2008 No 388

New South Wales

Medical Practice Regulation 2008

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*.

REBA MEAGHER, M.P.,
Minister for Health

Explanatory note

The object of this Regulation is to remake, with minor amendments, the provisions of the *Medical Practice Regulation 2003*, which is repealed on 1 September 2008 by section 10 (2) of the *Subordinate Legislation Act 1989*.

This Regulation makes provision with respect to the following:

(a) the requirements for the making and keeping of records by registered medical practitioners and medical corporations,

(b) the procedures for notifying that a registered medical practitioner or medical student has become a mentally incapacitated person,

(c) the offences that are excluded from the requirement that a court is to notify the Registrar of the New South Wales Medical Board if a registered medical practitioner is convicted of an offence,

(d) the restrictions on the advertising of medical services,

(e) the fees for inspecting, and having additional information recorded in, the Register of Medical Practitioners,

(f) the infection control standards that registered medical practitioners must comply with,

(g) savings and formal matters.

This Regulation is made under the *Medical Practice Act 1992*, including sections 70, 71 (1), 114, 126 (1) and 194 (the general regulation-making power) and clauses 21 (4) and 22 (2) of Schedule 1 and clause 10 of Schedule 4.

Contents

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Part 1 Preliminary

1 Name of Regulation

This Regulation is the *Medical Practice Regulation 2008*.

2 Commencement

This Regulation commences on 1 September 2008.

Note. This Regulation replaces the *Medical Practice Regulation 2003* which is repealed on 1 September 2008 by section 10 (2) of the *Subordinate Legislation Act 1989*.

3 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 Part 2.

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.

(3) Notes in this Regulation do not form part of this Regulation.

Part 2 Records

4 Records relating to patients

(1) A registered medical practitioner or medical corporation engaged in the provision of medical services must, in accordance with this Part and Schedule 1, 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.

(4) Subclause (1) does not apply to the following:

(a) a public health organisation within the meaning of the *Health Services Act 1997*,

(b) a private health facility,

(c) a nursing home within the meaning of the *Public Health Act 1991*.

(5) Subclause (4) does not affect the application of subclause (1) to a registered medical practitioner appointed, employed, contracted or otherwise engaged by a medical corporation referred to in subclause (4).

(6) In this clause:

private health facility means, until the commencement of Schedule 5.19 to the *Private Health Facilities Act 2007*, a private hospital or a day procedure centre.

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.

5 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.

6 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.

7 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 6 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:

(a) providing the records to the registered medical practitioner or medical corporation that acquires the outgoing practitioner's medical practice, or

(b) providing the records to the patient to whom they relate.

8 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.

Part 3 Miscellaneous

9 Notice of mental incapacity of registered medical practitioner or medical student

(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 or medical student who is a mentally incapacitated person and becomes a patient at a mental health facility because of that incapacity—the medical superintendent of the facility, or

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

(2) Notice for the purposes of section 70 of the Act is to be given by telephone by the next business day, and by post within the next 7 business days, after the day on which the registered medical practitioner or medical student is admitted to the facility or becomes a protected person, and is to specify the following:

(a) the name and residential address of the medical practitioner or medical student,

(b) the date on which the medical practitioner or medical student:

(i) was admitted to the facility at which the medical practitioner or medical student is a patient, or

(ii) became a protected person.

(3) In this clause, ***business day*** means any day other than a Saturday, a Sunday or a public holiday throughout New South Wales.

10 Excluded offences (offences for which notice of conviction or criminal finding not required)

(1) All the offences under the road transport legislation (within the meaning of the *Road Transport (General) Act 2005*) are prescribed offences for the purposes of section 71 of the Act, except for the following offences:

(a) an offence under section 25A (1), (2) or (3) of the *Road Transport (Driver Licensing) Act 1998*,

(b) an offence under section 171 (2) of the *Road Transport (General) Act 2005*,

(c) an offence under section 9, 12 (1), 42 (2), 43 or 70 of the *Road Transport (Safety and Traffic Management) Act 1999*,

(d) an offence under section 42 (1) of the *Road Transport (Safety and Traffic Management) Act 1999*, but only if the person is, by way of penalty, sentenced to imprisonment or fined a sum of not less than $200,

(e) any other offence under the road transport legislation if the court orders the disqualification of the person from holding a driver licence.

