Mobile health service establishment protocols for quality and safety — 2018

Sample model Health Service Establishment
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Sample model Health Service Establishment protocols for quality and safety for mobile sedation services
Introduction

The *Health Services Act 1988* requires private hospitals and day procedure centres in Victoria (health service establishment) to be registered with the department of Health and Human Services (the department) and to comply with updated regulations on patient safety and care.

The regulations that apply are: *Health Services (Health Service Establishments) Regulations 2013,* and the *Drugs, Poisons and Controlled Substances Regulations 2017.*

Under the Health Services regulations, the proprietor of a health service establishment must ensure the implementation and ongoing compliance with quality and safety protocols (hereinafter called “protocols”) for the establishment.

Purpose

The proprietor of a mobile sedation service must prepare health service establishment protocols.

Health service establishment protocols determine the accountability of the registered medical practitioner providing the mobile sedation service, to reduce risk and avoid harm. The protocols recommend robust governance processes that:

- provide for the internal governance of appointed registered medical practitioners;
- set out the requirements and procedures for the determination of practice rights and appointment of registered medical practitioners to provide mobile sedation services;
- provide for conditions of appointment; and
- set out clinical credentialing and scope of practice policies adopted by the proprietor;
- set out requirements and procedures for termination, suspension and variation of appointment (including practice rights) of registered medical practitioners.

This model may be adopted without change or adapted to meet the specific requirements of the mobile sedation service. Routine reviews are recommended to be undertaken to maintain currency and effective means of operation, competences and pathways.

