Application to change a Health Service Permit for Medical Treatment

Medicines and Poisons Act 2014

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INSTRUCTIONS and INFORMATION	
1.	This form is for requesting changes to an existing **Medical Treatment Permit** issued under the *Medicines and Poisons Act 2014.* This form MUST be completed by the current Permit holder or incoming Permit holder who is suitably qualified and understands the requirements and terminology contained in this application. If the Permit holder is a corporation or partnership, this form must be completed by the corporate officer or partner who originally applied for the Permit. **All communication will ONLY be with the Permit holder, corporate officer or partner.**
2.	**Types of changes that cannot be applied for using this form** DO NOT USE THIS FORM, if: • The Permit holder is changing from an individual person to a Permit held by a corporation or partnership, or • The Permit holder is changing from a corporation or partnership to an individual person or • The medical treatment business has changed ownership. These types of changes require the submission of a completely new application for a Medical Treatment Permit, found at: Application forms for Licences and Permits Permits cannot be transferred between one business entity and another.
3.	There are five parts to this form: Part 1 – Sections 1 to 22: Application to change a Medical Treatment Permit. Part 2 – Sections 23 to 29: Personal Information: new individual Permit holder, corporate officer or partner Part 3 – Sections 30 to 34: Personal Information: new responsible person for a site Part 4 – Sections 35, 36: Payment and checklist. Part 5 – Appendices
4.	Fees are **not** payable for the following type of changes to a Medica Treatment Permit: • Change of postal addresses or other contact details • Change to a person responsible for a site • Removal of site from the Permit • Removal of certain medicines from the Permit • Upgrade of storage or security such as installation of CCTV.
5.	A fee of **$90** is payable for the following type of changes to a Medical Treatment Permit: • Change of individual Permit holder (no change of ownership of the business) • Change of a corporate officer (only for Permits issued to a body corporate and not an individual person) • Increase the quantity of medicines on the Permit • Addition of medicines to the Permit • Relocation of an existing site to a new location • Addition of a new site to the to the Permit • Change of business or trading name without changing legal entity (no change of ownership) • Variation in the activities undertaken under the Permit Note: some variations may require a new application and issue of a different Permit type)

6.	**Changing the Permit holder for a Permit held by an individual person** The person nominated as the new Permit holder must also complete Part 2 Personal Information: Identification, Fitness and Probity and sign the declaration at Section 29. **6.1 Qualifications and/or experience of person nominated as the new Permit holder:** The new Permit holder must**:** • be medical practitioner**,** registered with Australian Health Practitioner Regulation Agency (AHPRA) • have authority within the business to determine policies and procedures in relation to handling and managing medicines on the Permit. **6.2 Permit holder responsibilities** It is the responsibility of the Permit holder to ensure compliance with the *Medicines and Poisons Act 2014* and Regulations 2016 and compliance with conditions placed on the Permit. The new Permit holder must also consider whether they have capacity to ensure compliance with the *Medicines and Poisons Act 2014* and Regulations 2016 and compliance with conditions placed on the Permit for every site listed on the Permit. The Department may request further information in relation to this capacity. There are penalties under the Act for providing false or misleading information when applying for a change to an existing Permit.
7.	**Changing the person responsible for a site listed on the Permit** A new responsible person will have overall responsibility for and manage the medicines on a day to day basis and be the contact person if the Permit holder is not available. The responsible person for a site must: • be employed or contracted by the Permit holder • complete Part 3: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 34. **7.1 Responsible person for a Permit issued to an individual person** The responsible person for a site when a Permit is issued to an individual medical practitioner can be: a) the individual Permit holder i.e. medical practitioner \ **or** b) another medical; practitioner who is the most senior medical practitioner for the site. **7.2 Responsible person for a permit issued to a corporation or partnership** The responsible person for a site when a Permit is issued to a corporation or partnership can be: a) the most senior medical practitioner for the site **or** b) the Medical Director (medical practitioner) employed by the corporation or partnership who has authority to determine policies and procedures to manage the medicines. Please note: a responsible person must consider whether they have capacity to oversee the day to day management of the medicines at every site for which they are responsible. Where a single person is responsible for multiple site, the Department may request further information in relation to this capacity.
8.	**Changing a corporate officer or partner for a Permit that is held by a corporation or partnership.** A new partner or corporate officer (directors, company secretary, chief executive officer or general manager and chief financial officer) must also complete Part 2: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 29.

9.	**Relocation or addition of a site** If a site listed on an existing Medical Treatment Permit: • is being relocated to a different premise **or** • another site is being added to the existing Medical Treatment Permit: and the relocated or added site (second site) is currently listed on a different Permit: ○ the application will not be processed until the Permit holder at the second site has submitted an application to the Department to have their site removed from their Permit. ○ In such cases, Permit holders requesting the relocation or addition of a new site may wish to liaise with the Permit holder at the second site to ensure the Department of Health is appropriately advised.
10.	**Relocation or addition of another site** If the site is being relocated or a new site added and that site is on an existing Treatment Permit, the Department requires the previous Permit holder to remove this site from their Permit by completing an Application to Change a Medical Treatment Permit. The application to remove this site from the previous medical treatments provider's Permit must be received by the Department prior to adding this site to your Permit. Conversely, if you are removing a site and a new medical treatment provider has been contracted, the application to add the site to the new medical treatment provider's Permit must be received by the Department before this site is removed from your Permit. You may have to liaise with the mining/resource company so that the change in medical treatment provider is coordinated, this ensures the medicines stored at the site are always on a Permit and the availability of medicines to employees is consistent. *The Department does not coordinate the change in medical treatment providers or their Permits.* *It is the responsibility of the medical treatment providers and the company contracting them to manage the change in a timely manner.*
11.	This type of permit is issued with the condition that there must be compliance with the Code of Practice for Health Service Permits for Medical Treatment. It is recommended that applicants read this Code prior to applying for this type of permit. Where administration or supply of scheduled medicines will occur without a prescriber issuing a verbal or written direction for each individual patient, there must be a Structured Administration and Supply Arrangement (SASA) in place for each medicine. Only a medical practitioner can issue a SASA. A SASA cannot be written for the supply of a Schedule 8 medicine for a patient to take away. If SASAs are issued, a copy of the terms of reference for the Clinical Governance Committee must be attached with the application. A Clinical Governance Committee means a committee constituted by at least three members including a medical practitioner, a registered nurse and a pharmacist. Copies of SASAs issued under Health Service Permits must be sent to the Department of Health. SASAs do not have to accompany this Application Form and the permit may be issued prior to the receipt of SASAs. Information about SASAs is available on the Department of Health website.
12.	**Schedule 2, 3, 4 and 8 medicines** Sections 16 and 17 relate to the storage and use of Schedule of 2,3, and 4 medicines and Section 17 relates to Schedule 8 (Controlled Drug) medicines.
13.	**Required documents** The applicant and responsible person are required to submit copies of certain documents. If documents are not in English, also attach a translation certified as completed by a National Accreditation Authority for Translators and Interpreters (NAATI) accredited translator. Copies of photographic identification documents, such as a driver's licence or passport must be certified as a true copy. A list of people who can certify copies of documents is found in Appendix C.

