caring @home

Symptom management for palliative patients

Guidelines for the handling of palliative care medicines in community services

These guidelines have been developed by NPS as a part of the *caring@home* project and are endorsed by Palliative Care Australia. They represent a consensus-based approach to the handling of palliative care medicines by community services, and consider jurisdictional legislative requirements, policies and guidelines across all Australian states and territories.

ACKNOWLEDGEMENT

caring@home and NPS MedicineWise would like to acknowledge the many people and organisations who have contributed their time and expertise in the development and review of this document.

- ACT: ACT Health Protection Service
- ACT: Calvary Healthcare
- QLD: Medicines Regulation and Quality, Queensland Department of Health
- NSW: NSW Poisons Information Centre
- NT: Medicines and Poisons Control, NT Department of Health
- SA: Medicines and Technology Programs, Department of Health and Wellbeing, SA Health
- Tasmania: Department of Health and Human Services
- VIC: Drugs and Poisons Regulation, Department of Health and Human Services
- WA: Medicines and Poisons Regulation Branch, WA Department of Health
- National: Palliative Care Australia

CONTENTS

1. INTRODUCTION

Many patients receiving palliative care wish to remain at home for as long as possible. To help achieve this aim, they need rapid access to medicines to provide symptom relief. If symptom relief is not achieved, patients may need to present to their local emergency department and this can result in unwanted admissions to acute care facilities and poor patient outcomes.

Community service providers recognise the need for patients receiving home-based palliative care to:

1. have their independence and quality of life maximised – this includes optimal pharmacological management of symptoms related to their disease processes
2. remain at home for as long as is desired and/or possible
3. be provided with suitable support, including support for their carers, to enable their wishes to be fulfilled.

This document presents consensus-based best practice for the handling of medicines by individuals and staff of community service providers.

The guidelines may be used by community service providers to develop detailed protocols and procedures tailored to the requirements of their individual service or facilities. Such protocols and procedures support health professionals in the practice of handling and administering medicine to palliative care patients living at home.

These guidelines have been developed as part of the *caring@home* project.

2. STATE VARIATIONS

As part of the development of these guidelines state poison regulations were reviewed and expert advice was sought from state poisons departments. Similarities and differences between states were noted and state variations are listed within each section of the guidelines. We would like to acknowledge all the state poisons departments who took part in the development of these guidelines. It is recommended that community service providers refer to the poisons regulations listed in Appendix A for further guidance on the safe handling of medicines in their state.

3. GLOSSARY OF TERMS

- **adverse drug reaction** – a noxious and unintended response to a medicine that occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.
- **authorised person** – a registered health professional authorised to possess, administer, supply, dispense or prescribe a medicine.
- **carer** – a person who provides personal care, support and assistance to another person who has a disability, medical condition or mental illness, or who is frail and aged.
- **cytotoxic medicine** – a medicine that is toxic to cells.
- **designated person** – a person who has been designated by the community service provider to perform a specific duty within the palliative care setting.
- **dose administration aid** – a device where medicines are stored and divided into containers according to an administration period.
- **drug register** – a register or administration book to record the receipt, administration and any other transaction of all Schedule 8 medicines that are stored at the service.
- **health professional** – a person who provides preventive, curative and promotional care with the aim of meeting the health needs and expectations of populations and individuals. Also known as *healthcare practitioner, healthcare professional*.
- **medical practitioner** – a physician (doctor).
- **medication order** – a written order by an authorised health professional for a medication to be dispensed by a pharmacy for administration to a patient.
- **medication record** – a written history of orders for the administration of medicines to a patient.
- **own medicine** – the patient's prescription or over-the-counter medicine.
- **palliative care** – care provided for a person of any age who has a life-limiting illness, with little or no prospect of cure, and for whom the primary treatment goal is quality of life.
- **person responsible** – the person who has the authority to make healthcare decisions on behalf of a patient whose ability to make decisions is permanently or temporarily impaired. The person responsible can consent to most healthcare issues.
- **prescriber** – a health professional authorised to write prescriptions and medication orders and give directions (verbal or written) about administration and supply of prescription-only medicines.
- **Schedule 4 medicine** – also known as *prescription-only medicine*.
- **Schedule 8 medicine** – also known as a *controlled drug* is a medicine with a higher risk of abuse and dependence, classified by the Poisons Standard. Also known as a *drug of dependence, controlled medicine, controlled poison* or *narcotic substance*.
- **scheduled medicine** – a medicine that is scheduled under the national classification system according to the level of regulatory control over the availability of the medicine, required to protect public health and safety.
- **stock medicine** – a medicine that has not been individually supplied for a specific patient (for example, by a pharmacist on prescription).
- **substitute decision-maker** – a person appointed or identified by law to make health, medical, residential or other personal decisions on behalf of a patient whose decision-making capacity is impaired.
- **transcribing** – the process whereby someone other than the authorised prescriber writes on a medication order to direct the subsequent administration of medicine to a palliative care patient.

4. COMMUNITY SERVICE PROVIDERS

Community service providers may use these guidelines to develop detailed protocols and procedures tailored to their individual service or facilities.

4.1. Medicine management

A multidisciplinary approach to the development of policies, procedures and medicine management processes within an organisation is advisable. This approach may be applied to:

- the development and approval of written medicine policies and procedures
- the rationalisation of medicine use in relation to efficacy, safety and cost
- the analysis of medicine incident reports
- any recommendations concerning the ongoing education of staff
- any recommendations concerning quality activities relating to medicine administration.

4.2. Medicine storage

PART A: SERVICES THAT ADMINISTER PATIENTS' OWN MEDICINE

4.2.1. Storage: All medicines

Advise patients and their carers that, to ensure medicine safety and effectiveness, appropriate storage is important. Medicines should be stored according to the instructions on the label.

