

Ahpra Protocol

Supervised access to medication(s)

This protocol applies to restrictions imposed or accepted from 16 September 2024

Australian Health Practitioner Regulation Agency
National Boards
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Ahpra Protocol: Supervised access to medication(s)

Overview

This Ahpra Protocol *Supervised access to medication(s)* (the Protocol) sets out the requirements that apply to practitioners with a registration restriction for medication <u>access</u>. We monitor compliance with this restriction to protect patient safety.

You will receive a monitoring plan that details contact information, due dates and the information you will need to provide to show that you are complying with your restrictions. The plan will be updated as you complete the requirements. s. Read your monitoring plan in conjunction with the Protocol/s.

The Ahpra website and <u>Register of practitioners</u> is located at https://www.ahpra.gov.au. Monitoring and compliance information is available under the Registration section. The online Protocols and forms are available from the National Restrictions Library 2.0 section of the monitoring and compliance web page.

In this Protocol:

'Restriction' and 'Restrictions' refers to:

• conditions and undertakings on your registration that are related to the requirements of this specific Protocol

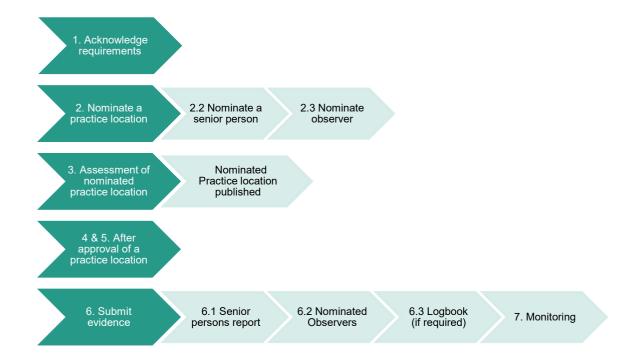
'We' 'us' and 'our' refers to:

- the Australian Health Practitioner Regulation Agency (Ahpra),
- the Board for the health profession you're registered for.

The Protocol includes:

- individually numbered paragraphs and sub-paragraphs to help you navigate the requirements.
- highlighted requirements that you must follow using this symbol:
- clarifying information and advice from us to help you follow the requirements, using this symbol:
- terms that we define in specific ways. The first time we use one of these terms,
 we've hyperlinked these to their <u>definitions</u> for your reference

The Protocol 's requirements fall into 5 main areas.



Requirements

1. Acknowledge the requirements

1.1 Practitioner Acknowledgement

- 1.1.1 You must acknowledge the requirements of the restriction on your registration and the Ahpra Protocol: *Supervised access to medication(s)* (the Protocol) within 3 calendar days of the start date of the restrictions.
- 1.1.2 Complete the Form [HPA.2.22]: Supervised access to medication(s) Practitioner Acknowledgement Form

2. Nominate a practice location

2.1 Nominate practice location





- 2.1.2 Any practice that occurs before or outside the published practice locations will be considered a breach of the restrictions and may result in further regulatory action.
- 2.1.3 Practice location nominations must include a nomination of a senior person and either: at least one nominated observer, or an acknowledgement that you must not access the substances defined in your restrictions. Incomplete nominations will not be assessed.
- 2.1.4 Nominate each practice location using the <u>Form [HPN 2.22]</u>: Supervised access to medication(s) Nomination of Practice Location
- 2.1.5 You must provide a nomination of a senior person and at least one nominated observer at <u>each</u> practice location when nominating a practice location.
- 2.1.6 A nomination of a practice location will only be considered when you have nominated and provided acknowledgements from a senior person and at least one nominated observer.
- 2.1.7 If requested, you must provide evidence of how your compliance with the restrictions will be supported.
- 2.1.8 If you do not nominate any observers with your practice location nomination, you must not access the substances defined in your restrictions.



2.2 Nominate a senior person

- 2.2.1 You must provide the details of the senior person for each nominated practice location using the form below.
- 2.2.2 Nominate the senior person on <u>Form [HPN 2.22]</u>: Supervised access to medication(s) Nomination of Practice Location
- The senior person may be the practice principal, or other person senior by position. This person should generally have oversight of the operational management of the practice and is responsible for managing staff rostering and patient complaints. Where possible your senior person should be another registered health practitioner.

Your senior person will provide information about the characteristics of nominated practice location(s) such as the number of other registered health practitioners on site and details of electronic booking or roster systems.

