

## Pharmacy Narcotic and Controlled Drugs Record Keeping and Other Requirements

Pharmacists are no longer required to submit bi-monthly Narcotic and Controlled Drugs sales reports to the Office of Controlled Substances.

However, in accordance with the *Narcotic Control Regulations* and the *Food and Drug Regulations*, pharmacists are still required to maintain, on their premises, up-to-date records (paper or electronic) of their purchases and sales transactions. This information must be made available, upon request, to the Minister of Health or a designated representative. Pharmacists are, however, to continue to exercise their professional responsibilities and maintain the same high degree of control over Narcotic and Controlled Drugs as done previously.

During routine field operations, SCP will monitor adherence to the regulatory requirements. SCP will advise the Office of Controlled Substances of any unresolved or critical concerns.

The purposes for SCP monitoring Narcotic and Controlled Drugs sales are:

- to assess the current level of control provided by pharmacists in the receipt, storage, security and distribution of Narcotic and Controlled Drugs;
- if substandard practices are noted, to encourage improvement;
- to reduce diversion and improper use of Narcotic and Controlled Drugs;
- to provide an opportunity for pharmacists to obtain clarification and interpretation of the legislation;
- if required, to accumulate details on the prescribing practices of certain practitioners;
- if required, to accumulate details on individuals receiving Narcotic or Controlled Drugs, pursuant to prescriptions where the medical need is questionable.

In order to assist pharmacists with this change, the following summary of federal legislation and SCP requirements has been developed to reduce complications when these records must be produced.

### 1) Filing of Narcotic and Controlled Drugs Prescriptions

- a) File N&G prescriptions in a separate file in sequence by date and number;
- b) Bundle, peg, or otherwise sort all N&G prescription hard copies into manageable groups of prescriptions, and enclose in a jacket or cover;
- c) Label N&G file covers in an appropriate fashion which clearly identifies the prescription series in that particular file (i.e.

prescription number and/or prescription date range);

- d) File prescriptions for Exempted Codeine Products in the N&G file;
- e) Keep N&G prescription records readily accessible for review for a period of **TWO** years;
- f) Make all N&G prescription files available at all reasonable times for audit or inspection by authorized inspectors of the Health Products and Foods Branch Inspectorate, the Saskatchewan College of Pharmacists or any other authorized individual or agency.

### 2) Sales Reports

- a) The pharmacy manager should review sales reports on a regular basis to ensure that all products required to be reported, are being reported;
- b) As required by federal legislation, maintain manual or computer generated sales reports of all reportable Narcotics & Controlled Drugs in a readily retrievable format;
- c) Sales reports must be readily available for review by authorized personnel;
- d) It is recommended that computer generated sales reports be printed with each month-end run, and filed in a readily retrievable location.

### 3) Receipt Records

- a) Maintain a manual or computer generated purchase report in a readily retrievable format;
- b) Print computer-generated purchase reports with each month-end run;
- c) As required, retain purchase invoices, or photocopies thereof, in a readily retrievable format, filed in order by date and invoice number;
- d) Ensure reports are dated for the date the product was received, not the invoice date;
- e) Include the strength of each medication.

### 4) Dispensing Details and Pharmacist Accountability

- a) Use a proper and complete cross-referenced paper audit trail for **G** repeats and **N** part-fills using the following procedure:
  - generate a new prescription record (a written or duplicate label is acceptable);
  - include a notation clearly indicating whether this is a **G** repeat or **N** part-fill so that the document will not be confused as being a new verbal order;
  - include the initials of the pharmacist generating the new record;

- assign this record a new prescription number and the current date;
  - reference the new record to the original prescription;
  - on the original prescription hardcopy, reference the new prescription number and date;
  - file the new record in sequence by date and prescription number.
- b) Ensure compliance to requirements for a straight Narcotic prescription;
  - c) Ensure compliance to proper repeat authority for Controlled Drugs;
  - d) Ensure compliance to the fact that Narcotics cannot be repeated, but that they may be dispensed in divided doses, subject to professional discretion, if total quantity is indicated on the order;
  - e) Ensure compliance that orders for straight Narcotics cannot be released unless a written, dated and signed order is received.

**5) Regular Inventory Counts**

- a) Conduct, at least semi-annually, a complete physical count of all Narcotic and Controlled Drugs;
- b) Check for outdated inventory and follow the correct protocol for return or destruction of outdated N&Gs.

**6) Perpetual Balance**

- a) For all high risk N&Gs; **or**
- b) For all N&Gs; **or**
- c) For all reportable N&Gs.

**7) Destruction of Expired Narcotic and Controlled Drugs**

- a) Prepare an inventory of the expired items (i.e. name, form and quantity);
- b) Requests for local destruction of unusable narcotic and controlled drugs and substances should be directed to the Compliance, Monitoring and Liaison Division; (*See address right*)
- c) Upon receipt of their authorization, items can be disposed of in an appropriate manner in the presence of another health professional (i.e. another pharmacist, a nurse or a physician). Each party signs the form which is retained by the pharmacy.

**8) Miscellaneous Points, Loss, Theft, Forgery**

- a) Verify the signature of the practitioner if not known to the pharmacist;
- b) Refer to Bylaws 14.2.6 & 14.2.7 respecting the stocking & sale of Exempted Codeine Products;
- c) Any returns to a wholesale or emergency supplies to another pharmacist must be documented in the prescription file and the sale reported;

- d) **Loss, Theft or Forgery** should be reported directly to the Compliance, Monitoring and Liaison Division; (*See address below*)
- e) Report **forgeries** on an HPB Forgery Report Form;
- f) Report **loss or theft** on an HPB Loss/Theft Report form within 10 days of its discovery. Fax a copy to Health Canada (fax number on form) and one to the Provincial Regulatory Authority. Keep original at the Pharmacy.
- g) Refer to the SCP policy on "*Facsimile Transmission of Prescriptions*" regarding protocols for the acceptance of fax orders for N&G Drugs.

**Compliance, Monitoring and Liaison Division**

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For additional details please consult the appropriate federal legislation, the SCP Regulations Chart, and the Security Guidelines.