Generally, medicines are stored in their original container in a cool, dry place. The stability and effectiveness of some medicines depends on correct storage temperature – for example, those medicines requiring refrigeration.

Patients and carers who require assistance with medicine management may also need help to store medicines in a safe manner – for example, out of reach of children.

Some patients and carers may be unable to read or understand medicine labels and instructions because of minimal reading skills, low health literacy or limited English proficiency. These people may need more help with medicine management and safe storage.

4.2.2. When a patient needs to take medicine away from home

Patients should be advised on appropriate storage and transport. For example, medicines normally stored in the fridge can be put in a portable icebox or insulated box with a cooler block. Keep the temperature between 2°C and 8°C during transport.

4.2.3. Individual responsibility for medicine storage and security

Inform patients and carers that they are responsible for safe storage of all medicines in their home.

4.2.4. Individual disposal of medicine

Medicines should be disposed of safely and in a way that is not harmful to the environment. Unwanted and expired medicines should be returned to community pharmacies, where they will be disposed of via the Return Unwanted Medicines (RUM) project, which provides a free and safe method for disposal.

Individual services should develop guidelines for the disposal of patient medicines and for the disposal of a patient's own stock of medicines after obtaining consent from the patient. See section 4.2.10 *Service disposal of medicine* for more information on the disposal of medicines. These guidelines can be adopted from Guiding Principles for Medicine Management in the Community.[1, 2]

PART B: SERVICES WITH HEALTH SERVICE APPROVAL

4.2.5. Service responsibility

The service manager or other designated person has overall responsibility for the storage of all medicine at the service. If the manager is not a registered nurse, this responsibility may be delegated to a specified senior nurse or nursing position (designated nurse) depending on state or territory law. This authorised person should ensure that correct storage conditions are met, in relation both to the legislation and manufacturer recommendations.

State and territory variations: Service responsibility

South Australia

The designated nurse or designated midwife for a ward of a health service facility is responsible for the storage of medicine at the service.

Western Australia

If scheduled medicines are stored as stock, a permit is required. The permit holder must be registered through the Australian Health Practitioner Regulation Agency (AHPRA) and have authority to possess and administer scheduled medicines under the Medicines and Poisons legislation. See the *Medicines and Poisons Act 2014* for further information.

Victoria

A division 1 registered nurse must be nominated as responsible for the storage of all medicine at the service.[3]

4.2.6. Ownership of medicine

Using one patient's own medicine as stock medicine for other patients is illegal, even if the medicine has been returned or donated to the organisation.[4]

4.2.7. Security: Schedule 8 medicines within the confines of the service

Storage of Schedule 8 medicines may depend on the number of doses to be stored and should comply with state and territory legislated requirements. Schedule 8 and Schedule 4 medicines are stored in a secure container that is not accessible to members of the public and is locked when not in use. The key or combination to the container is kept in the possession of the authorised person at all times.

The container should comply with the requirements of the relevant state or territory legislation, as outlined below.

State and territory variations: Service responsibility

Australian Capital Territory

Storage requirements for controlled medicines are outlined in the *Medicines, Poisons and Therapeutic Goods Act 2008*.

New South Wales

Storage requirements for controlled medicines are outlined in Medication Handling in NSW Public Health Facilities.

Northern Territory

Storage requirements for controlled medicines are outlined in Schedule 8 Substances, Volume 2 – Storage & Transportation.

Queensland

Storage requirements for controlled medicines are outlined in *Health (Drugs and Poisons) Regulation 1996: Section 119: Storage of controlled drugs generally*.

South Australia

Storage requirements for controlled medicines are outlined in Code of Practice for the Storage and Transport of Drugs of Dependence.

Tasmania

Narcotic substances must be stored apart from other goods in an enclosure that is constructed and secured in a manner approved by the Secretary of the Department of Health and Human Services. A medical practitioner, authorised health professional or authorised nurse practitioner may, for emergency purposes, keep narcotic substances in a bag in a vehicle or room that is kept securely locked when not occupied.[5] Storage requirements for narcotic substances must comply with Regulation 25(l)(a) of the Poisons Regulations 2008.

Victoria

There are exceptions in aged care services when controlled poisons are supplied in certain dose administration containers. See the Drugs, Poisons and Controlled Substances Regulations 2017 for more information.

Western Australia

Storage requirements for Schedule 8 medicines are dependent on dose: see Regulation 95 of the Medicines and Poisons Regulations 2016 for further guidance.[6]

4.2.8. Storage: Temperature-dependent medicines

Store all medicines at the temperature specified by the manufacturer and stated on the original packaging. Most medicines should be stored below 30°C, although some should be stored below 25°C and others must be stored in refrigerated conditions – taking care not to freeze them.

When possible, medicine that is in use or in the possession of the authorised person should be contained in a thermally-appropriate container such as an icebox or insulated box. Examine stock regularly for any visible discolouration, irregularities, precipitates and impurities.

Individual pre-prepared medicines should be stored in accordance with the manufacturer's recommendations.

Temperature may affect the stability of subcutaneous infusions. See section 4.11.1 *Storage of subcutaneous infusions* for more information.

4.2.9. Stock rotation

It is recommended that services have in place a routine procedure of stock rotation and monitoring of medicine expiry dates to prevent the accumulation of old stock.

4.2.10. Service disposal of medicine

Medicines should be disposed of safely and in a way that is not harmful to the environment. Services should develop their own guidelines for appropriate disposal of pre-prepared, excess and unused medicines.

This excludes cytotoxic medicines which are subject to other disposal restrictions. Refer to individual state and territory regulations for guidance on the disposal of cytotoxic medicines.