- 2.2.3 The nomination of each senior person must be accompanied by acknowledgement from each nominated person that they are aware we will contact them and exchange information.
- 2.2.4 The senior person must complete <u>Form [SPA 2.22]</u>: Supervised access to medication(s) Senior Person Acknowledgement Form
- 2.2.5 The nominated senior person must be senior to you by role and/or experience.

- 2.2.6 You must provide each nominated senior person a full copy of the restrictions on your registration and this Protocol
- 2.2.7 You must also provide each nominated senior person(s) the contact details of your Ahpra case officer or team.
- 2.2.8 Your senior person nominee must not have any perceived or actual conflict of interest in undertaking this role.
- 2.2.9 Both you and your nominee must declare any actual, potential, or perceived conflicts of interest. If requested, you must provide information on how you will manage the conflict.
- 2.2.10 If your senior person changes, you must notify your Ahpra case officer within 14 calendar days.
- Conflict of interest can arise from relationships that could compromise the nominee's judgement, decisions or actions when performing their role. These types of relationships include collegiate, family, social, financial and treating ones.

We must be confident that the senior person is able to give independent evidence of your compliance and be willing to provide reports to us if they identify concerns with your conduct, or compliance with your restrictions.

We might refuse your practice location nomination if there is not enough evidence that you will sufficiently manage a conflict.

Nominations that don't meet the above requirements may be considered in extenuating circumstances. Nominations not meeting the above requirements usually require longer timeframes for consideration.

We may refuse your nomination of a practice location

2.3 Nominate observer(s)

- 2.3.1 You must provide the details of <u>all</u> staff at each nominated practice location that are or will be responsible for observing your access to substances.
- 2.3.2 Provide observer details on <u>Form [OBN 2.22]</u>: Supervised access to medication(s) Nomination of Observer Form
- 2.3.3 Each nominated observer must be a health practitioner registered by the National Board and equivalent to you by role and/or experience.
- 2.3.4 If requested, you must provide a copy of each nominated observer's curriculum vitae, role description or the equivalent.
- 2.3.5 You must provide an acknowledgement from each nominated observer.
- 2.3.6 Each observer must complete <u>Form [OBA 2.22]</u>: Supervised access to medication(s) Observer Acknowledgement Form
- 2.3.7 Your observer nominee must not have any perceived or actual conflict of interest in undertaking this role.
- 2.3.8 Both you and your nominee must declare any actual, potential, or perceived conflicts of interest. If requested, you must provide information on how you will manage the conflict.
- A conflict may arise from being in a collegiate, family, social, employment or financial relationship which could compromise the nominee's judgment, decisions, or actions in performing the role.

The observer nominee must be confident that they are able to give independent evidence of your compliance and be willing to provide reports to us if they identify concerns with your conduct, or compliance with your restrictions.

We may refuse your nominated practice staff if there is insufficient evidence that any conflict will be sufficiently managed

- 2.3.9 You must provide all nominated observers a copy of the restrictions published on the public register on your registration, and this Protocol
- 2.3.10 You must also provide all observers the contact details of your Ahpra case officer or team.
- 2.3.11 If you do not nominate any observers with your practice location nomination, you must not access the substances defined in your restrictions.



Nominations that don't meet the above requirements may be considered in extenuating circumstances. Nominations not meeting the above requirements usually require longer timeframes for consideration.

We may refuse your nomination of a practice location

3. Assessment of a nominated practice location

3.1 Assessment of each nominated practice location

Practice locations will be assessed for approval based on the suitability of the nominated senior person, and the suitability of the practice location to accommodate the requirements of the restrictions on a case-by-case basis.

For a practice location to be approved, we must be confident that the nominated observer(s) and senior person are able to give independent information about your compliance and be willing to provide reports to us if they identify concerns.

- 3.1.1 Practice location nominations must include nomination of a senior person and either, at least one nominated observer or, an acknowledgement that you must not access the substances defined in your restrictions. Incomplete nominations will not be assessed.
- 3.2 Each nominated practice location must meet the following requirements:
- 3.2.1 You will not be the sole registered health practitioner at the practice location
- 3.2.2 The practice location is not your place of residence or the residence of patients
- 3.2.3 The senior person such as practice manager at the practice location does not have a direct personal relationship with you (for example, a spouse, de facto, sibling or other relative)
- 3.2.4 There is sufficient oversight or ability to provide independent evidence of compliance.
- Nominations that don't meet the above requirements may be considered in extenuating circumstances.