14.	**Signatures** All signatures must be signed in ink or via a verifiable electronic signature. An electronic signature is only acceptable if the submitted application allows the Department to verify the signature. A "signature" that is copied and pasted and a "signature" that is the person's name in a font style resembling handwriting will not be accepted. The current Permit holder must sign the Declaration for making a change to the Permit at Section 22. **Who can sign for a change to a Medical Treatment Permit:** If the Medical Treatment Permit is held by an individual person and the change is to request a new individual Permit holder within the same business and the current Permit holder is no longer employed by the business: • the new Permit holder should sign the Declaration and provide the reason the current Permit holder cannot sign the Declaration. If the Medical Treatment Permit is held by a partnership or body corporate, the person who signed the original Permit application should sign the Declaration.
15.	**Approving a change to a Permit** Applying for a change to an existing Permit does not guarantee the requested changes will be approved.
16.	**Processing applications** Applications will be processed in order of receipt after payment has been confirmed by Finance. To ensure a timely decision about your application please: • Complete all required sections of the application, • **Attach** all requested documentation to the application, • Respond to requests from the Department for additional information as soon as possible, • Make sure appropriate staff are available if the Department needs to conduct a site inspection, • Do not submit your application as a digital image (photograph).
17.	**Extra information** When applying for a change to an existing Permit, refer to the: Guide to applying for a Licence or Permit
18.	**Submitting the application** Please email completed form and other requested documentation to: mprb@health.wa.gov.au
Incomplete applications may be delayed or returned to the applicant	

Please keep a copy of the completed application form for reference

PART 1: APPLICATION to change a MEDICAL TREATMENT PERMIT

1.General information

Permit number: Name of current Permit holder:

Postal address: Suburb: Postcode:

Telephone: Fax: Email:

1.2 Type of change

Please check whichever applies:

Changes without a fee	**Complete**
☐ Change of postal addresses or other contact details	Part 1: Sections 2,22
☐ Change the name of the site	Part 1: Sections 3,22
☐ Change to a person responsible for a site	Part 1: Sections 4,22 Part 3: Sections 30 to 34
☐ Remove a site from the Permit	Part 1: Sections 5,7,22
☐ Remove certain medicines form the Permit	Part 1: Sections 6,7,22
☐ Upgrade to storage and security Upgrade drug safe	Part 1: Sections 8, 22 Part 1: Sections 8, 17.1,17.3,22
Changes with a fee of $90	
☐ Change of individual Permit holder	Part 1: Sections 9,22 Part 2: Sections 23 to 29 Part 4: Section 35
☐ Change of corporate officer or partner	Part 1: Sections 10,22 Part 2: Sections 23,26,27,28,29 Part 4: Section 35
☐ Increase quantity of medicines already listed on the Permit If increasing quantity of Schedule 8 medicines on the Permit	Part 1: Sections 11,22 Plus Sections 17.1, 17.3 Part 4: Section 35
☐ Addition of certain Schedule 2,3, and 4 medicines to the Permit If adding Schedule 8 medicines to the Permit	Part 1: Sections 12,22 Plus Section 17 Part 4: Section 35
☐ Relocation of an existing site to a new site If relocated site will be storing Schedule 8 medicines	Part 1: Sections 13,15,16,19,22 Plus Section 17 Part 4: Section 35
☐ Addition of another new site to the Permit If new added site will be storing Schedule 8 medicines	Part 1: Sections 14,15,16,18, 19,22 Plus Section 17 Part 4: Section 35
☐ Change of business or trading name without any change of the legal entity	Part 1: Section 20,22 Part 4: Section 35
☐ Variation in activities undertaken under the Permit, including use of the medicines	Part 1: Section 21,22 Part 4: Section 35

Note: if making multiple changes, only pay one fee of $90

1.3 Additional information to support application (optional):

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Changes without a fee

2.Change of postal address and other contact details

New Postal Address*: Suburb: Postcode:

Telephone: Fax: Email:

* Renewal reminders will be sent to this address

3. Change the name of the site

Previous site name:

New site name:

4.Change the person responsible for a site listed on the Permit

Refer to instruction number 8 for information on the requirements for being a responsible person for a site.

Site name:

Address: Suburb: Postcode:

Name of new incoming responsible person for this site:

Dr. Forename(s): Surname:

4.1 Details about the new person responsible for a site listed on the Permit

Is the new responsible person also the Permit holder or responsible for another site listed on the Permit?

☐ Yes: Confirm name:

Dr. Forename(s): Surname:

There is no requirement to complete Part 3.

☐ No: the new responsible person for the above-named site, must complete and **attach** Part 3: Personal Information: Identification, Fitness and Probity

5. Remove a site from the Permit

Site name:

Address: Suburb: Postcode:

Date the medical treatment provider will cease providing medical treatment at the site?

Is another Medical Treatment provider taking over the site? See instruction number 10.

5.1 ☐ Yes: please provide the name of the new medical treatment provider

5. 2 ☐ No, is there any remaining stock of medicines left?

☐ No

☐ Yes: please also complete Section 7

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6.Remove certain medicines from the Permit

Site name:

Address: Suburb: Postcode:

6.1 Please indicate the schedule of the medicines being removed from the above-named site:

☐ Schedule 2- Pharmacy medicine ☐ Schedule 3 – Pharmacist only medicine

☐ Schedule 4 – Prescription only medicine ☐ Schedule 8 – Controlled drug

If only a small number of specific individual medicines are to be removed from the site, please list below:

6.2 Is there any remaining stock left of the medicines being removed from the Permit at the above-named site

☐ No

☐ Yes: please also complete Section 7

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7. Information about disposal of medicines

Is there any remaining medicines left at the site which is being removed from the Permit (Section 4) or is there any remaining stock of certain medicines being removed from the Permit (Section 5)?

☐ No

☐ Yes: complete Section 7.1 and 7.2

7.1 What will happen to the remaining Schedule 2,3 and 4 medicines?

☐ Transferred to the medical treatment provider taking over the site:

Name of the new medical treatment provider: _____

or

☐ Transferred to a different site listed on the Permit:

Name of site: _____

or

☐ Returned to Permit holder**,** only if the Permit holder is a medical practitioner and not a corporation or partnership

or

☐ Returned to wholesaler for disposal

Name of wholesaler: _____

or

☐ *Destroyed* at the site, placed into a sharp's container, collected by a licensed clinical waste disposal service and incinerated[1]

Name of licensed clinical waste disposal service: _____

7.2 Schedule 8 medicines (Controlled Drug)

Are any Schedule 8 medicines remaining?

☐ No

☐ Yes

☐ Please confirm an inventory of **S8** medicines will be conducted before leaving the site or removing the Schedule 8 medicines from the Permit.

What will happen to the remaining Schedule 8 medicines?

☐ they will be transferred to the medical treatment provider taking over the site, transferred to a different site on the Permit, returned to the Permit holder or wholesaler **or**

☐ they will be destroyed at the site and collected by a licenced clinical waste disposal service – please confirm the following:

☐ S8 medicines will be *destroyed* by making them unidentifiable and unusable[1]

☐ destruction will be **conducted** by persons authorised by Medicines and Poisons Regulations 2016[2]

☐ destruction will be **witnessed** by persons authorised by Medicines and Poisons Regulations 2016[2]

[1] Disposal of medicines

[2] Persons authorised to destroy and make S8 medicines unidentifiable and persons authorised to witness this process include health professionals permitted to possess S8 medicines such as medical practitioners, registered nurses, paramedics, pharmacists and must be two different people.

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8.Upgrading storage and security

Site name:

Address: Suburb: Postcode:

Describe the change to the way the medicines are stored or the change to site security:

8.1 Upgrading a drug safe

If upgrading a drug safe for storing medicines in Schedule 8 please complete Sections 17.1 and 17.3. Do not make a payment if the Permit currently lists Schedule 8 medicines and the change is for upgrading the drug safe only.

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9.Change of individual Permit holder

Complete this section only if the new Permit holder is an individual medical practitioner

Refer to instruction number 6, for information on the requirements for being an individual Permit holder.

9.1 Name of new incoming permit holder:

Dr. Forename(s): Surname:

Address: Suburb: Postcode:

Telephone/Mobile: Email:

Position in business:

A new Permit holder must complete and **attach** Part 2: Personal Information: Identification, Fitness and Probity.

10.Change of corporate officer or partner

Note: Only applicable if the permit has been issued to a body corporate or company and not to an individual person.

10.1 Name of new incoming corporate officer or partner

Title: Forename(s): Surname:

Address: Suburb: Postcode:

Telephone/Mobile: Email:

Corporate officer/partner must complete and **attach** Part 2: Personal Information: Identification, Fitness and probity

10.2 Name of outgoing corporate officer or partner

Title: Forename(s): Surname:

10.3 Please **attach** a copy of the Current and Historical Company Extract from ASIC which includes details of all past and current corporate officers.

11. Increase quantity of medicines

Site name:

Address: Suburb: Postcode:

11.1 Medicines having their quantities increased at the above-named site

Medicine	Quantity on current Permit	Increase quantity to:

11.2 Increasing quantity of Schedule 8 medicines

If increasing the quantity of a Schedule 8 medicine/s, complete Sections 16.1 and 16.3. The total number of human doses of Schedule 8 medicines stored at the site will have to be calculated to determine if the current safe is still compliant.

