

Guide to the Drugs Poisons and Controlled Substances Regulations 2006

health

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This guide has been prepared by the Drugs and Poisons Regulation Group to assist health practitioners who are regulated by the *Drugs, Poisons and Controlled Substances Act 1981* (the Act) and the Drugs, Poisons and Controlled Substances Regulations 2006 (the Regulations).

It is intended to explain aspects of the regulations, to assist in achieving compliance and to provide, in some areas, one, though not necessarily the only, means of compliance. It is not intended to reiterate requirements or attempt to provide a legal or exhaustive interpretation. As the Regulations may be amended from time to time, this guide must be a dynamic one, so care should be taken to refer to the current version.

This guide does not include guidance for those regulations or sections of the regulations that appear to be self-explanatory. Contents of the guide are presented in the numerical order of the regulations to which they relate.

Should further explanation or clarification of any aspect of the Regulations be needed, officers of the Department of Health can be contacted on telephone 1300 364 545.

Approvals granted by the Secretary (of the Department of Health)

Some regulations allow for the Secretary to approve details that are not contained within the Regulations, e.g. Criteria for computer-generated prescriptions and the poisons or classes of poisons that may be possessed by the categories of person that are listed in regulation 5.

Details of matters "Approved by the Secretary" are separately listed, on the Drugs and Poisons website, to assist those persons who are affected by the approvals.

Details of matters "Approved by the Secretary" may change from time to time, so care should be taken to refer to the current version.

Regulation 4 - Definitions

Since 1 July 2010, the date on which the Australian Health Practitioner Regulation Agency (AHPRA) became the authority responsible for registration of most health practitioners in Australia, the definitions of corresponding practitioners have been amended to indicate that the person must be registered under the Health Practitioner Regulation National Law.

This regulation also defines the terms ovulatory stimulant, prostaglandin, retinoid plus thalidomide and thalidomide-like substance (i.e. lenalidomide) by reference to the Poisons Code, which is available on the Drugs and Poisons website (<http://www.health.vic.gov.au/dpu/poicode.htm>).

Regulations 8, 9, 10, 11, 12 and 13 - "all reasonable steps"

Regulations 8(1)(b), 9(1)(b), 10(1)(b) and 12(1)(a) require "all reasonable steps" to be taken to ascertain the identity of a person. If a patient is not already known to the prescriber or supplier, this could include asking for identification, such as a Driver's Licence, Medicare card or Health Concession card.

The phrase "take all reasonable steps" is used to provide flexibility of approach according to the circumstances. An objective test must be applied to the particular circumstances as to whether or not the steps taken were sufficient. Such a test would involve considering if the steps taken would be in accordance with those an ordinary competent person, or member of the profession, would take if put in that situation.

Generally, for a person to "take all reasonable steps to ensure a therapeutic need exists" (Regulations 8(1)(c), 8(2)(b), 9(1)(c), 9(2)(b), 10(1)(c), 10(2)(b), 11(b), 12(1)(b), 12(2) and 13(b)), the following would need to be taken into account:

With respect to the person who requests the supply of, or to the person (or animal) for whom it is proposed to prescribe or supply the substance -

- The medical or medication history
- The presenting symptoms or described condition
- Any past or current drug therapy
- Any signs of misuse or abuse of medicines/drugs

With respect to the substance requested or proposed to be prescribed or supplied –

- Its suitability for the treatment of the presenting symptoms or described condition
- Its potential for misuse or abuse

When a person is well known to the practitioner and the therapeutic need has been previously established, very little effort may be required in "taking all reasonable steps to ensure a therapeutic need exists".

However, for a new patient, a more thorough effort might be required to satisfy this requirement, especially where there is cause to suspect drug abuse or misuse.

In such circumstances, "all reasonable steps" might include examining the patient and confirming the patient's claims by contacting purported previous prescribers or suppliers.

Regulation 12 refers only to a pharmacist supplying a drug of dependence other than by wholesale or on the prescription of a medical practitioner, nurse practitioner, veterinary practitioner or dentist. Therefore, this regulation will apply only to those substances in Schedule 11 (of the Act) that a pharmacist can legally supply to a member of the public, i.e., Schedule 2 or Schedule 3 poisons or, in the case of emergency supply under regulation 15(2), Schedule 4 poisons.

