First Nations and Inuit Health Branch

POLICY AND PROCEDURES ON CONTROLLED SUBSTANCES FOR FIRST NATIONS HEALTH FACILITIES

Effective Date: July 2015

Cancels and Supersedes : August 2013

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

List of Annexes

List of Acronyms

ADM	**Assistant Deputy Minister**
CCC	**Clinical and Client Care**
CS	**Controlled Substances**
CDSA	**Controlled Drugs and Substances Act**
F&DA	**Food and Drugs Act**
FNIHB	**First Nations and Inuit Health Branch**
FN/I	**First Nation/Inuit**
HQ	**Headquarters**
IPS	**Interprofessional Practice Support– FNIHB**
NIC	**Nurse in Charge**
NIHB	**Non-Insured Health Benefits Directorate – FNIHB**
NP	**Nurse Practitioner**
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**
RN	**Registered Nurse**
RN(NP)	**Registered Nurse (Nurse Practitioner)**
RN(EC)	**Registered Nurse (Extended Class)**
RPh	**Registered Pharmacist**
ZNO	**Zone Nursing Officer**

1 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.

1.1 DEFINITION OF FIRST NATIONS HEALTH FACILITIES

In this document, First Nations Health Facilities are defined as health facilities where health services are managed by the First Nations and Inuit Health Branch.[1]

1.2 SCOPE

This policy applies to all registered nurses practicing in the FN facilities defined above, and to all other personnel involved in the distribution of CS at these FN facilities.

1.3 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 controlled substances 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*;
- *Section 56 Class Exemption for Registered Nurses Delivering Primary Health Care at a Health Facility in a Remote and/or Isolated Community*;
- *Section 56 Class Exemption for the Person in Charge of a Hospital who Supplies Controlled Substances to a Health Facility in a Remote and/or Isolated Community*; and
- the *Pharmacy Standards of Practice for First Nations and Inuit Health Branch Health Facilities*.

1.4 CONTEXT

In the context of health services delivery at FN Health Facilities, registered nurses may conduct certain activities with controlled substances in the course of their employment and as directed in this policy and procedures document. The activities of physicians, dentists, pharmacists, pharmacy clerks/technicians, facility staff, and other persons undertaking activities with controlled substances in these FN Health Facilities are also addressed in this document.

In November 2012, the *New Classes of Practitioners Regulations* came into force, which provides nurse practitioners with additional authority to prescribe controlled substances. Since then, the applicable provincial nurse regulatory bodies have been working to review nurse practitioners competencies and develop guidelines and standards for prescribing. At this time not all provinces have implemented this regulation; moreover, not all nurse practitioners will proceed with the additional authority. Therefore the use of the terms “registered nurse [general class] or a nurse practitioner not authorized to prescribe and/or order CS” will be used throughout this document.

[1] These facilities are often referred to as nursing stations, or health centers with a treatment component

2 POLICY

FNIHB requires accountability for controlled substances 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 headquarters 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 his/her authority to the Interprofessional Practice Support Pharmacy of the Population Health and Primary Care Directorate, Office of Primary Health Care, Primary Health Care Systems Division. The IPS Pharmacy will develop national policies and procedures governing activities with controlled substances, for approval by the Senior FNIHB ADM in consultation with the FNIHB Regional Operations ADM.

3.3 Every FNIHB Regional Executive is accountable to the FNIHB Regional Operations ADM for all activities conducted with controlled substances at the FN Health Facilities located within their region. The Regional Executives will also take measures to ensure that these substances remain secure, and inform FNIHB HQ (IPS Pharmacy) in addition to the Office of Controlled Substances (OCS) whenever a loss or theft is identified.

3.4 Regional procedures related to controlled substances 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 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 FN Health Facilities is authorized to conduct with controlled substances, and to ensure the proper management, record-keeping and security of controlled substances.

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 controlled substances at First Nations Health Facilities[2]. These procedures supplement the *Pharmacy Standards of Practice for FNIHB Health Facilities* and the preceding *FNIHB Policy on Controlled Substances for First Nations Health Facilities*.

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

1.3 In every health facility where the provision of controlled substances is under the direct responsibility of FNIHB, the Nurse in Charge 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.

2. RESPONSIBILITIES

2.1 Senior FNIHB ADM and the FNIHB Regional Operations ADM

- Approval of the FNIHB Policy and Procedures on CS for FN 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 FN Health Facilities[2]
- Regular reporting to FNIHB HQ on compliance level, in accordance with paragraph 3.2.7

2.3 IPS Pharmacy - PHPCD

The IPS Pharmacy is accountable to the ADM of FNIHB through the Executive Director 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] For the purpose of this document, First Nations Health Facilities are defined as health facilities where health services are managed by First Nations and Inuit Health Branch (FNIHB).

