



National Association of Pharmacy Regulatory Authorities
Association nationale des organismes de réglementation de la pharmacie

Benzodiazepines Regulations:

Model Operational Procedures for Pharmacists complying with the requirements of the Benzodiazepines and Other Targeted Substances Regulations in Community & Institutional Practices

Since the enactment of the *Benzodiazepines and Other Targeted Substances Regulations* on September 1 2000, the pharmacy licensing bodies have responded to hundreds of inquiries from members in both hospital and community settings seeking clarification on various operational aspects of the legislation.

To achieve a consistent application and understanding of this federal legislation, the Registrars of NAPRA's Inter-provincial Pharmacy Regulatory Committee (IPRC) in conjunction with the Canadian Society of Hospital Pharmacists developed model guidelines to assist pharmacists complying with the requirements of the *Benzodiazepines and Other Targeted Substances Regulations* in community and institutional practices. These guidelines have also been reviewed by Health Canada's Office of Controlled Substances.

This document was approved by NAPRA Council in November, 2001.

1. Advertising
Notwithstanding provincial rules permitting the advertising of drugs, Targeted Substances cannot be advertised to the general public.
2. Diversion
Any loss or theft of Targeted substance must be reported to the federal Minister of Health within ten days of discovery and a copy of the report is to be forwarded to the Provincial or Territorial Pharmacy Regulatory Authority. Loss and theft reporting forms are available through the federal Office of Controlled Substances, Compliance, Monitoring and Liaison Division, Address Locator 3502B, or by telephone at (613) 954-1541 or by fax at (613) 957-0110.
3. Pharmacists receiving Targeted Substances
Pharmacists receiving Targeted Substances from a licensed dealer, another pharmacy or hospital must keep a record (either in a register or an invoice record system) showing the brand name, quantity (where applicable including package size and number of packages), strength, the name and address of the supplier, and the date it was received. The record must be kept for a minimum of 2 years or longer if required by provincial pharmacy legislation.

In the hospital setting, only a pharmacist or practitioner practising in the hospital and authorized by the person in charge of the hospital may order a Targeted Substance on behalf of the hospital.
4. Storage
Targeted Substances received by the community pharmacy, hospital pharmacy department or nursing unit must be stored in a secure environment.



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5. Pharmacists' prescription records

Pharmacists are required to keep on file all written prescriptions and a written record of verbal prescriptions for two years from the last filling date. (Provincial or Territorial rules may require that the record be retained longer.) Prescriptions for Targeted Substances may be filed in the regular prescriptions and not in the separate file created for narcotic and controlled medications.

The Regulations do not specifically require that, in hospitals:

- (a) all issues of Targeted Substances to and returns from nursing units be recorded,
- (b) the receiving nursing unit signs for the receipt of Targeted Substances,
- (c) the recording of administered doses to patients be on a document other than the Medication Administration Record (MAR), or that
- (d) a dose which is not administered to the patient, but returned to stock, be documented

However, the person in charge of the hospital may wish to implement additional controls should these be required in that particular setting.

6. Prescription refills

The pharmacist can refill a prescription for a Targeted substance where refills are authorized by the practitioner and the pharmacist makes documentation at the time of the refill. Refills must be provided in accordance with the interval that may be specified on the prescription.

A prescription cannot be refilled one year after the date on the prescription regardless of remaining refills.

7. Prescription transfers

With Targeted Substances, a pharmacist may transfer the remaining refills of a prescription to another pharmacist in another pharmacy. Section 54 prohibits the further transfer of the prescription once it has been received at a second pharmacy. As with Schedule F medications, a prescription cannot be transferred more than once by any one pharmacist. The pharmacist receiving the transferred prescription may not further transfer remaining refills.

8. Prescribers of Targeted Substances

Only a licensed medical, dental or veterinary practitioner can prescribe Targeted Substances.

9. Destruction of Targeted Substances

If the pharmacist deems it appropriate to destroy Targeted Substances, prior approval from Health Canada is not required. However, records including the name, strength per unit, and quantity of the Targeted substance destroyed must be kept for 2 years, or longer if required by provincial or territorial pharmacy legislation.

The destruction must render the product unusable and it must be witnessed by another health care professional. An exemption is made for hospital practice where a hospital employee who is a health care professional, may destroy an opened ampoule containing amounts of a Targeted Substance without a witness.



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10. "Double-doctoring" and possession
As described in Section 4 of the *Controlled Drug and Substance Act*, "double-doctoring" and rules for possession apply for Targeted Substances.

11. Exporting Targeted Substances
The regulations prohibit the exportation of Targeted Substances by pharmacists, including through the mail, pursuant to a prescription for a patient residing outside Canada.