Regulation 16

In regulation 16(2), examples of satisfactory certification by the pharmacist who received the original prescription, or has supplied the substance previously include:

- the imprint of a pharmacy stamp and annotation as to the item(s) supplied, or
- the durable attachment of an adhesive sticker which identifies the pharmacist and item supplied, or
- the attachment of a completed PBS Repeat Authorisation

Regulation 17

A pharmacist is **not** permitted to supply a Schedule 8 poison on a prescription written by a veterinary practitioner unless that practitioner is registered in the State of Victoria.

A similar prohibition, which related to other registered health practitioners, became inoperative on 1 July 2010 - the date on which the Australian Health Practitioner Regulation Agency (AHPRA) became the authority responsible for registration of other health practitioners throughout Australia.

Regulation 26

The Secretary has given approval in general for a person referred to in regulation 25 to issue computer-generated prescriptions under circumstances that satisfy the criteria set out in "Approved by the Secretary".

As the criteria for computer-generated prescriptions may vary in different states, medical practitioners and other authorised prescribers are strongly advised to seek, prior to purchase, verification from the software supplier that their software enables compliance with the specified criteria.

Regulation 27

The phrase "as soon as practicable" is used to allow some flexibility according to the circumstances. The dictionary defines "practicable" as "capable of being done", "feasible". Accordingly, in this case some circumstances will demand a rapid provision of the document while in others a less speedy response may be acceptable. For example, in situations where a prescription is to be forwarded to the pharmacist by post, it would be considered sufficient compliance with this regulation if the prescription is written and posted so that it can arrive with the next mail delivery.

Regulation 29

The "date of recording" refers to the date on which the prescription is processed. It is recognised that the date of supply may be different from the date of processing a prescription.

Regulation 32

A pharmacist may have reason to believe that a prescriber is already aware of a previous supply or prescription in cases such as the following:

- There is an established general practitioner/specialist relationship
- The prescribers are in partnership, or work in the same practice
- A locum is working at the practice of the patient's usual prescriber

Division 4 - Storage

This Division specifies minimum standards for drug storage while giving the Secretary flexibility to set tighter security requirements when it is appropriate to do so.

Regulation 35(1)(f)

Expert advice received by the Department indicates that the requirement to be securely attached is satisfied by -

- **HARD CORE WALL:** The cabinet to be secured by use of four (4) Loxin or Dyna Bolts, each 10mm by 50mm minimum.
- **STUD AND PLASTER OR HOLLOW BLOCK:** The cabinet to be secured by use of four (4) 10mm coach bolts through wall and through 3mm mild steel backing plate. This backing plate must, at minimum, be the same size as the back of the drug cabinet.

Division 5 - Records

This Division seeks to ensure that adequate records are kept without restricting the method of keeping records.

Regulation 38

This regulation defines the "transactions" for which records are to be kept.

Regulation 39

This regulation specifies the persons who must keep true and accurate records. **Note:** This regulation does not require patients and their agents (e.g. family members or others acting on their behalf), carriers and messengers to keep records.

To satisfy this regulation, transaction records should include the following:

- Medical practitioners, nurse practitioners, pharmacists, veterinary practitioners, dentists, endorsed optometrists and endorsed podiatrists:
 - Records of administration and supply
 - Records of destruction or disposal
- Hospitals, aged care services with high care residents, bush nursing centres and other Health service providers:
 - Records of administration and supply
 - Records of transfers between different storage locations
 - Records of destruction or disposal
- Licence and permit holders:
 - Records of supply
 - Records of use - e.g., in manufacturing operations; in laboratory quality control work or as laboratory standards; administration to laboratory and other experimental animals.
 - Records of transfers between different storage locations - e.g., records of retention samples
 - Records of destruction or disposal
- Other approved persons (regulation 5):
 - Records of administration
 - Records of transfers between different storage locations
 - Records of destruction or disposal

Note: Regulations 50 and 51 identify the persons who may destroy Schedule 8 poisons.

Regulation 40

Regulation 40 specifies the details of transactions that must be recorded.

Regulation 40(1)(c) and (i): In the case of Schedule 4 or Schedule 8 poisons supplied or administered to an individual and specific person, the name of the prescriber and the name of the person carrying out the transaction must be entered in the record. However, it would be acceptable for the names to be entered in the form of a code (e.g., initials), provided the record makes provision for identifying the person to whom the code refers.

