SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Inpatient Management of Patients Admitted to SESLHD Facilities using Medicinal Cannabis Products
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/620
DATE OF PUBLICATION	May 2024
RISK RATING	High
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 1 – Governance for Safety and Quality in Health Service Organisations (1.18) Standard 4 – Medication Safety (4.2, 4.3, 4.10, 4.13)
REVIEW DATE	May 2026
FORMER REFERENCE(S)	Nil
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FUNCTIONAL GROUP(S)	Medicines and Therapeutics Related Policy Documents Medicine
KEY TERMS	Cannabis
SUMMARY	This procedure establishes the processes for the management of medicinal cannabis products when patients are admitted taking or using these products, including prescription, supply, secure storage and administration in patient care areas at SESLHD.

Feedback about this document can be sent to SESLHD-Policy@health.nsw.gov.au

Inpatient Management of Patients Admitted to SESLHD facilities using Medicinal Cannabis Products

SESLHDPR/620

1. POLICY STATEMENT

There is growing use of cannabis products for medicinal purposes in the community. A number of legislative and regulatory changes have been made by the Commonwealth Department of Health and NSW Ministry of Health to facilitate access to medicinal cannabis products to appropriate patients. There are a range of legal medicinal cannabis products available in Australia.

NSW Ministry of Health has also taken steps to allow adults with a terminal illness to possess illegal cannabis products through the Medicinal Cannabis Compassionate Use Scheme with less fear of prosecution. The Scheme does not supply cannabis or cannabis products or endorse the use of cannabis products not lawfully prescribed.

This procedure establishes a process for SESLHD staff to follow when a patient presents to hospital using a cannabis product for medicinal purposes. It should be read in conjunction with NSW Health Policy Directive PD2022_032 - Medication Handling.

2. BACKGROUND

There are several ways in which patients may access cannabis products, which affect the way the product should be managed during an inpatient admission.

- **Legally prescribed TGA approved medications:** Nabiximols (Sativex®) is an oral spray which is registered in Australia for spasticity in multiple sclerosis. Epidyolex® (cannabidiol) is an oral solution which is registered in Australia for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) for patients 2 years of age and older. These may be prescribed for other indications as an off-label use. Other TGA registered products also fall under this category.

- **Legally prescribed TGA unapproved medications:** Most medicinal cannabis products are considered to be unapproved medicines, which have not been assessed by the TGA for safety, quality or effectiveness. They are accessible through the Special Access Scheme, Authorised Prescriber Schemes or via clinical trials (on the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes). Further details are available at the TGA Medicinal cannabis hub.

- **Cannabis or cannabis products used under the Medicinal Cannabis Compassionate Use Scheme (not legally prescribed):** This Scheme provides guidelines for NSW Police Officers to use their discretion not to charge adults with a terminal illness and their identified carers for possession of cannabis if they are registered with the Scheme. The Scheme does not supply cannabis or cannabis products, and products obtained for use by these patients are not lawful.

- **Cannabis or cannabis products in any form that have been obtained unlawfully and are not legally prescribed:** This includes products that are not regulated but may also include registered or unregistered medicines obtained without a legal prescription.

The scope of this procedure is limited to the management patients admitted taking medicinal cannabis products. When starting a patient on new treatment the requirements of the TGA and/or NSW Ministry of Health must be followed. Further information can be found at:

- Medicinal cannabis: Access pathways and patient access data | Therapeutic Goods Administration (TGA)
- How to apply to prescribe or supply Schedule 8 and unregistered cannabis medicines - Cannabis medicines (nsw.gov.au)

In addition to TGA and NSW Ministry of Health requirements, SESLHDPD/183 – Medicine Formulary Policy also applies.

3. DEFINITIONS

Medicinal cannabis: Refers to the therapeutic use of cannabinoids derived from the cannabis plant, or synthetically made cannabinoids such as dronabinol and nabilone.

Tetrahydrocannabinol (THC): One of the cannabinoids which may be extracted as a therapeutic good from the cannabis plant. THC is responsible for the euphoric, psychoactive effects of the cannabis plant. THC is listed as a Controlled Drug in Schedule 8 (S8) of the Poisons Standard and products containing greater than 2% THC are handled as S8 medicines.