(2) All offences relating to the parking of motor vehicles are prescribed offences for the purposes of section 71 of the Act.

Note. An offence prescribed by this clause is an ***excluded offence*** for the purposes of the Act. A conviction or criminal finding for an offence listed in this clause (apart from the offences listed in subclause (1) (a)–(e)) is not required to be notified or disclosed to the Registrar or to the Board under the provisions of the Act that require convictions and criminal findings made against medical practitioners to be so notified or disclosed (see sections 71, 127A and 127B of the Act and clause 3A of Schedule 1 to the Act).

11 Advertising

(1) For the purposes of section 114 of the Act, a person (including a corporation) may advertise medical services in any manner, except as otherwise provided by this clause.

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.

(2) Medical services must not be advertised 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.

(3) Any scientific or statistical information used in advertising must be presented in a manner that can be readily understood by persons without any medical or scientific training or experience.

(4) Any advertising that contains two or more photographs for the purpose of depicting a person before and after the person has received medical services must comply with the following:

(a) photographs that purport to be of the same person must in fact be of the same person,

(b) the person or persons photographed must in fact have received the medical services that are being advertised,

(c) the medical services must have been performed by the medical practitioner whose services are being advertised or, in the case of advertising for medical services by a medical corporation, a

medical practitioner who is currently employed or otherwise engaged by the medical corporation to perform the medical services,

(d) photographs of the same person must be presented in the same or a similar manner (including the same or similar framing, lighting and make-up).

(5) Photographs of a person (or part of a person) used in advertising that depict, or claim to depict, the results of medical services (including photographs of a kind referred to in subclause (4)):

(a) must not be altered or manipulated in a misleading or deceptive manner, and

(b) must be accompanied by a statement, prominently displayed or communicated, to the effect that:

(i) the photographs show the result of the medical service performed on one person, and

(ii) there is no guarantee that other persons will experience the same or a similar result.

12 Fee for inspection of Register

For the purposes of clause 21 (4) of Schedule 1 to the Act, the prescribed amount (being the maximum fee for an inspection of the Register) is $10.

13 Fee for additional information to be recorded in Register

For the purposes of clause 22 (2) of Schedule 1 to the Act, the prescribed fee (being the fee for recording additional particulars in the Register) is $20.

14 Infection control standards

(1) A registered medical practitioner must not, without reasonable excuse, fail to comply with the infection control standards set out in Schedule 2 to the extent that they apply to the medical practitioner in the practice of medicine.

(2) In determining whether or not a registered 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).

15 Savings and transitional

(1) Any act, matter or thing that, immediately before the repeal of the *Medical Practice Regulation 2003*, had effect under that Regulation continues to have effect under this Regulation.

(2) Section 176 of the Act, as amended by the *Medical Practice Amendment Act 2008*, applies only to a Committee constituted by the Board under section 168 of the Act as amended by the *Medical Practice Amendment Act 2008*.

Schedule 1 Records relating to patients

(Clause 4)

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 the following:

(a) any information known to the registered medical practitioner who provides the medical treatment or other medical services to the patient that is relevant to his or her diagnosis or treatment (for example, 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),

(b) particulars of any clinical opinion reached by the registered medical practitioner,

(c) any plan of treatment for the patient,

(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,

(b) the nature of the treatment,

(c) the name of any person 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 shorthand 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.

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.

Schedule 2 Infection control standards

(Clause 14)

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.

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 registered medical practitioner who is assisting in performing a procedure in the same way as they apply to a registered medical practitioner who is actually performing the procedure.

Part 2 General standards applying to registered medical practitioners

2 General precautions and aseptic techniques

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

(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:

(a) immediately before and after any direct patient care, and

(b) immediately after handling blood or body substances.

(2) Subclause (1) does not apply in circumstances where medical treatment is required to be performed urgently and cleaning facilities are not readily available.

(3) Hands may be cleaned by:

(a) using washing facilities involving water and a soap or antiseptic, or

(b) using non-water cleansers or antiseptics.