Regulation 41

Regulation 41 sets out the criteria by which the records are to be retained and retrieved. It does not limit the way the records are to be kept other than they must be true, accurate and readily retrievable. Therefore, it allows records to be kept in a book or on a computer provided that regulation 41(5) is satisfied in that, in the case of Schedule 8 or 9 poisons, the records cannot be altered, obliterated, deleted or removed without detection.

Records concerning Schedule 8 and Schedule 9 poisons have additional requirements, contained in Regulation 41(1), which specify that they:

- are able to be readily sorted by poison; and
- show a true and accurate balance of each poison; and
- show the name of the person carrying out the transaction

Compliance with the requirements of regulation 41 for Schedule 8 and Schedule 9 poisons can be achieved by using a *Drug register* or a *Drug administration book*, which is in the form of a bound volume with consecutively numbered pages and which can commonly be obtained from wholesale suppliers of Schedule 8 poisons.

Before introducing an alternative form of records, a person must ensure that the alternative form of records will comply with the requirements of regulation 41(1).

Regulation 41(1)(b) requires that a *true and accurate balance* be recorded in the transaction records for Schedule 8 and 9 poisons. This might not be achieved if a calculated balance rather than an actual balance is recorded.

To ensure a true and accurate balance is recorded, it may be necessary to confirm the stock on hand at the completion of a transaction. Frequent stock checks are recommended, especially where more than one person has access to the Schedule 8 or 9 poisons, e.g., in hospitals and in residential aged care services that opt to maintain a Schedule 8 and 9 poison drug register.

Regulation 46

Sub-regulation (1), (2) and (3): The phrase "in writing in a legible and durable form" allows for other than handwritten orders, e.g., computer-generated medication charts. The phrase "confirm ... with his or her signature", allows for other than handwritten signatures (such as would apply with electronically transmitted orders).

Regulation 47

The phrase "as soon as practicable" is used to allow some flexibility according to the circumstances. The dictionary defines "practicable" as "capable of being done", "feasible". Accordingly, in this case some circumstances will demand a rapid provision of the document while in others a less speedy response may be acceptable.

For example, in situations where a prescription is to be forwarded to the pharmacist by post, it would be considered sufficient compliance with this regulation if the prescription is written and posted so that it can arrive with the next mail delivery.

Regulations 53 and 54

These regulations relate only to ovulatory stimulants, prostaglandins, retinoids and thalidomide, as defined in Regulation 4, when they are for human use. When they are for animal use, the substances are subject to the same controls as for other Schedule 4 poisons.

Part 4 - Schedule 3 poisons

The regulations for Schedule 3 poisons place similar requirements on all persons authorised under Section 13(1) of the Act (i.e., medical practitioners, nurse practitioners, pharmacists, veterinary practitioners and dentists) who may administer, prescribe or supply Schedule 3 poisons. Refer to the entry for regulations 8 to 13 for comments on the term "all reasonable steps to ensure a therapeutic need exists".

In cases where there is reason to believe a Schedule 3 poison might be being misused (e.g., overused) or abused, a person supplying the Schedule 3 poison should -

- in order to "take all reasonable steps to ensure a therapeutic need exists", make a record, similar to the record required for Schedule 4 poisons, of the details of the supply so that reference can be made to it if further supplies are sought in the future; and
- in order to demonstrate compliance with regulation 63(1)(b) and (c), confirm verbal directions for use on a dispensing label attached to the Schedule 3 poison

Regulation 61 - "all reasonable steps" by pharmacists

The requirement for a pharmacist to take "all reasonable steps" to ensure there is a therapeutic need before supplying a Schedule 3 poison is unlikely to be achieved unless the pharmacist is able to personally examine and communicate with the person seeking to obtain the poison.

Therefore, unless the pharmacist knows the person and has already taken the necessary steps to ensure a therapeutic need exists, Schedule 3 poisons must not be supplied in response to requests forwarded by correspondence or via the internet.

Note: This Part does not preclude the supply of a Schedule 3 poison for inclusion in first aid kits, e.g., in a school or workplace or for a first aid service such as St John Ambulance.

Regulation 69

This regulation does not preclude the filling of dose administration containers from the original containers in which poisons or controlled substances were supplied, provided the dose administration container is labelled so its contents can be identified (i.e. with the names, strengths and doses of all medications).

For further information

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