



New South Wales

Medical Practice Regulation 1998

under the
Medical Practice Act 1992

His Excellency the Lieutenant-Governor, with the advice of the Executive Council, has made the following Regulation under the *Medical Practice Act 1992*.

ANDREW REFSHAUGE, M.P.,
Minister for Health

Explanatory note

The object of this Regulation is to repeal and remake the provisions of the *Medical Practice Regulation 1993*. This Regulation prescribes certain matters under the *Medical Practice Act 1992* for the purposes of the administration of that Act. In particular, this Regulation:

- (a) specifies the persons who are required to give notice to the Registrar of the Medical Board of the mental incapacity of a registered medical practitioner and the contents of that notice, and
- (b) specifies the offences that are exempted from section 71 of the Act (that section requires a court to notify the Registrar if a registered medical practitioner is convicted of an offence), and
- (c) specifies the time in which an appeal against a decision on a point of law by a Professional Standards Committee must be made, and
- (d) provides for restrictions on advertising by medical practitioners. and
- (e) prescribes fees for inspecting, and having additional information recorded in, the Register of the Board, and
- (f) specifies the infection control standards that medical practitioners must comply with.

1998 No 506

Medical Practice Regulation 1998

Explanatory note

Previous detailed provisions relating to the advertising of medical services have been streamlined, and new provisions have been inserted relating to records of medical services.

This Regulation is made under the *Medical Practice Act 1992*, including sections 114 (advertising), 126 (records to be kept) and 194 (the general regulation-making power).

This Regulation is made in connection with the staged repeal of subordinate legislation under the *Subordinate Legislation Act 1989*.

Contents

	Page
1 Name of Regulation	3
2 Commencement	3
3 Notes	3
4 Definitions	3
5 Notice of mental incapacity of registered medical practitioner	3
6 Offences for which notice of conviction of medical practitioner not required	4
7 Appeal against decision of the Committee on point of law	5
8 Prohibition against advertising cures for certain diseases	5
9 Advertising-generally	5
10 Fee for inspection of Register	6
11 Fee for additional information to be recorded in Register	6
12 Infection control standards	6
13 Records relating to patients	6
14 When records are to be made	7
15 How long records are to be kept	7
16 Disposal of medical practice	8
17 Storage	8
18 Repeal	8
Schedule 1 Infection control standards	9
Schedule 2 Records relating to patients	16

Medical Practice Regulation 1998

1 Name of Regulation

This Regulation is the *Medical Practice Regulation 1998*.

2 Commencement

This Regulation commences on 1 September 1998.

3 Notes

The explanatory note, table of contents and notes in the text of this Regulation do not form part of this Regulation.

4 Definitions

(1) In this Regulation:

medical corporation means a corporation engaged in the provision of medical services.

patient means a person to whom medical treatment or other medical services are provided.

record means a record required to be made and kept under clause 13.

the Act means the *Medical Practice Act 1992*.

(2) In this Regulation, a reference to a registered medical practitioner who provides medical treatment or other medical services to a patient includes a reference to a registered medical practitioner who does so on behalf of a medical corporation.

5 Notice of mental incapacity of registered medical practitioner

(1) For the purposes of section 70 of the Act, the person required to cause notice of mental incapacity to be given to the Registrar is:

(a) in the case of a registered medical practitioner who is a mentally incapacitated person and becomes a patient at an institution because of that incapacity—the medical superintendent of the institution, or

(b) in the case of a registered medical practitioner who is a mentally incapacitated person because of being a protected person under the *Protected Estates Act 1983*—the Protective Commissioner.

1998 No 506

Clause 5 Medical Practice Regulation 1998

- (2) Notice for the purposes of section 70 of the Act is to be given by telephone within 1 day, and by post within 7 days, after the registered medical practitioner is admitted to the institution or becomes a protected person, and is to specify the following:
- (a) the name and residential address of the medical practitioner,
 - (b) the date on which the medical practitioner was admitted to the institution at which the medical practitioner is a patient or became a protected person.

