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NARCOTIC & CONTROLLED SUBSTANCE DRUG ACCOUNTABILITY GUIDELINES

Goal: To establish self-monitoring procedures for pharmacy managers, which will provide accountability for ~~narcotic and controlled drug~~ controlled substance transactions, detect drug diversion, and deter pilferage.

Definitions:

“Controlled Drug” means a drug set out in the Schedule to Part G of the Food and Drug Regulations (FDR), including a preparation.

“Controlled Substance” means is any narcotic, controlled or targeted drug as laid out in Schedules I, II, III, IV or V of The Controlled Drugs and Substances Act.

“Narcotic” means any substance set out in the Schedule to the Narcotic Control Regulations or anything that contains any substance set out in that Schedule.

“Targeted Substance” means a controlled substance that is included in Schedule 1 to the Benzodiazepines and Other Targeted Substances Regulations (BOTSR) or a product or compound that contains a controlled substance that is included in Schedule 1 to the BOTSR.

Required Procedures:

The following procedures are applicable to all controlled substances. ~~A controlled substance is any narcotic, controlled or targeted drug as laid out in Schedules I, II, III, IV or V of The Controlled Drugs and Substances Act. The specific drugs included shall be all products covered under the Manitoba Prescribing Practices Program (M3P) previously known as the triplicate prescription program, and other such drugs as determined by Council and the College of Physicians and Surgeons.~~

Accurate Perpetual Inventory Records Log

A perpetual inventory log record must be maintained for all controlled

substances. The perpetual inventory log~~record~~ is an ongoing system for recording accurate quantities of controlled substances received, dispensed, or otherwise distributed by a pharmacy in real time. Either manual count sheets or the equivalent in computer software may be used. Each pharmacy will establish a start count by completing a full physical count.

Received quantities (including medication dispensed, but not picked-up and returns from personal care home to the contract provider for re-dispensing) will be added to the start count, and dispensed drug will be subtracted from the total.

Manual Inventory Adjustments

An explanation must be clearly documented for any manual inventory adjustment of a controlled substance. Documentation must include the reason for the adjustment, the person who performed the adjustment and the date the adjustment was made.

Each pharmacy manager will be responsible for ensuring manual inventory adjustments are reviewed at least once every three months for trends consistent with diversion. For example, large adjustments, repeated adjustments, adjustments without documented explanation, etc. If the pharmacy manager identifies any concerns, they should be investigated and addressed. Documentation must include the date and name of the person completing the review.

Physical Inventory Count and Reconciliation

sThe purpose of performing reconciliation on controlled substances is to detect, investigate, resolve, and document any differences between the actual amount of physical inventory counted (“on-hand”) with the expected amount of inventory that should be on-hand (derived from purchase and sale records).

Each pharmacy manager will be responsible for ~~completing performing~~ and recording a physical count and reconciliation of ~~these drugs~~all controlled substances at least once every three months.

The records of stock on hand will be compared with the net count from the perpetual inventory log sheets~~record~~, ~~and, and~~ any discrepancies are to be investigated, addressed, and documented by the pharmacy manager ~~where it would be deemed prudent to do so.~~ A review of purchase and sale records should be included in the investigation of any discrepancy.

The inventory count record will include the signature of the person who completed the count and the date the count was completed. The results of the inventory count are retained in the pharmacy’s records for a five-year

period in a readily retrievable format.

Change of Manager Inventory Count

Every change of pharmacy manager, resulting in the re-issuing of a pharmacy license, will require an additional physical count of these drugs by both the departing manager and the new manager. The signature of each manager shall be recorded on the count documents, which shall be retained for five years.

Reporting Discrepancies

The manager shall initiate the necessary steps to identify the cause of the shortage, the responsible staff person and initiate corrective actions. Any unexplained loss, theft or diversion of a controlled substance must be reported to the CPhM and Health Canada within 10 days of discovery.

Sales reports

The pharmacy manager must ensure narcotic, controlled, and targeted drug sale reports are reviewed, with documentation, at least once every three months for trends consistent with diversion and inappropriate prescribing.

A sales report is a report of all narcotic, controlled, and targeted drugs dispensed or sold by the pharmacy for which the sale of the drug is required to be reported to Health Canada. The report should be cross-referenced/reconciled against the filed prescriptions to determine, for example:

- all prescriptions/orders are accounted for, i.e., no prescriptions or prescription numbers are missing
- the prescriptions are valid and meet the requirements of the relevant legislation
- any unusual names, drugs, quantities or patterns are identified

The frequency of review must be at least once every three months, or more often depending on the pharmacy environment. For instance, recent or frequent staff turnover; temporary, relief or casual staff; high volume of controlled substances dispensed; history of past discrepancies identified; etc.

