



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

## Frequently asked questions on the Benzodiazepines and Other Targeted Substances Regulations

### Questions and Answers Regarding the Guidance Document for Pharmacist - published August 29, 2000

**Q:** As of September 1, 2000, pharmacists must keep records of their receipt of Targeted Substances from licensed dealers, other pharmacists or hospitals. Was it the Branch's intention that pharmacists take an inventory of their existing stock as of this date, as well?

**A:** The regulations did not require that pharmacists take an inventory of Targeted Substances on September 1, 2000. However, since pharmacists must keep records of received, dispensed and supplied quantities as of September 1, 2000, an inventory of existing stock could be useful to have.

**Q:** If pharmacists are to keep records of receipts of Targeted Substances but are not required to maintain sale records (other than regular prescription records), how can they fulfil their obligation to report losses to the Minister? How will the pharmacist know how much or when a loss has occurred?

**A:** One way a pharmacist can fulfill this obligation is by applying the same procedure that is currently used for non-reportable narcotics and controlled drugs, i.e. by checking the physical inventory of the drugs against the record of receipts and prescription files.

**Q:** If a Targeted Substance is properly transferred from Pharmacy "A" to Pharmacy "B", can Pharmacy "B" then transfer it to Pharmacy "C" if requested (providing that all the administrative requirements for transfer are met)?

**A:** Section 54 of the Regulations permits the transfer of a Targeted Substance prescription from Pharmacy "A" to Pharmacy "B". However, this section prohibits Pharmacy "B" from then transferring it to Pharmacy "C".

**Q:** Does the *Controlled Drugs and Substances Act* regarding trafficking, possession and double doctoring also apply to Targeted Substances?

**A:** The "trafficking" provisions of the *Controlled Drugs and Substances Act* applies to the substances listed in Schedules I to IV of this Act. Thus, the "trafficking" provisions apply to all Targeted Substances, because they are currently all listed in either Schedules III or IV of the Act.

The "possession" offences in the *Controlled Drugs and Substances Act* applies only to drugs listed in Schedules I to III of the Act. Targeted Substances meeting this requirement are listed in Part 2 of Schedule I of the *Benzodiazepines and Other Targeted Substances Regulations*. Flunitrazepam is currently the only Targeted Substance for which there is a "possession" offence.

Sub-section 4(2) of the *Controlled Drugs and Substances Act* makes it an offence to seek or obtain a substance listed in Schedules I to IV of this Act from a practitioner, unless the person discloses to the practitioner particulars relating to the acquisition by the person of every substance in those Schedules, and of every authorization to obtain such substances, from any other practitioners within the preceding thirty (30) days. Thus, the "Double Doctoring" prohibition applies to all Targeted Substances as currently all are listed in either Schedule III or IV of the Act.



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**Q:** Where are the requirements for transferring a Targeted Substance to a person authorized by the Minister?

**A:** The conditions under which a Targeted Substance may be provided by a pharmacist to a person to whom an exemption has been granted under section 56 of the Act are described in paragraph 55(1)(d) of the Regulations.

**Q:** Can pharmacists continue to mail out benzodiazepines to patients who are residing outside of the country?

**A:** As of September 1, 2000, pharmacists are not permitted to mail a Targeted Substance to another country. This activity is considered an exportation and only Licensed Dealers can export a Targeted Substance, after they have received an export permit from the Office of Controlled Substance.

**Q:** Are faxed prescriptions acceptable for dispensing benzodiazepines?

**A:** The issue of faxed prescriptions was discussed with the National Association of Pharmacy Regulatory Authorities (NAPRA) a few years ago. At that time, NAPRA presented a document establishing conditions under which prescriptions, including those for narcotics and controlled drugs, could be transmitted using facsimile technology. This document is available on NAPRA's website. The Office of Controlled Substances is not prohibiting the use of facsimile technology for the transmission of prescriptions for Targeted Substances when the following conditions are met:

- the provincial licensing authority has no objection with respect to the utilization of facsimile technology for the transmission of prescriptions for Targeted Substances and;
- control measures, as described in NAPRA proposal, are in place to prevent diversion.

**Q:** If a practitioner or a pharmacist has his/her narcotics and/or controlled drugs prescribing and purchasing privileges restricted, does this restriction also apply to Targeted Substances as of September 1, 2000?

**A:** The current restriction does not cover Targeted Substances. Specific restriction notices with respect to those substances would be issued under the *Benzodiazepines and Other Targeted Substances Regulations*.

