Record Keeping Requirements for CDSA Drugs

In accordance with the *Controlled Drugs and Substances Act* (CDSA), *Narcotic Control Regulations,* Part G *Food and Drug Regulations, and the Benzodiazepine and other Targeted Substances Regulations,* **pharmacists are required to maintain, on their premises, up-to-date records (paper or electronic) of their purchases and sales transactions for all drugs listed in the schedules to the CDSA***. This information must be made available upon request to the Federal Minister of Health or a designated representative. Pharmacists are to exercise their professional responsibilities and maintain a high degree of control over all drugs listed in the schedules to the CDSA as part of their Standard of Practice.

During routine field operations, the Saskatchewan College of Pharmacy Professionals (SCPP) will monitor adherence to the regulatory requirements. SCPP will advise Health Canada, Office of Controlled Substances (OCS) of any unresolved or critical concerns.

The purposes for SCPP monitoring the record keeping and other requirements of drugs listed in the schedules to the CDSA sales are:

- to assess the current level of control provided by pharmacists in the receipt, storage, security and distribution of drugs listed in the schedules to the CDSA;
- if substandard practices are noted, to encourage improvement;
- to reduce diversion and improper use of drugs listed in the schedules to the CDSA;
- to provide an opportunity for pharmacists to obtain clarification and interpretation of the legislation;
- to monitor the dispensing of Prescription Review Program medications to achieve the goals of the program (Please refer to the Prescription Review Program guidance document for more information).

To assist pharmacists in maintaining appropriate records, the following summary of federal legislation and SCPP requirements has been developed to reduce complications when these records must be produced.

1. **Filing of Narcotic and Controlled Drugs Prescriptions**

   a) File CDSA drug prescriptions in a separate file in sequence by date and number (if an exact copy of the original can be produced in sequence, an electronic file can be maintained);

   b) Sort and label all paper copies of Narcotic and Controlled Drugs in acceptable file covers/jackets clearly identifying the prescription number sequence and date range; or

c) If filing electronically, ensure a printable report, which meets all of the requirements of federal legislation, can be produced upon request by an inspector (SCPP or OCS);

d) File any prescriptions for low-dose (exempted) codeine roducts in the CDSA drugs file;

e) Keep Narcotic and Controlled Drugs prescription records readily accessible for review for a period of *TWO years from the date of the last fill/transaction;*

f) Make all CDSA drug prescription files available at all reasonable times for audit or inspection by authorized inspectors of Office of Controlled Substances; the Saskatchewan College of Pharmacy Professionals or any other authorized individual or agency.

2. Sales Reports

A sales report is a report of all CDSA drugs dispensed or sold by the pharmacy for which the sale of the drug is required to be reported to Health Canada

a) The pharmacy manager should review sales reports on a regular basis to ensure that all products required to be reported, are being captured appropriately for reporting purposes;

b) As required by federal legislation, maintain manual or computer generated sales reports of all reportable CDSA Drugs in a readily retrievable format and have available for review.

3. Receipt Records

Purchase (Receipt) Records are records of ALL drugs purchased by the pharmacy which are listed in the schedules to the CDSA

a) Maintain a manual (invoices) or computer generated purchase report in a readily retrievable format; or

b) Retain purchase invoices, or photocopies thereof, in a readily retrievable format, filed in order by date and invoice number;

c) Ensure purchase records are dated for the date the product was received, not the invoice date;

d) Include the strength and quantity of the drug;

e) Records must be maintained for two years from the date of receipt of the product.

4. Dispensing Details and Pharmacist Accountability

a) Complete a cross-referenced audit trail for CDSA drug part fills (or repeats of controlled drugs or benzodiazepines)*:

   i. generate a new prescription record for each fill of the drug;

   ii. ensure the record clearly indicates “part-fill” or “refill” to distinguish it from the first fill of a new prescription or the first fill of a previous logged prescription;

   iii. include the initials of the pharmacist generating the new record;

   iv. ensure the records contains a new transaction/prescription number and the current date;

   v. reference the new record to the original prescription number;

   vi. file the new record in sequence by prescription/transaction number and the date of filling.

b) Ensure the prescription is in compliance with Prescription Review Program requirements;

c) Prescriptions for drugs listed in the schedules to the CDSA cannot be released unless a written*, dated and signed order is received by the pharmacist and where the signature of the physician is not known to the pharmacist, it is verified.

5. Regular Inventory Counts

a) At least quarterly, conduct a complete physical count of all drugs listed in the schedules to the CDSA or more often depending on the pharmacy volume of prescriptions;

b) Verify the accuracy of computer perpetual balance records by reviewing the “drug history report”;

c) Perform a regular review of purchases and sale of all CDSA drugs as well as records regarding inventory adjustments, emergency purchase and sales and other relevant documentation;

d) Perform a narcotic reconciliation as part of your routine review of CDSA drug purchasing, dispensing and record keeping reviews;

e) Check for outdated inventory and follow the correct protocol for return or destruction of outdated narcotic and controlled drugs.

6. Perpetual Balance

A perpetual balance record is recommended to ensure that the pharmacists are aware of the on-hand balance of drugs at all times. The computer balance should be compared with a physical count all drugs as per section 5.

7. Miscellaneous Points, Loss, Theft, Forgery

a) **Verify the signature of the practitioner** if not known to the pharmacist;

b) Refer to the section 7 and 8 of Part J of the SCPP Regulatory Bylaws respecting the stocking and sale of low-dose (exempted) codeine products;

c) Any returns to a wholesale, or emergency supplies to another pharmacist must be documented and retained in the prescription file and the sale reported; see SCPP guidelines entitled *Destruction of Narcotics, Controlled Drugs and other Targeted Substance;*

d) **Loss, Theft or Forgery** should be reported directly to the Office of Controlled Substances, Health Canada;

e) Report **forgeries** on a Forgery Report form;

f) Report **loss or theft** on a Loss/Theft Report form within 10 days of its discovery. Fax a copy to Health Canada (fax number on form) and one to SCPP. Keep the original at the Pharmacy;

g) Refer to the SCPP policy statement and guidelines on *"Electronic Transmission of Prescriptions"* regarding protocols for the acceptance of fax orders for drugs listed in the schedules to the CDSA.

For clarification purposes regarding electronically generated and/or retained records, as per Health Canada's policy which is stated in "Electronic Transmission of Prescriptions Policy Statement and Guidelines for Pharmacists" electronically generated and retained records are acceptable documentation requirements.*

Questions?
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