Cannabidiol (CBD): Another one of the cannabinoids which may be extracted as a therapeutic good from the cannabis plant. CBD is not psychoactive. It is included under Schedule 4 (S4) Prescription Only Medicine of the Poisons Standard when preparations for therapeutic use contain 2% or less of other cannabinoids. An example of cannabidiol registered product is Epidyolex®.

Nabiximols: Nabiximols (Sativex®) is an oral spray which is registered in Australia for spasticity in multiple sclerosis. It has a combination of CBD and THC in a 50:50 ratio is a Schedule 8 product.

ARTG: The public database of therapeutic goods that can be legally supplied in Australia. The ARTG can be searched to find details of therapeutic goods approved for supply.

TGA Authority: A number issued by the TGA allowing a medical officer the right to prescribe an unregistered medicinal cannabis product for a particular patient or group of patients. No TGA authority is required to prescribe registered cannabis product, including for off label indications.

NSW Ministry of Health (MoH) Authority: A number issued by the NSW MoH allowing the prescriber to prescribe and supply a Schedule 8 cannabis medicine (registered or unregistered). NSW MoH Authority is required in the following circumstances:

- to prescribe to a drug-dependent person including a person treated under the Opioid Treatment Program, or
- to prescribe a compounded medicine, or
- to supply under a clinical trial (if an unregistered product).

Products containing CBD-only are Schedule 4 medications and do not require NSW Health Authority.

4. RESPONSIBILITIES

4.1 Employees will:

- Manage legally prescribed cannabis products in accordance with NSW Health Policy Directive PD2022_032 - Medication Handling.
- Ensure that non-legally prescribed cannabis products are not handled as medicines.
- Escalate any patient safety or legal concerns regarding a patient's use of cannabis products to their line manager.

4.2 Line Managers will:

- Provide support for the implementation of these procedures.

4.3 Medical staff will:

- When a patient presents to hospital using a cannabis product for medicinal purposes, establish if the cannabis is legally prescribed.
- Obtain copies of relevant Authority documentation and file in the patient's Health Care Record
- Assess the appropriateness of continuation of a legally prescribed cannabis product during the patient's inpatient stay. Prescribe legally prescribed medicinal cannabis products on an approved medication chart or electronic equivalent, include the name of the authorised prescriber.
- Document clearly in the Health Care Record all relevant information surrounding the patient's use of a medicinal cannabis product.
- Actively inform patients and/or their carers regarding the application of these procedures.

4.4 Nursing Staff will:

- Administer legally prescribed cannabis products to the patient in accordance with an authorised prescriber's prescription (e.g., Medical Officer or Nurse Practitioner).
- Ensure that a patient's own supply is available for use and request further patient's own supply be obtained when necessary.
- Not administer or store non-legally prescribed cannabis products.

4.5 Pharmacy Staff will:

- Provide advice on obtaining further supply of legally prescribed cannabis products and liaise with community providers where necessary.
- Verify the relevant Authority numbers as documented by the Medical Officer.

5. PROCEDURE

5.1 Establish whether the patient's cannabis is legally prescribed for medicinal purposes

Both TGA registered and unregistered cannabis products can be legally prescribed in Australia for medicinal purposes. When a patient presents to hospital using a medicinal cannabis product, the admitting Medical Officer must make every effort to ensure that the cannabis product has been legally obtained under appropriate authorisation where required.

5.1.1 The Medical Officer must:

- Confirm and document the name of the doctor who prescribed the medicinal cannabis for the patient prior to admission.
- Confirm and document the usual place of supply.
- Obtain copies of relevant TGA and/or MoH Authority documentation and file in the patient's Health Care Record (see section 3 for Authority requirements).
- Communicate directly with the prescribing doctor and dispensing pharmacist to clarify the product, dose and amount supplied to the patient.

Out of hours, clinical judgment should be applied, and the legality confirmed at the earliest opportunity. All legally obtained medicinal cannabis products will have been prescribed by a medical practitioner and dispensed by a pharmacist, and there should be evidence of routine pharmacy labelling on the product.