2.4 Regional Executive - First Nations and Inuit Health Branch

2.4.1 General

The FNIHB Regional Executive is accountable to the FNIHB Regional Operations ADM for the administrative control of CS, where the procurement of CS for FN Health Facilities is under the direct responsibility of the FNIHB regional office. The Regional Executive is responsible for determining which health facilities are entitled to order and possess CS. The Regional Executive is also responsible to determine whether the HC-managed FN facilities (nursing personnel) in their region will use the FNIHB Drug Classification System[3]. The Regional Executive 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 Regional Executive (RE) is responsible for the appointment of the RCSO and an alternate for the region. The RCSO and the alternate must be a pharmacist, registered nurse, physician, or dentist. If the appointed RCSO is a registered nurse [general class][4] 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[5] 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 FN Health Facilities adhere to the *FNIHB Policy and Procedures on Controlled Substances* ;
- monitoring the utilization of CS by FN 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 [general class] or a nurse practitioner with the condition indicating not authorized to prescribe and/or order CS, he/she 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 [general class] 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 [general class] 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 s/he will not be able to act as the RCSO and the RE must designate an alternate.

[3] The regions where the Drug Classification System is used are listed in Annex 10

[4] Is a registered nurse not licensed as a nurse practitioner.

[5] As defined in Section 1 of the *New Classes of Practitioners Regulations* and when authorized by the applicable provincial nurse regulatory bodies.

2.6 Designated Signing Officer for CS Stock Requests

2.6.1 When the RCSO is a registered nurse [general class] 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 facilities, the Designated Signing Officer must verify with the RCSO (nurse) that the orders are legitimate, and check for utilization anomalies reported by the RCSO as outlined in paragraph 2.5.2.

2.7 Zone Nursing Officer (ZNO) or Equivalent[6]

The ZNO, or equivalent, is accountable to the RCSO and responsible for monitoring the possession, record-keeping, accounting, and security of CS held by FN Health Facilities within their Zone[7].

2.8 Nurse in Charge (NIC) or Designate[8]

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

2.9 Pharmacy Clerks/Technicians

Pharmacy clerks/technicians are accountable to the Nurse in Charge, or designate, and provide technical and clerical assistance to the registered nurses at a FN Health Facility. Pharmacy clerks employed at FN Health Facilities are often trained on the job. The Nurse in Charge may authorize them to access CS while they are under direct supervision of a nurse, in accordance with paragraph 3.1.10.

2.10 Other Designated Health Facility Staff

The Nurse in Charge 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 FN Health Facility, and/or to provide/deliver medication packages to pharmacy clients in accordance with paragraph 4.3.5.

2.11 Non-Insured Health Benefits (NIHB) Pharmacy Providers (Retail Pharmacists)

Client medications. The NIHB 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.

Bulk supply of CS Bulk supply or routine supply of controlled substances to the health facility can only be supplied from a licensed dealer and not by NIHB Pharmacy Providers (Retail Pharmacists).

[6] A ZNO is also called “Area Nursing Manager” or “Nursing Officer”, depending on the region
[7] A Zone is also called "Area", depending on the region.
[8] In this document, the term "Nurse in Charge" is used interchangeably for "Charge Nurse" or his/her designate

2.12 Licensed dealers[9]

Approval from the IPS Pharmacy is required before regional offices make formal agreements with licensed dealers for the bulk supply of CS to remote health facilities, and/or for the return of CS for destruction. Note: Licensed dealers may supply CS to FN Health Facilities only after receiving stock requests signed by the registered nurse at the respective FN 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 FN Health Facilities Providing Clinical and Client Care*[10]. 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 *Pharmacy Room Specifications for FNIHB Health Facilities Providing Clinical and Client Care.*

3.1.2 Registered 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 registered nurse or authorized pharmacy clerk/technician in the room. Maintenance or cleaning personnel must always be accompanied by a registered nurse, pharmacy clerk, or technician, when performing work in the pharmacy room, whether it is done during normal hours of operations or after hours.

3.1.3 The Nurse in Charge 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 Nurse in Charge will secure the second set in a locked area that is only accessible to him/her. It should be kept in a sealed envelope bearing his/her signature and dated.

