



## PARLIAMENTARY COUNSEL

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# *Opinion*

Health Practitioner Regulation National Law (NSW)  
Proposed Health Practitioner Regulation (New South Wales) Regulation 2010

Your ref:  
Our ref: AOC s2010-186-d08

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In my opinion the attached draft Regulation may legally be made.

The Regulation should be published on the NSW legislation website on or before 1 July 2010.

A handwritten signature in blue ink, appearing to read 'D Colagiuri', with a stylized flourish at the end.

(D COLAGIURI)  
Parliamentary Counsel

23 June 2010

Director-General  
Department of Health



New South Wales

# Health Practitioner Regulation (New South Wales) Regulation 2010

under the

Health Practitioner Regulation National Law (NSW)

Her Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Health Practitioner Regulation National Law (NSW)*.

Minister for Health

## Explanatory note

The objects of this Regulation are:

- (a) to provide for the membership of the Chiropractic Council, Optometry Council, Osteopathy Council and Podiatry Council established by the *Health Practitioner Regulation National Law (NSW)*, and
- (b) to set infection control standards that medical practitioners, nurses, midwives, pharmacists, physiotherapists and podiatrists practising in New South Wales must comply with, and
- (c) to provide for the records a medical practitioner, or a corporation that engages medical practitioners to provide medical services, must make and keep in relation to each patient of the medical practitioner or corporation, and
- (d) to provide for the standards that premises must comply with for approval by the Pharmacy Council to be given for those premises to be used for a pharmacy business, and
- (e) to provide for the amount of the fee that is payable for the inspection of the Register of Pharmacies kept by the Pharmacy Council, and
- (f) to provide that the medical superintendent of a mental health facility is the person who must notify the Council for a health profession if a health practitioner or student registered in the profession becomes a patient at the facility, and

Health Practitioner Regulation (New South Wales) Regulation 2010

Explanatory note

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- (g) to provide that the NSW Trustee and Guardian is the person who must notify the Council for a health profession if a health practitioner or student registered in the profession becomes a protected person under the *NSW Trustee and Guardianship Act 2009*, and
- (h) to provide that each Council is to pay an amount, as certified by the Minister for Health by order published in the Gazette, to reimburse the Department of Health for the costs incurred by the Department in establishing the national scheme for the registration of health practitioners and students, and
- (i) to provide that each Council is to pay an amount, as certified by the Minister for Health by order published in the Gazette, to the Australian Health Practitioner Regulation Agency as a contribution to the operational costs of the National Health Practitioner Boards for the financial year beginning on 1 July 2010, and
- (j) to provide that the amount to be paid by the Dental Council into an account to be used for the purposes of educating dental technicians is to be the amount certified by the Minister for Health by order published in the Gazette, and
- (k) to provide for matters of a savings and transitional nature consequent on the enactment of the *Health Practitioner Regulation National Law (NSW)*.

This Regulation is made under the *Health Practitioner Regulation National Law (NSW)*, including section 247A.

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## Health Practitioner Regulation (New South Wales) Regulation 2010

under the

Health Practitioner Regulation National Law (NSW)

### Part 1 Preliminary

#### 1 Name of Regulation

This Regulation is the *Health Practitioner Regulation (New South Wales) Regulation 2010*.

#### 2 Commencement

- (1) Subject to subclause (2), this Regulation commences on 1 July 2010 and is required to be published on the NSW legislation website.
- (2) Part 2 commences on 1 January 2011.

#### 3 Definitions

- (1) In this Regulation:
  - medical corporation* means a corporation engaged in the provision of medical services by medical practitioners.
  - patient* means a person to whom health care treatment or other health services are provided.
  - professional services room* has the same meaning as it has in Schedule 5F to the Law.
  - the Law* means the *Health Practitioner Regulation National Law (NSW)*.
- (2) Notes included in this Regulation do not form part of this Regulation.