5.2 Continuing Legally Prescribed Cannabis in Hospital

The appropriateness for continuation of legally prescribed medicinal cannabis during the patient's admission must be confirmed by the treating team in discussion with the patient and/or carer, and the original prescriber. Discussion with an appropriate specialist (e.g. palliative care, neurology, pain) is also recommended. The patient's wishes must be duly respected whilst balanced with any risks, for example potential drug interactions and suspected adverse drug effects.

5.2.1 Prescribing

If appropriate to continue, the treating Medical Officer will prescribe the patient's own medicinal cannabis in the approved medication chart or electronic equivalent as per NSW Health Policy Directive PD2022_032 - Medication Handling.

The order must include:

- The name of the original prescriber
- The relevant Authority number/s from either the TGA, NSW MoH or both (see section 3 for Authority requirements)
- The name of the usual place of supply.

A new Authority is not required when continuing treatment with a medicinal cannabis product for a patient in hospital if the patient was the subject of an Authority immediately prior to hospital admission.

5.2.2 Supply for Inpatient use

SESLHD Pharmacy Departments do not routinely stock any medicinal cannabis products. Supplies are obtained under authorisation and the patient's own supply must be used for administration in hospital. This should be explained to the patient and their agreement documented in the Health Care Record.

Prior to use, the patient's own medicinal cannabis product should be checked by a Pharmacist, Medical Officer or Registered Nurse (RN) to confirm:

- It is the correct prescribed medication for that patient,
- It is appropriately labelled,
- It is in date,
- The approximate quantity remaining (if possible to determine),
- That the product is in good condition and suitable for use.

It may be necessary to arrange for the patient's family / carer to obtain further supply via the usual prescriber and community pharmacy. This should be arranged as soon as possible following admission if there is insufficient quantity to last for the expected duration of the admission.

If the patient's own supply cannot be used and further supply cannot be obtained in the community, options should be discussed with the facility Pharmacy Department.

Different medicinal cannabis products have different compositions and clinical judgement should be applied before changing to a different product. The implications for future supply (e.g. availability, Authority to Prescribe etc.) post-discharge should also be considered.

5.2.3 Storage and Handling for Patient's Own Legally Prescribed Cannabis Products

5.2.3.1 Products Containing CBD only

Products containing CBD only are Schedule 4 medicines and do not have any special storage or handling requirements. They should be managed in accordance with SESLHDPR/758 Patient's Own Medications (POMs) – Handling and Storage in Hospital.

5.2.3.2 Products Containing THC

For products containing THC, Schedule 8 (S8) medicine storage and handling requirements must be followed in accordance with NSW Health Policy Directive PD2022_032 - Medication Handling.

Recording in the S8 Drug Register

Patient's own supplies must be documented as the patient's own in the S8 Drug Register. The drug name (THC or CBD or both), the strength and formulation, e.g. tablet (mg) or liquid (mg/mL), must be clearly documented in the S8 Drug Register. A separate page of the drug register should be designated for that drug and that patient only. See SESLHDPR/758 Patient's Own Medications (POMs) – Handling and Storage in Hospital for further details.

Oral liquids must not be decanted for measuring by anyone other than a pharmacist, or delegate approved by the nurse/midwife in charge of the patient care area. When recording a patient's own cannabis oral liquid, recording of the 'amount received' volume in the S8 Drug Register is not required. All other records in the Schedule 8 drug register must be in accordance with NSW Health Policy Directive PD2022_032 - Medication Handling Section 5.14.1.

Storage of Non–Refrigerated THC-containing Products
The patient's own medicinal cannabis must be stored in the S8 medication storage unit.

Storage of THC-containing Products requiring Refrigeration
Where the product requires refrigeration, the product must be stored:

- In a locked medication refrigerator, which is securely attached to the structure of the building, or in a refrigerator that is in a locked room to which the public does not have access.
- If goods other than Schedule 4 Appendix D medicines are to be kept in the refrigerator, the Schedule 8 medicines must be kept separated from them, such as in a locked box attached to the refrigerator.
- If these requirements are not able to be met on the ward, the medicine should be stored in a nearby ward / area where the requirements can be met.
- The refrigerator will remain locked when not in immediate use and the keys to the refrigerator will be kept with the S4D/S8 keys which will be managed in accordance with NSW Health Policy Directive PD2022_032 - Medication Handling.

