



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

Benzodiazepine Regulations: Guidance Document for Hospitals

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Guidance Document for Hospitals

Subject: Benzodiazepines and Other Targeted Substances Regulations

The *Benzodiazepines and Other Targeted Substances Regulations* have been published in Canada Gazette, Part II, on June 21, 2000. They will come into force on **September 1, 2000**. They are available on the Therapeutic Products Programme website at the following location <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/schedule.html>

The following document is provided to explain regulatory requirements coming with the promulgation of these new regulations. Attached is a list of targeted substances to whose the regulations will apply.

Orders

Only a pharmacist or a 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.

Administration or provision to a patient

A targeted substance may only be sold, provided or administered to a patient or an animal under treatment as an in-patient or a out-patient of the hospital pursuant to a prescription or authorization issued or given by a practitioner practising in the hospital.

Supply to non-patients

A targeted substance may be sold or provided to the following persons, without a prescription, upon receipt of an order specifying the name, quantity and, if applicable, the strength per unit of the targeted substance :

- a) a licensed dealer who sold or provided the targeted substance or who is licensed to destroy targeted substances other than those that he produced, made, assembled, sold or provided,
- b) a practitioner or a pharmacist if the order states that the targeted substance is required because of a delay or shortfall in an order placed for the substance,
- c) another hospital, if the order is placed by a pharmacist or practitioner practising in the other hospital and authorized by the person in charge of that hospital to order targeted substances on behalf of that hospital and if the order states that the targeted substance is required because of a delay or shortfall in an order placed for the targeted substance,
- d) the Minister, if the order is written and signed on the Minister's behalf,
- e) a person to whom an exemption with respect to the targeted substance has been granted under Section 56 of the Controlled Drugs and Substances Act and that person is an employee of or associated with the hospital and the order is written and accompanied by a copy of the exemption.



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Orders from a licensed dealer, a pharmacist, a practitioner or another hospital can be verbal. In such cases, the following information must be recorded before filling the order :

- a) the date on which the order was received,
- b) the name and address of the person placing the order,
- c) the brand name of the targeted substance or, if the substance has no brand name, the specified name,
- d) the quantity of the targeted substance ordered,
- e) the name of the person recording the information . This person should be a pharmacist practising in the hospital or an individual authorized by the person in charge of the hospital to fill orders on behalf of the hospital.

Records

The following information must be recorded :

- a) the brand name or, if the targeted substance has no brand name, the specified name , the quantity of any targeted substance received by the hospital and the date on which it was received,
- b) the name and address of the licensed dealer, pharmacist or other hospital that sold or provided the targeted substance,
- c) the disposition of the targeted substance (transactions such as distribution to a ward, supply to non-patients, returns to licensed dealers, destruction,etc...) and the date of its disposition,
- d) the name and address of any out-patient to whom a targeted substance is sold or provided.

Although it is not specified in the regulations how this information is to be recorded, the information should be recorded in a manner that permits an audit or an investigation to be conducted.

Destruction

The person in charge may destroy a targeted substance if the following conditions are met :

- a) the hospital records, before the destruction, information with respect to the destruction, including the name, strength per unit and quantity of the targeted substance to be destroyed,
- b) the targeted substance is destroyed using a method of destruction that conforms with all applicable federal, provincial and municipal environmental legislation,
- c) the person records the date of destruction,
- d) the destruction is witnessed by a pharmacist or a practitioner,
- e) immediately after the destruction, the person who destroyed the targeted substance and the witness sign and print their names on a joint statement, indicating that they witnessed the destruction and that the targeted substance has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.

There will be no authorization or approval document issued by the Office of Controlled Substances with respect to this activity.

Open ampoule

The remainder of an open ampoule containing a targeted substance, the partial contents of which have been administered to a patient, may be destroyed by a hospital employee who is a licensed health professional without a witness.

Closure

Whenever a hospital closes or the pharmacy department within a hospital closes, the person in charge of the hospital must inform the Minister of the date of the closure, the location to which the



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targeted substance was moved and the quantity of the targeted substance that was moved. This has to be done no later than ten days after the closure.

Storage

The person in charge of a hospital must store a targeted substance in a place used for the purpose of conducting their business or professional practice and in an area in that place where only authorized employees have access. The person in charge of the hospital must take any reasonable steps to ensure the security of the targeted substances and to prevent their loss or theft.

Loss and Theft

The person in charge of the hospital must report to the Minister any loss or theft of a targeted substance no later than 10 days after its discovery. Loss and Theft Report forms are available at the Office of Controlled Substances.

Since this document is only intended to summarize the main points of the content of the new Benzodiazepines and Other Targeted Substances Regulations, please refer to the regulations in their entirety.

Should you have any question on this document or on the Regulations, do not hesitate to contact us at (613) 954-1541.

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List of Benzodiazepines and other targeted substances :

1. Benzodiazepines, their salts and derivatives, including
 - (1) Alprazolam
 - (2) Bromazepam
 - (3) Brotizolam
 - (4) Camazepam
 - (5) Chlordiazepoxide
 - (6) Clobazam
 - (7) Clonazepam
 - (8) Clorazepate
 - (9) Cloxazolam
 - (10) Delorazepam
 - (11) Diazepam
 - (12) Estazolam
 - (13) Ethyl Loflazepate
 - (14) Fludiazepam
 - (15) Flurazepam
 - (16) Halazepam
 - (17) Haloxazolam
 - (18) Ketazolam
 - (19) Loprazolam
 - (20) Lorazepam



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- (21) Lormetazepam
- (22) Medazepam
- (23) Midazolam
- (24) Nimetazepam
- (25) Nitrazepam
- (26) Nordazepam
- (27) Oxazepam
- (28) Oxazolam
- (29) Pinazepam
- (30) Prazepam
- (31) Quazepam
- (32) Temazepam
- (33) Tetrazepam
- (34) Triazolam
- (35) Flunitrazepam
- 2. Clotiazepam
- 3. Ethchlorvynol
- 4. Ethinamate
- 5. Fencamfamin
- 6. Fenproporex
- 7. Mazindol
- 8. Mefenorex
- 9. Meprobamate
- 10. Methyprylon
- 11. Pipradol