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12. Addition of medicines

Site name:

Address: Suburb: Postcode:

12.1 Medicines to be added to the above-named site

☐ Schedule 2- Pharmacy medicine ☐ Schedule 3 – Pharmacist only medicine

☐ Schedule 4 – Prescription only medicine ☐ Schedule 8 – Controlled drug: plus, complete Section 17

If only a small number of specific individual medicines are to added oved, please list below:

12.2 Storage and temperature monitoring of Schedule 2, 3, and 4 medicines added to the Permit

12.2.1 Storage of non- refrigerated medicines in Schedule 2, 3, and 4 (Please check which one applies)

☐ Locked room ☐ Locked cupboard ☐ N/A no non-refrigerated medicines

12.2.2 Storage of refrigerated medicines in Schedule 2, 3, and 4 (Please check which one applies)

☐ Locked room with refrigerator ☐ Locked refrigerator ☐ N/A no refrigerated medicines

12.2.3 Temperature monitoring for refrigerated medicines in Schedule 2,3 and 4

Please indicate how the temperature of refrigerated medicines will be monitored

☐ Vaccine refrigerator with an inbuilt thermometer and data logger that can download data.

☐ Normal refrigerator with temperature data logger that can download data.

Manual thermometers are not sufficient for continuous monitoring of temperature sensitive medicines. The temperature data logger:

- must record multiple data points (not just maximum and minimum temperatures) and
- must create an alarm if the temperature is outside the designated range.

12.3 Usage of the medicines being added to the Permit

Will the medicines being added, be used for the same purpose as other medicines listed on the Permit?

☐ Yes

☐ No: please describe the purpose for which the medicines will used:

Some variations in the conditions of use may require a new application for a different type of Permit

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13.Relocation of an existing site

13.1 **Current address of site:**

Site name:

Address: Suburb: Postcode:

13.2 **New address of relocated site:**

Site name:

Address: Suburb: Postcode:

Telephone: Fax: Email:

Date of possession of the site (settlement date/lease commencement/handover of site):

Note: Permit will be issued with "Valid from" date on or after this date.

13.3 **Plus,** complete Sections 15,16,19, 22 and 35 (payment) and complete all of Section 17 if Schedule 8 medicines will be stored at the relocated site.

14. Addition of another new site

14.1 Site name:

Site Address: Suburb: Postcode:

Telephone: Fax: Email:

Date of possession of the site (settlement date/lease commencement/handover of site)

Note: Permit will be issued with "Valid from" date on or after this date.

14.2 **Plus,** complete Sections 15,16,19,22 and 35 (payment) and complete all of Section 17 if Schedule 8 medicines will be stored at the new added site.

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15. Information about the relocated or new added site

Is this site being transferred from a different Medical Treatment provider? Please see instruction number 10.

☐ No ☐ Yes: Name of Medical Treatment provider:

The Department requires the previous Permit holder at the relocated or new added site to remove the site from their Permit. The application to remove the site from the previous Permit holder's Permit must be received by the Department prior to adding the relocated or new added site to your Permit.

15.1 Site details

Name of resource company contracting the medical treatment provider:

15.2 Medical practitioner responsible for the relocated or new added site

Dr. Forename(s): Surname:

Position in business:

Is the responsible person for the relocated or new added site also responsible for another site on the Permit or are they the Permit holder?

☐ Yes: Confirm name:

Dr. Forename: Surname:

☐ No: the responsible person for the relocated or new added site must complete and **attach** Part 3: Personal Information: Identification, Fitness and Probity.

15.3 Geographic location

GPS coordinates for site:

Distance to the nearest population centre:

Number of personnel being serviced at the site:

15.4 Employees at site:

Are employees on the mining/resource/industrial site from one mining/resource/industrial company?

☐ Yes

☐ No

15.5 Does the site currently have a Royal Flying Doctor (RFDS) Chest?

☐ No ☐ Yes: the chest must be returned to the RFDS, please contact them to organise its return.

15.6 Building security

Please check all that apply:

☐ Dedicated monitored alarm system ☐ Video surveillance system (CCTV) ☐ Motion detectors

☐ Perimeter fence with lockable gate ☐ Perimeter alarm

☐ Other – please describe:

15.7 Details of staff administering and supplying medicines at relocated or new added site

Qualifications of staff who will be administering and supplying medicines on site:

a. ☐ Medical practitioner ☐ Registered nurse[1] ☐ Enrolled nurse[2] ☐ AHPRA registered paramedic

b. ☐ Medic[3]

☐ Please check to confirm all medics employed by the Medical Treatment provider have a minimum qualification of Cert IV in Healthcare Ambulance, First Aid or equivalent from a RTO.

☐ Please check to confirm all medics[3] employed by the Medical Treatment provider, provide a National Police Clearance certificate (NPC) issued in the last 12 months prior to commencing employment.

[1] Includes nurse practitioner

[2] An enrolled nurse can administer medicines unless they have a notation on their registration which advises that they have not completed education related to the handling of medicines.

[3] A medic is not registered with AHPRA and does not have a Degree in paramedicine but has a minimum qualification of Cert IV in Healthcare Ambulance, First Aid or equivalent from a RTO.

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16. Information about the medicines at relocated or new added site

List of medicines to be used at relocated or new added site

Please check all the apply:

☐ Schedule 2- Pharmacy medicine ☐ Schedule 3 – Pharmacist only medicine

☐ Schedule 4 – Prescription only medicine ☐ Schedule 8 – Controlled drug: plus, complete Section 17

If only a small number of individual medicines will be required at relocated or new added site, please list below:

16.1 Storage and temperature monitoring of Schedule 2, 3, and 4 medicines

16.1.1 Storage of non- refrigerated medicines in Schedule 2, 3, and 4 (Please check which one applies)

☐ Locked room ☐ Locked cupboard ☐ N/A no non-refrigerated medicines

16.1.2 Storage of refrigerated medicines in Schedule 2, 3, and 4 (Please check which one applies)

☐ Locked room with refrigerator ☐ Locked refrigerator ☐ N/A no refrigerated medicines

16.1.3 Temperature monitoring for refrigerated medicines in Schedule 2,3 and 4

Please indicate how the temperature of refrigerated medicines will be monitored

☐ Vaccine refrigerator with an inbuilt thermometer and data logger that can download data.

☐ Normal refrigerator with temperature data logger that can download data.

Manual thermometers are not sufficient for continuous monitoring of temperature sensitive medicines.
The temperature data logger:

- must record multiple data points (not just maximum and minimum temperatures) and
- must create an alarm if the temperature is outside the designated range.

16.2 Storage area for medicines in Schedule 2,3, and 4 at the relocated or new added site

Please provide information for all areas storing Schedule 2,3 and 4 medicines at the site:

Building name/number, room number	Building name/number, room number

16.3 Usage of the medicines at the relocated or new added site

Will the medicines at the relocated or new site be used for the same purpose as at the previous site or other site on the Permit?

☐ Yes

☐ No: please describe the purpose for which the medicines will used:

Some variations in the conditions of use may require a new application for a different type of Permit

Section 16 continues next page

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16.4 Administration and supply of Schedule 2,3 and 4 medicines to patients at relocated or new added sites

Type of health practitioner authorising administration and supply of Schedule 2, 3,4 medicines to patients

16.4.1 ☐ **Medical Practitioner**

a) ***Administration*** of **Schedule 4 medicines** (please check ONE option only):

- ☐ Doses of **Schedule 4** medicines will only be *administered* by the medical practitioner or in accordance with a direction by a medical practitioner for each individual patient **OR**
- ☐ A combination of individual directions to *administer* and Structured Administration and Supply Arrangements (SASAs)[1] will be used for *administration* of doses of Schedule 4 medicines **OR**
- ☐ All *administration* of doses of Schedule 4 will be in accordance with a SASA[1]

b) ***Supply*** of **Schedule 2,3** and **4** medicines for patients to take away **(**please check ONE option only):

- ☐ Schedule 2,3, and 4 medicines will not be *supplied* to patients to take away **OR**
- ☐ Schedule 2,3 and 4 medicines for patients to take away will be personally *supplied* by medical practitioner[2] **OR**
- ☐ A combination of individual supply by the medical practitioner and SASAs[1] will be used to supply Schedule 2,3 and 4 medicines to the patient[2] **OR**
- ☐ Schedule 2, 3 and 4 medicines will be *supplied* to patients to take away via SASAs[1] only[2]

[1]Note: Structured Administration and Supply Arrangements (SASA's) can only be written:

- and approved by a medical practitioner and not a nurse practitioner
- for acute conditions or a public health issue

Information on SASAs are available at: Structured Administration and Supply Arrangements

Once completed, copies of SASAs must be forwarded to the Medicines and Poisons Regulation Branch. Completion of SASAs is not required as part of the Permit application process.