3.1.4 During working hours, a registered nurse must carry the keys to the CS cupboard and the pharmacy room on his/her person at all times. After hours or when there is no other registered nurse in the facility, the Nurse in Charge or designate must keep the keys in a locked area only accessible to him/her. When a combination lock is used to access the pharmacy room during working hours, only the registered nurses will know the combination code. The Nurse in Charge 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 Nurse in Charge or designate will get the lock(s) replaced immediately.

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[9] *Narcotic Control Regulations* http://laws-lois.justice.gc.ca/PDF/C.R.C., c. 1041.pdf (section 8.1 and 8.2)

[10] The *FNIHB Pharmacy Room Specifications for FN Health Facilities Providing Clinical and Client Care* are approved at the FNIHB HQ/national level in order to meet the requirements set in the FNIHB Pharmacy Standards of Practice.

3.1.5 Only registered 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 Nurse in Charge. For the purpose of an audit, the RCSO or other Health Canada personnel authorized by the Regional Executive may access the CS cupboard in the presence of the Nurse in Charge or designate.

3.1.6 Outside hours of operation when there is no registered nurse in the 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 facility operating hours.

3.1.7 Storage of Emergency or Refrigerated CS

The Nurse in Charge 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 registered 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 at the First Nations health facility are under the responsibility of the Nurse in Charge 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 remotely located, when a patient may require a prescription for a controlled substance. If the dentist agrees with this requirement, he/she must give a verbal prescription to the registered nurse and forward the written prescription by fax or by mail. The registered nurse is responsible for providing and/or administering the CS directly to the patient, in accordance with paragraph 3.7.

If a dentist is not available, the dental therapist must consult with a registered nurse at the FN Health Facility. Under these circumstances, the registered 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 registered 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).

3.1.10 Access to CS by Pharmacy Clerks/Technicians

The Nurse in Charge is the only person authorized to grant access to the CS kept at the facility to pharmacy clerks/technicians working in the 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/technicians cannot act as a witness for the destruction or wastage of CS. The role of the pharmacy clerk/technician may be further restricted by the Nurse in Charge 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 he or she supervises;
- the registered nurse must be authorized by the Nurse in Charge and/or the Health Director, as applicable, to supervise the performance of the activities relating to controlled substances 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 controlled substances; and
- the registered nurse must be able to observe and promptly intervene and stop or change the actions of the individual he or she supervises.

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 registered nurses and pharmacy clerks/technicians must sign and initial the CS Signature and Acknowledgment Form (Annex 1), in each facility where they have access to CS. By signing this form, the registered nurses or pharmacy clerks/technicians confirm that they have read and understood the *FNIHB Policy and Procedures on Controlled Substances for FN Health Facilities.* The use of this form enables the tracking of all facility staff that had access to CS over a given period. Personnel must re-sign this form every 2 years.

3.2.2 CS Register [11]

A registered 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 registered 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 registered 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 controlled substances 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.

[11] See Annex 11 for Regional Suboxone Register Form – Drug Count Combined Form

3.2.3 CS Drug Counts

All controlled substance counts must be done by two registered nurses. In the event that two registered nurses are not available, a registered nurse may perform the count with a pharmacy clerk/technician authorized by the Nurse in Charge. One registered nurse will witness the other registered 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 registered nurses will record each controlled substance count on the CS Register Form (Annex 2A or Annex 2B). The registered nurses are required to count all of the CS stored at the facility at least once a week, and at every nursing staff change, whether CS have been provided/administered or not during that interval. The RCSO, ZNO or Nurse in Charge may determine that more frequent counts are required in their region, zone, or in specific facilities, at their discretion. This should be indicated in writing in the regional edition of the national Policy and Procedure document.

3.2.4 Start/Termination of Employment of the Nurse in Charge and Other Nursing Staff

CS Hand Over. At the start of her/his employment at the facility, the Nurse in Charge assuming custody of the controlled substances must perform a physical count with the departing Nurse in Charge and acknowledge receipt of the inventory from her/him, by signing and dating the stock balance for each CS in the CS Register, confirming that stocks and register balances agree. The departing Nurse in Charge 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 Nurse in Charge.

When other registered nurses start their employment at the health facility, the Nurse in Charge must ensure that the arriving registered nurses read and understand the *FNIHB Policy and Procedures on Controlled Substances*, and complete a CS Signature and Acknowledgement Form (Annex 1), before granting them access to the CS. Before first accessing the CS, the arriving registered nurse will perform a complete drug count with the Nurse in Charge or designate, to confirm that stock and balances agree.

At the end of her/his employment, any registered nurse departing the health facility will perform a drug count with the Nurse in Charge or designate before leaving.