## Part 2 Membership of Councils

### 4 Membership of certain Councils

- (1) For the purposes of section 41E (1) (b) of the Law, each Council that is not a relevant Council consists of 4 members who are appointed by the Governor.

**Note.** Under section 41E (1) (b) of the Law the following Councils are not relevant Councils:

- (a) the Chiropractic Council,
  - (b) the Optometry Council,
  - (c) the Osteopathy Council,
  - (d) the Podiatry Council.
- (2) The members of a Council are to consist of:
- (a) 3 health practitioners who are:
    - (i) registered in the health profession for which the Council is established, and
    - (ii) nominated by the Minister, and
  - (b) one Australian lawyer nominated by the Minister.
- (3) At least one of the health practitioners nominated by the Minister under subclause (2) (a) must have a principal place of practice in this State.

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## Part 3 Infection control standards

### 5 Definition

In this Part and in Schedule 1:

*relevant health practitioner* means:

- (a) a medical practitioner, and
- (b) a nurse or midwife, and
- (c) a pharmacist, and
- (d) a physiotherapist, and
- (e) a podiatrist.

### 6 Infection control standards

- (1) A relevant health 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 health practitioner in the practice of the health practitioner's profession.
- (2) In deciding whether or not a relevant health 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 health practitioner's employer failed to provide the necessary equipment, including providing access to it and training in its use, that would have enabled the health practitioner to comply with the standard (and whether the failure to provide such equipment was reported by the health practitioner to the Director-General).
- (3) If there is any inconsistency between the infection control standards set out in Schedule 1 and a registration standard, code or guideline published by a National Board, the registration standard, code or guideline prevails to the extent of the inconsistency.

## **Part 4 Matters relating to the medical profession**

### **7 Records relating to patients**

- (1) A medical practitioner or medical corporation must, in accordance with this Part 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 medical corporation.
- (2) A contravention of subsection (1) by a medical practitioner does not constitute an offence but may constitute behaviour for which health, conduct or performance action may be taken.
- (3) 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 within the meaning of the *Private Health Facilities Act 2007*,
  - (c) a nursing home within the meaning of the *Public Health Act 1991*.
- (4) Subclause (3) does not affect the application of subclause (1) to a medical practitioner appointed, employed, contracted or otherwise engaged by a medical corporation referred to in subclause (3).

### **8 Medical services corporation to appoint practitioner to be responsible for record keeping**

- (1) A medical corporation must, by written notice given to the Medical Council, appoint a medical practitioner to be responsible for record keeping by the corporation. There must be such an appointment in force at all times, otherwise the medical corporation is guilty of an offence.  
Maximum penalty: 2 penalty units.
- (2) The notice of appointment must be accompanied by a notice of acceptance of the appointment signed by the appointed person.
- (3) An appointment may be revoked by written notice given to the Medical Council given either by the corporation or by or on behalf of the appointed person. The appointment is automatically revoked if the person appointed ceases to be a medical practitioner.
- (4) If a medical corporation contravenes this Part or Schedule 2, the person appointed under this section to be responsible for record keeping by the corporation at the time of the contravention is taken to have contravened the provision that the corporation contravened.

**9 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.

**10 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 the record* means the date the patient concerned was last provided with medical treatment or other medical services by the medical practitioner or medical corporation who provided that treatment or those services.

**11 Disposal of medical practice**

- (1) If a medical practitioner or medical corporation disposes of a medical practice, the practitioner or corporation is taken to have complied with clause 10 if the practitioner or corporation makes reasonable efforts to ensure the records are kept in accordance with that clause.
- (2) In this clause:  
*reasonable efforts* include:
  - (a) providing the records to the medical practitioner or medical corporation that acquires the medical practice, or
  - (b) providing the records to the patient to whom they relate.

