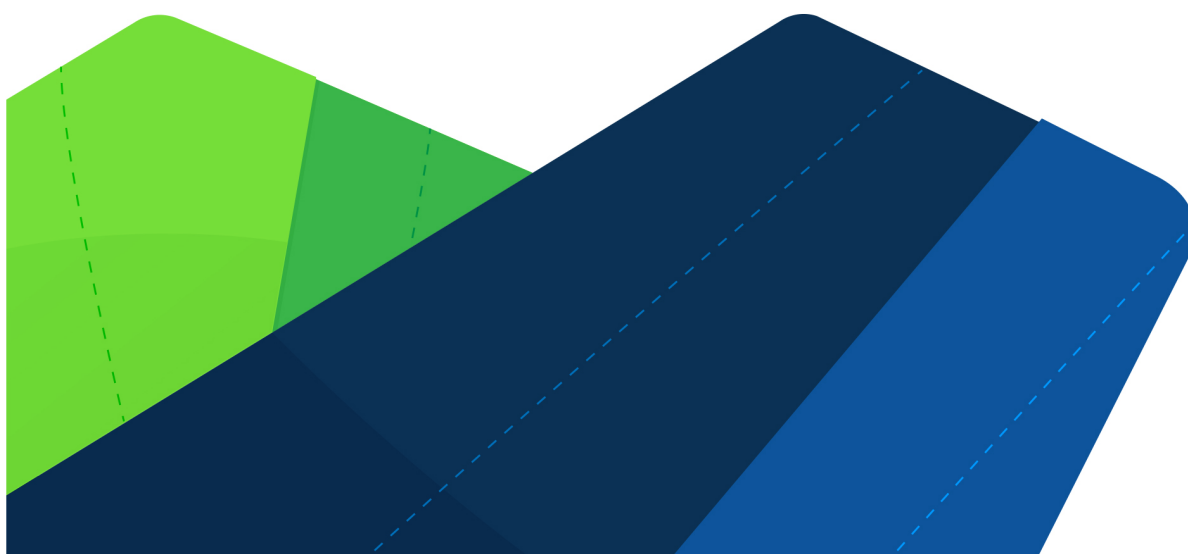


Standard for security of medicinal cannabis stock

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Chief Medical Officer and Healthcare Regulation Branch,
Prevention Division



Queensland
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Summary

This standard provides the minimum requirements for medicinal cannabis stock security and storage where the medicinal cannabis is a controlled drug.

Objective

All medicinal cannabis products, particularly those containing tetrahydrocannabinol (THC), have a high diversion value, and must have comprehensive security controls in place to manage this risk. Products containing THC are scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard) as controlled drugs or S8 medicines, while those containing cannabidiol are scheduled as prescription only medicines, or S4.

Storing is a component of possession and it is the authorised person's responsibility to demonstrate that all necessary measures have been taken to prevent diversion of the product for illicit use, that the integrity of the product is maintained and that the stocks are stored to be fit-for-purpose.

This standard provides levels of control that should be used to achieve these outcomes while providing flexibility by allowing the responsible person, in a range of different circumstances, to demonstrate that the proposed security arrangements will provide security that meets the outcomes required.

Principles

To prevent diversion and tampering and to ensure public safety, stocks of medicinal cannabis products must be secured in a way that prevents unauthorised access, maintains the integrity of the products and maintains a level of security that is commensurate with the risk of public harm as indicated by the Poisons Standard.

There are a number of underpinning principles that should be reflected in security arrangements:

Deter: to discourage a person or people from attempting to breach the security measures

Delay: making the breach of security more difficult or slower allowing for response

Deny: allowing access only to those who require it

Detect: allowing early detection of security breaches

Defend: actions taken to respond to a security breach.

Mandatory requirements

The regulation places the onus on the institution or authorised person to ensure compliance with this standard. The following tables provide examples of controls that could be put in place to meet the principles described above. However, these examples are not mandatory requirements and it is anticipated that this standard will provide opportunity for 'layering' of security arrangements; therefore, providing a level of flexibility for persons required to secure medicinal cannabis products on site.