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

When a registered 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) he/she must immediately advise the Nurse in Charge/designate. If the discrepancy cannot be resolved, the Nurse in Charge or designate must notify the ZNO immediately. The ZNO will provide direction to the Nurse in Charge or designate, after consulting with the RCSO, if necessary.

When there is a loss that cannot be explained or when theft is suspected, the Regional Executive 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 Regional Executive will take appropriate measures to investigate the loss/theft as soon as possible.

On the CS Register Form, where the discrepancy has occurred, the Nurse in Charge and a second nurse, or another officer authorized by the Regional Executive 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 Nurse in Charge and the ZNO or other personnel designated by the Regional Executive will investigate the loss or theft and complete a *Loss or Theft Report Form for Controlled Substances and Precursors* - HC/SC 4010 (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 Regional Executive 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 controlled substance is wasted as part of normal professional practice (see Section 3.8).

The NIC must also complete and submit to his/her manager a First Nations and Inuit Health Branch Occurrence Report, indicating the theft under Section 1: Security Violations. 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 Occurrence Report 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 Office of Controlled Substances (Health Canada) in Ottawa, 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 HQ, attention: IPS Pharmacy, PHPCD. IPS Pharmacy 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 Nurse in Charge of the facility and managers in the line of authority for the region, such as the ZNO, 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 Nurse in Charge will complete the CS Month End Inventory and Usage Report (Annex 3) on a monthly basis, or more frequently at the discretion of the ZNO or RCSO. The completed report will be forwarded to the RCSO through the ZNO within a week following month end. This report will be reviewed by the ZNO and the RCSO and kept on file for a minimum period of two (2) years in accordance with paragraph 3.2.9.

The ZNO and RCSO must examine unexplained changes in utilization rates at a 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 HQ (FNIHB/PHPCD)

For every occurrence[12]:
Loss and Theft Reports (Annex 7).

- In addition to the copy sent to Office of Controlled Substances, the regions will send a duplicate copy to FNIHB HQ/IPS Pharmacy (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 HQ'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, 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).

[12] The RCSO must always inform the Regional Executive of all CS issues/incidents reported to HQ.

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 Nurse in Charge and the ZNO. 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[13] and audit by officers authorized by the FNIHB Regional Executive. The Nurse in Charge is responsible for ensuring that all records, including prescriptions for controlled substances, 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 ZNO (or regional representative if a ZNO 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 each 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 ZNO will provide timely verbal and written reports to the Nurse in Charge, 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 Nurse in Charge of the facility will sign all CS stock requests for replenishing the inventory from a supplier (i.e., licensed dealer). The Nurse in Charge will submit the requests to the ZNO for verification of entitlement and quantities. The ZNO may recommend the requests as such or with changes and forward them to the regional office for approval. The RCSO will verify and approve

[13] "Inspector" means a person who is designated as an inspector under section 30 of the *Controlled Drugs and Substances Act*.

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 [general class] 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.

3.4.2 Emergency stock requests

When a registered nurse at a facility has identified an emergency need for controlled substances listed in the 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 Nurse in Charge will advise the ZNO. The ZNO 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 controlled substance from a hospital, 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*[14]. The RCSO and ZNOs are collectively responsible for establishing the minimum and maximum levels of each controlled substance to be stored in inventory at each health facility, in consultation with the Nurse in Charge. The Nurse in Charge will ensure the maximum level of each controlled substance is indicated in the CS Register, and that the CS quantities are within these parameters.

3.4.4 Utilization monitoring

The ZNO is responsible for examining any request that falls outside normal parameters, e.g., sudden increases or larger utilization compared to other facilities. When any registered 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 Regional Executive is advised as soon as possible, through the line of responsibility when possible. The Regional Executive/RCSO will take appropriate measures after assessment of the situation with the staff involved, the ZNO and/or the Nurse in Charge.

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 registered 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 registered nurses to verify its contents.

3.5.2 Normal Receipt of Controlled Substances in Good Condition

Upon receipt of a shipment containing controlled substances in good condition, the registered 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

[14] FNIHB will provide the Office of Controlled Substances a list of CS that may be ordered and stocked at FN health facilities, until the national FNIHB Nursing Station Formulary is implemented across all FNIHB regions. 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.

registered nurses. In the event that two registered nurses are not available, a registered nurse may open the shipment and perform the recording with a pharmacy clerk/technician authorized by the Nurse in Charge 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 (e.g. DDC Edmonton), quantity received, new balance, and signature of the registered nurse receiving/recording the receipt of the CS. If Register Form Annex 2B is used, the registered 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 registered nurse at the facility (after hours), the registered nurse will ensure that the shipment is kept in a secure place until there are two authorized staff available.

