Options for amendments to the ACT controlled medicine storage requirements.

September 2019
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contents</td>
<td>i</td>
</tr>
<tr>
<td>Purpose</td>
<td>2</td>
</tr>
<tr>
<td>Scope</td>
<td>2</td>
</tr>
<tr>
<td>Background</td>
<td>2</td>
</tr>
<tr>
<td>Issues</td>
<td>3</td>
</tr>
<tr>
<td>Issue 1: Refrigerated controlled medicines</td>
<td>3</td>
</tr>
<tr>
<td>Issue 2: Acute treatment protocols within institutions</td>
<td>4</td>
</tr>
<tr>
<td>Issue 3: Medicines in automated dispensing systems</td>
<td>5</td>
</tr>
<tr>
<td>Issue 4: Controlled medicines used in Research and Education</td>
<td>5</td>
</tr>
<tr>
<td>Issue 5: Daily use Opioid Maintenance Treatment (OMT) in community pharmacies</td>
<td>7</td>
</tr>
<tr>
<td>Issue 6: Possession of controlled medicines for emergency administration in residential care facilities</td>
<td>8</td>
</tr>
<tr>
<td>Submissions</td>
<td>9</td>
</tr>
</tbody>
</table>
Purpose

The purpose of this paper is to explore options for amendments to the controlled medicine storage requirements in the Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation).

Scope

This paper will explore several issues identified by ACT Health in relation to each of the following matters:

- Refrigerated controlled medicines;
- Injectable analgesia used under protocol within institutions;
- Medicines in automated dispensing systems;
- Controlled medicines used in Research and Education;
- Daily use Opioid Maintenance Treatment (OMT) in community pharmacies; and
- Possession of controlled medicines for emergency administration in residential care facilities.

ACT Health is inviting submissions from key stakeholders regarding the options presented in this paper. ACT Health also invites submissions on any additional issues identified by members of the ACT healthcare community in relation to the storage or possession of controlled medicines. Submissions will be used to inform advice to the Minister for Health regarding preferred policy option(s) for updates to the current regulatory scheme.

Background

Under section 61 of the Medicines Poisons and Therapeutic Goods Act 2008 (MPTG Act), a person commits an offence if they are authorised to possess a medicine, poison or prohibited substance and they fail to store it as prescribed by regulation. Under section 36 of the MPTG Act, a person also commits an offence if they possess a controlled medicine and are not authorised to possess it.

Controlled medicines are Schedule 8 medicines as defined by the Commonwealth Poisons Standard. Examples of these medicines include morphine, oxycodone, dexamfetamine and alprazolam. Controlled medicines have additional restrictions due to their risk of misuse, abuse or dependence.

Controlled medicines must be stored in accordance with Schedule 5 of the MPTG Regulation. Schedule 5 outlines the requirements for controlled medicine storage receptacles, such as medicine cabinets and safes. These requirements exist to reduce the risk of diversion or theft and resulting harms due to abuse of controlled medicines in the community.

Authorisations for persons to possess controlled medicines are described in Schedule 1 of the MPTG Regulation.
ACT Health has identified the following issues in relation to the MPTG Regulation storage and possession requirements for controlled medicines:

**Issue 1: Refrigerated controlled medicines**

Some controlled medicines, including some medicinal cannabis and depot buprenorphine formulations must be stored in a refrigerator. Commercially available refrigerators do not meet the requirements outlined in Schedule 5 of the MPTG Regulation. This creates a barrier for supply of some medicines in the ACT as pharmacies are unable to store refrigerated controlled medicines in compliance with ACT law.

The New South Wales (NSW) and Queensland (QLD) Governments have issued directions and standards respectively, on the storage of medicinal cannabis and other Schedule 8 medicines requiring refrigeration.