**12 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 5 Matters relating to the pharmacy profession**

### **Division 1 Approval of premises used for pharmacy business**

#### **13 Standards for approval of pharmacy premises**

- (1) For the purposes of clause 12 (8) (a) of Schedule 5F to the Law, the following standards are prescribed for premises other than professional services rooms:
  - (a) at least one doorway allowing direct public access to the premises is to be provided,
  - (b) the premises, including any doors, windows, floors or ceilings, are to be secure,
  - (c) the premises are to be equipped with a dispensing area of at least 8 square metres or such lesser area as the Pharmacy Council may approve in a particular case,
  - (d) there is a part of the premises in which a consultation conducted by a pharmacist is not reasonably likely to be overheard by a person not party to the consultation,
  - (e) the premises are to be equipped with:
    - (i) the equipment listed in Schedule 3, and
    - (ii) any other equipment necessary to ensure the safe and competent delivery of the pharmacy services delivered in those premises,  
installed and maintained in accordance with the manufacturer's instructions or if no such instructions exist, to the standard necessary for the safe and competent delivery of pharmacy services,
  - (f) the publications listed in Schedule 3 are to be kept in the premises or are to be accessible by electronic means from the premises in accordance with clause 15.
- (2) The following standards are prescribed for a dispensing area referred to in subclause (1) (c):
  - (a) it is to be adequately lit and ventilated,
  - (b) it is to have adequate heating facilities for dispensing and compounding drugs,
  - (c) it is to be equipped with a stainless steel or similarly impervious sink that has an impervious surround and is supplied with hot and cold running water,

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- (d) it is to have a bench that is at least 40 centimetres wide, and of sufficient length to provide not less than 1 square metre of free working space, and that has an impervious covering,
  - (e) it is to have at least one dispensary barcode scanner connected to each dispensing station in the dispensing area.

#### **14 Standards for approval of professional services room premises**

- (1) For the purposes of clause 12 (8) (a) of Schedule 5F to the Law, the following standards are prescribed for professional services rooms:
  - (a) all reasonable steps to prevent public access to the premises are to have been taken,
  - (b) the premises, including any doors, windows, floors or ceilings, are to be secure,
  - (c) the premises are to be equipped with a dispensing area of at least 8 square metres or such lesser area as the Pharmacy Council may approve in a particular case,
  - (d) the premises are to be laid out and equipped so that:
    - (i) any drug stored in the premises can be stored in accordance with the relevant drug's storage conditions, and
    - (ii) all the drugs being prepared, packaged or stored in the premises, for supply to a particular patient or to a health care facility for supply to a particular patient or resident of that facility, can be stored together, and
    - (iii) any documentation physically stored in the premises relating to that patient or resident can be stored with those drugs,
  - (e) the publications listed in Schedule 4 are to be kept in the premises or are to be accessible by electronic means from the premises in accordance with clause 15.
- (2) The following standards are prescribed for a dispensing area referred to in subclause (1) (c):
  - (a) it is to be adequately lit and ventilated,
  - (b) it is to be equipped with a stainless steel or similarly impervious sink that has an impervious surround and is supplied with hot and cold running water,
  - (c) it is to have a bench that is at least 40 centimetres wide, and of sufficient length to provide not less than 1 square metre of free working space, and that has an impervious covering,
  - (d) it is to have at least one dispensary barcode scanner connected to each dispensing station in the dispensing area.

**15 Access to electronic versions of publications**

The following provisions apply to access by electronic means to publications referred to in clauses 13 (1) (f) and 14 (1) (e) that are not kept in the premises:

- (a) any relevant software or data licence in respect of the publication is to provide for access for each pharmacist in the premises (including a locum),
- (b) a document is to be kept, in the premises and available to each pharmacist in the premises (including a locum), setting out how each pharmacist can readily access the current version of the publication,
- (c) if the publication is accessed via the Internet—access to the Internet is to be maintained while any pharmacist is dispensing or compounding drugs in the premises and the current version of the publication is to be readily accessible (by way of web browser bookmarks or otherwise).