3.5.3 Receipt of CS in damaged condition

If a shipment containing CS is received in damaged condition (which may include breakage or a shipment comprised by lack of temperature control), the Nurse in Charge/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 ZNO who will advise the regional office, by means of or followed by a completed FNIHB Occurrence Report form. The ZNO is responsible for providing disposal instructions to the Nurse in Charge as soon as possible.

If possible, the ZNO or the RCSO will arrange for the return of the CS to the supplier for credit. The ZNO or RCSO will obtain written or email authorization from the supplier prior to returning any CS to the supplier, and forward it to the Nurse in Charge. The Nurse in Charge 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 ZNO 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 ZNO 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 Descrepancy 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 Nurse in Charge/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 ZNO who will advise the regional office, by means of or followed by a completed FNIHB Occurrence Report form. The ZNO is responsible for providing instructions to the Nurse in Charge as soon as possible, when applicable.

If possible, the ZNO 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 ZNO 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 Nurse in Charge.

The Nurse in Charge 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[15] are authorized to prescribe controlled substances.

3.6.2 Written prescriptions

When present at the health facility, the physician, dentist or nurse practitioner 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 physician, dentist or nurse practitioner (in addition to the health record entry) and not remitted to the patient at that time, the registered nurse, physician or dentist will attach the prescription form to the patient's health record until the drug can be provided. Once the registered nurse provided the drug to the patient, he or she 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 physician, dentist or nurse practitioner at the health facility, the registered nurse should consult a physician, dentist or nurse practitioner located off-site before providing or administering a CS to a patient. If the physician, dentist or nurse practitioner deems it is necessary to prescribe a CS, he/she must give a verbal prescription to the registered nurse. The registered nurse accepting a verbal prescription from a physician, dentist or nurse practitioner 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 prescribing physician, dentist or nurse practitioner 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 physician, dentist or nurse practitioner is scheduled to visit the health facility within the next month, the registered 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 controlled substances, a physician, dentist or nurse practitioner should transmit a CS prescription by fax from his/her office or health facility to the appropriate registered nurse in the FN health facility. The elements of the fax prescription must be met (See Annex 9).

[15] As defined in Section 1 of the *New Classes of Practitioners Regulations* and when authorized by the applicable provincial nurse regulatory bodies.

The physician, dentist or nurse practitioner 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 registered nurse at the FN health facility is required to keep the fax prescription on the respective patient file for the same length of time.

In addition, a physician, dentist or nurse practitioner located at the FN 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 Annex 9. In these cases, the FN health facility must keep the original prescription on the respective patient file for at least two years of making the prescription.

NOTE: Registered nurses cannot fax a CS prescription received by fax from an off-site physician, dentist or nurse practitioner to an off-site pharmacist for dispensing. Instead, the physician, dentist or nurse practitioner must fax their prescription directly to the pharmacist.

3.6.5 Chronic medication sheet

When the CS are prescribed by a physician, dentist or nurse practitioner for a chronic condition, the registered 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 registered nurse may request a copy of the medication profile from the pharmacy dispensing the chronic medications, and/or keep a copy of the prescriptions that were sent to the 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 registered 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 controlled substances stocked at the health facility, nor be providing them directly to the patients.

3.7.2 Registered nurses may provide or administer CS to patients at the health facility based on a written or verbal prescription (confirmed by fax) from a physician, dentist or nurse practitioner. In regions where the *FNIHB Drug Classification System* is used, in an urgent situation where it is not possible to consult with a physician, dentist or nurse practitioner, registered nurses [general class] 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 the *FNIHB Drug Classification System* (DCS). The prerequisites for providing/ administering controlled substances in accordance with the DCS are listed in the *FNIHB Nursing Station Formulary (See Annex 10).* In regions where the *FNIHB Drug Classification System* is not used, registered nurses [general class] or a nurse practitioner not authorized to order CS must always obtain a prescription (written or verbal prescription confirmed by fax) from a physician, dentist or

nurse practitioner prior to providing/administering any controlled substance. The registered nurse [general class] or a nurse practitioner not authorized to order CS may then provide or administer the CS in accordance with the most recent *FNIHB Clinical Practice Guidelines* and the *FNIHB Nursing Station Formulary.*

Notwithstanding the above paragraphs, Regional Executives may impose limits on the provision/administration of CS by registered nurses within their region that are more, but not less, restrictive than those set out in this document.