On request, a copy of the completed protocols must be provided to the Secretary, Department of Health and Human Services, Victoria.
<table>
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<th>Requirement</th>
<th>Detail</th>
<th>Frequency of review</th>
<th>Evidence</th>
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<tr>
<td><strong>1. Roles and Responsibilities</strong></td>
<td>Establishment protocol</td>
<td>To develop and implement health service establishment protocols (guided by this model) that are:</td>
<td>Ongoing</td>
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<td>• documented in writing;</td>
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<td>• published by the health service establishment (website/on file); and</td>
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<td>• made available to the Secretary, on demand</td>
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<td></td>
<td>Constitution</td>
<td>The proprietor:</td>
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<td>• determines the constitution and capability of the health service establishment.</td>
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<td>• determines and documents the scope of clinical practice of each registered medical practitioner.</td>
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<td>• documents processes determining scope of practice of each unregistered facility in which care is delivered and where appointed registered medical practitioners will enter; use equipment and facilities for the purpose of providing clinical care and services as are specified in the conditions of appointment.</td>
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<td>• takes all other action necessary that ensures safe and quality care is provided within the scope of clinical practice determined</td>
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<td><strong>Policies and processes</strong></td>
<td>The proprietor ensures:</td>
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<td>Proof of public liability.</td>
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<td>• pre-admission assessment processes must be recorded for audit purposes</td>
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<td>• implementation of policies that ensure mobile sedation services are safe and performed within the scope of practice of the registered medical practitioner, and <em>in actu</em> the mobile sedation service</td>
<td></td>
<td>Written open disclosure policy</td>
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<td>• implementation of record keeping processes, and processes that handle complaints received</td>
<td></td>
<td>Complaints handling process.</td>
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<td>• implementation of a written open disclosure policy (this falls under the statutory duty of candour - a legal obligation to ensure that consumers of healthcare and their families are apologised to, and communicated with, openly and honestly when things have gone wrong in their care)</td>
<td></td>
<td>Credentialing and scope of practice</td>
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<td>• implementation of procedure for remedial action that determines the grounds for remedial action, and types of remedial action.</td>
<td></td>
<td>Remedial action procedure</td>
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<td>• compliance with implemented processes.</td>
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<td>Requirement</td>
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<td><strong>Appointments, scope of clinical practice and credentialing</strong></td>
<td>The proprietor:</td>
<td>&lt; 3 yearly maximum</td>
<td>Qualification/competency Board endorsement</td>
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<td></td>
<td>• receives and considers applications from registered medical practitioners seeking appointment to provide clinical care</td>
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<td>Proof of Registration incl. conditions of license)</td>
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<td></td>
<td>• grants short term practice rights</td>
<td></td>
<td>20 recent clinical case records</td>
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<td>• determines and reviews the scope of clinical practice of each appointed registered medical practitioner</td>
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<td>References of contracting proprietors/practitioners</td>
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<td></td>
<td>• reviews the credentials, competence and eligibility of appointment of each registered medical practitioner</td>
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<td>Proof of continuing CPD</td>
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<td>• determines appointment fees (where applicable)</td>
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<td>Academic endorsement</td>
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<td>• takes disciplinary action in relation to an appointed registered medical practitioner</td>
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<td><strong>Safety and quality reviews</strong></td>
<td>The proprietor establishes routine peers/multi-disciplinary safety and quality reviews including but not limited to sentinel event reviews, root cause analyses of untoward events</td>
<td>Annual (minimum)</td>
<td>Documented reviews of sentinel events and untoward events, including root cause analyses, available for inspection</td>
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<td>2. Roles and responsibility: Registered medical practitioner</td>
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<td>Requirement</td>
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| Application | The applicant practitioner:  
  - submits an application for appointment to the proprietor  
  - demonstrates recognised qualifications, registration and experience for the practice they undertake  
  - is registered as a registered medical practitioner with the Medical Board of Australia (or any successor body)  
  - holds appropriate medical indemnity insurance in respect of the practitioner’s scope of clinical practice (or proposed scope of clinical practice) that is consistent with the health service establishment policy requirements  
  - does not have a conflict of interest with [name of health service establishment]  
  - adheres and upholds The Medical Board of Australia code of conduct | On application  
Qualification/competency  
Board endorsement  
Proof of Registration incl. conditions of license  
20 recent clinical case records  
References of contracting proprietors/practitioners  
Proof of continuing CPD |
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<th>Evidence</th>
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| Accreditation | The appointed registered medical practitioner:  
- receives clear terms of appointment  
- fulfils practice rights, as agreed with the proprietor  
- is responsible for disclosing personal, legal or professional impediments to fulfilling the requirements of the role or that could affect patient safety  
- notifies immediately, all health services where they are providing services of any conditions imposed on their practice by the Australian Health Practitioner Regulation Agency (AHPRA)  
- maintains professional standard requirements relevant to their area of practice, supported by accreditation and/or endorsement of relevant academic body  
- is aware of the requirements and capabilities of the health service establishment and aware that these requirements and capabilities may change over time | < 3 yearly maximum | Documented Terms of Appointment  
Documented accreditation of registered medical practitioner  
Academic endorsement of registered medical practitioner |
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<td><strong>Scope of clinical practice</strong></td>
<td>The appointed registered medical practitioner:</td>
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<td>• where licensed, enters and uses equipment and facilities at nominated non-registered facility for the purpose of providing clinical care and such other services as are specified in the conditions of appointment, subject to and in accordance with:</td>
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<td>a. any limitations applicable to the category of appointment</td>
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<td>Determined by license, practice rights</td>
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<td>b. the registered medical practitioner’s scope of clinical practice</td>
<td></td>
<td>Conditions of registration</td>
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<td>c. the registered medical practitioner continuing to comply with all conditions of appointment</td>
<td></td>
<td>Conditions of appointment</td>
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<td>d. the availability of beds, facilities and/or equipment, and nurses and/or allied health practitioners that are sufficient and appropriate for the type of clinical care provided by the registered medical practitioner</td>
<td></td>
<td>Documented pre-admission assessment &gt;24 hours prior to procedure</td>
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<td>e. such other conditions, limitations or restrictions as may be imposed in accordance with these protocols</td>
<td></td>
<td>Documented clinical assessment that each facility is suited to safe delivery of care</td>
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<td></td>
<td>• provide advice in relation to matters relating to the efficient and effective provision of safe and quality health services</td>
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1. Roles and responsibilities

Proprietor

The role and functions of the proprietor include to:

