justice.gc.ca/eng/regulations/SOR-2012-230/page-1.html) (SOR/2012-230) 2014
14. [Guidance Document for Pharmacists and Dealers Licensed to Destroy Narcotics, Controlled Drugs or Targeted Substances:](https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/controlled-substances/compliance-monitoring/compliance-monitoring-controlled-substances/post-consumer-returns.html) *Handling and Destruction of Post-consumer Returns Containing Narcotics, Controlled Drugs or Targeted Substances*
15. *Mandatory Training for FNIHB Employed Nurses Delivering Primary Care Services in Nursing Stations within First Nations Communities. July 2018.*
16. *Nursing Education Policy regarding Controlled Substances. November 2013.*
17. [*Subsection 56 (1) Exemption for Nurses who provide Health Care at a Community Health Facility*](https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/subsection-56-exemption-nurses-providing-primary-care-community-health-facility.html). Health Canada. January 2019.
18. [*Subsection 56 (1) Exemption for the Person in Charge of a Hospital and/or Pharmacist who Supplies Controlled Substances to a Community Health Facility.*](https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/subsection-56-class-exemption-person-in-charge-hospital-pharmacist-controlled-substances-community-health-facility.html)Health Canada. January 2019.

# ADDENDUM FOR FIRST NATIONS HEALTH AUTHORITY NURSING STATIONS

## 5.1 Security and Access to CS

The statement in 3.1.1 “CS must be kept in a locked cupboard or cabinet, which is secured with two locks” is replaced by “CS must be kept in a locked cupboard or cabinet, which is secured with a lock, and which is kept in a locked pharmacy room”.

The statement in 3.1.4 “The NIC will ensure the combination code is changed every 6 months or earlier when it is suspected the code is known by an unauthorized person, or when a loss or theft of CS has occurred” is replaced by “The NIC will ensure the combination code of the CS cupboard is changed when it is suspected the code is known by an unauthorized person, or when a loss or theft of CS has occurred”.

The statement in 3.1.6 “Outside hours of operation when there is no nurse in the health facility, the door of the pharmacy room must be locked in a manner that does not allow entry without a key, i.e., any combination or card lock that is used on the pharmacy room door must be disabled so the door can only be opened with a key. If the combination or cardlock cannot be disabled, a deadbolt lock must be installed and kept engaged outside health facility operating hours” is removed as nurses have 24-hour access to the pharmacy room.

## 5.2 Accounting

The statement in 3.2.5 “The NIC must also complete and submit to their manager a First Nations and Inuit Health Branch Incident Management Form” is replaced by “The NIC must also complete a FNHA HAÍⱢCÍSTA Clinical Incident Report”.

The statement in 3.2.9 “Records can only be destroyed after the 2-year period and when an on-site audit has been completed” is replaced by “Records can be destroyed after the 2-year period and when an on-site or virtual audit has been completed”.

## 5.3 CS Audits and Inspections

The statement in 3.3.2 “On-site audits will be conducted by the DNM (or regional representative if a DNM is not available) twice a year” is replaced by “On-site or virtual audits will be conducted by the DNM or RCSO once a year”.

## 5.4 CS Stock Requests

The statement in 3.4.3 “The NIC will ensure the maximum level of each CS is indicated in the CS Register” is replaced by “The NIC will ensure the maximum level of each CS is indicated in Annex 10 – Controlled Substances Order Form”.

## 5.5 Delivery / Receipt of Controlled Substances

The term in 3.5.3 and 3.5.4 “FNIHB Incident Management Form” is replaced by “FNHA HAÍⱢCÍSTA Clinical Incident Report”.

## 5.6 Provision and Administration of Controlled Substances

The statement in 3.7.6 “The nurse will make a note on the patient health record and on the *[CS Register Form]* each time the medication is provided to this client, and amounts remaining must be verified in the weekly CS counts and reported as "patient specific medications" on the *[Annex 3 Month End Inventory and Usage Report]*” is followed by “At the discretion and with the agreement of the NIC, DNM, and RCSO, the total quantities of medication from multiple patients can be reported on the *[Annex 3 Month End Inventory and Usage Report]*”.

## 5.7 Wastage of Controlled Substances

The statement in 3.8.1 “The nurse must register the quantity wasted on the *[CS Register Form]* under the wastage column” is replaced by “The nurse must register the quantity wasted on the *[CS Register Form]* on the next line”.

The statement in 3.8.1 “The healthcare professional witnessing the wastage should indicate whether they are witnessing all the circumstances leading up to and including the wastage, or only the wastage” is removed.

1. https://www.canada.ca/en/health-canada/services/healthy-living/your-health/medical-information/opioid-pain-medications.html [↑](#footnote-ref-1)
2. These facilities are often referred to as nursing stations, or health centers with a treatment component. [↑](#footnote-ref-2)
3. 3 For the purpose of this document, First Nations health facilities are defined as a health facility where health services and/or pharmacy services are managed by First Nations and Inuit Health Branch. [↑](#footnote-ref-3)
4. The regions where the Drug Classification System is used are listed in Annex 10. [↑](#footnote-ref-4)
5. Is a registered nurse not licensed as a nurse practitioner. [↑](#footnote-ref-5)
6. As defined in Section 1 of the *New Classes of Practitioners Regulations* and when authorized by the applicable provincial nurse regulatory bodies. [↑](#footnote-ref-6)
7. 7 *Narcotic Control Regulations* [http://laws-lois.justice.gc.ca/PDF/C.R.C.,\_c.\_1041.pdf](https://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._1041.pdf) (section 8.1, 8.2 and 8.3) [↑](#footnote-ref-7)
8. The *FNIHB Pharmacy Room Specifications for First Nations Health Facilities providing Clinical and Client Care* are approved at the FNIHB national level in order to meet the requirements set by provincial Pharmacy Standards of Practice. [↑](#footnote-ref-8)
9. See Annex 11 for Regional Suboxone Register Form – Drug Count Combined Form [↑](#footnote-ref-9)
10. The RCSO must always inform the Regional Executive of all CS issues/incidents reported to national office**.** [↑](#footnote-ref-10)
11. “Inspector” means a person who is designated as an inspector under section 30 of the *Controlled Drugs and Substances Act*. [↑](#footnote-ref-11)
12. FNIHB will provide the Compliance and Monitoring Division, Health Canada a list of CS that may be ordered and stocked at First Nations health facilities. This list and the formulary will be maintained and updated by FNIHB in consultation with regions, on a regular basis as part of continuing formulary reviews. [↑](#footnote-ref-12)
13. As defined in Section 1 of the *New Classes of Practitioners Regulations* and when authorized by the applicable provincial nurse regulatory bodies. [↑](#footnote-ref-13)
14. Refer to the regional edition of the national FNIHB Policy and Procedures document where applicable. [↑](#footnote-ref-14)
15. If the RCSO is a registered nurse or a nurse practitioner not authorized to prescribe and/or order CS, they must get the destruction request form approved and signed off by the Designated Signing Officer, before returning the authorization for destruction to the Nurse in Charge. [↑](#footnote-ref-15)
16. Slurry method is a means of safe disposal of expired and unusable medications. [↑](#footnote-ref-16)