3.7.3 Recording the Provision/Administration of CS

The registered nurse will record the provision or administration of the CS in the patient's health record. In some regions the registered 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[16]. The registered 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/administered. The following information must be recorded: date (year, month written out, date), e.g., 2011 Apr 31, 31 Apr 2011 or Apr 31, 2011, 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 registered 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 a remote retail pharmacist (NIHB pharmacy provider).

When CS are prescribed for a patient to take home, the registered nurse may immediately provide the complete quantity of medication to the patient, or may decide to send the prescription to the NIHB pharmacy provider for dispensing by a remote pharmacist, based on the registered nurse's judgment of the urgency of the situation, the CS inventory available at the facility, and the patient's health and security.

If the registered nurse provides a part of the medication to the patient immediately and an additional amount is to be dispensed later by a remote retail pharmacist, the physician, dentist or nurse practitioner must write two separate prescriptions, one for the quantity provided on site by the registered nurse, and the other for sending to the remote pharmacy provider for dispensing.

3.7.6 Partial-fills for CS dispensed by retail pharmacies

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

[16] Refer to the regional edition of the national FNIHB Policy and Procedures document where applicable

Should there be an exceptional client need, as agreed upon by NIC and prescribing physician, dentist or nurse practitioner**,** which requires the nursing station to hold at the health facility any amount of client-specific CS coming from a pharmacy for re-distributing in smaller quantities at a time to this client, *or for bridging therapy,* the registered nurse will initiate a separate CS Register Form (Annex 2A or 2B) for this client's controlled substances, to be kept with the facility CS Register. These smaller quantities should come from the pharmacy in the appropriate packaging with the appropriate amount of medication in each package. The registered 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 controlled substances sold or dispensed by a 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 physicians, dentists, nurse practitioner and 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 nursing station stock.

3.8 Wastage of Controlled Substances

3.8.1 A registered nurse is authorized to destroy immediately an unserviceable, injectable controlled substance, in quantities that represent a partial dose from an ampoule. In this case, the registered nurse must register the quantity wasted on the CS Register Form on the next line, sign it, and get the note co-signed by another registered nurse who witnessed the wastage. A separate line entry is used to clearly document wastage. The registered nurse witnessing the wastage should indicate whether he/she is witnessing all the circumstances leading up to and including the wastage, or only the wastage. In situations where only one registered nurse is present in the health facility, he/she may enter only his/her signature on the CS Register Form, subject to prior written direction provided by the ZNO or RCSO. When possible, alternate authorized personnel may co-sign the wastage in the CS Register.

3.8.2 If a registered nurse spills a liquid, drops and loses a pill, or breaks an ampoule accidentally, the registered 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 registered nurse. The registered nurse witnessing the wastage should indicate if he/she is 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 a wastage, after reporting the damaged shipment to the ZNO 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 registered nurse must keep unserviceable/unusable doses of CS in the CS cupboard, ensuring that they are clearly identified as such 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 registered 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 registered nurse. The overage/underage of over 5% must be reported to the ZNO 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, registered 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 Nurse in Charge 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. The appropriate box indicating the type of substance to be destroyed should be checked at the top of the Request Form. A copy of the Request Form should be kept in the CS Register.

3.9.4 The Nurse in Charge will forward all the CS Destruction Request Forms to the RCSO, through the ZNO. The RCSO[17] may approve the CS Destruction Requests Forms for Targeted Substances (Benzodiazepines), and forward the CS Destruction Requests Forms (Narcotics and Controlled Drugs) to the Health Canada Office of Controlled Substances for their acknowledgement.

3.9.5 The RCSO will return the approval letters (for targeted substances) and/or the acknowledgement letters (for narcotics and/or controlled drugs) to the Nurse in Charge through the ZNO, and keep a copy in the regional office CS files.
These destruction documents will indicate the following:

- only the drugs listed in the destruction request may be destroyed; and
- the CS must be destroyed within 60 days from the date on the letter of approval/ acknowledgement.

3.9.6 After receipt of the approval/acknowledgement letter(s) with the inventory list of items for destruction (Annex 4), the Nurse in Charge will perform the destruction, in the presence of a physician, dentist, pharmacist, or another registered nurse. The destruction will be recorded on the appropriate CS Register Form and the balance adjusted accordingly. Both health 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 controlled substances destroyed have been altered or denatured to such an extent that its consumption has been rendered impossible or improbable. The Nurse in Charge is responsible for ensuring that the destruction is carried out using an appropriate method and in compliance with all applicable municipal, provincial and federal environmental legislation.