- determine the constitution, scope of clinical practice and capability of the premises and procedures of the medical staff, in consultation with the medical staff;
- determine appointment fees (where relevant);
- establish appointment and credentialing processes for the [name of health service establishment];
- receive and consider applications from registered medical practitioners seeking appointment to provide clinical care at/with [name of health service establishment];
- make decisions about such appointments, including establishing a registered medical practitioner's credentials and eligibility for appointment and determining an appointed registered medical practitioner's scope of clinical practice;
- grant short term practice rights;
- subject to these protocols, take disciplinary action in relation to an appointed registered medical practitioner;
- determine how compliance with processes will be implemented and frequency of reviews;
- take other decisions or take other action as specified in these protocols; and
- implement a written open disclosure policy.

2. Appointments and peer-reviewed credentialing processes

The proprietor shall establish appointments and credentialing processes to provide peer-review, advice and assistance in relation to appointment, scope of clinical practice related issues and credentialing.

- a registered medical practitioner must not be appointed without the application having first been considered through a peer-reviewed appointments and credentialing process.
- robust appointments and credentialing processes recommended within the Australian Commission on Safety and Quality in HealthCare (ACSQHC) Standard (2004), for credentialing and defining the scope of clinical practice of registered medical practitioners.
- the appointments and credentialing processes shall be as determined by the proprietor from time to time to provide advice and assistance and may be varied according to need for advice or assistance in relation to particular areas of specialisation or practice or particular expertise.

3. Processes to licence and right to provide mobile sedation services

An appointed registered medical practitioner has:

- Practice rights at [name of health service establishment]; and
- A licence to enter and to use equipment and facilities of non-registered facilities for the purpose of providing clinical care and such other services as are specified in the conditions of appointment - subject to and in accordance with:
  - any limitations applicable to the category of appointment;
  - the registered medical practitioner's scope of clinical practice;
  - the registered medical practitioner continuing to comply with all conditions of appointment;
– the availability of medication (determined by the Drugs and Poisons Health Service Permit issued by the department), equipment, and nursing staff that are sufficient and appropriate for the type of clinical care provided by the registered medical practitioner; and
– such other conditions, limitations or restrictions as may be imposed in accordance with these protocols.

4. Application for appointment

a. Eligibility for appointment

A registered medical practitioner is eligible to be appointed to provide clinical care at facilities determined by [name of health service establishment] if, and only if:

• the practitioner is registered as a registered medical practitioner with the Medical Board of Australia or any successor body; and
• the practitioner holds appropriate medical indemnity insurance in respect of the practitioner's scope of clinical practice or proposed scope of clinical practice and consistent with organisational policy requirements; and
• the practitioner does not have a conflict of interest with [name of health service establishment]; and
• the practitioner agrees to adhere and uphold the code of conduct (where applicable).

b. Application to be made to proprietor

A registered medical practitioner who seeks to be appointed to provide clinical care for [name of health service establishment] must apply in writing to the proprietor.

c. Contents of application

i. The application must be made in writing in any manner and form (including electronically) approved by the proprietor and must specify the applicant registered medical practitioner’s proposed:
   – specialty;
   – scope of clinical practice;
   – notice of any current investigation by AHPRA into the registered medical practitioners activities; and
   – details of any criminal convictions; and
ii. be accompanied by the information and documents determined by the proprietor as requirements for application of appointment; and
iii. contain or be accompanied by a declaration (in a form specified by the [name of the health services establishment]), signed by the applicant.

5. Determination of application for appointment

a. The proprietor’s functions

The proprietor may obtain such further information as he or she considers necessary to properly consider an application for appointment, including by:

• interview of the applicant (which may be conducted by the proprietor, and his or her nominee(s));
• requiring the applicant to provide further information or documents;
• in accordance with authorisations provided by the applicant, to consult with or obtain information from the applicant's referees, medical indemnity insurer, previous employers, the medical board
and any other persons the proprietor considers may be able to provide information relevant to the application.