[2] Complete Section 16.5

16.4.2 ☐ **Nurse Practitioner**

a) ***Administration*** of **Schedule 4** medicines

- ☐ Check to confirm that **Schedule 4** medicines will only be *administered* by a nurse practitioner or *in* accordance with a direction by a nurse practitioner for each individual patient**.**

b) ***Supply*** of **Schedule 2,3** and **4** medicines for patients to take away (please check ONE option only):

- ☐ Schedule 2,3, and 4 medicines will not be *supplied* to patients to take away **OR**
- ☐ All Schedule 2,3 and 4 medicines for patients to take away will be personally *supplied* by nurse practitioner: complete Section 15.5

16.5 Supplying Schedule 2,3 and 4 medicines to patients

Complete Section 16.5, only if Schedule 2,3 or 4 medicines will be supplied to patients to take away.

☐ Please check to confirm Schedule 2 and 3 medicines will only be supplied to patients in their original packs.

☐ Please check to confirm Schedule 4 medicines supplied to patients, will be labelled according to Appendix L of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

More information is found at: Labels on Medicines and Poisons and Code of Practice for Health Service Permits for Medical Treatment

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17.Schedule 8 medicines (Controlled Drug)

Complete Sections 17.1 and 17.3 if the drug safe has been upgraded as per Section 8.1
Complete Sections 17.1 and 17.3 if increasing the quantify of Schedule 8 medicines as per Section 11.2
Complete all of Section 17 if adding Schedule 8 medicines to the Permit as per Section 12.1
Complete all of Section 17 if a relocated site will be storing Schedule 8 medicines as per Section 13.3
Complete all of Section 17 if a new added site will be storing Schedule 8 medicines as per Section 14.2

Is this site being transferred from another medical treatment provider? see instruction number 10.

☐ No ☐ Yes: name of medical treatment provider: _____

Are Schedule 8 medicines being transferred from the medical treatment provider?

☐ No ☐ Yes: please confirm an inventory of S8 medicines will be conducted at the time of handover

Will S8 medicines be stored in multiple areas/rooms at the site?

☐ No: complete all of Section 17

☐ Yes: complete all of Section 17 for the first drug safe and Sections 17.1 and 17.3 for every other drug safe.

17.1 Required Schedule 8 medicines

Confirm address of site:

17.1.1 Location of drug safe (building number/name, room number):

17.1.2 Please list all required S8 medicines stored in the **drug safe** at the location named in Section 17.1.1

Name, strength and form of medicine	Quantity required	Number of *human doses*

17.1.3 Total number of *human doses* of S8 medicines stored in the drug safe:

How to calculate the number of *human doses*:

a. For divided doses such as tablets, capsules, ampoules, patches: 1 tablet, 1 ampoule, 1 patch =1 dose, regardless of strength. For example, 1 fentanyl patch = 1 human dose, 1 ampoule = 1 human dose.

b. For mixtures, calculate the number of doses in the bottle using the information in the following table:

Preparation	Size of bottles	Human dose	Total doses per bottle
Morphine mixture 2 mg per mL	200 mL	5 mg	80
Morphine mixture 5 mg per mL	200 mL	5 mg	200
Oxycodone mixture 1 mg per mL	250mL	5mg	50
Hydromorphone mixture 1 mg per mL	473mL	2mg	237
Codeine linctus 5 mg per mL	100mL	5mL	20

17.2 Number of human doses of Schedule 8 medicines and drug safe requirements

The number of human doses of Schedule 8 medicines stored in the drug safe will determine the size of the safe.

Number of human doses	Compliant drug safe	Motion detector
≤ 250	Small	Not required
Between 251- 500	Small	Required
> 500	Large	Required

PART 1: APPLICATION to change an AMBULANCE SERVICE PERMIT
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17.3 Number of Schedule 8 human doses and required drug safe. Complete Section 17.3 for each dug safe.
Check to confirm the number of doses calculated at 16.1.3 stored in the drug safe identified in Section 17.1.1

☐ ≤ 250: complete Section 17.3.1

☐ 250-500: complete Section 17.3.2

☐ > 500: complete Section 17.3.3 and 17.3.3. a

17.3.1 ☐ **≤ 250** human doses will be stored in a small drug safe with no motion detector required.

Schedule 8 small drug safe make and model number:

What is the safe bolted to?

☐ Concrete floor ☐ Brick wall ☐ Other, describe:

☐ **If** safe is not bolted to a concrete floor or brick wall, please check to confirm the safe is bolted to a structural element of the building such as a steel beam or floor joist. See Appendix A for information.

☐ Check to confirm the safe is compliant with requirements for a small drug safe as per Appendix A.

Please **attach** photos showing:

- safe with the door closed
- safe with the door open, with a ruler held against the door edge to show the thickness of the door plate
- how the safe has been bolted into place with four bolts as per Appendix A Requirements for a small safe

17.3 .2 ☐ **251- 500** human doses will be stored in small drug safe and monitored by a motion detector device.[1]

Schedule 8 small drug safe make and model number:

What is the safe bolted to?

☐ Concrete floor ☐ Brick wall ☐ Other, describe:

☐ **If** safe is not bolted to a concrete floor or brick wall, please check to confirm the safe is bolted to a structural element of the building such as a steel beam or floor joist. See Appendix A for information.

☐ Check to confirm the safe is compliant with requirements for a small drug safe as per Appendix A.

☐ Check to confirm safe is covered by motion detector linked to continuously monitored alarm system.

Please **attach** photos showing:

- safe with the door closed.
- safe with the door open, with a ruler held against the door edge to show the thickness of the door plate
- how the safe has been bolted into place with four bolts as per Appendix A.
- location of motion detector/s in relation to the drug safe.

17.3.3 ☐ **>500** human doses will be stored in a large safe, continuously monitored by a motion detector device[1].

Schedule 8 large drug safe make and model number:

☐ Check to confirm the safe is compliant with requirements for a large drug safe as per Appendix B.

☐ Check to confirm safe is covered by motion detector linked to continuously monitored alarm system.

Does the large safe weigh more than one tonne?

☐ Yes

☐ No: check to confirm the safe is mounted on a concrete floor as per Appendix B.

Please **attach** photos showing:

- safe with the door closed
- safe with the door open, with a ruler held against the door edge to show the thickness of the door plate
- the locking mechanism as per Appendix B
- the door is secured with at least 2 locking bolts of at least 32mm
- how the safe has been bolted onto a concrete floor as per Appendix B if safe weights less than 1 tonne
- location of motion detector/s in relation to the drug safe.

17.3.3 a Please **attach** evidence to show the safe was installed by a person licensed under the *Security and Related Activities (Control) Act 1996* to install safes.

[1]Motion Detectors: drug safe must be covered by movement detector attached to a continuously monitored alarm system

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17.4 Access to Schedule 8 medicines

☐ Please check to confirm that only AHPRA registered health practitioners authorised under the *Medicines and Poisons Act 2014* to possess Schedule 8 medicines and employed by the medical treatment service will have unsupervised access to S8 medicines and keys/entry codes to storage rooms and drug safes.

17.5 Record keeping for Schedule 8 medicines

Check to confirm which type of recording system will be used to record administration or supply of S8 medicines:

☐ Patient notes OR ☐ Other- please describe: _____

Which type of drug register will be used to record the receival of and administration or supply of S8 medcicines[1]

☐ Paper Schedule 8 register – HA14 OR

☐ Department of Health approved Electronic Schedule 8 register

Name of approved electronic register: _____

☐ Check to confirm records of administration or supply and registers will be kept for a minimum of 5 years[1]

17.6 Inventory, loss, theft and discrepancies of Schedule 8 medicines

☐ Check to confirm an inventory (balance check) of S8 medicines will be conducted at least monthly[2].