[17] If the RCSO is a nurse, he or she 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.

3.9.7 The Nurse in Charge must ensure that the approval/acknowledgement letter with the inventory list of CS destroyed, and the signed statement of destruction at the bottom of Annex 4 are kept on file in the CS Register at the facility. These documents 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

Approval from the IPS Pharmacy is required before regional offices make formal arrangements with a licensed dealer to destroy unserviceable/unusable CS. This will enable the IPS Pharmacy to check the status of the licensed dealer with the Health Canada Office of Controlled Substances.

Where such arrangements are in place, the Nurse in Charge, ZNO 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 Nurse in Charge 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.

4. ADDITIONAL INFORMATION

4.1 Transportation and Security of Controlled Substances during Facility Closure or during an emergency evacuation

The following procedures should be implemented to maintain security of the FN Health Facility CS inventory during a facility closure. However at no time should the Nurse in Charge (NIC) or other FN health facility staff compromise their personal security in order to secure or transport the FN Health Facility controlled substances inventory.

4.1.1 Closure for an indeterminate period

A FN 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 facility. When CS are stocked at the facility, the NIC/designate must advise the RCSO through the ZNO. The RCSO must inform the Office of Controlled Substances within 10 calendar days of the closure. The controlled substances 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 FN Health Facility, community pharmacy or hospital pharmacy, after obtaining appropriate authorizations from the receiving party. The RCSO must notify the Office of Controlled Substances as to where the CS will be relocated, prior to the relocation or no later than 10 calendar days after the relocation.

The Nurse in Charge /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 registered 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 ZNO and Office of Controlled Substances (through the RCSO) of the completed relocation and the quantity of CS relocated.

4.1.2 Closure for a limited period/emergency evacuation

A FN 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/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 FN 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 Nurse in Charge/designate accompanied by a registered nurse, pharmacy clerk/technician, physician, dentist, or pharmacist, must perform a drug count of all CS in the FN 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 FN 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 Nurse in Charge/designate should take the complete (current) CS Register with him/her (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/designate will maintain custody of the register sheets at all times and secure them until return to the FN Health Facility.

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

When a registered nurse is required to transport controlled substances 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 registered 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 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 a pharmacist (NIHB pharmacy provider) pursuant to a prescription, for a specific client. Client-specific medication packages delivered through FN 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

Retail pharmacists are responsible for the dispensing of the medications they sell or provide to their clients, including provision of patient counselling. 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. The Nurse in Charge of the FN health facility, the Chief and Council, and the regional staff may be required to collaborate with the retail pharmacists in order to set up a routine system for the delivery of client-specific medications which does not use the health facility as an intermediary.

4.3.3 Delivery to clients through a FN health facility

When there is no other alternative, the registered nurse or a designated person under his/her direct supervision, such as a pharmacy clerk/technician or a Community Health Representative, may accept medication packages from retail pharmacists to be provided to the pharmacists' clients by way of the FN health facility, thus accepting responsibility for their safeguarding and delivery to the clients. This delivery arrangement does not remove the pharmacists' responsibility to comply with their provincial regulations for the dispensing and delivery of medications to their clients.

All medication packages, irrespective of whether they contain CS, must remain unopened until delivered to/picked up by clients, in order to maintain patient privacy and to avoid compromising pharmacist responsibility for dispensing. For as long as the packages remain unopened and until delivered to their clients, the pharmacists retain responsibility for the contents of the medication packages, for the act of dispensing (including provision of drug information), and for reporting to the Office of Controlled Substances whenever client-specific packages containing CS have been lost or stolen prior to delivery to their clients.

4.3.3.1 Recording client specific medications

The FN facility must record the receipt and delivery of these client packages in a log indicating the date received, the name and signature of the person receiving them at the health facility, from which pharmacy/pharmacist, the names of the intended recipients, the date each intended recipient picks up the package, and the signature of the intended recipient (or date package returned to pharmacy and name of pharmacy, when applicable)

4.3.3.2 Shipment

When shipping medication packages to First Nations Health Facilities, pharmacy providers and NIC should make arrangements to obtain a nominal list (packing slip) for all of the clients for whom there is a medication package in the shipment, in order to facilitate checking of shipments received and log recording.

4.3.3.3 Receipt

A registered nurse or a designated person under his/her direct supervision, such as a pharmacy clerk/technician or a Community Health Representative, is responsible for receiving these shipments at the health facility and verifying the quantity of medication packages against the nominal list/packing slip received with the shipment. The registered nurse or designated personnel must acknowledge receipt of the medication packages by signing the packing slip, and must advise the pharmacy provider if there is any discrepancy between the packing slip and packages included in the shipment.