Key concepts

- 1. Access controls:** This ensures that the medicinal cannabis is only accessed by those persons who have a need to access it. It ensures that only pharmacists or medical practitioners dispensing medicinal cannabis products are the only ones with access to the products.
- 2. Intruder resistance:** This could be a number of physical and technological measures. This relates specifically to delaying any unauthorised access or forcible attack. It may also include attempts to tamper with the products.
- 3. Detection and response:** This may include a number of technological measures ensuring early detection of unauthorised access and appropriate responses. This may also include policies and procedures that ensure early identification of discrepancies or loss of product.
- 4. Procedural security measures:** This ensures that the person in charge of the facility holding the medicinal cannabis product has appropriate policies and procedures in place to inform those working within the facility of the actions that are required if there is a breach of security.
- 5. Disposal and destruction of medicinal cannabis products:** This ensures there are policies and procedures in place to address the appropriate disposal and destruction of the product.
- 6. Product integrity:** This includes maintaining appropriate storage conditions for the various forms of the products likely to be available.

All persons who need to secure medicinal cannabis products can use this document to determine the security measures they need to put in place.

It should be noted that this document applies to medical practitioners who are storing and dispensing products from their practice premises and pharmacists, both hospital and community, who are storing and dispensing products for patients.

Manufacturers and wholesalers will also be required to address security measures for medicinal cannabis products however, the *Guideline: Security of Medicinal Cannabis*, produced by the Commonwealth Government, Department of Health, Office of Drug Control can be used in conjunction with this document to outline the requirements for security at those facilities.

Updating of the standard

The Security Standard will be reviewed as required to ensure it is up-to-date with the latest information in relation to storage and security measures available in the community. The next section describes the mandatory requirements for security, the rationale and provides examples that can be in place to meet the requirements. This document can be used as a guide to the type of options available for addressing each of the outcomes.

1. Access controls

Mandatory requirement: The authorised person **must** maintain a set of access controls preventing unauthorised access to medicinal cannabis, throughout the pharmacy and practice facility. Access controls should be managed by one person who takes on that responsibility e.g. the Pharmacist in charge/pharmacy owner/medical practitioner.

Expectations	Rationale	Example
Medicinal cannabis storage sites shall be controlled so that access from non-authorised persons can be prevented	This is to minimise the number of people that have direct access and therefore reduces the risk of unauthorised access and diversion of product.	<ul style="list-style-type: none"> No access to the storage site from public areas in the facility. No advertising of the business that indicates medicinal cannabis is available on site.
No person shall be permitted access to a medicinal cannabis storage site key other than a person who is authorised under the regulation to possess medicinal cannabis and is working at the premises on which a medicinal cannabis storage site is located. Key includes a proximity card or passcode that provides access to the medicinal cannabis.	To reduce the possibility of unauthorised access to the medicinal cannabis.	<ul style="list-style-type: none"> Physical controls that limit access such as: Proximity card/key/passcode access to room where storage receptacle is kept which may be limited to particular hours Key/passcode/proximity card/individual identification process (e.g. finger print technology) access to storage receptacle itself
The authorised person or their nominated delegate should control who can access and operate security and	This provides a single point for management of the security systems for the site, reducing the risk of unauthorised	<ul style="list-style-type: none"> Monitoring of security, including audits of access. Procedures for issuing of keys/proximity cards/passcodes

Expectations	Rationale	Example
surveillance equipment/facilities.	access to secured areas.	are in place and monitored.
Only persons authorised under the regulation can take possession of medicinal cannabis products on transfer from manufacturer.	Reduces the opportunity for unauthorised access to the products.	<ul style="list-style-type: none">• Only persons authorised under the regulation can take possession of the product on delivery and sign for receipt of product.• Persons authorised under the regulation must ensure the tamper proof packaging has not been compromised.

2. Intruder resistance

Mandatory requirement: The authorised person **must** maintain an intruder resistant pharmacy/facility, designed to prevent intrusion by external parties and to prevent theft.