☐ Check to confirm any discrepancies that have not been accounted for are reported to MPRB ASAP[2]

☐ Check to confirm loss / theft of S8 medicines will be reported to MPRB and police ASAP[3]

17.7 Disposal/destruction of Schedule 8 medicines at relocated or new added site

17.7.1 ☐ Check to confirm an inventory of S8 medicines will be conducted prior to being disposed of or destroyed.

17.7.2 Please indicate how expired or substandard Schedule 8 medicines will be disposed of:

☐ Returned to wholesaler for disposal

Name of wholesaler: _____

or

☐ *Destroyed* at the site, placed into a sharp's container, collected by a licensed clinical waste disposal service and incinerated[4]

Name of licensed clinical waste disposal service: _____

Please confirm the following:

☐ Schedule **8** medicines will be *destroyed* by making them unidentifiable and unusable[4]

☐ destruction will be **conducted** by persons authorised by Medicines and Poisons Regulations 2016[4,5]

☐ destruction will be **witnessed** by persons authorised by Medicines and Poisons Regulations 2016[4,5]

[1] Schedule 8 drug registers

[2] Recording of Schedule 8 transactions in an approved register

[3] Reporting loss or theft of medicines and poisons

[4] Disposal of medicines

[5] Persons authorised to destroy and make S8 medicines unidentifiable and persons authorised to witness this process include health professionals permitted to possess S8 medicines such as medical practitioners, registered nurse, paramedics, pharmacists.

Section 17 continues next page

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17.8 Administration and supply of Schedule 8 medicines to patients at relocated or new added site

Type of health practitioner authorising administration and supply of Schedule 8 medicines to patients

17.8.1 ☐ **Medical Practitioner**

a) ***Administration*** of **Schedule 8** medicines (please check ONE option only):

- ☐ Doses of Schedule 8 medicines will only be *administered* by the medical practitioner or in accordance with a direction by a medical practitioner for each individual patient **OR**
- ☐ A combination of individual directions to *administer* and Structured Administration and Supply Arrangements (SASAs)[1] will be used for *administration* of doses of Schedule 8 medicines **OR**
- ☐ All *administration* of doses of Schedule 8 will be in accordance with a SASA[1]

b) ***Supply*** of **Schedule 8** medicines for patients to take away (please check ONE option only):

- ☐ Schedule 8 medicines will not be *supplied* to patients to take away **OR**
- ☐ All Schedule 8 medicines for patients to take away will be personally *supplied* by a medical practitioner: complete Section 17.9

[1]Note: Structured Administration and Supply Arrangements (SASA's) can only be written:
- and approved by a medical practitioner and not a nurse practitioner
- for acute conditions or a public health issue
- for the administration and not the supply of Schedule 8 medicines.

Information on SASAs are available at: Structured Administration and Supply Arrangements

Once completed, copies of SASAs must be forwarded to the Medicines and Poisons Regulation Branch. Completion of SASAs is not required as part of the Permit application process.

17.8.2 ☐ **Nurse Practitioner**

a) ***Administration*** of **Schedule 8** medicines

- ☐ Please check to confirm Schedule 8 medicines will only be *administered* by a nurse practitioner or *in* accordance with a direction by a nurse practitioner for each individual patient.

b) ***Supply*** of **Schedule 8** medicines for patients to take away (please check ONE option only):

- ☐ Schedule 8 medicines will not be *supplied* to patients to take away **OR**
- ☐ All Schedule 8 medicines for patients to take away will be personally *supplied* by a nurse practitioner: complete Section 17.9

17.9 *Supplying* Schedule 8 medicines to patients

Complete Section 17.9 only if Schedule 8 medicines will be supplied to patients to take away.

☐ Please check to confirm Schedule 8 medicines supplied to patients, will be labelled according to Appendix L of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

More information is found at: Labels on Medicines and Poisons and Code of Practice for Health Service Permits for Medical Treatment

18. Structured Administration and Supply Arrangements (SASA)

Refer to instructions number 11. Once issued, copies of SASAs must be sent to MPRB@health.wa.gov.au

18.1 If SASAs are issued by the organisation, tick each box to confirm that each of the following requirements of Regulation 34 of the Medicines and Poisons Regulations are met:

- ☐ Each SASA is reviewed by a Clinical Governance Committee that meets the requirements of Regulation 34(1) of the Medicines and Poisons Regulations 2016.
- ☐ Each SASA is signed by the most senior medical practitioner in the organisation.
- ☐ Each SASA is issued by the Chief Executive Officer of the organisation.

18.2 Terms of reference of Clinical Governance Committee: Please attach a copy of the terms of reference ☐

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19. Auditing and Standard Operating Procedures at relocated or new added site

19.1 Please indicate the process/es used to ensure compliance with the legislation and the Code of Practice for Health Service Permits for Medical Treatment at the reloacted or new added site

- ☐ Site visits by permit holders – Frequency:
- ☐ Site visits by other company representative – Frequency:
- ☐ External auditing – Frequency:
- ☐ Other methods, please specify:

19.2 Standard operating procedures (SOP's)

Will SOPs for the Medical Treatment service at the site be the same as for another site listed on the Permit?

☐ Yes: SOP is the same as:

☐ No: please **confirm** the Medical Treatment provider has the following SOPs

☐ **SOP** for **ordering** scheduled medicines, which support the following requirements:

a) Orders must be approved by Permit holder or a registered health practitioner authorised to possess scheduled medicines who has been authorised to approve orders by the Permit holder. If the Permit holder does not personally authorise each order, they must regularly review medicines being ordered.

b) Only medical practitioners, nurse practitioners, registered nurses, enrolled nurses, registered paramedics or medics should receive medicines when delivered by wholesalers. Other staff such as administration staff cannot be designated as responsible for this task.

c) Scheduled medicines must be ordered from a licensed pharmaceutical wholesaler.

☐ Please check the box to confirm that orders will be sent directly to the site by the wholesaler.

If orders are not sent directly to the site by the wholesaler, explain why and describe the alternative arrangements:

☐ **SOP** for **recording** administration and supply of medicines, which support the following requirements:

a) When a direction is given by telephone or other electronic means by a prescriber, an entry is made into the patients' clinical record by the prescriber within 24 hours of giving the direction.

b) All medicines administered or supplied (only medicines in Schedule 2, 3 and 4 can be supplied) are recorded in the patients' medical notes.

c) All schedule 8 medicines that are administered are also recorded in the Paper Schedule 8 register – HA14 or Department of Health approved Electronic Schedule 8 register.

d) A record of the administration or supply of a medicine in Schedule 4 is kept for a minimum of 2 years.

e) A record of the administration of a medicine in Schedule 8 is kept for a minimum of 5 years

☐ **SOP** for **labelling** Schedule 2, 3 and 4 medicines for supply, which support the following requirements:

a) A medicine in Schedule 2 or 3 is only supplied in the manufactures original pack.

b) A medicine in Schedule 4 must be labelled for the individual patient in compliance with the Medicines and Poisons Regulations 2016. See Code of practice for Health Service Permits for Medical Treatment for details.

Section 19 continues next page

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19.2 Standard Operating Procedures (SOP)

☐ **SOP** for checking and recording an **inventory** of Schedule 8 medicines (if Schedule 8 medicines will be stored). SOP must support the following requirements:

a) Completed by permit holder or appropriate person delegated in writing by the permit holder.

b) Inventory for medicines in Schedule 8 will be performed at least monthly and whenever the on-site person responsible for the S8 medicines changes.

c) Includes: date inventory is made, name, quantity and strength of S8, signed.

☐ **SOP** for **investigating** and **reporting loss** or **theft** of **Schedule 4** or **8** medicines to permit holder and WA Department of Health, which support the following requirements:

a) Notifying Department of Health if loss or theft involves medicines in Schedule 4 or 8.

b) WA police notified immediately if it appears that Schedule 8 medicines have been stolen.

c) Notifying the permit holder.

d) Reporting is completed by permit holder or appropriate person delegated in writing by the permit holder.