Unwanted and expired medicines should be returned to the community pharmacy to be disposed of via the Return Unwanted Medicines (RUM) project, which provides a free and safe method for disposal.

Note: Schedule 8 medicines should not be placed in RUM bins for disposal.

4.2.11. Emergency medicine for home visits

A service may hold a small range of medicine in a secure bag that can be taken on home visits for use in an emergency. The service should determine a set list of the medicines and quantities held in the bag. The medicines from this list may be obtained by requisition as stock medicine, as described in section 4.3 *Acquisition of stock medicine*. While held at the service, the emergency medicines bag should be securely stored.

Although Schedule 8 medicines should not be routinely included in an emergency medicines bag, in some situations or locations a service may consider this to be necessary. In these cases, it is recommended that only a minimal quantity be held in the emergency bag supply. Keep a register of Schedule 8 stock and its use, as per state and territory legislative requirements.

Schedule 8 medicines being transported between the service's place of practice and a patient's home should be kept in a lockable metal container – refer to section 4.2.7 *Security: Schedule 8 medicines within the confines of the service.*

Only personnel who are authorised to possess, supply and administer emergency stock medicine to patients may access and carry the emergency medicines bag – refer to section 4.5.1 *Who can administer?* Administration should also be authorised – refer to section 4.4.1 *Medicine authorisation.*

State and territory variations: Emergency medicine for home visits

Victoria

The service needs to hold a Health Services Permit to lawfully possess Schedule 4 or Schedule 8 poisons that have not been supplied for the treatment of a specific patient. See the Drugs, Poisons and Controlled Substances Regulations 2017: Part 1 – Possession for more information.

Tasmania

The registered nurse must be granted an authorisation under Section 25A of the Poisons Act 1971 to be in possession of restricted or narcotic substances. See the Tasmania Poisons Act 1971 for more information.

4.2.12. Transport

Keep medicine that is transported between the service facility and a patient's home in a lockable metal container that has:

- either a combination lock or a tamper-proof lock
- sturdy tamper-proof hinges with continuous welding to the lid and body – they should also be concealed on the inside of the container, if possible.

While on home visits to patients, avoid storing medicine in a vehicle wherever possible. However, if required medicine may be temporarily secured in the boot of a vehicle, provided:

- the authorised person is in possession of the key to the vehicle, and
- the scheduled medicines are not visible from the outside of the vehicle (for example, stored under a luggage cover in the back of a station wagon).

Following the visit, ensure that the metal container is locked and safely stored in the vehicle and return it to the service at the earliest convenience.

Note: Be mindful of the vehicle temperature if medicine is stored inside and ensure that any specified storage requirements are followed.

State and territory variations: Transport

Western Australia

See Sections 90(3) and 95(3) of the Medicines and Poisons Regulations 2016 for further information on the necessary steps to be taken to protect medicine from being lost or stolen when attending a patient at a place other than the health professional's usual place of practice.

4.3. Acquisition of stock medicine

A service may hold a small range of stock medicine for use on home visits in an emergency, subject to state and territory regulations. The service should determine the list of medicines held and the quantities.

A nurse or medical practitioner administers the record of stock medicines. This record should show each medicine's name, strength and quantity; the patient's name; the health professional's name and signature; and the date administered.

See section 4.6.1 *Drug register* regarding record keeping for Schedule 8 medicines.

State and territory variations: Stock medicine

Northern Territory

The definition of a nurse includes most enrolled nurses.

In order to possess and use stock medicines, a written purchase order must be signed by an authorised staff member. The medicine supplier has the right to request evidence that the facility can hold the particular medicine ordered and ask for the credentials of the person ordering. The stock medicine list must have been approved in content and quantity through the governance process for the service. Regular review of this list and any incidents is required.

Queensland

Endorsed enrolled nurses are authorised to administer medicines 'under supervision' but are not authorised to supply them.[4,7]

Victoria

The definition of a nurse includes most enrolled nurses.

Palliative care services need to hold a Health Services Permit to lawfully possess Schedule 4 and Schedule 8 poisons that have not been supplied for the treatment of a specific patient. See the Drugs, Poisons and Controlled Substances Regulations 2017 for further information.

4.4. Prescribing

4.4.1. Medicine authorisation

Schedule 4 medicines should not be supplied or administered to a patient unless an authorised prescriber has provided a prescription or order. The instruction should preferably be written on a medication order but emergency telephone orders may also be given (see section 4.4.2 *Emergency telephone orders*).

The prescriber should enter the following information on the medication order; black ink is preferred:

- the patient's identifying particulars
- any drug allergies
- the name, strength and form of the medicine
- full directions for medicine use including the dose, route and frequency of administration
- the maximum dose allowable over a 24-hour period
- the minimum time periods between dosing
- the nominated review period, as per state and territory regulations
- the date of the medication order
- the prescriber's name (printed), signature and date (each medication order should be signed – it is not sufficient to sign across several orders).

The medication order should bear the name of the community service provider.

The prescriber should regularly review medication orders. Services should implement their own procedures for the review of medication orders.

The details on the medication order should also be included in the patient's medicine record so that a complete and up-to-date reference record is available. Any changes in dosage, route and/or frequency are included in this record.

State and territory variations: Medicine authorisation

Queensland

The period for review must not exceed 6 months for controlled medicines or 12 months for restricted medicines. When ordering PRN (as required) medicine, Queensland Health services should comply with the Statewide Medication Chart Guidelines.[8] The medication order must include the full directions for PRN use including dose, route and frequency of administration and the maximum dose allowable over a 24-hour period.

South Australia

Black ink is not required for the entry of information on the medication order.

Victoria

Administration of prescription-only medicine should be done in accordance with instructions on the label of the lawfully supplied medicine.