6 Offences for which notice of conviction of medical practitioner not required

- (1) All the offences under the *Traffic Act 1909* and the *Motor Traffic Regulations 1935* are prescribed offences for the purposes of section 71 of the Act, except for the following offences:
- (a) an offence under section 4 of that Act relating to driving a motor vehicle upon a public street furiously or recklessly or at a speed or in a manner which is dangerous to the public.
 - (b) an offence under section 4 of that Act relating to driving a motor vehicle upon a public street negligently if the registered medical practitioner is, by way of penalty, sentenced to imprisonment or fined a sum of not less than \$200,
 - (c) any offence under section 5 (1) of that Act (which relates to refusing to produce a motor vehicle driver's licence when required or to state name and place of abode, or stating a false name and place of abode).
 - (d) any offence under section 5 (2) of that Act (which relates to driving etc while under the influence of alcohol or any other drug),
 - (e) any offence under section 7A (2) (a), (b) or (c) of that Act (which relates to driving while unlicensed).
 - (f) any offence under section 8 of that Act (which relates to failing to stop after an accident and give assistance or particulars).
 - (g) any offence under section 4E of that Act (Prescribed concentration of alcohol in person's blood).

- (h) an offence under section 4AA of that Act (Menacing driving),
 - (i) any other offence under that Act or those Regulations if the court orders the disqualification of the medical practitioner from holding a driver's licence.
- (2) All offences relating to the parking of motor vehicles are prescribed offences for the purposes of section 71 of the Act.

7 Appeal against decision of the Committee on point of law

For the purposes of section 88 (2) of the Act, an appeal (being an appeal with respect to a point of law during an inquiry conducted by a Committee) must be made within 28 days of the date of the Committee's decision on the point of law which is the subject of the appeal.

8 Prohibition against advertising cures for certain diseases

The following diseases are prescribed as diseases to which section 108 of the Act applies:

acquired immunodeficiency syndrome (AIDS)
cancer
diabetes
epilepsy
hepatitis
human immunodeficiency virus (HIV) infection
leukemia
multiple sclerosis
poliomyelitis
tuberculosis

9 Advertising—generally

For the purposes of section 114 of the Act, a person (including a corporation) may advertise medical services in any manner except in a manner that:

- (a) is false, misleading or deceptive. or
- (b) creates an unjustified expectation of beneficial treatment.
or
- (c) promotes the unnecessary or inappropriate use of medical services.

1998 No 506

Clause 9 Medical Practice Regulation 1998

Note. Section 114 of the Act makes it an offence for a person (including a corporation) to advertise medical services except in accordance with the regulations.

10 Fee for inspection of Register

For the purposes of clause 21 (2) of Schedule 1 to the Act, the prescribed amount (being the maximum fee for an inspection of the Register) is \$10.

11 Fee for additional information to be recorded in Register

For the purposes of clause 22 (1) of Schedule 1 to the Act, the prescribed fee (being the fee for recording additional particulars in the Register) is \$20.

12 Infection control standards

- (1) A medical practitioner must not, without reasonable excuse, fail to comply with the infection control standards set out in Schedule 1 to the extent that they apply to the medical practitioner in the practice of medicine.
- (2) In determining whether or not a medical practitioner has a reasonable excuse for failing to comply with a standard, particular consideration is to be given to the following:
 - (a) whether the circumstances involved the provision of emergency treatment,
 - (b) whether the medical practitioner's employer failed to provide the necessary equipment, including providing access to it and training in its use, that would have enabled the medical practitioner to comply with the standard (and whether the failure to provide such equipment was reported by the medical practitioner to the Director-General of the Department of Health).

13 Records relating to patients

- (1) A registered medical practitioner or medical corporation engaged in the provision of medical services must, in accordance with clauses 14 to 17 and Schedule 2, make and keep a record, or ensure that a record is made and kept, for each patient of the medical Practitioner or corporation.

- (2) This clause does not affect section 127 (4) of the Act.
- (3) For avoidance of doubt, contravention of this clause is not an offence.

Note. Although contravention of this clause is not an offence, section 36 of the Act provides that any contravention of the regulations by a registered medical practitioner is unsatisfactory professional conduct.

In the case of a corporation that is engaged in the provision of medical services, section 127 of the Act requires the corporation to appoint a registered medical practitioner to be responsible for record keeping by the corporation. If the corporation contravenes the record keeping requirements imposed by the regulations, the person so appointed is taken to have contravened the regulations.

Section 126 (2) of the Act requires a person who makes or keeps a record under the regulations to ensure that when the record is disposed of it is disposed of in such a manner as to preserve its confidentiality. Contravention of that provision is an offence.

14 When records are to be made

- (1) A record must be made contemporaneously with the provision of the medical treatment or other medical service or as soon as practicable afterwards.
- (2) This clause may be complied with by the making of further entries in a single record that relates to the patient concerned.