Nominations not meeting the above requirements usually require longer timeframes for consideration.

We may refuse your nomination of a practice location

4. Following the restrictions

4.1 After approval of a practice location

- 4.1.1 If we approve the practice location nomination, and the approved practice locations are published on the National register, you can commence practising in accordance with the Protocol
- 4.1.2 You must only practise at published practice locations that are published on the online <u>register of practitioners</u>.



- 4.1.3 You must only practice at approved and published practice locations.
- 4.1.4 You must not access the substances as defined in your restrictions unless you are <u>directly observed</u> by a nominated observer.

- Directly observes' means that the nominated observer is always physically present when you are accessing substances as defined by the restrictions.
 - 4.1.5 New nominated observers must not observe your access to substances until written confirmation is provided to you that they have been approved to act as observer.
 - 4.1.6 If you stop practising at any of your published practice locations, you must notify your Ahpra case officer or team within 14 calendar days.

5. Treatment

5.1 Health condition

- 5.1.1 If requested, you must provide evidence of the specific medical condition that caused you to require access to a substance(s) for the treatment of your health condition.
- 5.1.2 Treatment of a health condition will only be accepted as an exemption from the requirements in the following circumstances:
 - you hold, or held, a valid prescription for the medication issued to you by another registered health practitioner as part of treatment for a health condition and the prescription was dispensed to you after the prescription was issued, or
 - supporting evidence of the health condition is provided by you from another registered health practitioner.

6. Submit evidence

6.1 Senior persons report

Your nominated senior person may be asked to provide reports to us to confirm your compliance with your restrictions. If regular reporting is required, the frequency will be detailed in your Monitoring plan.

Reports may include copies of rosters, pay slips, appointment diaries, billing information and the like and may, on request, include clinical records, audit logs, and the equivalent.

Your senior person will also provide a report if they have a concern or become aware of a concern regarding your conduct or professional performance.

6.2 Observer reporting

(j) Your nominated observers may be asked to provide information to us to confirm your compliance with your restrictions.

6.3 Logbook

6.3.1 Compliance with the following requirements is only required if your restrictions require you to maintain a logbook.



- 6.3.2 You must submit the logbook at least monthly.
- 6.3.3 The log must be completed in an approved format and at a minimum completed at the end of each day.
- 6.3.4 The logbook must record at a minimum:
- 6.3.5 Date and time of the patient contact
 - Location
 - Patient full name
 - Patient date of birth
 - Substance prescribed or otherwise accessed, and
 - The name of the nominated observer
- 6.3.6 You must record any other information as directed.

7. Monitoring

7.1 Monitoring your compliance

- 7.1.1 If requested you must provide authority for Ahpra to obtain information from State and Territory drugs and poisons authorities about prescribing, dispensing or access to medications
- 7.1.2 If requested you must provide authority for Ahpra to access information from private health insurers, the Department of Veteran's Affairs and the National Disability Insurance Scheme about services rendered and billing of item numbers.
- (i) We will conduct activities to monitor your compliance with the restrictions.

For the purpose of monitoring the restrictions, we may:

- obtain data from Services Australia relating to prescribing and services rendered to patients to monitor any:
 - o practice whilst there are no approved practice locations published on the public register and you are prohibited from practising
 - o prescribing of substances limited by your restrictions; and
 - o practice if your registration status alters (for example, when the registration is suspended or transitioned to non-practising registration, or if you fail to renew your registration)
- obtain data from private health insurance companies, state and territory drugs and poisons entities, and other third parties relating to access to medications to monitor any:
 - o practice whilst there are no approved practice locations published on the public register and you are prohibited from practising
 - o access to substances limited by your restrictions; and
 - o practice if your registration status alters (for example, when the registration is suspended or transitioned to non-practising registration, or if you fail to renew your registration)

8. Extensions of time

8.1 Requesting an extension

- (i) Extensions of time are generally not permitted.
 - 10.1.1 If you are seeking an extension of time, you must provide a written request.
 - 10.1.2 You must request an extension of time before the applicable due date.
 - 10.1.3 You must provide a proposed timeframe for completion of the requirement when making an extension request.
 - 10.1.4 You must indicate the reason for your request and provide evidence of the basis of the extension.
 - 10.1.5 If you are granted an extension, you must complete the relevant action or requirements within the extended timeframe.