4.4.2. Emergency telephone orders

Where a patient is in urgent need of a medicine and the treating doctor is not in attendance, an authorised prescriber may give a telephone order.

The person receiving this order should be a registered nurse, a medical practitioner or a pharmacist. This person reads back the medication order to the prescriber to confirm that it is correct. The prescriber may need to confirm the order with a second person, depending on state and territory requirements.

The order should be recorded by the authorised health professional in the patient's medical record (or in the notes if no record currently exists). The dose given is also recorded in the patient's medicine record.

The prescriber confirms this record of administration within 24 hours and sends the original copy to the service provider. The service provider records in the patient's records that written authorisation has been received.

If the medicine is to be ongoing, the prescriber should either:

- write a prescription for dispensing at a community or hospital pharmacy, or
- write in the regular or PRN (as required) section of the medication order to authorise that the medicine can continue to be administered.

Note:

- It is recommended that services have in place a procedure to ensure that emergency telephone orders are followed up if confirmation is not forthcoming within the designated period.

State and territory variations: Emergency telephone orders

New South Wales and Victoria

Telephone orders do not need to be repeated to a second person if there is no second person available.[9]

South Australia

For controlled medicines, prescribers are required to confirm the order to a second person. Requirements for telephone orders are specified in Part 4 of the Controlled Substances (Poisons) Regulation 2011.

Western Australia

The prescriber must sign the medication chart or clinical record for Schedule 4 or Schedule 8 medicines within 24 hours of giving the direction. See Regulation 15(3) in the Medicines and Poisons Regulations 2016 for further information.

4.5. Medicine administration

4.5.1. Who can administer?

In considering who may administer medicine to a patient, a distinction is made between:

- stock medicine, as described in section 4.5.1.1 *Stock medicine* and
- a patient's own medicine, dispensed and labelled by a pharmacist on prescription or other lawful mechanism.

4.5.1.1. Stock medicine

Only an authorised person may administer Schedule 4 stock medicine as well as non-prescription scheduled medicines. Administration should be on the prior direction of a medical practitioner or nurse practitioner in accordance with the directions of the prescriber or standing order. See section 4.4.1 *Medicine authorisation*.

4.5.1.2. Patient's own medicine

On request from a community-based palliative care patient, their carer or substitute decision-maker, an authorised person can:

- prepare an injection using prescribed medicine directly from the patient's own labelled medicine container
- administer an injection using prescribed medicine directly from the patient's own labelled medicine container

- fill a dose administration aid with prescribed medicine directly from the patient's own labelled medicine container
- enable a patient to take or administer their own prescribed medicine, and/or
- assist a carer to administer a patient's own prescribed medicine.

Note: If a dose administration aid is considered appropriate, it is recommended that this be filled by a community pharmacist, although the patient's family may also assume this responsibility.

A health professional who is not an authorised person may, on request, provide assistance to enable a patient to take their own prescribed medicine. Such assistance includes the administration of prescribed medicine directly from the patient's own labelled medicine container or dose administration aid but excludes the preparation and administration of injections and the filling of a dose administration aid.

State and territory variations: Patient's own medicine

Tasmania

An aged care worker who is not a nurse may administer, or make available for self-administration, to another person who is being provided with community care service, a medicinal poison potent substance, restricted substance or narcotic substance under conditions specified in Regulation 95F of the Poisons Regulations 2008.[5]

Victoria

Except in the course of actual use of a poison or controlled substance, a person must not remove that poison or controlled substance from the container in which it was dispensed, sold or supplied. For more information, see Regulation 151(b) of the Drugs, Poisons and Controlled Substances Regulations 2017.

State and territory variations: Nurse-initiated medicine

Queensland

Nurse-initiated medicines can be selected from Schedule 2 and Schedule 3 categories.

4.5.1.3. Role of the carer

Carers need appropriate training to safely assist with medicine administration.

If a patient is unconscious or unable to consent to receiving medicine, their carer can be appointed as the person responsible. There is no requirement to complete forms or formally appoint the person responsible.

4.5.2. Transcribing

Only an authorised person can write and sign orders in a patient's medication record. The practice known as 'transcribing' should not occur. Similarly, attachments should not be added to the original medicine authorisation to extend therapy.

4.5.3. Procedure for administering medicine

See also section 4.4.1 *Medicine authorisation*.

A registered nurse administering a stock medicine refers directly to the prescriber's written instructions except in the case of emergency telephone orders (see section 4.4.2 *Emergency telephone orders*) or nurse-initiated stock medicine (see section 4.5.5 *Nurse-initiated stock medicine (single-dose only)*).

The same health professional should select and prepare the medicine. Each time a stock medicine is administered to a patient, it should be recorded on the patient's medication record or in the patient's notes.

The health professional should also:

- contact the prescriber for clarification if the medication order is unclear or ambiguous – or, if this is not possible, contact another medical practitioner or nurse practitioner, or pharmacist
- carefully read the label on the container and check the name and strength against the medication order to avoid selecting the wrong medicine
- use a new syringe and needle for each administration of an injected medicine
- discard any unused portion of a single-use ampoule according to workplace policies and document the dose administered in the medication order. Schedule 8 medicines should also be documented in the drug register.

4.5.4. Reconstituting

Medicine is left in the container as supplied by the community or hospital pharmacy (for example, medicine box or dose administration aid) and administered to the patient directly from that container, except when indicated below:

- A registered nurse may need to prepare up to 24 hours' supply of injectable 'as required' medicine if the patient's carer is unable to do so. This medicine may need to be stored in a fridge in a child-resistant and appropriately labelled container for the carer to administer to the patient at a later time. Each syringe should be individually labelled with the following:
  - medicine name and dose
  - date
  - signature of the registered nurse who prepared the medicine.