15 How long records are to be kept

- (1) A record must be kept for at least 7 years from the date of last entry in the record, unless the patient was less than 18 years old at the date of last entry in the record.
- (2) If the patient was less than 18 years old at the date of last entry in the record, the record must be kept until the patient attains or would have attained the age of 25 years.
- (3) In this clause:

date of last entry in a record means the date the patient concerned was last provided with medical treatment or other medical services by the registered medical practitioner or medical corporation who provided that treatment or those services.

16 Disposal of medical practice

- (1) If a registered medical practitioner or medical corporation disposes of a medical practice, the outgoing practitioner is taken to have complied with clause 15 if the outgoing practitioner makes reasonable efforts to ensure that the records are kept in accordance with that clause.

- (2) In this clause:

outgoing practitioner means the registered medical practitioner or medical corporation disposing of a practice.

reasonable efforts include, but are not limited to, the following:

- (a) providing the records to the registered medical practitioner or medical corporation that acquires the outgoing practitioner's medical practice.
- (b) providing the records to the patient to whom they relate.

17 Storage

- (1) All reasonable steps must be taken to ensure that all records are kept in such a manner as to preserve the confidentiality of the information that is contained in them and to prevent them from being damaged, lost or stolen.
- (2) Despite subclause (1), a record must be reasonably accessible for the purpose of treating the patient to whom it relates.

18 Repeal

- (1) The *Medical Practice Regulation 1993* is repealed.
- (2) Any act, matter or thing that, immediately before the commencement of this Regulation, had effect under the *Medical Practice Regulation 1993* is taken to have effect under this Regulation.

Schedule 1 Infection control standards

(Clause 12)

Part 1 Preliminary

1 Definitions

- (1) In this Schedule:

body substance includes any human bodily secretion or substance other than blood,

invasive procedure means any one or more of the following:

- (a) surgical entry into body tissue, cavities or organs,
- (b) surgical repair of injuries,
- (c) cardiac catheterisation and angiographic procedures,
- (d) vaginal or caesarean delivery or any other obstetric procedure during which bleeding may occur,
- (e) the manipulation, cutting, or removal of any oral or peri-oral tissue, including tooth structure, during which bleeding may occur,

patient includes (but is not limited to) a person who is accessing medical or health services or who is undergoing any medical or health procedure,

sharps means any object capable of inflicting penetrating injury. and includes hollow bore needles, suture needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware.

- (2) The requirements set out in this Schedule apply to a medical practitioner who is assisting in performing a procedure in the same way as they apply to a practitioner who is actually performing the procedure.

Part 2 General standards applying to medical practitioners

2 General precautions and aseptic techniques

- (1) Precautions must be taken to avoid direct exposure to a patient's blood or other body substance. This requirement applies regardless of whether there is any perceived risk of infection.

1998 No 506

Medical Practice Regulation 1998

Schedule 1 Infection control standards

- (2) Aseptic techniques must be used in the course of complying with the requirements of this Schedule.

3 Hand and skin cleaning

- (1) Hands must be cleaned immediately before and after any direct patient care. This requirement does not apply in circumstances where medical treatment is required to be performed urgently and cleaning facilities are not readily available.
- (2) Hands may be cleaned by:
 - (a) using washing facilities involving water and a soap or antiseptic, or
 - (b) if any of the items specified in paragraph (a) are unavailable, using non-water cleansers or antiseptics.
- (3) Hands or other skin surfaces that are contaminated with a patient's blood or other body substance must be cleaned as soon as it is practicable to clean them.
- (4) The requirement to clean hands applies regardless of whether gloves are also required to be worn.

4 Protective gowns and aprons

A gown or apron made of impervious material must be worn during any procedure where there is a likelihood of clothing being splashed or contaminated with blood or other body substances.

5 Gloves

- (1) Gloves must be worn while handling blood or other body substances.
- (2) In particular, gloves must be worn:
 - (a) during any procedure where direct contact is anticipated with a patient's blood or other body substance, mucous membranes or non-intact skin. and
 - (b) while suctioning a patient. and
 - (c) while handling items or surfaces that have come into contact with blood or other body substances. and
 - (d) while performing an invasive procedure, venipuncture or a finger or heel stick.