Some refrigerated products may be stored out of the refrigerator once in use. Check the product packaging and/or liaise with the Pharmacy Department to clarify this for individual products. If able to be stored at room temperature, the date of removal from the refrigerator and use-by date should be clearly recorded on the packaging, and the product stored in the S8 medication storage unit.

At time of discharge
When returning the medication to the patient, the drug must be signed out of the S8 Drug Register in accordance with NSW Health Policy Directive PD2022_032 - Medication Handling.

If the S8 medication is not to be returned to the patient, the medication must be destroyed by a pharmacist or the authorised officer of the medication supply service at a facility where no pharmacist is employed/contracted, with a registered nurse/midwife acting as the witness to the destruction in accordance with NSW Health Policy Directive PD2022_032 - Medication Handling.

5.2.4 Additional Requirements for Children

When a Schedule 8 cannabis medicine is prescribed to a child (under 16 years), an exemption under the *Children and Young Persons (Care and Protection) Act 1998* (NSW) must be sought, by making an application to the Ministry. If the child has been undergoing treatment with the Schedule 8 cannabis medicine prior to admission, an exemption may already be in place. The Ministry of Health should be contacted to seek clarification and details of the exemption documented in the child's Health Care Record.

5.3 Management of Patients Using Non-Legally Prescribed Cannabis Products under the Medicinal Cannabis Compassionate Use Scheme

The NSW Government has developed The Medicinal Cannabis Compassionate Use Scheme (the Scheme) to extend compassion to adults with a terminal illness. NSW residents who are aged 18 years and over who have a terminal illness are eligible to register for the Scheme. Even if a patient is registered under the Scheme, products obtained for use under the Scheme are not legally prescribed and remain unlawful.

On admission to a SESLHD facility, a history of the patient's use of non-legally prescribed cannabis (NLPC) must be taken and disclosure of use encouraged. The patient / carer must provide the registration documentation issued from the NSW Department of Justice for themselves and their carers registered under the Scheme. The Scheme registration documents must be copied and filed in the patient's Health Care Record. The originals must be given back to the patient / carer.

Non-legally prescribed cannabis products MUST NOT be prescribed for continuation in hospital, even if the patient is registered under the Scheme. SESLHD staff MUST NOT administer or assist patients or carers in the administration of non-legally prescribed cannabis products, either in hospital or in the patient's home. SESLHD staff CAN NOT store any non-legally prescribed cannabis products on site, including in the ward drug trolley or S8 medication storage unit. Staff should request that a patient or carer remove any non-legally prescribed cannabis products from hospital premises.

Patients should be fully informed that their cannabis products cannot be prescribed, administered, or stored by SESLHD staff. Patients should be made aware that continued use of any illegal cannabis preparation remains unlawful and of the risks of using non-legally prescribed cannabis products of unknown composition and concentrations of cannabinoids and other potentially dangerous substances, and the risk of drug interactions.

If the patient wishes to continue their use of non-legally prescribed cannabis products whilst in hospital, they should be asked to advise the nursing staff, medical officer and/or multidisciplinary staff of each use. Patients are responsible for the safe storage of their own cannabis products.

If the patient's cannabis product is smoked, the patient must be advised that smoking is restricted to designated smoking zones as per hospital site regulations.

All advice given including any changes to therapy and the decision of the patient MUST be recorded in the patient's Health Care Record. All reported use of cannabis by the patient MUST also be recorded.

If harm has resulted from use of an illegal cannabis preparation, and the supplier can be identified, the hospital should consider bringing the matter to the attention of NSW Police.