Manufacturers vary according to the recommended length of time that a particular medicine, in a pre-filled syringe, can be stored before administration. Further, there are no recommended times for some of the medicines used for symptom control in the last few weeks of life. Consensus-based practice is that pre-filled syringes, drawn up under aseptic conditions and secured with a bung, can be stored for 24 hours. This time may need to be extended to 48 or 72 hours for terminal palliative patients who may be geographically or otherwise isolated, to ensure symptom control and quality of life. Clinical judgement needs to be exercised when determining the risk-benefit balance between unlikely microbiological contamination and patient comfort.

See section 4.6.2 *Witness to administration and discarding of a patient's own medicine*.

See also section 4.5.1.2 *Patient's own medicine*.

Injectable medicines are a high-risk therapy for patients and health professionals. All injectable medicines drawn up in a syringe that will leave the hand of the person filling it should be labelled immediately, including those medicines intended for bolus use. If colour-coded labels are used when labelling syringes, the colour coding should be consistent with Australian and New Zealand Standards (see Appendix E *User-applied labels for use on syringes containing drugs used during anaesthesia*).

4.5.5. Nurse-initiated stock medicine (single-dose only)

The service may approve a list of unscheduled and Schedule 2 and Schedule 3 medicines that may be administered by a registered nurse/nurse practitioner without a medical practitioner's authorisation provided appropriate detailed written protocols for use are also developed.

Before administering a nurse-initiated medicine, it is the registered nurse/nurse practitioner's responsibility to ensure that there are no interactions with the patient's existing medicines. Check for all other medicines (including over-the-counter and complementary medicines) that might interact with prescription and non-prescription medicines. Contact the local pharmacy or poisons information centre for further guidance on medicine interactions.

- If there are no documented interactions, the medicine can be administered.
- If there are documented interactions, contact the prescriber to obtain appropriate instructions. A medicines review may be required to determine best management. Pharmacists and medical practitioners also have a responsibility to check there are no drug interactions.

After a dose of medicine from the approved list has been administered to a patient, make an indelible record on the medication order including, as a minimum, the following details:

- the date and time given
- the name, strength, route and dose of the medicine
- the reason for administration of the medicine
- the signature of the administering person, printed name and designation.

If a medicine from this list needs to be administered on a regular basis, a medication order should be written up and the medical practitioner's authority sought. A medicine review should be performed to assess the patient and to determine whether a regular order should be prescribed.

4.6. After-hours emergency situations

It is recommended that services develop procedures to deal with after-hours emergency situations. This includes provision for access to appropriately qualified health professionals.

See section 4.4.2 *Emergency telephone orders*.

See section 4.2.7 *Security: Schedule 8 medicines within the confines of the service* regarding storage of Schedule 8 medicines.

4.6.1. Drug register

The authorised person at the service keeps the drug register or administration book to record the receipt, administration and any other transaction of all Schedule 8 medicines that are stored at the service. The record in the drug register should be accurate and contemporaneous, made as soon as practicable after the transaction occurs, and definitely on the same day. The drug register should be kept in accordance with state and territory legislative requirements.

Each medicine and its strength, is written on a separate page in the drug register or column in the administration book. Patients' own medicines stored by the service are recorded on a separate page for each patient and each medicine.

Details required in the register should comply with state, territory and local policy regulations but generally include the following, in ink, as a minimum:

- the date of the 'transaction'
- the time of day (note: this is not a mandated regulatory requirement in Victoria)
- the name and address of each person involved (ie, the person it is being received from and the person it is being supplied to)
- the medicine name, strength and form
- the amount received, for medicine from the pharmacist
- the amount used, for administration of medicine to a patient
- the amount discarded, if only part of an ampoule or tablet is administered to the patient
- the balance of stock remaining after the transaction has been made
- the signature of the authorised person making the entry
- the signature of the person who witnessed receipt of the medicine, its administration to the patient or the discarding of the remainder; see also section 4.6.2 *Witness to administration and discarding of a patient's own medicine*. (note: a witness is not a mandatory requirement in Victoria)
- the prescription reference number if the medicine is supplied in accordance with a prescription.

The authorised person making an entry in the drug register should not make any:

(i) false or misleading entries

(ii) alterations, obliterations or cancellations (including crossing out or drawing a line through an entry). If a mistake is made, it must be left as it is, marked with an asterisk and the entry rewritten as appropriate. A note explaining the error must be made in the margin or at the foot of the page, initialled and dated.

State and territory variations: Drug register

Australian Capital Territory

An electronic controlled drug register may be used, ensuring that a separate record is kept for each form and strength of controlled medicine.[10]

A controlled medicine contained in a dose administration aid does not need to be recorded in the drug register if the medicine is held at a residential aged care facility or residential disability care facility.[10]

The requirements for entering information into the drug register are detailed in the Medicines, Poisons and Therapeutic Goods Regulation 2008, Section 543, noting that the time of dealing is not required.

Signing of register entries is mandated under the Medicines, Poisons and Therapeutic Goods Act, Section 52.

South Australia

A person making an entry in a drug register can cross out or draw a line through an entry as long as the entry is clearly legible.

Tasmania

For Schedule 8 poisons, the record should be kept for at least 2 years from the date on which the medicine is administered or supplied.

An electronic controlled medication register may be used provided it has been approved by the Department of Health and Human Services.

Victoria

Computerised records that cannot be altered or deleted are also lawful.

Western Australia

The record should also include the following:

- the strength and form of the medicine supplied or administered
- the address and date of birth of the person being treated
- the name and address of the prescriber
- the prescription reference number and the date of issue of the prescription if the medicine is supplied in accordance with a prescription.