For more information, visit: Reporting loss or theft of medicines and poisons

☐ **SOP** for checking and **managing expired** and/or **substandard** medicines which support the following requirements:

a) Completed by permit holder or delegated by permit holder in writing to appropriate staff.

b) Stocktakes are undertaken regularly, and short dated stock flagged
- For Medicines in Schedule2,3 and 4
- Expired and damaged stock are isolated and labelled so they are not used
- Returned to Permit holder or placed in a drug waste container which is taken by controlled waste management contractor for incineration.

c) For medicines in Schedule 8 (if Schedule 8 medicines are required):
- Stock is isolated and labelled for destruction
- Returned to Permit holder or kept in safe until authorised person is available to witness destruction.
- If destroyed at site:
  - Destroyed by making medicine unidentifiable and chemically or physically unusable.
  - Transfer to drug waste bin and taken by controlled waste management contractor for incineration OR
  - Only placed in sharps container, if it is certain that it is incinerated.
- Written out of register when returned to permit holder or destroyed.

For more information please visit: Disposal of medicines

☐ **SOP** for **implementing** a pharmaceutical sponsor or supplier consumer level **product recall**. SOP must support the following requirements:

a) Recall notice checked against stock and affected stock quarantined and labelled appropriately

b) Incoming stock is monitored.

c) Checking if recalled medications have been supplied and request, they be returned.

PART 1: APPLICATION to change a MEDICAL TREATMENT PERMIT
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20.Change of business or trading name

Complete this Section if the business or trading name will change without any change in legal entity.
If there is a change in ownership, an application for a new Permit is required.

20.1 Previous business or trading name:

New business or trading name:

Attach a copy of the Current and Historical Business Name Extract from ASIC

20.2 Australian Business Number:

21.Variation in the activities undertaken under the Permit

Please describe the proposed change in the way the medicines will be used:

Note: Some variations in the conditions of use will require a new application and issue of a different Permit type.

22.Declaration by Permit holder

This declaration relates to the application to change the Permit and must be signed by the individual Permit holder (medical practitioner) or if the Permit is issued to a corporation or partnership, the declaration must be signed by a corporate officer of partner.

Please refer to Instruction 14 for information on acceptable signatures.

I am the: ☐ current Permit holder ☐ incoming Permit holder

☐ the corporate officer or partner who signed the original Permit application.

If the current Permit holder cannot sign please provide the reason:

I (provide full name):

of (provide full address):

hereby declare:

i. The information contained in this application form is true and correct

ii. I am aware that penalties apply under the *Medicines and Poisons Act 2014* for providing false or misleading information in this application.

Signature of applicant: Date:

PART 2: PERSONAL INFORMATION: new PERMIT HOLDER

Part 2 assesses identification, fitness and probity of the Permit holder.
If the new Permit holder is an individual health practitioner, all sections of Part 2 must be completed.
If the Permit is held by a corporation or partnership, and there is a new corporate officer or partner, all sections of Part 2 except Sections 24 and 25 must be completed by each new corporate officer or each new partner.

23.Identification of new Permit holder, corporate officer or partner

23.1 Personal Details

Title: First name: Surname: Date of birth:

Address: Suburb: Postcode:

Postal address: Suburb: Postcode:

Mobile number: Email:

Position in business:

23.2 Certified true copy of a photographic identification document

ATTACH a certified [1] copy of a WA State Government or Australian Government issued photographic identification document such as drivers Licence or passport. Non-government issued identification documents will not be accepted.

[1]Copy of photographic identification document must be certified as a true copy by a person authorised to witness statutory declarations (see Appendix C for a list of persons authorised to certify a true copy)

23.3 Role in relation to the Permit

☐ A new medical practitioner who will be the new Permit holder on behalf of the business. Complete remainder of Part 2.

☐ a new corporate officer. Type of corporate officer:

☐ Director ☐ General Manager ☐ Company secretary ☐ CEO ☐ CFO ☐ COO

Complete Sections 26,27,28 and 29 of Part 2 and **attach** a CV[1]

☐ a new partner

Complete Sections 26,27,28 and 29 of Part 2 and **attach** a CV[1]

[1]A new **corporate officer or partner must provide a CV and qualifications.** These will be used to assess whether the corporate officer or partner meets the requirements of the *Medicines and Poisons ACT 2014.*

24.Qualifications of new Permit holder

Complete this section if you are an individual medical practitioner applying to be the new Permit holder.
Do not complete this section, if the Permit has been issued to a corporation or partnership.

Refer to instruction number 6 for information on the requirements for being an individual Permit holder.

AHPRA registration number: Registration expiry date:

Attach a copy of your current annual registration certificate or wallet card provided to you by AHPRA.
Note: please **do not** provide an extract of the information available on AHPRA's public website.

PART 2: PERSONAL INFORMATION: new PERMIT HOLDER

25.Authority, access, Standard Operating Procedures (SOPs)

Complete this section if you will be the new individual Permit holder, i.e. medical practitioner.
Do **not** complete this section, if the Permit holder is a corporation or partnership.

☐ Please check to confirm that as the new Permit holder, you will have authority within the business to determine policies and procedures on the management, storage and administration of medicines.

☐ Please check to confirm that you will always have access to the medicines listed on the Permit.

☐ Please check to confirm that only yourself, responsible person or other authorised employees of the Medical Treatment provider will have unsupervised access to the medicines.

25.1 Confirmation of SOPs by new individual Permit holder (medical practitioner)

As the new Permit holder, confirm the Medical Treatment provider has the following SOPs for medicines:

☐ **SOP** for **ordering** scheduled medicines, which support the following requirements:

a) Orders must be approved by Permit holder or a registered health practitioner authorised to possess scheduled medicines who has been authorised to approve orders by the Permit holder. If the Permit holder does not personally authorise each order, they must regularly review medicines being ordered.

b) Only medical practitioners, nurse practitioners, registered nurses, enrolled nurses, registered paramedics or medics should receive medicines when delivered by wholesalers. Other staff such as administration staff cannot be designated as responsible for this task.

c) Scheduled medicines must be ordered from a licensed pharmaceutical wholesaler.

☐ Please check the box to confirm that orders will be sent directly to the site by the wholesaler.

If orders are not sent directly to the site by the wholesaler, explain why and describe the alternative arrangements:

☐ **SOP** for **recording** administration and supply of medicines, which support the following requirements:

a) When a direction is given by telephone or other electronic means by a prescriber, an entry is made into the patients' clinical record by the prescriber within 24 hours of giving the direction.

b) All medicines administered or supplied (only medicines in Schedule 2, 3 and 4 can be supplied) are recorded in the patients' medical notes.

c) All schedule 8 medicines that are administered are also recorded in the Paper Schedule 8 register – HA14 or Department of Health approved Electronic Schedule 8 register.

d) A record of the administration or supply of a medicine in Schedule 4 is kept for a minimum of 2 years.

e) A record of the administration of a medicine in Schedule 8 is kept for a minimum of 5 years

☐ **SOP** for **labelling** Schedule 2, 3 and 4 medicines for supply, which support the following requirements:

a) A medicine in Schedule 2 or 3 is only supplied in the manufactures original pack.

b) A medicine in Schedule 4 must be labelled for the individual patient in compliance with the Medicines and Poisons Regulations 2016. See Code of practice for Health Service Permits for Medical Treatment for details.

☐ **SOP** for checking and recording an **inventory** of Schedule 8 medicines (if Schedule 8 medicines will be stored). SOP must support the following requirements:

a) Completed by permit holder or appropriate person delegated in writing by the permit holder.

b) Inventory for medicines in Schedule 8 will be performed at least monthly and whenever the on-site person responsible for the S8 medicines changes.

c) Includes: date inventory is made, name, quantity and strength of S8, signed.

Section 25.1 continues next page

PART 2: PERSONAL INFORMATION: new PERMIT HOLDER

25.1 Confirmation of SOPs by new individual Permit holder (medical practitioner)

☐ **SOP** for **investigating** and **reporting loss** or **theft** of **Schedule 4** or **8** medicines to permit holder and WA Department of Health, which support the following requirements:

a) Notifying Department of Health if loss or theft involves medicines in Schedule 4 or 8.

b) WA police notified immediately if it appears that Schedule 8 medicines have been stolen.

c) Notifying the Permit holder.

d) Reporting is completed by permit holder or appropriate person delegated in writing by the permit holder.