The applicant must provide such further consents and authorisations as are reasonably requested by the proprietor to enable information about the applicant to be obtained for the purpose of considering the application.

b. Consideration of application

In considering an application for appointment (including the proposed scope of clinical practice) the proprietor may have regard to:

- the training, formal qualifications (including any college fellowships) and professional competence and performance of the applicant;
- the character, professional standing, reputation and experience of the applicant;
- the values, resources, needs, expectations, priorities and strategic directions of [name of health service establishment];
- the availability at [name of health service establishment] of appropriate equipment, facilities and staff to support the provision of safe, high quality patient care within the proposed scope of clinical practice; and
- any other matter the proprietor considers to be relevant.

6. Appointment and credentialing processes

a. The proprietor may grant or refuse application for appointment

The proprietor shall not grant an application for appointment unless:

- the proprietor is satisfied that the applicant is eligible for appointment;
- the applicant has paid the initial appointment fee (where relevant); and
- the proprietor is satisfied that the applicant will not compromise the delivery of safe clinical care and efficient operation of [name of health service establishment] or the interests of patient care.

b. Short term (probationary and emergency) practice rights

The proprietor may determine that a registered medical practitioner who is eligible for appointment; but is not appointed – should be granted practice rights on a short-term basis, if the proprietor is satisfied that the practitioner:

- should undergo a period of probation in order to enable his or her suitability for appointment to be further assessed or confirmed; or
- should be given practice rights on a locum or similar short term basis in the interests of a patient receiving clinical care [name of health service establishment] or; or
- urgently requires practice rights in order to avert a threat to the life of, or other serious harm to a patient.

Where the proprietor decides to grant short term practice rights in accordance with b (above), the proprietor shall:

- determine the registered medical practitioner’s scope of clinical practice; and
- specify a maximum period (not exceeding 6 months) during which the registered medical practitioner may exercise those practice rights; and
- the registered medical practitioner is not an appointed member of the medical staff during the period; and
the registered medical practitioner must comply with any requirements and conditions specified by
the proprietor (or delegate) including, so far as is applicable having regard to the term and purpose
of the short-term practice rights, the general conditions of appointment determined by the
proprietor.

c. Scope of clinical practice

The proprietor must specify the scope of clinical practice for every appointed registered medical
practitioner and every registered medical practitioner who is granted short term practice rights.

In doing so, the proprietor may:

• identify practices or procedures that the registered medical practitioner may only undertake or
  perform as special privileges;
• exclude from the scope of clinical practice practices or procedures which would normally be
  considered to fall within the scope of clinical practice of a registered medical practitioner having the
  qualifications of the applicant;
• specify a period for which the registered medical practitioner may exercise practice rights which is
  less than the maximum appointment period;
• limit the scope of clinical practice by reference to any matter he or she considers relevant,
  including:
  – the [name of health service establishment] nominated facilities at which the practices or
    procedures may be undertaken or performed; and
  – the range of practices and/or procedures that may be undertaken or performed; and
  – the number of practices and/or procedures that may be undertaken or performed in a specified
    period; and
  – that practices or procedures must be subject to supervision and/or audit.

d. Conditions of appointment

Every appointment of a registered medical practitioner shall be:

• for a period of up to three years;
• subject to the special conditions specified in relation to the proprietor’s appointment;
• subject to any general conditions of appointment determined by the proprietor (add as appendix
  A); and
• subject to any other conditions or limitations the proprietor considers appropriate (including
  conditions or limitations as to scope of clinical practice).

7. Suspension, variation or termination

a. Grounds for remedial action

The proprietor may take remedial action in respect of an appointed medical practitioner if he or she
believes that one of the following grounds exists:

The registered medical practitioner has engaged in notifiable conduct.

The conduct, competence or performance of the registered medical practitioner is such as to put at
risk:

• the safety, health, wellbeing or welfare of any patient receiving care from [name of health service
  establishment] and/or staff member; or
• the good standing and reputation of [name of health service establishment].

The registered medical practitioner has acted in a manner that is inconsistent with [name of health service establishment] values.