In NSW, controlled medicines in a pharmacy or institution that require refrigeration may be stored in a refrigerator instead of a safe. Storage must be in accordance with the requirements of the Poisons and Therapeutic Goods Regulation 2008, specifically that:

- The refrigerator containing the controlled medicine must be in a room or enclosure to which the public does not have access, such as the dispensary.
- The refrigerator must be securely attached to the premises and locked when not in immediate use.
- The controlled medicine may be stored with other medicines, but not with food or other goods.
- The refrigerator containing the controlled medicine may be accessed only by a pharmacist. This means, any other medicine in the refrigerator where a controlled medicine is stored may be accessed only by a pharmacist.
- Any key or other device, or any code or combination required to access or unlock the refrigerator, room, cupboard or other receptacle must be kept, and be accessible, only by a pharmacist.

In QLD, the Health (Drugs and Poisons) Regulation 1996 provides alternative requirements for the storage of refrigerated medicinal cannabis products. The Standard for Security of medicinal cannabis stock, June 2019, establishes six subjective outcome based storage requirements that institutions must meet in order to store medicinal cannabis lawfully, specifically:

- access controls to ensure that only pharmacists or prescribers have access to the cannabis products.
- intruder resistance measures to delay unauthorised access.
- detection and response measures to ensure early detection of unauthorised access.
- procedural security policies and procedures to inform those working within the facility of the actions that are required if there is a breach of security.
• disposal procedures for medicinal cannabis products.
• appropriate storage conditions for the various forms of the products likely to be available. This includes keeping the medicine refrigerated.

Options

**Option 1** - Status Quo: no amendments to Schedule 5 of the MPTG Regulation. Refrigerated controlled medicines cannot practically be lawfully stored within the ACT.

**Option 2**: Amend the MPTG Regulation to align with NSW specific requirements.

**Option 3**: Amend the MPTG Regulations to align with QLD subjective outcome based requirements.

ACT Health proposes to adopt Option 2, to align with NSW specific requirements. This is because it provides a relatively a low cost solution that ensures secure storage of refrigerated controlled medicines, provides clear instructions for pharmacies and can be easily regulated by ACT Health. Option 3 is not recommended as it does not provide clear requirements for pharmacy businesses and may incur additional costs to business, that may not be justified for medicines that are held infrequently.

**Issue 2: Acute treatment protocols within institutions**

Some acute care hospitals administer injectable analgesia to patients under protocol. This may involve drawing up of a controlled medicine in a single syringe with incremental doses provided to the patient according to their pain or other medical needs.

The storage of a controlled medicine in a syringe outside of a safe between doses is not permitted under the MPTG Regulation, as the medicine is considered not to be within ‘immediate use’.

Some hospital units have requested they be able to keep the syringe near the patient and out of the safe between doses, to assist with nursing workflows and facilitate timely administration of the medicine to patients.

ACT Health considers the risks of diversion or harm posed within this setting to be low, where the syringes are used under protocol within a secure area of a facility, with appropriate witnessing across the entire supply chain, including discarding of unused medicine.

Options

**Option 1**: Status quo – No regulatory changes are made to the MPTG Regulation.

**Option 2**: Enable syringes containing a controlled medicine to be kept out of the safe between doses during an acute treatment protocol in an institution, by clarifying the interpretation of ‘immediate use’ in the MPTG Regulation.
Option 3: Enable syringes containing a controlled medicine to be kept out of the safe between doses during an acute treatment protocol in an institution, by inserting specific requirements for facility access security and witnessing within the MPTG Regulation.

ACT Health proposes Option 2 - that the term ‘immediate use’ within the MPTG Regulation be clarified so that controlled medicines within a syringe used in an acute treatment protocol within an institution are considered in ‘immediate use’ between doses.

This option would impose no additional requirements upon acute care facilities seeking to store controlled medicines out of the safe between doses. Existing controls for witnessing of controlled medicine dose administration and discarding of remaining stock would remain in place.

Issue 3: Medicines in automated dispensing systems

Automated dispensing systems (ADSs) are computerised drug storage devices or cabinets that allow medications to be stored and dispensed near the point of care, while controlling and tracking medicines distribution.

ADSs incorporate a number of security features to prevent unauthorised access, however do not fit the physical requirements of a medicine cabinet as currently described in Schedule 5 of the MPTG Regulation.

ACT Health considers the use of ADSs by institutions to store controlled medicines within the ACT to present a low risk of theft or diversion where the cabinets are appropriately secure.