For Schedule 8 poisons, the record should be kept for at least 5 years from the date on which the medicine is administered or supplied.[6]

4.6.2. Witness to administration and discarding of a patient's own medicine

Where a registered nurse visits a patient at home (or in another residential setting) to administer a Schedule 8 medicine that has been brought from the service, the nurse records the amount administered to the patient in the drug register.

Often it is not possible for a second staff member to be present at a patient's home to witness medicine administration and so, in this case, a countersignature in the register reflects only that a second person witnessed the removal of the medicine from the designated storage.

The actual amount administered and any amount discarded is also recorded in the patient's medication record by the administering nurse.

Where a patient holds a Schedule 8 medicine at home, no service register record is required when the medicine is administered by service staff.

State and territory variations: Witness to administration and discarding of a patient's own medicine

Australian Capital Territory

Those who witness the discarding of a controlled substance must be listed under Section 545 of the Medicines, Poisons and Therapeutic Goods Regulation 2008.

Victoria

Having a witness to the administration and discarding of a patient's own medicine is not a mandatory requirement.

4.6.3. Balance checks

It is recommended that the balance of Schedule 8 medicines held by the service be checked regularly, such as once a week, depending on state or territory requirements. This check can be carried out by a registered nurse and a second person and confirmed by a signed entry in the drug register on the relevant page for each medicine.

State and territory variations: Balance checks

Australian Capital Territory

There is no requirement for balance checks of controlled medicines. Individual institutions develop their own policies on the frequency of balance checks.

New South Wales

Balance checks of all Schedule 8 medicines held in the service must be made during March and September each year as a minimum, and at other times as deemed necessary by the director of pharmacy and approved by the drug and therapeutics committee.[9]

Northern Territory

The balance in the register must be correct at all times. It is up to the service to risk-manage this requirement and institute a balance check interval that suits its service.

Tasmania

A balance check is not legally required but is recommended.[5]

4.6.4. *Loss or theft of a Schedule 4 or Schedule 8 medicine*

Procedures following the loss or theft of a Schedule 4 or Schedule 8 medicine differ between the states and territories, as follows.

Australian Capital Territory

- For loss or suspected loss of a controlled medicine – notify the Chief Health Officer of the nature of the loss and how it occurred no later than 7 days after becoming aware of the loss.[11]
- For theft or suspected theft – notify a police officer and the Chief Health Officer in writing no later than 24 hours after becoming aware of the theft or suspected theft.

New South Wales

- Notify the Director-General of the pharmaceutical service.
- Make an accurate inventory of all medicines of addiction held at the premises and enter the particulars of the medicines held in a new drug register.

Northern Territory

- For loss or suspected loss of a controlled medicine – notify the Chief Health Officer of the nature of the loss and how it occurred no later than 7 days after becoming aware of the loss.

Queensland

- Inform the local police.
- As soon as practicable, report by telephone the loss to the Director of Environmental Health Service at the local Population Health Unit and follow their instructions.

South Australia

- In the case of a suspected theft, a report should be made to the South Australian Police and Controlled Substances Licensing, Department for Health and Ageing.
- In the case of unaccounted loss, a report should be made to Controlled Substances Licensing. A report to the South Australian police may also be required.

Tasmania

- The health professional who discovers the loss must inform another health professional as soon as practicable.

- Both health professionals must enter the details of the loss in the narcotic substances register and sign that entry, as soon as practicable.
- The health professional who discovered the loss must report the loss to the authorised officer as soon as practicable.
- In the event of theft of a narcotic substance, a local police officer and the pharmaceutical services branch should also be informed.

Victoria

- Immediately inform the Department of Human Services, Drugs and Poisons Unit.
- Notify the local police.

Western Australia

- Notify the CEO of the service in writing.

4.6.5. *Destruction of unusable Schedule 8 medicines*

Schedule 8 medicines that are stored at the service and have become unusable (for example, expired, damaged or no longer in use) should be destroyed in accordance with state and territory regulations.

State and territory variations: Destruction of unusable Schedule 8 medicines

Western Australia

Schedule 8 medicines can be destroyed only when they are no longer suitable for patient use because they are expired, contaminated, damaged or otherwise unfit for human or animal use.

Destruction of Schedule 8 medicines must be independently witnessed by another authorised person.

Each time a Schedule 8 medicine is destroyed, this action must be recorded in the approved transaction register, including the date, item and quantity destroyed and the reason for destruction.

Tasmania

A person who is licensed or authorised to be in possession of a narcotic substance must not wilfully destroy that narcotic substance or cause or permit the narcotic substance to be destroyed.

4.6.6. *Loss of a drug register*

If the service's drug register is lost or destroyed:

- immediately report the fact and the circumstances of the loss in writing to the service director
- notify the Pharmaceutical Services Branch of the loss along with any other interested parties, as per state or territory requirements
- make an inventory of all Schedule 8 medicines held in stock at the service and enter the particulars in a new drug register
- retain the new drug register at the service for a minimum of 2 years from the date of the last entry made in it.

State and territory variations: Loss of a drug register

Northern Territory

Notify the Chief Health Officer no later than 7 days after becoming aware of the loss.

Victoria

Report the circumstances surrounding lost or stolen records to the secretary of the service without delay.

4.7. Dose administration aids

A variety of dose administration aids are available. Individual medicines are frequently mixed within these containers and it can be difficult to identify each one.

If a dose administration aid is considered appropriate for a palliative care patient, a community pharmacist should be approached to provide and fill the aid. Family may also assume responsibility for filling the aid.

4.8. Complementary and alternative medicines (CAM)

CAM are seldom 'prescribed' by medical and nurse practitioners and are not listed on the Pharmaceutical Benefits Scheme. CAM can potentially interact with other medicines and it is recommended that services develop local policies on their approach to the administration of CAM.