Expectations	Rationale	Example
<p>The pharmacy/ facility is designed and maintained to deter intruders.</p>	<p>Through its physical design, the ability to covertly access the medicinal cannabis storage area is reduced and therefore intruders may be deterred from breaking in.</p>	<ul style="list-style-type: none"> • 24 hour Closed Circuit Television (CCTV) surveillance, particularly monitoring access to the storage receptacle. • Sensors in the ceiling cavity to detect and alert to intruders. • Pharmacy/facility is well lit, including after hours. • Walls/doors are reinforced to prevent ram raids. • Alarms are directed to the authorised person or their nominated delegate and security/Police • Location of the pharmacy/facility e.g. in a shopping centre that is not open to the public after business hours or patrolled by security firm.
<p>The medicinal cannabis should be stored in a storage receptacle that prevents ready access to the receptacle's contents and is not able to be easily removed.</p>	<p>Storage receptacle should delay and deter any intruder therefore allowing more time for police/security to attend the site.</p>	<ul style="list-style-type: none"> • Storage receptacle consistent with requirements under the Health (Drugs and Poisons) Regulation 1996. • Storage receptacle locked/proximity card access/passcode/individual identification technology but not consistent with HDPR requirements (i.e. not a safe). • Storage receptacle attached (physically or electronically) to the floor or wall. • Storage receptacle (stand alone and not locked in any way) in a locked room with restricted access and not visible to the public.

Expectations	Rationale	Example
		<ul style="list-style-type: none"> Medicinal cannabis products are in a locked drawer/container within the receptacle.
Medicinal cannabis products should not be easily identified within the storage receptacle.	This makes it difficult for an intruder to identify the product and may delay or deter the intruder from attempting further access.	<ul style="list-style-type: none"> No external advertising of the storage of medicinal cannabis. Cannabis stored in such a way that it is not visible to the public e.g. in an unmarked box within the storage receptacle. Dispensed medicinal cannabis products should be contained in the normal pharmacy brand bag/plain paper bag that does not allow identification of the product inside.
The pharmacy/ facility should be designed and maintained to prevent the theft or loss of cannabis during daily operations.	<p>Thorough careful physical design, the ability for anyone to access and remove medicinal cannabis without authorisation is minimised.</p> <p>Employees and customers should not be presented the opportunity to remove cannabis product.</p>	<ul style="list-style-type: none"> Work areas separate from break areas. Physical separation of office space from drug storage receptacles. Dispensing area in pharmacy staffed at all time. Waiting rooms in facilities have no visibility of drug storage areas or storage receptacle. Patients are escorted to medical practitioner rooms and not able to wander freely in the facility.
During the transportation medicinal cannabis should be contained within two intruder resistant physical barriers.	This expectation should be covered regardless of mode of transportation, air, road, rail or shipping.	<ul style="list-style-type: none"> Cannabis stowed in a secure locked receptacle in a secure vehicle. Cold chain is maintained during transit. No external signage or symbols on vehicles or containers that would indicate that cannabis is being transported.
Medicinal cannabis should be transported in tamper-evident containers or packaging.	This is to ensure integrity of the consignment along the end-to-end transport route.	<ul style="list-style-type: none"> Tamper evident tapes or seals or security bags or pouches. Time delay access to containers. Secure receptacle requiring key/pin access.

3. Detection and response

The authorised person **must** have measures in place to detect and respond to intrusion or unauthorised access, theft or loss of medicinal cannabis.

The authorised person **must** have arrangements in place with security services and police to deal with loss or theft of medicinal cannabis.

Expectations	Rationale	Example
The premises should have a physical intruder detection system that monitors and records activity.	This is to detect if intrusion or unauthorised access occurs and provide the evidence for any possible investigation.	<ul style="list-style-type: none"> • 24-hour CCTV surveillance. • An alarm system monitored by a security company or the premises are supervised 24 hours a day, or the premises are patrolled by a security guard when not supervised • Motion sensors that raise an alarm to the authorised person or their nominated delegate/police/security firm. • In-ceiling sensors. • Electronic tethering of storage receptacle to the wall with alarms to the owner/pharmacist in charge/police.
The authorised person or their nominated delegate should have procedures in place to rapidly respond to unauthorised access.	The procedures should outline how the pharmacist/medical practitioner uses the physical detection system with operational procedures to detect intrusion or unauthorised access.	<ul style="list-style-type: none"> • Procedures to respond to alarms. • Alarms are connected to hired security firm/police as well as the authorised person or their nominated delegate to ensure rapid response to alarm. • Regular and random checks of access logs, and review of CCTV footage. • Training and regular drills for staff in preparation for intrusion.
The authorised person or their nominated delegate should retain all video recordings for a minimum of 30 days. The pharmacist/facility should retain all access records (for electronic passes).	This is to ensure that recordings can be reviewed to identify the source of theft or loss and for assistance of law enforcement during any potential investigation.	<ul style="list-style-type: none"> • IT systems to back up CCTV recordings. • Access logs on pass access (where available) are much smaller in size and might be useful in security auditing. • Back up for surveillance equipment should there be a power failure.