Unserviceable Pharmacy Inventory and Post-Consumer Returns ~~Expired-Narcotics and Patient Returns~~ for destruction

As there is often a time lag between when the drug becomes unserviceable (for example expired or damaged) ~~expired~~ or is returned for disposal, and the actual destruction, each pharmacy must maintain an inventory count of these ~~drugs~~controlled substances until the time of destruction.

The pharmacy manager will be responsible for ~~completing-performing~~ and recording a physical count of these drugs at least once every three months. The inventory records of unserviceable pharmacy inventory and post-consumer returns should be kept separate from the active inventory records and~~expired and returned narcotics and controlled drugs stock~~ shall include the date of entry into the expired narcotic inventory~~inventory~~ log and quantity of the drug. A physical inventory count will compare the stock on hand with the inventory log~~count from the expired and returned narcotics and controlled drugs inventory sheet~~. Any discrepancies are to be investigated, addressed, and documented by the pharmacy manager.

By tracking unserviceable pharmacy inventory and post-consumer return~~expired and returned narcotic and controlled drugs inventory~~, diversion of ~~these medications~~controlled substances by pharmacy staff can be prevented.

Change of Manager Inventory Count

~~Every change of pharmacy manager, resulting in the re-issuing of a pharmacy license, will require an additional physical count of these drugs by both the departing manager and the new manager. The signature of each manager shall be recorded on the count documents, which shall be retained for five years.~~

Reporting Discrepancies

~~Should discrepancies be identified during inventory counts, the manager shall record the incident on an "incident report" and keep a record at the pharmacy.~~

~~The manager shall initiate the necessary steps to identify the cause of the shortage, the responsible staff person and the initiate~~initiate ~~corrective actions. Significant shortages~~Any unexplained loss, theft or diversion incidents of a controlled substance must be reported to the CPhM and Health Canada.

Other Policies:

Patient reports of shortages on individual prescriptions:-

Where a patient reports a shortage in their prescription, the inventory control system would verify or refute the shortage.

If the prescription is redispensed, documentation of the date, time, and reason for redispensing shall be noted on the prescription and cosigned by the manager and, except in sole practice situations, one other pharmacist.

Breakage of "Controlled Substance":

When a breakage occurs, a report shall be filed on the pharmacy records of perpetual inventory, as a negative quantity.

Documentation of the date, time and place of breakage could be co-signed by the manager and, except in sole practice situations, one other pharmacist.

Disposal:

Health Canada does not require the pharmacy to obtain permission from the Office of Controlled Substances to destroy controlled substances~~narcotic and controlled drugs~~. The pharmacist can proceed with destruction of unserviceable pharmacy inventory and post-consumer returns~~expired and returned narcotic and controlled drugs~~ without contacting Health Canada for approval. The pharmacy must keep a record of the ~~narcotic and controlled drugs~~controlled substances that are destroyed and the records must be kept for a period of 5 years.

There are two options for the destruction of ~~the narcotic and controlled drugs~~controlled substances. The first option is to destroy the drugs by altering or denaturing the drug such that consumption becomes impossible or improbable. The destruction of the ~~narcotic and controlled drugs~~controlled substances must be carried out in the presence of a pharmacist and one other~~two~~ health professionals. Health care professionals include: pharmacists, practitioners, ~~nurses~~, pharmacy interns and ~~regulated~~ pharmacy technicians. The following information must be recorded:

1. Name, strength, and quantity of the drug.
2. Date of destruction.
3. Method of destruction.
4. Name and signature of the two health care professionals witnessing the destruction.

3.5. A joint statement that certifies the substances were altered or denatured to such an extent as to render consumption impossible or improbable.

Another option for the destruction of ~~narcotic and controlled drugs~~ controlled substances is to return them to a dealer who is licensed to destroy them. With this option, the pharmacist must request authorization from a licensed dealer to return the ~~narcotic and controlled drugs~~ controlled substance to them. The pharmacist must then receive a written, signed order from the licensed dealer authorizing the return. The information must include the drug name, strength, and quantity of the drug to be returned. It must also indicate that the drug being provided to the licensed dealer is for the sole purpose of destruction.

Once the letter is received from the licensed dealer, the pharmacist can send the drugs to be destroyed to the licensed dealer for destruction. It is very important that the pharmacy keep a record of this authorization to return. The following information must be recorded:

1. Name, strength, and quantity of drug
2. Name and address of the licensed dealer to whom the ~~narcotic and/or controlled drugs~~ controlled substances were provided
3. The date it was provided
4. The name of the pharmacist requesting destruction
5. A copy of the authorization to return the ~~narcotic or controlled drug~~ controlled substance

Please see next page for ~~Narcotics and Controlled Drugs~~ Controlled Substances Perpetual Inventory Form

~~NARCOTICS AND CONTROLLED~~ SUBSTANCES ~~DRUGS~~ PERPETUAL INVENTORY FORM

DRUG NAME & STRENGTH: _____ **DOSAGE FORM:** _____ **DATE:** _____

[illegible]