5.4 Management of Patients Using Cannabis Products that Have Been Obtained Unlawfully

On admission to a SESLHD facility, a history of the patient's use of non-legally prescribed cannabis must be taken. Patients should be made aware of the risks of using non-legally prescribed cannabis products of unknown composition and concentrations of cannabinoids and other potentially dangerous substances, and the risk of drug interactions. Advice given MUST be recorded in the patient's Health Care Record. All reported or suspected use of cannabis by the patient MUST also be recorded.

Non-legally prescribed cannabis products MUST NOT be prescribed for continuation in hospital. SESLHD staff MUST NOT administer or assist with patients or carers in the administration of non-legally prescribed cannabis products, either in hospital or in the patient's home. SESLHD staff CAN NOT store any non-legally prescribed cannabis products on site, including in the ward medication trolley or S8 medication storage unit. Staff should request that a patient or carer remove any non-legally prescribed cannabis products from hospital premises.

Patients should be monitored for cannabis withdrawal and managed in accordance with Management of Withdrawal from Alcohol and Other Drugs Clinical Guidance and Handbook.

Any concerns regarding the safety or wellbeing of a patient must be discussed with the treating Senior Medical Officer and escalated to the Director of Clinical Services or Executive on-call as required.

If harm has resulted from use of an illegal cannabis preparation, and the supplier can be identified, the hospital should consider bringing the matter to the attention of NSW Police.

6. DOCUMENTATION

S8 Accountable Drug Register
Medication Chart (where used)
Approved electronic Medication Management System
Health Care Record
IIMS Reports

7. AUDIT

To be included in regular audits of Accountable Drug Registers.