4.9. Adverse drug reactions (ADRs)

ADRs include allergic reactions and dose-related side effects. Reactions can vary in severity from being minimally inconvenient to life-threatening. All information on any ADRs needs to be shared within the extended healthcare team to support administration and intention-to-treat decisions.

A patient having an ADR record is not, in itself, a contraindication to administering the involved medicine (unless the reaction is life-threatening) but provides guidance on future therapy for the patient.

To minimise the risk of ADRs:

- Ask patients whether they have experienced any ADRs (patients may be more familiar with the terms 'allergy' and 'side effects' rather than ADR, so these may be a better prompt).
- If a patient is unaware of any previous ADR, record 'Nil known' in the documentation. If ADR status is unknown, record 'Unknown'. If a health professional adds information to the documentation after the initial interview, they should sign next to the addition, print their name and date the entry.
- Record ADR details (the medicine and the nature of the reaction) in a manner that shares this information within the extended healthcare team.
- If requested to administer a medicine to which the patient has previously experienced an ADR, consult with the patient's medical or nurse practitioner for clarification of the safety of the order.

State and territory variations: Adverse drug reactions

New South Wales

Any suspected adverse drug reaction should be reported in accordance with local reporting protocols and sent to the TGA using the Blue Card adverse reaction reporting form 'Report of suspected adverse reaction to medicine or vaccines' by post (pre-paid), facsimile, email or online.[9]

4.10. Medication errors

Patients receiving palliative care are at risk of medication errors due to their declining physical condition and the use of high-risk medicines such as opioid analgesics. Medication errors include errors causing harm to the patient, errors due to the administration of the wrong therapy with or without harm, and errors in documentation.[1,12] It is important that community service providers are clear on these definitions and develop procedures for documenting and managing medication errors, including emergency procedures in cases of overdose from opioids.

State and territory variations: Medication errors

Northern Territory

In the event of a medication error, an incident report needs to be generated and the incident reviewed by the medication governance committee according to the organisation's process.

4.11. Subcutaneous infusion devices

While the preferred route of medicine administration in palliative care is oral, subcutaneous infusion devices are commonly used for symptom management in palliative care patients where oral administration is impractical, no longer clinically viable or undesirable. Many medicines used in subcutaneous infusion devices have narrow margins of error. Adverse drug events can result due to prescription, preparation and administration errors.

To prevent these errors, services should consider adopting the following principles:

- To avoid confusion, use only one type of infusion device in each setting.
- Use the same brand of syringe each time to minimise errors in setting up the device and calculating the rate.
- Use an aseptic technique when preparing and setting up an infusion.
- Set up a minimum volume extension to minimise dead space in the line.
- Prime the line after drawing up the prescribed medicine when changing the extension set and/or cannula. After priming the line, measure the syringe volume and the time the syringe is calculated to finish as per the infusion order (usually 24 hours).
- Ensure that medicines being delivered are compatible and keep a record of any problematic combinations for future reference. Check compatibility tables and references for different medicines before commencing.
- Ensure that medicine calculations are checked according to best practice, legislative requirements and organisational policy when the infusion device is set up.
- Carefully inspect tubing for patency and syringe volume remaining, recommended to be at least every 4 hours, and document findings.

The insertion site of a subcutaneous line should be inspected as part of routine care and includes checking for tenderness, the presence of swelling and leaking at the insertion site. Educating patients and carers to inspect insertion sites is important and they should be provided with instructions on what to do if there is a problem.

Note: Local protocols may specify a maximum number of medicines to use simultaneously to minimise the likelihood of incompatibility occurring. Regular monitoring of the syringe contents and tubing is required to check for incompatibility (for example, clouding and colour change) when medicines are combined. However, lack of visible evidence does not necessarily mean that medicines are compatible.

4.11.1. Storage of subcutaneous infusions

- Temperature may affect the stability of medicines. Ensure infusion devices are placed on top of bedclothes and outside of clothing, rather than beneath.
- Prepare infusions immediately before infusion.
- Protect infusions from light where possible.

APPENDIX A

For further information on the safe handling of medicines in each state or territory, see the regulations listed below:

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Regulation 2008

New South Wales

Poisons and Therapeutic Goods Regulation 2008

Northern Territory

Medicines, Poisons and Therapeutic Goods Regulations 2017

Queensland

Health (Drugs and Poisons) Regulation 1996

South Australia

Controlled Substances (Poisons) Regulations 2011

Tasmania

Poisons Regulations 2008

Victoria

New Drugs, Poisons and Controlled Substances Regulations 2017

Western Australia

Medicines and Poisons Regulations 2016

APPENDIX B CONTACT DETAILS FOR STATE AND TERRITORY REGULATORS

Australian Capital Territory

Pharmaceutical Services
Health Protection Services
Locked Bag 5005
Weston Creek ACT 2611
Tel: 02 6205 0997
hps@act.gov.au

New South Wales

Pharmaceutical Services
NSW Ministry of Health
Tel: 02 9391 9944
pharmserv@doh.health.nsw.gov.au

Northern Territory

Medicines and Poisons Control
Department of Health
Tel: 08 8922 7341
poisonscontrol@nt.gov.au

Queensland

Medicines Regulation and Quality Unit
Office of the Chief Medical Officer and Healthcare Regulation Branch
Prevention Division, Department of Health
Tel: 07 3328 9890
mrq@health.qld.gov.au

South Australia

Medicines labelling and scheduling
Medicines and Technology Programs
Tel: 08 8204 1942
Health.MTPP@sa.gov.au

Poisons labelling and scheduling
Scientific Services, Public Health Services
Department for Health and Ageing
Tel: 08 8226 7100
HealthControlledSubstances@sa.gov.au

Tasmania

Pharmaceutical Services Branch
Department of Health and Human Services
Tel: 03 6166 0400