- (3) Sterile gloves must be worn if the procedure involves contact with tissue that would be sterile under normal circumstances.
- (4) Gloves must be changed and discarded:
 - (a) as soon as they are torn or punctured, and
 - (b) after contact with each patient.
- (5) Gloves must also be changed if separate procedures are being performed on the same patient and there is a risk of infection from one part of the body to another.

6 Masks and protective eye wear

- (1) A mask and protective eye wear must be worn while performing any procedure where there is a likelihood of splashing or splattering of blood or other body substances.
- (2) In cases where a mask is required to be worn, it must be worn and fitted in accordance with the manufacturer's instructions.
- (3) A mask must be discarded once it has been worn and it must not be used again.
- (4) In cases where protective eye wear is required to be worn, it must be worn and fitted in accordance with the manufacturer's instructions.
- (5) Protective eye wear must be discarded once it has been worn and not used again unless it is reusable in which case it is to be cleaned in accordance with the manufacturer's instructions.

7 Sharps

- (1) Sharps must not be passed by hand between a medical practitioner and any other person. However, this requirement does not apply if, in any case involving an invasive procedure, the proper conduct of the procedure would be adversely affected.
- (2) A puncture resistant tray must be used to transfer sharps.

1998 No 506

Medical Practice Regulation 1998

Schedule 1 Infection control standards

- (3) A needle must not be removed from a disposable syringe for disposal, or be purposely broken or otherwise manipulated by hand, unless:
 - (a) it is necessary to remove the needle for technical reasons, or
 - (b) the medical practitioner is performing a procedure in which the needle is required to be bent.
- (4) A needle must not be bent after it is contaminated with blood or other body substances.
- (5) In any case where resheathing of a needle is required:
 - (a) the needle must be properly recapped, and
 - (b) the sheath must not be held in the fingers, and
 - (c) either a single handed technique or forceps, or a suitable protective guard designed for the purpose, must be used.
- (6) Reusable sharps must, immediately after being used, be placed in a puncture resistant container specially kept for that purpose and labelled as such.
- (7) Non-reusable sharps must, immediately after being used, be disposed of in a puncture resistant container.

8 Management of waste

- (1) Clinical waste must be properly packaged to protect against potential exposure to infectious agents and to facilitate the proper handling, storage and treatment or disposal of the waste.
- (2) Splashing or contamination of skin while disposing of blood or other body substances must be avoided as far as practicable.

Part 3 Specific standards applying to medical practitioners

9 Sterile medications and solutions

- (1) A medication or solution may be taken from a multi-dose vial or ampoule (or other similar container) only if the medication or solution is not readily available in another form.

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- (2) If any medication or solution is taken from a multi-dose vial or ampoule (or other similar container), a sterile needle and syringe must be used to withdraw the contents.
 - (3) The needle and syringe must be discarded once the needle and syringe have been used.
 - (4) Precautions must be taken to ensure that the injection of contaminated material or fluid into a multi-dose vial or ampoule (or other similar container) does not happen.

10 Anaesthetic breathing circuits

- (1) This clause applies in any case where an anaesthetic breathing circuit is used.
- (2) If the breathing circuit uses a filter:
 - (a) the filter must be discarded after each patient, and
 - (b) the part of the breathing circuit between the patient and the filter must be discarded, or cleaned and disinfected, after each patient, and
 - (c) in any case where a carbon dioxide absorber is also used—the part of the breathing circuit between the carbon dioxide absorber and the filter must be discarded, or cleaned and disinfected, at the end of each procedure list, and
 - (d) in those cases where a carbon dioxide absorber is not used—the breathing circuit tubing that conducts the gas to and from the filter must be discarded, or cleaned and disinfected, at the end of each procedure list.
- (3) If the breathing circuit does not use a filter, the breathing circuit must be discarded, or be cleaned and disinfected, after each patient.

11 Invasive procedures

- (1) In cases where it is technically feasible, retractors must be used for exposure and access during an invasive procedure.

1998 No 506

Medical Practice Regulation 1998

Schedule 1 Infection control standards

- (2) Fingers must not be used for the purposes of an invasive procedure to expose or increase access for the passage of a suture.
- (3) Only one sharp at a time is to be placed in a puncture resistant tray that is being used in connection with an invasive procedure.