• The registered medical practitioner has contravened these protocols.
• The registered medical practitioner has contravened the conditions of appointment.
• The registered medical practitioner has ceased to be eligible for appointment.
• The continuing appointment of the registered medical practitioner will compromise the efficient operation of any site or the interests of [name of health service establishment] generally.
• The registered medical practitioner has failed to pay an appointment fee (where relevant).

b. Types of remedial action

If grounds for remedial action exist, the proprietor may do one or more of the following with respect to a registered medical practitioner:

• give a formal warning;
• vary, limit or suspend his or her practice rights; or,
• terminate his or her appointment.

c. Procedure for remedial action

The proprietor must not take remedial action in respect of a registered medical practitioner unless the proprietor (has first:

• given the registered medical practitioner written notice;
• setting out the remedial action proposed to be taken;
• setting out the grounds for the proposed remedial action (including details of any allegations or factual circumstances on which such grounds are based);
• stating that the registered medical practitioner may make a submission as to why the proposed remedial action should not be taken and specifying a reasonable time (which must not be less than 14 days) within which the registered medical practitioner may do so; and
• had regard to any relevant matters put by the registered medical practitioner in any submission given in response to the notice.

The proprietor may consult with and seek advice from the appointments and credentialing committee in relation to any proposed remedial action.

The proprietor shall consider and determine the remedial action or proposed remedial action in an unbiased manner.

d. Formal warning

If the proprietor considers that grounds for remedial action exist but the circumstances do not warrant variation, limitation or suspension of practice rights or termination of appointment, the proprietor may give the registered medical practitioner a formal warning.

A formal warning must be recorded in writing.

Where the proprietor gives a formal warning to a registered medical practitioner, the proprietor shall provide such support and assistance (if any) that the proprietor considers appropriate to the registered medical practitioner to improve his or her performance or correct unsatisfactory behaviour.

If the proprietor considers that grounds for remedial action exist in respect of a registered medical practitioner who has been given a formal warning on two previous occasions, the proprietor must not
give any further formal warning but must take such other remedial action as he or she considers appropriate. The remedial action may be to vary, limit or suspend practice rights.

8. Review of scope of clinical practice and variation of practice rights

The proprietor may at any time undertake a review of an appointed registered medical practitioner’s scope of clinical practice and practice rights. Such a review may take into consideration the following, but not limited to:

- safety and quality concerns relating to a registered medical practitioner’s practice;
- resource implications for [name of health service establishment] relating to a registered medical practitioner’s practice;
- financial effects of a registered medical practitioner’s practice on [name of health service establishment]; and
- alignment or misalignment of a registered medical practitioner’s practice with the strategic direction of [name of health service establishment].

a. Procedure for review

The proprietor must not vary, limit or suspend the registered medical practitioner’s practice rights unless he or she has first:

- given the registered medical practitioner written notice:
  - setting out how the practice rights are proposed to be varied, limited or suspended;
  - setting out the grounds for the proposed variation, limitation or suspension; and
  - stating that the registered medical practitioner may make a submission as to why the practice rights should not be varied, limited or suspended and specifying a reasonable time (which must not be less than 14 days) within which the registered medical practitioner may do so.

- had regard to any relevant matters put by the registered medical practitioner in any submission given in response to the notice.

The proprietor shall consider and determine any matter in relation to a registered medical practitioner’s scope of clinical practice and practice rights in an unbiased manner.

b. Notice of variation, limitation or suspension of practice rights

a. If the proprietor (or delegate), decides to vary, limit or suspend the practice rights of an appointed registered medical practitioner, the proprietor must give written notice to the registered medical practitioner setting out:

- the effect of the variation, limitation or suspension;
- the date from which it is to take effect;
- its duration (if it is to be take effect for a limited time); and
- the right (if any) of the registered medical practitioner to seek review of the decision.

c. Immediate variation, limitation or suspension of practice rights

If the proprietor suspects that the conduct, competence or performance of an appointed registered medical practitioner is such as to give rise to a serious and imminent threat to the safety, health, wellbeing or welfare of any [name of health service establishment] patient or staff member, he or she may immediately vary, limit or suspend the registered medical practitioner’s practice rights without first complying with clause b (above), but must comply with that clause as soon as practicable after the suspension, variation or limitation takes effect.
d. Short term (probationary, temporary and emergency) practice rights
The proprietor may immediately, and without providing reasons, vary, limit, suspend or terminate short term practice rights accorded to a registered medical practitioner. The proprietor must give written notice of any such variation, limitation, suspension or termination.