Victoria

Drugs and Poisons Regulation
Department of Health and Human Services
Tel: 1300 364 545
dpcs@dhhs.vic.gov.au

Western Australia

Medicines and Poisons Regulation Branch
Tel: 08 9222 6883
poisons@health.wa.gov.au

APPENDIX C AUSTRALIAN/NEW ZEALAND STANDARD 'USER-APPLIED LABELS FOR USE ON SYRINGES CONTAINING DRUGS USED DURING ANAESTHESIA'

Standard background colours for user-applied labels for use on syringes containing the most common 'as required' medicines

Table 3

Drug classification	Examples	Colour
Antiemetics	Metoclopramide	**Salmon**
Anticholinergic agents	Atropine, hyoscine, butylbromide	**Green**
Induction agents	Ketamine	**Yellow**
Major tranquillisers	Haloperidol, chlorpromazine	**Salmon**
Narcotics	Morphine, fentanyl	**Blue**
Tranquillisers	Midazolam, diazepam	**Orange**

APPENDIX D MEDICINE STORAGE DATA

Table 4 [13-16]

Drug	Storage
Clonazepam	Stable for 24 hours in plastic syringes. Protect from light and store at 15–30˚C
Dexamethasone	Protect from light and store for 24 hours at 15–30˚C
Fentanyl	Protect from light
Haloperidol	Protect from light
Hydromorphone (Dilaudid)	Store at 15–30˚C
Hyoscine hydrobromide	Protect from light
Hyoscine N-butylbromide	Protect from light
Ketamine	Protect from light and store below 30˚C
Metoclopramide	Protect from light and store at 15–30˚C
Midazolam	Protect from light. Diluted solutions must be stored at 2–8˚C and used within 24 hours
Morphine	Stable in plastic syringes with plastic caps (not needles) for 67–72 days. Stability is dependent on protection from air and light. Solution becomes darker on exposure to light. Store at 15–30˚C
Prochlorperazine	Protect from light
Promethazine	Stable for 24 hours in plastic syringes. Protect from light and store at 15–30˚C
Octreotide	Must be stored in refrigerator

REFERENCES

1. Australian Pharmaceutical Advisory Council. Guiding principles for medication management in the community Canberra: Commonwealth of Australia, 2006. http://www.health.gov.au/internet/main/publishing.nsf/Content/0A434BB6C6456749CA257BF0001A9578/$File/booklet.pdf (accessed 14 March 2018).

2. Australian Pharmaceutical Advisory Council. Guiding principles to achieve continuity in medication management Canberra: Commonwealth of Australia, 2005. http://www.health.gov.au/internet/main/publishing.nsf/Content/5B47B202BBFAFE02CA257BF0001C6AAC/$File/guiding.pdf (accessed 14 March 2018).

3. Palliative Care Victoria. Guidelines for the handling of medication in community-based palliative care services in Victoria. 2002.

4. Brisbane South Palliative Care Collaborative. Guidelines for the handling of medication in community-based palliative care services in Queensland 2015. https://www.health.qld.gov.au/__data/assets/pdf_file/0028/141778/medguidepall.pdf (accessed 16 March 2018).

5. Tasmanian Government. Poisons Regulations 2008. 2017. https://www.legislation.tas.gov.au/view/whole/html/inforce/current/sr-2008-162 (accessed 14 March 2018).

6. Western Australian Government. Medicines and Poisons Act 2014: Medicines and Poisons Regulations 2016. 2014. https://www.slp.wa.gov.au/pco/prod/filestore.nsf/FileURL/mrdoc_29809.pdf/$FILE/Medicines%20and%20Poisons%20Regulations%202016%20-%20%5B00-a0-02%5D.pdf?OpenElement (accessed 14 March 2018).

7. Queensland Government. Health (Drugs and Poisons) Regulation 1996. 2018. https://www.legislation.qld.gov.au/view/html/inforce/current/sl-1996-0414 (accessed 14 March 2018).

8. Queensland Health Procedure. Statewide Medication Chart Guidelines, Section 5.1 As required (PRN) medicines. 2007.

9. NSW Health. Medication handling in NSW public health facilities. North Sydney: Ministry of Health, NSW, 2013. http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_043.pdf (accessed 14 March 2018).

10. Australian Capital Territory Government. Medicines, Poisons and Therapeutic Goods Regulation 2008. 2017. http://www.legislation.act.gov.au/sl/2008-42/current/pdf/2008-42.pdf (accessed 16 March 2018).

11. Australian Capital Territory Government. Medicines, Poisons and Therapeutic Goods Act 2008. 2016. http://www.legislation.act.gov.au/a/2008-26/current/pdf/2008-26.pdf (accessed 16 March 2018).

12. Australian Commission on Safety and Quality in Health Care. Literature Review: Medication Safety in Australia. Sydney: ACSQHC, 2013. https://www.safetyandquality.gov.au/wp-content/uploads/2014/02/Literature-Review-Medication-Safety-in-Australia-2013.pdf (accessed 14 March 2018).

13. Trissel LA . American Society of Health System Pharmacists. Handbook on injectable drugs. 6th ed. Bethesda, Maryland, USA: American Society of Hospital Pharmacists, 1990.

14. Allinson Y, James A. Australian injectable drugs handbook. South Melbourne: Society of Hospital Pharmacy of Australia, 1997.

15. Bing C, Chamallas S, Hayes J, et al. Extended stability for parenteral drugs. 3rd ed. Bethesda, Maryland, USA: American Society of Health System Pharmacists, 2005.

16. Trissel LA, Leissing NC. Trissel's tables: Trissel's tables of physical compatibility. Lake Forest, Ill.: Multimatrix, 1996.

NOTES