4. Procedural security measures

Mandatory requirement: The authorised person must design and maintain operational policies and procedures to support physical security measures and prevent the theft or loss of medicinal cannabis.

Expectations	Rationale	Example
The authorised person, or their nominee, should have policies and procedures in place to minimise the opportunity of theft or loss of medicinal cannabis.	Ensuring staff are aware of procedures around activity in the pharmacy/facility reduces the risk of diversion. Divergence from standard operating procedures should be seen as a risk and reviewed.	<ul style="list-style-type: none"> • Procedures for checking and reconciliation of stock. • Frequency of stock reconciliation – daily may be required. • Documentation of reviews of procedures.
The authorised person, or their nominee, should have policies and procedures in place for responding to unauthorised access or theft of medicinal cannabis by an internal source.	The existence of such policies may act as a deterrent to internal staff.	<ul style="list-style-type: none"> • Policies and procedures for staff management and referral to the Department of Health and law enforcement once unauthorised access or theft has been detected. • Contingency plans in the event of staff suspension or termination.
Medicinal cannabis should be reconciled against records once custody of the cannabis is formally transferred, including receipt.	This is to make a clear point where responsibility is transferred and to identify any loss or theft at different stages.	<ul style="list-style-type: none"> • Procedures for transfer and receipt of the medicinal cannabis are in place. • Procedures to validate tamper evident packaging along chain of custody.
The authorised person, or their nominee, should have procedures to track the movement of cannabis through the procurement and supplying process processes.	This is to ensure that theft or loss of cannabis can be identified at an early stage.	<ul style="list-style-type: none"> • Policies and procedures outlining reconciliation, receipt of product, storage, dispensing, supplying and destruction of medicinal cannabis.

The authorised person, or their nominee, should have procedures in place to maintain and test the efficacy of the security equipment and procedures.	This is to ensure that the system is working as expected.	<ul style="list-style-type: none"> • Regular testing of security systems and drills for procedures. • Regular inspections of equipment and infrastructure.
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5. Disposal and destruction of cannabis

Mandatory requirements: The authorised person, or their nominee, **must** have procedures in place to ensure that all cannabis that is not dispensed is disposed of or destroyed in the proscribed safe and secure manner.

Expectations	Rationale	Example
The authorised person should have procedures that identify medicinal cannabis that requires disposal or destruction.	To ensure that all medicinal cannabis is accounted for, and appropriately disposed of, or destroyed.	<ul style="list-style-type: none"> • Procedures around sending for destruction. • Procedures for notifying Queensland Health and the Therapeutic Goods Administration (TGA) of destruction of stock.

6. Product integrity

Mandatory requirements: The authorised person, or their nominee, **must** have storage and procedures in place to ensure the integrity of the product while in their possession.

Expectations	Rationale	Example
Product is fit-for-purpose when provided to the patient.	Ensures the patient receives a product that is safe and effective.	<ul style="list-style-type: none"> • There is an uninterrupted series of storage and distribution activities which maintains a given temperature range, based on the sponsor's recommended conditions for product stability and integrity (cold chain). • A common temperature range for a cold chain is 2 to 8°C. Temperature monitoring equipment should be installed in receptacles used to store cold chain medicines to enable air and/or product temperatures as appropriate to be recorded.
If the pharmacy/facility cannot meet the standards for security and maintaining secure cold chain management of products, alternative arrangements have been made to ensure integrity of product.	This will limit the time the medicinal cannabis is in the pharmacy/medical practitioner facility while ensuring a product remains effective and safe.	<ul style="list-style-type: none"> • Arrangements are in place to deliver medicinal cannabis product on the day it is being picked up by the patient. • Cold chain management is ensured at the place of storage.