For more information, visit: Reporting loss or theft of medicines and poisons

☐ **SOP** for checking and **managing expired** and/or **substandard** medicines which support the following requirements:

a) Completed by Permit holder or delegated by permit holder in writing to appropriate staff.

b) Stocktakes are undertaken regularly, and short dated stock flagged

- For Medicines in Schedule2,3 and 4
- Expired and damaged stock are isolated and labelled so they are not used
- Returned to permit holder or placed in a drug waste container which is taken by controlled waste management contractor for incineration.

c) For medicines in Schedule 8 (if Schedule 8 medicines are required):

- Stock is isolated and labelled for destruction
- Returned to Permit holder or kept in safe until authorised person is available to witness destruction.
- If destroyed at site:
  - Destroyed by making medicine unidentifiable and chemically or physically unusable.
  - Transfer to drug waste bin and taken by controlled waste management contractor for incineration OR
  - Only placed in sharps container, if it is certain that it is incinerated.
- Written out of register when returned to Permit holder or destroyed.

For more information please visit: Disposal of medicines

☐ **SOP** for **implementing** a pharmaceutical sponsor or supplier consumer level **product recall**. SOP must support the following requirements:

a) Recall notice checked against stock and affected stock quarantined and labelled appropriately

b) Incoming stock is monitored.

c) Checking if recalled medications have been supplied and request, they be returned.

PART 2: PERSONAL INFORMATION: new PERMIT HOLDER

26.Prior permits/licences for medicines/poisons

To be completed by a new Permit holder, new corporate officer or new partner.

26.1 Have you (or a company of which you were a corporate officer or a partner) previously held a Permit or Licence , under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory, that was suspended or cancelled?

☐ No

☐ Yes: please provide details of the Permit or Licence number, the name of the business, when the cancellation or suspension occurred, the reason for the cancellation or suspension and which state or territory the cancellation or suspension occurred in:

26.2 Have you (or a company of which you were a corporate officer) ever been refused a Permit or Licence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory?

☐ No

☐ Yes: please provide details of the name of the business, what type of Permit or Licence you applied for, why your application was refused and which state or territory the refusal occurred in:

27.Criminal check for new Permit holder, corporate officer or partner

27.1 Offences under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory.

Have you ever been convicted of or are there charges pending for an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory?

☐ No

☐ Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include the:
- Name of the court including state/territory or country, all relevant dates and any sentences received
- The nature of the alleged offence and circumstances surrounding the offences

27.2 Indictable offences[1]

Role in relation to the Permit:

a. ☐ individual medical practitioner.

Have you been convicted of, or are there charges pending for indictable[1] offences since you last applied for renewal of your registration as a health practitioner?

☐ No

☐ Yes: please **attach** full details in the form of a Statutory Declaration and include the:
- Name of court including state/territory/ country, relevant dates and any sentences received
- The nature of the alleged offence and circumstances surrounding the offences.

b. ☐ a corporate officer or partner.

i **Attach** a copy of your National Police Clearance certificate (NPC) which is less than 12 months old.

ii Have you been convicted of, or are charges pending for indictable[1] offences since the date on your NPC?

☐ No

☐ Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include:
- Name of court including state/territory or country, relevant dates and any sentences received
- The nature of the alleged offence and circumstances surrounding the offences.

[1] Minor traffic offences are not classified as indictable offences

PART 2: PERSONAL INFORMATION: new PERMIT HOLDER

28.Financial resources of new Permit holder, corporate officer or partner

To be completed by a new Permit holder, new corporate officer or new partner.

28.1 Have you been declared bankrupt or a debtor under any bankruptcy law?

☐ No

☐ Yes: What date was/will your bankruptcy be discharged? _____

28.2 Have you ever been a corporate officer of a company that was wound up or subject to an application for, or placed in, receivership or liquidation? ☐ Yes ☐ No

29.Declaration by new Permit holder, corporate officer or partner

This declaration must be signed by the new individual Permit holder (medical practitioner), corporate officer or partner and is about personal information and includes probity check consent.

Please refer to Instruction 14 for information on acceptable signatures.

a. In accordance with Section 39 of the *Medicines and Poisons Act 2014*, I give consent to the Western Australian Department of Health to carry out all relevant searches to determine my fitness and probity in relation to holding a Medical Treatment Permit. These searches may include (without limitation) corporate searches, checks with health professional registration boards (including registration status and release of information on any current or ongoing investigations) and criminal record checks. I also understand I may be requested to provide further information relevant to determining fitness and probity.

b. I am at least 21 years of age.

c. The information contained in this application form is true and correct.

d. I am aware there are penalties under the *Medicines and Poisons Act 2014* for providing false or misleading information.

e. I am aware of my responsibility for the safe storage and use of medicines and will ensure compliance with the *Medicines and Poisons Act 2014* and Medicines and Poisons Regulations 2016, and compliance with conditions placed on the Permit.

f. I will notify the Department of Health if I can no longer employed by the Medical Treatment provider, or I am no longer a corporate officer or a partner of the company that holds the Permit.

Signature: _____ Name: _____ Date: _____

PART 3: PERSONAL INFORMATION: new RESPONSIBLE PERSON

30.Identification of new responsible person

The role of the responsible person is to manage the medicines on a day to day basis and be the contact person, if the Permit holder is not available.

Refer to instruction number 7 for information on the requirements for being a responsible person for a site.

30.1 Is the new responsible person, also the Permit holder or responsible for another site listed on the Permit?

☐ Yes: Confirm name: Dr. First name: _____ Surname: _____

There is no requirement to complete Part 3.

☐ No: complete remainder of Part 3.

30.2 Personal details of new responsible person

Dr. First name: _____ Surname: _____ Date of birth: _____

Postal Address: _____ Suburb: _____ Postcode: _____

Mobile number: _____ Email: _____

Position in business: _____

30.3 Certified true copy of a photographic identification document

ATTACH a certified [1] copy of a WA State Government or Australian Government issued photographic identification document such as drivers licence or passport. Non-government issued identification documents will not be accepted.

[1] Copy of photographic identification document must be certified as a true copy by a person authorised to witness statutory declarations (see Appendix C for a list of persons authorised to certify a true copy).

31.Qualifications of new responsible person

AHPRA registration number: _____ Registration expiry date: _____

Attach a copy of your current annual registration certificate or wallet card provided to you by AHPRA.
Note: please **do not** provide an extract of the information available on AHPRA's public website

32.Prior permits/licences for medicines/poisons held by new responsible person

32.1 Have you (or a company of which you were a corporate officer or a partner) previously held a Permit or Licence, under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory, that was suspended or cancelled?

☐ No

☐ Yes: please provide details of the Permit or Licence number, the name of the business, when the cancellation or suspension occurred, the reason for the cancellation or suspension and which state or territory the cancellation or suspension occurred in:

32.2 Have you (or a company of which you were a corporate officer) ever been refused a Permit or Licence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or corresponding law in another state or territory?

☐ No

☐ Yes: please provide details of the name of the business, what type of Permit or Licence you applied for, why your application was refused and which state or territory the refusal occurred in:

PART 3: PERSONAL INFORMATION: new RESPONSIBLE PERSON

33.Criminal check for new responsible person

33.1 Offences under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory.

Have you ever been convicted of or are there charges pending for an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory?

☐ No

☐ Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include the:
- Name of the court including state/territory or country, all relevant dates and any sentences received
- The nature of the alleged offence and circumstances surrounding the offences

33.2 Indictable offences

Have you been convicted of or are there charges pending for indictable[1] offences since you last applied for renewal of your registration as a health practitioner?

☐ No

☐ Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include the:
- Name of the court including state/territory or country, all relevant dates and any sentences received
- The nature of the alleged offence and circumstances surrounding the offences

[1] Minor traffic offences are not classified as indictable offences

34.Declaration by new responsible person

This declaration must be signed by the new responsible person and includes probity check consent.