9. Exemptions

(i)

Exemptions may be permitted in very limited circumstances where the restrictions may cause concerns about continuity of care or referral of vulnerable patient groups for ongoing treatment with another registered health practitioner.

Exemptions will only be granted in circumstances where the exemption is limited to the definition of practise and contact to enable transfer of clinical records to another registered health practitioner and/or referral of the patient.

Exemptions will not be granted where you propose to contact a patient directly via correspondence or <u>telecommunication</u>.

We may refuse your request for an exemption.

10. Costs

10.1 Responsibility for costs

10.1.1 You are responsible for all costs associated with complying with this restriction and Protocol.

11. Privacy

11.1 Collection of personal information



We are committed to protecting your personal information.

The ways in which we may collect, use and disclose your information are set out in our <u>Privacy</u> <u>Policy</u>.

The privacy policy and further information regarding <u>Ahpra's Privacy</u>, <u>Freedom of Information and Information publication scheme</u> is available on Ahpra's website.

Definitions

For the purposes of the restrictions and this Protocol the following terms are defined:

Term	Definition
Access	Prescribing, possessing, supplying, administering, handling, dispensing, accessing and checking of substances(s).

Drug of dependence	 g) Any illicit drug h) Any prescription only and any controlled drug medication contained in Schedule 8 of the Standard for the Uniform Scheduling of Medications and Poisons (the SUSMP) as amended from time to time and as published at https://www.tga.gov.au/publication/poisons-standard-susmp, and i) Any pharmaceutical items with an active ingredient listed below: 			
	Bromazepam	Lisdexamfetamine	Pregabalin	
	Chloral hydrate	Lorazepam	Primidone	
	Clobazam	Midazolam	Propofol	
	Clonazepam	Modafinil	Pseudoephedrine	
	Codeine*	Nitrazepam	Quetiapine	
	Diazepam	Oxazepam	Temazepam	
	Dihydrocodeine	Paraldehyde	Tramadol	
	Ephedrine	Perampanel	Trihexyphenidyl	
	Flunitrazepam	Phenobarbitone	Zolpidem	
	Gabapentin	Phentermine	Zopiclone	
	*Including when compounded with other therapeutically active substances (e.g. paracetamol, phenylephrine).			
Practice location	Any location where the practitioner practises the profession including any place where the practitioner: f. is self-employed			
	g. shares premises with other registered health practitioners			
	 h. is engaged by one or more entities under a contract of employment, contract for services or any other arrangement or agreemen i. provides services for or on the behalf of one or more entities, whether in an honorary capacity, as a volunteer or otherwise, whether or not the practitioner receives payment from an entity for the services, or 			
	j. provides pro patient.	ofessional services at the re	sidential premises of a	
Practise	Any role, whether remunerated or not, in which the individual uses their skills and knowledge in their registered health profession. It is not restricted to the provision of direct clinical care and includes using the knowledge and skills in a direct non-clinical relationship with a client, working in management, administration, education, research, advisory, regulatory or policy development roles and any other roles that impact on safe, effective delivery of services in their registered health profession.			

Appendix A: Drugs of Dependence

'Drug of dependence' is defined as:

- d. any prescription only and any controlled drug medication contained in Schedule 8 of the Standard for the Uniform Scheduling of Medications and Poisons (the SUSMP) as amended from time to time and as published at https://www.tga.gov.au/publication/poisons-standard-susmp, and
- e. including any pharmaceutical items with an active ingredient listed in schedule 8 of the SUSMP, and

f. any pharmaceutical items with an active ingredient listed below irrespective of how they are scheduled in the SUSMP or any other state or territory legislation:

Bromazepam	Lisdexamfetamine	Pregabalin
Chloral hydrate	Lorazepam	Primidone
Clobazam	Midazolam	Propofol
Clonazepam	Modafinil	Pseudoephedrine
Codeine*	Nitrazepam	Quetiapine
Diazepam	Oxazepam	Temazepam
Dihydrocodeine	Paraldehyde	Tramadol
Ephedrine	Perampanel	Trihexyphenidyl
Flunitrazepam	Phenobarbitone	Zolpidem
Gabapentin	Phentermine	Zopiclone

^{*}Including when compounded with other therapeutically active substances (e.g. paracetamol, phenylephrine).