Options

Option 1: Status Quo – No regulatory changes to the MPTG Regulation, which would mean that ADSs cannot be lawfully used to store controlled medicines within the ACT as mobile units.

Option 2: Recognise ADSs in the MPTG Regulation with specific construction requirements to permit their use within institutions.

Option 3: Develop outcome-based requirements for the use of ADS within ACT institutions.

ACT Health invites submissions from stakeholders regarding the preferred option including requirements that may apply to potentially enable these storage systems to be legally used in the ACT.

Issue 4: Controlled medicines used in Research and Education

Section 440 of the MPTG Regulation authorises a controlled medicines research and education (CMR&E) program licence holder to possess a controlled medicine.

Many CMR&E licence holders store very small quantities of controlled medicines; often less than three grams of the controlled substance. The risk of diversion or misuse is considered low in these facilities as the research areas are typically separated from the public in secure
areas. All licensed CMR&E programs must be conducted at or under a recognised research institution, defined by the MPTG Act.

CMR&E licence holders currently have the same controlled medicine storage requirements as health institutions and pharmacies that hold large stocks of these medicines. This is often considered excessive, due to the need for a heavy duty steel medicine cabinet or a safe that is bolted to the floor or wall. Small, less expensive safes cannot be secured to a floor or wall using internal fixings so are effectively precluded by the MPTG Regulation. The cost of compliance has been raised as an issue by some facilities.

Section 532 of the MPTG Regulation allows less stringent storage requirements for controlled medicines held by some health professionals working outside of an institution and First-Aid kit licence holders.

The requirements are that:

a) The person must ensure that the controlled medicine is stored in—
    (i) a locked container that prevents ready access to the container’s contents and is securely attached to a building; or
    (ii) a locked drawer, cupboard, room or vehicle;

a) if the medicine is kept in a container that is unlocked by a combination lock—the person must keep the combination confidential.

b) If the medicine is kept in a container that is unlocked by a key—the person must keep personal custody of the key;

c) if the medicine is kept in a drawer, cupboard, room or vehicle—the person must keep personal custody of the key to the drawer, cupboard, room or vehicle.

CMR&E licence holders are not currently captured by this provision.

Medicines and poisons regulations in most other states and territories allow for more flexible storage for small quantities of a controlled medicine by defined persons.

Options

Option 1: Status quo – no changes to the MPTG Regulation. CMR&E licence holders would be required to continue to store controlled medicines in a compliant safe or vault.

Option 2: An amendment is made to Section 532 of the MPTG Regulation to include CMR&E licence holders in the list of persons who may store controlled medicines in secure place, other than a compliant safe or vault.

Option 3: Amend the MPTG Regulation to insert new specific storage requirements for CMR&E licence holders.

ACT Health’s proposes Option 2 - that Section 532 be amended to include CMR&E licence holders as being permitted to store controlled medicines in secure place, that is otherwise not a compliant safe or vault. This is because the current provisions for First Aid Kit licence holders are considered to be adequate and should provide a clear and low cost solution for research and education facilities.
Issue 5: Daily use Opioid Maintenance Treatment (OMT) in community pharmacies

Community pharmacies that dispense OMT are often required to dispense and supervise multiple doses of OMT each day. Medicines used for OMT are methadone and buprenorphine.

The MPTG Regulation requires pharmacists to store all controlled medicines in a locked medicines cabinet, safe, strong room or vault when not in immediate use.

Currently the pharmacist must access the safe each time a client attends the pharmacy. This can lead to delays in dispensing as it may require the pharmacist to access the secure storage area multiple times a day.

Community pharmacies have raised this as an issue that is impacting workflow. Some pharmacies have requested that they be able to store bottles of methadone liquid in a lockable secure cupboard within the dispensary to enable more convenient access for the pharmacist when dispensing and supervising methadone doses during business hours.

The Western Australian Medicines and Poisons Regulation 2016 authorises pharmacists to store controlled medicines in a lockable storage cabinet or drawer if the cabinet is supervised at all times by the pharmacist.

Options

Option 1: Status Quo - No regulatory changes to the MPTG Regulation. OMT controlled medicines must be stored in a locked medicines cabinet, safe, strong room or vault that complies with the requirements of Schedule 5 when not in immediate use.