Please refer to instruction 14 for information on acceptable signatures.

a) I acknowledge my role is to manage the medicines on a day to day basis and be the contact person, if the Permit holder is not available.

b) I give consent to the Western Australian Department of Health to carry out all relevant searches to determine my fitness and probity to be named as the responsible person on the Medical Treatment Permit. These searches may include (without limitation) corporate searches, and criminal record checks. I also understand I may be requested to provide further information relevant to determining fitness and probity.

c) I am at least 21 years of age.

d) The information contained in this application form is true and correct.

Signature: _____ Name: _____ Date: _____

PART 4: PAYMENT and CHECKLIST

35.Payment (where required)

Fee: $90

1. ☐ Credit Card – American Express and Diners not accepted

   Card type: ☐ MasterCard ☐ Visa

   Name on card: _____ Card number: _____

   Expiry date: _____ Amount: **$90**

   Signature of cardholder: _____ Date: _____

2. ☐ Direct debit to bank

   Please quote Permit number and business name in the reference when making a direct debit payment

   Bank: Commonwealth Bank: **BSB**: 066 040 **Account number:** 13300018 Amount: **$90**

   Receipt Number: _____ Payment date: _____

3. ☐ Cheque or money order – made payable to DEPARTMENT OF HEALTH

Please keep a copy of the completed application form for reference

Please email completed form and other requested documentation to mprb@health.wa.gov.au

A fee of $90 is payable for the following types of changes to a Medical Treatment Permit:

- Change of individual Permit holder (medical practitioner) (no change of ownership of the business)
- Change of a corporate officer (only for Permits issued to a corporation and not an individual person)
- Increase quantity of medicines
- Add medicines to a Permit for an existing site.
- Relocation of an existing site to a new location
- Addition of a new site
- Change of business or trading name without changing legal entity (no change of ownership).
- Variation in the activities undertaken under the permit, including the use of the medicines

Note: if making multiple changes, only pay one fee of $90

Fees are not payable for the following type of changes to a Medical Treatment Permit:

- Change of postal address and other contact details
- Change of name of site
- Change to a person responsible for a site
- Removal of a site from the permit
- Removal of medicines from the permit
- Upgrading storage or security including upgrading a drug safe

PART 4: PAYMENT and CHECKLIST

36.Checklist

Please ensure all the appropriate requested documentation is attached for:

Part 1 Application to change a Medical Treatment Permit

- ☐ If changing a responsible person for a site: completed Part 3: Personal Information (Section 4.1)
- ☐ If changing an individual Permit holder: completed Part 2: Personal Information (Section 9.1)
- ☐ If changing a corporate officer/partner: completed Part 2: Personal Information (Section 10.1)
- ☐ If changing a corporate officer/ partner: copy of the Current and Historical Company Extract from ASIC (Section10.3)
- ☐ If a site is relocated or a new site is added to the Permit, and the responsible person is not responsible for any other site or is not the Permit holder: completed Part 3: Personal Information-Form (Section 15.2)
- ☐ If storing Schedule 8 medicines, attach photos of safe etc as required in Section 17.
- ☐ If storing S8 medicines in a large safe, evidence to show the safe was installed by a person licensed under the Security and Related Activities (Control) Act 1996 to install safes. (Section 17.3.3.a)
- ☐ If SASAs are issued, a copy of the terms of reference of the Clinical Governance Committee (Section 18.2)
- ☐ If there is a change of business or trading name without a change of legal entity: copy of the Current and Historical Business Name Extract from ASIC (Section 20.1)
- ☐ Declaration signed and dated by individual Permit holder, corporate officer or partner (Section 22)

Part 2: Personal information, fitness and probity for new Permit holder, corporate officer or partner

- ☐ Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 23.2). See Appendix C for a list of persons authorised to witness a signature
- ☐ If there is a new corporate officer/partner, attach a CV and qualifications for each new officer/partner (Section 23.3)
- ☐ If the new Permit holder is an individual medical practitioner, attach a copy of the person's current annual registration certificate or wallet card provided by AHPRA. **Do not** provide an extract of the information available on AHPRA's public website (Section 24)
- ☐ If applicable, a Statutory Declaration relating to an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory (Section 27.1)
- ☐ If the new Permit holder is an individual medical practitioner and they have been convicted of or there are charges pending for an indictable offence since they last renewed their AHPRA registration, attach a Statutory Declaration relating to the offence (Section 27.2.a)
- ☐ If there is a new corporate officer or partner, attach a copy of the NPC for each new corporate officer or partner which is less than 12 months old (Section 27.2.b i)
- ☐ If there is a new corporate officer or partner and they have been convicted of, or there are charges pending for an indictable offence since the date on the NPC, attach a Statutory Declaration relating to the offence (Section 27.2.b ii)
- ☐ Declaration signed and dated by new Permit holder, new corporate officer or partner (Section 29)

Part 3: Personal information, fitness and probity for new responsible person

- ☐ Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 30.3). See Appendix C for a list of persons authorised to witness a signature
- ☐ The responsible person's current annual registration certificate or wallet card provided by AHPRA. **Do not** provide an extract of the information available on AHPRA's public website (Section 31)
- ☐ If the new responsible person has been convicted of or there are charges pending for an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law or corresponding law in another state or territory, attach a Statutory Declaration relating to the offence (Section 33.1)
- ☐ If the new responsible person has been convicted of or there are charges pending for an indictable offence since they last renewed their AHPRA registration, attach a Statutory Declaration relating to the offence (Section 33.2)
- ☐ Declaration signed and dated by new responsible person (Section 34)

Part 4: Payment and checklist

- ☐ Payment details completed with correct signature if paying by credit card (Section 35)

PART 5: APPENDICES

Appendix A: Requirements for a small safe

The requirements for a small drug safe are set out in the Table.

Table

	Requirements
Cabinet/body	Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thick All joints must be continuously welded
Door	Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thick Must be fitted flush to the cabinet/body with a maximum clearance of 1.5 mm when closed Hinge system must be a system that does not allow the door to be opened if the hinge is removed
Lock	Must be a 6 lever key lock or a 4 wheel combination lock or a digital lock that provides security that is equivalent to a 6 lever key lock or 4 wheel combination lock
Mounting	Must be mounted on a concrete floor or a brick or concrete wall with at least 4 expanding bolts of at least 12 mm in diameter If mounting on a concrete floor or a brick or concrete wall is not possible must be securely mounted on structural elements of the building such as studs or floor joists

PART 5: APPENDICES

Appendix B: Requirements for a large safe

The requirements for a large safe are set out in the Table.

Table

	Requirements
Cabinet/body	Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thick All joints must be continuously welded
Door	Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thick Must be fitted flush to the cabinet/body with a maximum clearance of 1.5 mm when closed Hinge system must be a system that does not allow the door to be opened if the hinge is removed Must be secured with at least 2 locking bolts of at least 32 mm diameter
Lock	Must be a 6 lever key lock or a 4 wheel combination lock or a digital lock that provides security that is equivalent to a 6 lever key lock or 4 wheel combination lock
Mounting	Must be mounted on a concrete floor with an expanding bolt with a diameter of at least 16 mm unless the safe weighs more than 1 tonne
Installation	Must be installed by a person licensed under the *Security and Related Activities (Control) Act 1996* to install safes
Weight	Must have a minimum weight of 250 kg

PART 5: APPENDICES

Appendix C: Certifying true copies of photographic identification

Suggested wording for certification is as follows:

I certify that this appears to be a true copy of the document produced to me on <date>
Signature
Name
Profession or occupation group

Persons who can certify documents	
Academic (tertiary institution)	Medical practitioner
Accountant	Member of Parliament
Architect	Minister of religion
Australian Consular Officer	Nurse
Australian Diplomatic Officer	Optometrist
Bailiff	Patent attorney
Bank manager	Pharmacist
Chartered secretary	Physiotherapist
Chiropractor	Podiatrist
Company auditor or liquidator	Police officer
Court officer (judge, master, magistrate, registrar or clerk)	Post Office manager
Defence Force officer	Psychologist
Dentist	Public servant
Engineer	Public notary
Industrial organisation secretary	Real Estate agent
Insurance broker	Settlement agent
Justice of the Peace	Sheriff or deputy Sheriff
Lawyer	Surveyor
Local government CEO or deputy CEO	Teacher
Local government councillor	Tribunal officer
Loss adjuster	Veterinarian
Marriage celebrant	