4.3.3.4 Secure storage

Packages containing medications sold or provided by retail pharmacists for individual clients should be kept orderly and stored in a secure, locked area until picked up by or delivered to the individual client or representative. These individual packages may contain CS; therefore, package contents should not be indicated on the outside, and the packages should remain unopened until provided to the client. Every effort should be made to provide clients with their medications as soon as possible. The packages remain the property of retail pharmacists until delivered to the clients or returned.

4.3.3.5 Delivery/Provision

The Nurse in Charge may designate appropriate facility staff in lieu of registered nurses, e.g., pharmacy clerks, Community Health Representatives, clerks, for providing/delivering the medication packages to the clients. In all cases the chain of signature must be maintained, i.e., the staff person must sign upon receipt of the medication shipment from the pharmacy provider and the client must sign for their medication package upon receipt from the staff person. Clients having questions concerning their medications or the contents of their package should contact their pharmacist (NIHB-pharmacy provider).

4.3.3.6 Return of unclaimed packages to NIHB-pharmacy providers

There must be a method in place to return unclaimed medication packages to the pharmacies (NIHB-pharmacy providers) when it is determined that these packages cannot be provided/delivered to the client in a timely fashion, e.g., normally one month after receipt at the health facility. The return shipments must be done through a commercial carrier providing a tracking system. Pharmacy clients' controlled substances (or any other client medications) should not be added to the health facility CS inventory and should not be used to treat other patients.

4.3.3.7 Loss or theft of client-specific medications

The NIC must report any loss or theft of any client-specific medication packages to the pharmacist who provided them[18]. Pharmacists have an obligation to report the details of the loss to the Office of Controlled Substances if controlled substances are missing, in accordance with CS regulations. The NIC must complete and submit to his/her manager a First Nations and Inuit Health Branch Occurrence Report, indicating the theft under Section 1: Security Violations. In addition, the NIC must take other appropriate measures such as consulting with the local law enforcement agency and notifying the Regional Security Manager.

[18] The NIC must report any theft or loss to the dispensing pharmacy, if the diversion has occurred after the medication was signed into the nursing station but before the client is in receipt of his/her medication(s).

5. REFERENCES

A. *Controlled Drugs and Substances Act (*1996, c.19), and Regulations under the Act
B. *Food and Drugs Act*, (R.S. 1985, c. F-27), and Regulations under the Act.
C. *Benzodiazepines and Other Targeted Substances Regulations: Guidance Document for Hospitals* (2000). Health Canada, Healthy Environments and Consumer Safety Branch.
D. *First Nations and Inuit Health Branch Nursing Station Formulary.* (April 2011). Health Canada, FNIHB
E. *First Nations and Inuit Health Branch Drug Classification System.* (April 2011). Health Canada, FNIHB.
F. CPS - *Compendium of Pharmaceuticals and Specialties* (2011). Canadian Pharmacists Association.
G. *Pharmacy Standards of Practice for First Nations and Inuit Health Branch Facilities* (2001). Health Canada, FNIHB. Available on the Health Canada - FNIHB website
H. *FNIHB Documentation Guidelines for Nurses in Primary Care* (2009 - pending). Health Canada, FNIHB.
I. *FNIHB Pharmacy Room Specifications for FN Health Facilities Providing Clinical and Client Care* (Draft February 2012). Health Canada, FNIHB.
J. *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.
K. *FNIHB Clinical Practice Guidelines for Nurses in Primary Care.* Health Canada - FNIHB. Available on the Health Canada - FNIHB website.
L. *FNIHB Pediatric Clinical Practice Guidelines for Nurses in Primary Care.* Health Canada - FNIHB. Available on the Health Canada - FNIHB website.
M. *Fax Prescription Model Policy* (Rev. November 2001) - National Association of Pharmacy Regulatory Authorities. As accessed on NAPRA.org website March 31st, 2010.
N. *FNIHB Privacy Standard Operating Procedures.* Available on the Health Canada - FNIH intranet website. http://intranet.hc-sc.gc.ca/alt_format/pdf/ahc-asc/branch-dirgen/fnihb-dgspni/od-bd/bpm-pga/2011-tppir-eng.pdf (as accessed on December 20th, 2012).
O. *Narcotic Control Regulations* (C.R.C., c.1041) 2014
P. *New Classes of Practitioner Regulations* (SOR/2012-230) 2014