Part 4 Processing of instruments and equipment

12 Cleaning of instruments and equipment

- (1) Any instrument or equipment that comes into contact with intact skin must be cleaned before it is used.
- (2) Any instrument or equipment that is required under this Part to be sterilised or disinfected must be cleaned before it is sterilised or disinfected.
- (3) The process of cleaning must involve water and mechanical or physical action (such as washing machines) and a cleaning agent.
- (4) All cleaning agents must be removed from instruments and equipment by rinsing prior to further processing.
- (5) In this clause *cleaning agent* means a detergent and includes proteolytic enzyme substances.

13 Disinfection of instruments and equipment

- (1) Any instrument or equipment that comes into contact with non-sterile tissue (other than intact skin) must, before it is used, be disinfected with a disinfectant specified in the *Australian Register of Therapeutic Goods*, and the relevant manufacturer's instructions must be followed.
- (2) The process of disinfection must involve either thermal or chemical methods. Chemical disinfection may only be used in cases where thermal methods are unsuitable.

14 Sterilisation of instruments and equipment

- (1) Any instrument or equipment used to enter, or that is capable of entering, tissue that would be sterile under normal circumstances, or the vascular system of a patient, must be sterilised before it is used.

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- (2) The method of sterilisation must be compatible with the particular type of instrument or equipment.
 - (3) A benchtop/portable steriliser may be used only if it is one that is specified in the *Australian Register of Therapeutic Goods*.
 - (4) If a steriliser is used (whether it is a benchtop/portable steriliser or a permanently plumbed or wired steriliser), the following criteria must be met:
 - (a) the relevant manufacturer's instructions must be followed.
 - (b) an ongoing monitoring program must be followed which reflects the requirements of Table 7.1 "STERILIZER TESTS AND TEST FREQUENCIES" of *Australian Standard AS 4187-1998*.

Schedule 2 Records relating to patients

(Clause 13)

1 Information to be included in record

- (1) A record must contain sufficient information to identify the patient to whom it relates.
- (2) A record must include:
 - (a) any information known to the medical practitioner who provides the medical treatment or other medical services to the patient that are relevant to his or her diagnosis or treatment (eg information concerning the patient's medical history, the results of any physical examination of the patient, information obtained concerning the patient's mental state, the results of any tests performed on the patient and information concerning allergies or other factors that may require special consideration when treating the patient), and
 - (b) particulars of any clinical opinion reached by the medical practitioner, and
 - (c) any plan of treatment for the patient. and
 - (d) particulars of any medication prescribed for the patient.
- (3) The record must include notes as to information or advice given to the patient in relation to any medical treatment proposed by the registered medical practitioner who is treating the patient.
- (4) A record must include the following particulars of any medical treatment (including any medical or surgical procedure) that is given to or performed on the patient by the registered medical practitioner who is treating the patient:
 - (a) the date of the treatment.
 - (h) the nature of the treatment.
 - (c) the name or names of the person or persons who gave or performed the treatment.
 - (d) the type of anaesthetic given to the patient (if any).
 - (e) the tissues (if any) sent to pathology.
 - (f) the results or findings made in relation to the treatment.

- (5) Any written consent given by a patient to any medical treatment (including any medical or surgical procedure) proposed by the registered medical practitioner who treats the patient must be kept as part of the record relating to that patient.

2 General requirements as to content

- (1) In general, the level of detail contained in a record must be appropriate to the patient's case and to the medical practice concerned.
- (2) A record must include sufficient information concerning the patient's case to allow another registered medical practitioner to continue management of the patient's case.
- (3) All entries in the record must be accurate statements of fact or statements of clinical judgment.

3 Form of records

- (1) Abbreviations and short hand expressions may be used in a record only if they are generally understood in the medical profession in the context of the patient's case or generally understood in the broader medical community.
- (2) Each entry in a record must be dated and must identify clearly the person who made the entry.
- (3) A record may be made and kept in the form of a computer database or other electronic form, but only if it is capable of being printed on paper.

4 Alteration and correction of records

A registered medical practitioner or medical corporation must not alter a record, or cause or permit another person to alter a record, in such a manner as to obliterate, obscure or render illegible information that is already contained in the record.

1998 No 506

Medical Practice Regulation 1998

Schedule 2 Records relating to patients

5 Delegation

If a person is provided with medical treatment or other medical services by a registered medical practitioner in a hospital, the function of making and keeping a record in respect of the patient may be delegated to a person other than the registered medical practitioner, but only if:

- (a) the record is made and kept in accordance with the rules and protocols of the hospital, and
- (b) the registered medical practitioner ensures that the record is made and kept in accordance with this Schedule.