Option 2: The MPTG Regulation be amended to permit the storage of controlled medicines for OMT within a secure cupboard or draw subject to the following conditions:

- The cupboard or drawer is lockable, securely fixed to a floor or wall and is always kept locked except when items are being placed in or removed from it.
- A pharmacist can supervise the access to the cupboard or drawer all the time.
- If access to the cupboard or drawer is by using a key – pharmacist should keep immediate and personal possession of the key.
- If access to the cupboard or drawer is by using an access code — pharmacist should take all reasonable measures to ensure that the access code is not given to any other person.
- The door of cupboard or drawer is not in direct view of the public.
- The maximum allowed quantity stored in the cupboard or drawer for each controlled medicine for opioid dependency treatment is one commercially available pack.
- All controlled medicines are stored in a compliant safe by the end of pharmacy business hours.

ACT Health proposes Option 2, to enable the storage of OMT medicines within a secure cupboard or draw during business hours subject to conditions. The risk of theft or diversion associated with storage of controlled medicines in a secure cupboard or draw is considered
low and approximately the same as using a compliant safe during pharmacy trading hours. This is because a pharmacist is always available to supervise the locked cupboard during business hours.

This option would help to enable more convenient access for the pharmacist when dispensing and supervising OMT doses during business hours.

**Issue 6: Possession of controlled medicines for emergency administration in residential care facilities**

Under Part 3.3 of the MPTG Regulation, the director of nursing or medical superintendent for a residential aged care facility may issue purchase orders, obtain, possess and supply the following controlled medicines within the facility for administration to residents:

- not more than 5 ampoules, each of 1mL or less, of morphine sulfate, at a concentration of 30mg or less of morphine sulfate per mL.

ACT Health understands that hydromorphone is commonly prescribed in some residential care facilities. Some ACT services have requested the current provisions which limit possession to morphine be expanded.

Hydromorphone, also known as dihydromorphinone, is an opioid used to treat moderate to severe pain.

**Options**

**Option 1:** Status Quo - No regulatory changes to the MPTG Regulation. The current possession limits for morphine would remain unchanged.

**Option 2:** Amend the MPTG Regulation to permit the director of nursing or medical superintendent for a residential aged care facility issue a purchase order, obtain, possess and supply a suitable quantity of hydromorphone, for administration to residents.

**Option 3:** Amend the MPTG Regulation to permit the director of nursing or medical superintendent for a residential aged care facility issue a purchase order, obtain, possess and supply a suitable quantity of hydromorphone and other controlled medicines, for administration to residents.

ACT Health’s proposes Option 3 to expand the range of controlled medicines able to be held by residential care facilities. ACT Health seeks feedback from stakeholders about which controlled medicines and their quantities are required for administration to residents.
Submissions

The Health Protection Service is inviting submissions from key stakeholders regarding the options presented in this paper.

Submissions will be used to inform advice to the Minister for Health regarding preferred policy option(s) for updates to the current regulatory scheme.

Submissions on any additional issues identified by members of the ACT healthcare community in relation to the storage or possession of controlled medicines are also encouraged.

All submissions received may be subject to release by ACT Health under the Freedom of Information Act 2016. If your submission reveals any sensitive information about commercial operations or arrangements, you are strongly advised to label the submissions as ‘commercial in-confidence’.

Interested parties and individuals are invited to provide a written submission commenting on the options outlined in this paper. Submissions are requested by close of business 15 November 2019.

Submissions can be provided through one of the following options:

Stakeholders are invited to provide feedback as written comments by email to hps@act.gov.au or by completing the online survey that can be accessed at this webpage: https://arcg.is/jeTKS

Email: hps@act.gov.au

Post: Attn – ACT Chief Pharmacist
C/- The Health Protection Service
Locked Bag 5005 Weston ACT 2611

ACT Health acknowledges the Traditional Custodians of the land, the Ngunnawal people. ACT Health respects their continuing culture and connections to the land and the unique contributions they make to the life of this area. ACT Health also acknowledges and welcomes Aboriginal and Torres Strait Islander peoples who are part of the community we serve.