(4) Hands or other skin surfaces that are contaminated with a patient's blood or body substance must be cleaned as soon as it is practicable to clean them.

(5) 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 body substances.

5 Gloves

(1) Gloves must be worn while handling blood or body substances.

(2) In particular, gloves must be worn:

(a) during any procedure where direct contact is anticipated with a patient's blood or body substance, mucous membranes or skin that is not intact, and

(b) while suctioning a patient, and

(c) while handling items or surfaces that have come into contact with blood or 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 discarded:

(a) as soon as they are torn or punctured, and

(b) after contact with each patient.

(5) Nothing in subclause (4) affects the operation of subclauses (1)–(3).

(6) Gloves must 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 fluid repellent mask and protective eye wear must be worn while performing any procedure where there is a likelihood of splashing or splattering of blood or body substances.

(2) A mask must be worn when in close contact with patients known by the registered medical practitioner to have an infectious disease (or suspected by the medical practitioner of having such a disease) if the disease is capable of being transmitted by the airborne or droplet route. If the disease is tuberculosis, the mask must be a particulate mask that is capable of filtering to 0.3μm.

(3) In cases where a mask is required to be worn, it must be worn and fitted in accordance with the manufacturer's instructions.

(4) A mask must be discarded once it has been worn and it must not be used again.

(5) In cases where protective eye wear is required to be worn, it must be worn and fitted in accordance with the manufacturer's instructions.

(6) 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 registered 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.

(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 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 body substances must be avoided as far as practicable.

(3) Nothing in this clause limits any other requirement under this Part.

Part 3 Specific standards applying to registered medical practitioners

9 Sterile medications and solutions

(1) A sterile needle and syringe must be used to withdraw any medication or solution from a vial or ampoule (or other similar container).

(2) The needle and syringe must be discarded once the needle and syringe have been used.

(3) 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 reasonably available in another form.

(4) Precautions must be taken to ensure that contaminated material or fluid is not injected into a multi-dose vial or ampoule (or other similar container).

10 Anaesthetic apparatus

(1) This clause applies in any case where anaesthetic apparatus is used.

(2) Any anaesthetic apparatus that comes into contact with a patient or is contaminated with blood or body substances must be discarded, or cleaned and disinfected, after each patient.

(3) If the anaesthetic apparatus is a breathing circuit and 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 or operation list (as applicable), 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 or operation list (as applicable).

11 Invasive procedures

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

(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.

(4) Forceps or a needle holder must be used when carrying out suturing both to pick up the suture needle and to draw it through tissue.

Part 4 Processing of instruments and equipment

12 Definitions

In this Part:

AS/NZS 4187 means AS/NZS 4187:2003, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*, as in force from time to time.

AS/NZS 4815 means AS/NZS 4815:2006, *Office-based health care facilities—Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*, as in force from time to time.

13 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:

(a) must involve water and mechanical or physical action (such as washing machines) and a cleaning agent (with the cleaning agent being removed from instruments and equipment by rinsing), and

(b) must be consistent with AS/NZS 4187 or (in the case of an office-based practice) AS/NZS 4815.

(4) In this clause ***cleaning agent*** means a detergent and includes proteolytic enzyme substances.

14 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 that is maintained under the *Therapeutic Goods Act 1989* of the Commonwealth, and the relevant manufacturer's instructions must be followed.

(2) The process of disinfection:

(a) must involve either thermal methods or (if thermal methods are unsuitable) chemical methods, and

(b) must be consistent with AS/NZS 4187 or (in the case of an office-based practice) AS/NZS 4815.

15 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.

(2) The method of sterilisation must be:

(a) compatible with the particular type of instrument or equipment concerned, and

(b) consistent with AS/NZS 4187 or (in the case of an office-based practice) AS/NZS 4815.

(3) If a steriliser is used (whether it is a benchtop or 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 Calibration, Monitoring and Maintenance of Sterilizers of AS/NZS 4187 or (in the case of an office-based practice) Table 7.1 Performance Testing, Monitoring, Calibration and Maintenance of Sterilizers of AS/NZS 4815.