#### **Questions and Answers Regarding the Guidance Document for Hospitals - published August 29, 2000**

**Q:** What are the record keeping and physical security requirements for hospitals?

**A:** The person in charge of a hospital is responsible for determining the appropriate level of control within the institution and to take any steps that are necessary to ensure the security of Targeted Substances.

Records should be kept in a manner that permits the tracking of Targeted Substances, the conduct of an audit or investigation and allows the detection of any loss and theft.



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The requirements with respect to record keeping are described in section 66 of the regulations which state the following:

"The person in charge of a hospital must record or cause to be recorded the following information:

- the brand name or, if the Targeted Substance does not have a brand name, the specified name, the quantity of any Targeted Substance received by the hospital and the date on which it was received;
- the name and address of the Licensed Dealer, pharmacist or other hospital that sold or provided the Targeted Substance;
- the disposition of the Targeted Substance and the date of its disposition; and
- the name and address of any out-patient to whom a Targeted Substance is sold or provided under section 64."

In addition, sub-sections 2 (2) and (3) provide the information that must be recorded and the documents that must be kept in case of destruction of Targeted Substances.

With regard to the storage of Targeted Substances, section 6 states that Targeted Substances must be stored in the place used for conducting business or professional practice and in an area in that place where only authorized employees have access.

**Q:** Are hospitals expected to report to the Minister every single loss of a Targeted Substance dose on a day-to-day basis? If so, please provide a suggested method to do so.

**A:** Any loss or theft of a Targeted Substance must be reported to the Minister within ten days of its discovery. The Loss and Theft form should be completed and returned to the Office of Controlled Substances. This form can be obtained from the Office of Controlled Substances.

**Q:** Destruction of an open ampoule, e.g. Valium 10mg/2ml ampoule for seizure. If there is 1ml left over, how should the nurse and pharmacist handle it? Does the nurse need to document such destruction? Is there a need for witness to destruction and signature of witness?

**A:** Subsection 2(2) and (3) of the Regulations specify that the remainder of an open ampoule, the partial content of which has been administered to a patient, may be destroyed by a licensed health professional without a witness. Such a destruction needs to be documented. As part of the security measures in place and in order to prevent diversions, a hospital may choose to increase this regulatory requirement.

**Q:** Most hospitals do not have a separate numbering system for narcotics because they are ward stocks. The accountability of individuals involved in the process lies in the narcotic flow sheet that nurses sign for doses administered to patients. If we do not use such sheets for Targeted Substances, do we have to number the prescriptions in a separate way from other drugs?

**A:** There is no requirement for a special prescription numbering system for Targeted Substances in hospitals. It remains with the hospital to determine what will be required as measure to fit into the overall hospital control strategy.

**Q:** In servicing homes for aged persons, should we refer to these individuals as out-patient?



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**A:** The hospital provisions of the *Benzodiazepines and Other Targeted Substances Regulations* apply to establishments that are licensed, approved or designated as a hospital under the laws of a province to provide health care and treatment to individuals. Whenever a nursing home meets that definition, the Hospital's Part of the Regulations applies. A hospital may only provide drugs to either an in-patient or an out-patient of that hospital.

Other facilities that do not meet the definition of a hospital are excluded from the application of Part 4 of the Regulations. However, in these instances the dispensing will follow requirements for practitioners and pharmacists.

**Q:** How should hospitals handle the destruction of Targeted Substances returned by a patient or by the person responsible for the estate?

**A:** For returns from a patient, the regulatory procedure used for the destruction of Targeted Substances applies along with the recording of the source of the substance.

For deceased patients, the form "Destruction-Estate" should be used and the drugs destroyed. This form can be obtained from the Office of Controlled Substances.

**Q:** How do pharmacists record an overage or shortage of a Targeted Substance?

**A:** Overages or shortages should be recorded in the manner currently used for narcotics and controlled drugs.

**Q:** Respiratory Technicians (RT) often request a stock of Midazolam vials for the purpose of administering to endoscopy patients prior to procedures. They will sign later in charts. Pharmacy does not document patients' or RT's names for such usage. Can Pharmacy still supply Benzodiazepines in such manners? What extra documentation is needed?

**A:** Should the administration of a Targeted Substance to a patient prior to endoscopy procedures fall under the scope of their accepted practice, a physician's order must be issued for each patient prior to this procedure. Records must be kept in order to follow the flow of distribution of Targeted Substances from the pharmacy department to the administration of these drugs to the patient.

#### **OTHER QUESTIONS**

**Q:** How do the new regulations affect the dispensing privileges of nurse practitioners?

**A:** As nurse practitioners are not physicians, dentists, veterinarians or pharmacists, the Regulations do not grant them dispensing privileges.