9. Review of decisions affecting appointment
The procedures in this clause apply where the proprietor decides to:
- terminate the appointment of an appointed registered medical practitioner;
- vary, limit or suspend the practice rights of an appointed registered medical practitioner (other than by immediate suspension); and
- not grant an application from an appointed registered medical practitioner for a further appointment period.

a. No review of decision affecting short term practice rights
A decision to vary, limit, suspend or terminate short term practice rights is not subject to review.

b. Application for review
Within 7 days of being notified of a decision, the registered medical practitioner may apply to the proprietor for review of the decision.

c. Review of the decision
The proprietor may, if he or she considers it appropriate to do so, establish a panel to review the decision (review panel).

d. Review panel
A review panel shall consist of three members, appointed at the discretion of the proprietor provided that, as far as practicable:
- all members of the review panel shall be specialist registered medical practitioners in the relevant discipline; and
- one member of the review panel shall be nominated by the registered medical practitioner who has requested the review.

The following persons may not be members of the review panel:
- the proprietor;
- a registered medical practitioner who acted as nominee or delegate of proprietor in relation to:
  - remedial action taken; or
  - a proposed variation, limitation or suspension of practice rights; or
  - any other person with a material interest in the outcome of the decision.

e. Proceedings of review panel
The review panel may order its own proceedings and inform itself by any means it considers appropriate.

The review panel must give the registered medical practitioner a reasonable opportunity to show cause as to why the decision should not be confirmed. The registered medical practitioner may make a written or oral submission and present evidence but is not entitled to be legally represented.
The review panel shall hear and determine the matter before it in an unbiased manner.

**f. Decision**

Having had regard to:

- the reasons for the decision given;
- any submissions or evidence put by the registered medical practitioner; and
- any advice provided by the review panel — proprietor may affirm, vary or revoke the decision.

The decision of the proprietor is final.

The proprietor must notify the appointed registered medical practitioner of the decision in relation to the review as soon as possible but in any case, within 7 days of the decision.

**g. Variation, limitation, suspension of practice rights by agreement**

The practice rights of a registered medical practitioner under these protocols may be varied by agreement between the registered medical practitioner and the proprietor.

**10. Information**

**a. Confidentiality**

Subject to these protocols and to disclosures reasonably required to make and implement decisions made in accordance with these protocols, any information obtained by the proprietor and any other person in connection with the appointment, scope of clinical practice, remedial action or other decision or action authorised or required to be taken under these protocols shall be treated as confidential and must not be disclosed except:

- with the consent of the person to whom it relates;
- for the purpose of disclosing notifiable conduct or making a voluntary notification under the Health Practitioner National Law 2009; or
- as otherwise required or authorised by law.

**b. Proprietor to be informed about notifiable conduct**

If notifiable conduct by an appointed registered medical practitioner is notified under the Health Practitioner National Law 2009, the proprietor must immediately be informed of the fact and circumstances of the notification.

**11. Relationship**

Nothing in these protocols creates any relationship of employer/employee between [name of health service establishment] and any appointed registered medical practitioner.

**12. Amendment of these protocols**

Only the proprietor is authorised to amend these protocols and reserves the right to do so from time to time.
ACKNOWLEDGMENT

The department acknowledges the use of background intellectual property that has informed the framework of this sample model protocols for registered mobile health services. The department absolves itself and background IP holders of all responsibility, without recourse, related to the adoption or adaptation of these sample model protocols by registered mobile health services.

No commercialisation of IP should be contemplated, the enforcement of IP rights may be necessary to discourage potentially inappropriate use of the material by other parties.

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REFERENCES

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