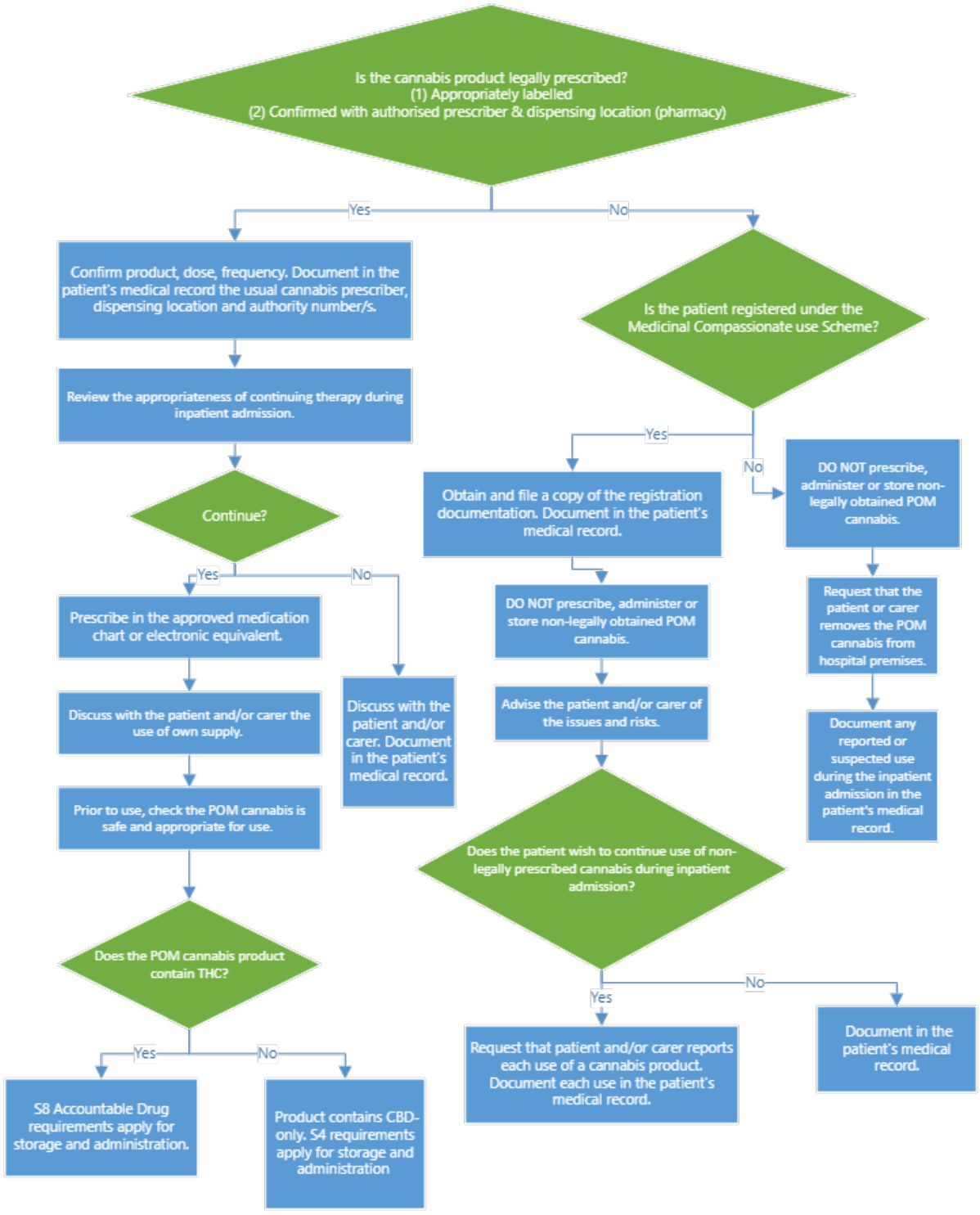
8. REFERENCES

1. NSW Ministry of Health Policy Directive PD2022_032 - Medication Handling
2. NSW Ministry of Health - Management of Withdrawal from Alcohol and Other Drugs Clinical Guidance and Handbook.
3. SESLHDPD/183 - Medicine Formulary Policy
4. Health professionals | Centre for Medicinal Cannabis Research and Innovation (nsw.gov.au)
5. TGA, Accessing unapproved products, Medicinal cannabis – guidance documents
6. St Vincent's Health Australia Guidelines for the Safe Prescribing, Dispensing and Administration of Medicinal Cannabis
7. Therapeutic Goods Administration. Guidance for the use of medicinal cannabis in Australia: Overview. Version 1, December 2017
8. Clinical guidance for cannabis medicine prescribers - Pharmaceutical services (nsw.gov.au)

9. VERSION AND APPROVAL HISTORY

Date	Version	Version and approval notes
May 2018	DRAFT	Drafted by K. Hargreaves
June 2018	DRAFT	Feedback from Prof Richard Chye and advice from NSW Health Chief Pharmacist incorporated.
July 2018	DRAFT	Feedback from Dr Nick Lintzeris, Director of Drug and Alcohol Services incorporated.
August 2018	DRAFT	Feedback from Working Party members incorporated
August 2018	DRAFT	Further feedback from Working Party members incorporated following meeting
October 2018	DRAFT	Feedback received following Drafts for Comment period reviewed by Working Party and incorporated where relevant
November 2018	DRAFT	Processed by Executive Services prior to submission to SESLHD Quality Use of Medicine Committee and SESLHD Clinical and Quality Council.
December 2018	DRAFT	Approved at December SESLHD Quality Use of Medicine Committee
January 2019	1	Approved at December Clinical and Quality Council Meeting for publication.
November 2019	2	Changes made in accordance with revised MoH requirements as outlined in IB2019_041
December 2019	2	Approved at December Quality Use of Medicines Committee. To be tabled at the Clinical Quality Committee's February 2020 meeting.
March 2020	2	Approved at February 2020 Clinical and Quality Committee, noting that General Managers to manage refrigeration of S8 drug until March. Published by Executive Services.
March 2022	3	Minor review by Erica Wales: hyperlinks updated. Approved by Executive Sponsor. To be tabled at Quality Use of Medicines Committee.
April 2022	3	Approved at Quality Use of Medicines Committee.
10 May 2024	3.1	Minor review to reflect changes in PD2022_032 Medication Handling; references updated; hyperlinks reviewed; appendix amended. Approved by SESLHD Drug and Therapeutics Committee and Executive Sponsor.

Appendix A: Flowchart – Management of Patients presenting to SESLHD for inpatient admission taking Cannabis for Medicinal Purposes



Patient's Own Medicine (POM)
CBD (Cannabidiol)
THC (Tetrahydrocannabinol)