**Division 2 Other matters**

**16 Fee for inspection of Register of Pharmacies**

For the purposes of clause 14 (4) of Schedule 5F to the Law, the prescribed amount is \$30.

## Part 6 Miscellaneous

### 17 Notice of mental incapacity of registered health practitioner or student

- (1) For the purposes of section 151 of the Law, the person required to cause notice to be given of a registered health practitioner or student becoming a mentally incapacitated person, or being involuntarily admitted to a mental health facility, is:
  - (a) for a registered health practitioner or student who is a mentally incapacitated person, and becomes a patient at a mental health facility because of that incapacity, or is involuntarily admitted to a mental health facility—the medical superintendent of the facility, or
  - (b) for a registered health practitioner or student who is a protected person under the *NSW Trustee and Guardianship Act 2009*—the NSW Trustee and Guardian.
- (2) The notice must specify:
  - (a) the name and residential address of the registered health practitioner or student, and
  - (b) the date on which the registered health practitioner or student:
    - (i) was admitted to the facility at which the health practitioner or student is a patient, or
    - (ii) became a protected person.
- (3) The notice must be given:
  - (a) by telephone on the next business day after the day on which the registered health practitioner or student is admitted to the facility or becomes a protected person, and
  - (b) by post within 7 business days after the day on which the registered health practitioner or student is admitted to the facility or becomes a protected person.

## Part 7 Transitional and savings provisions

### 18 Assets and liabilities

- (1) From the commencement of this clause:
  - (a) the assets and liabilities of a former Board for a health profession immediately before the commencement of this clause are taken to be assets and liabilities of the Council for that health profession, and
  - (b) a contract, other than an employment contract, entered into by or on behalf of a former Board for a health profession and all guarantees, undertakings and securities given by or on behalf of the former Board, in force immediately before the commencement, are taken to have been entered into or given by or to the Council for that health profession, and
  - (c) any property that, immediately before the commencement, was held on trust, or subject to a condition, by a former Board for a health profession continues to be held by the Council for that health profession on the same trust, or subject to the same condition.
- (2) In this clause:

**employment contract** means either of the following under which a person is employed:

  - (a) a contract of employment,
  - (b) a contract for services.

### 19 Councils to pay certain amounts relating to establishing and operating national scheme

- (1) Each Council for a health profession is to pay:
  - (a) an amount to the Department of Health reasonably required to reimburse the Department for the costs it incurred in establishing the national registration and accreditation scheme, and
  - (b) an amount to the National Agency, for payment into the account kept in the Agency Fund for the National Board established for that health profession, as a contribution to the operational costs of the Board for the financial year beginning on 1 July 2010.
- (2) The amounts payable by a Council under this clause are the amounts certified by the Minister by order published in the Gazette.

**20 Minister to certify amount to be paid into Education Account for dental technicians**

For the purposes of clause 21 (2) of Schedule 5A to the Law, the amount to be paid into the Education Account is the amount certified by the Minister by order published in the Gazette.

**21 Inspectors**

A person who was, immediately before the commencement of this clause, an inspector appointed by a former Board for a health profession (other than under the *Pharmacy Practice Act 2006*) is taken to have been appointed as an authorised officer by the Council for that health profession.

**22 Delegations**

- (1) This clause applies if, immediately before the commencement of this clause, an instrument was in force delegating any of the functions of a former Board for a health profession to a person.
- (2) From the commencement, the instrument of delegation continues in force, with any necessary changes, as if it had been made by the Council for the health profession until the earlier of the following:
  - (a) the delegation is revoked by the Council,
  - (b) 30 September 2010.

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## Schedule 1 Infection control standards

(Clause 6)

**Note.** The infection control standards set out in this Schedule apply to all relevant health practitioners (see clause 5). However, certain infection control standards refer to activities or procedures that would only be undertaken by health practitioners registered in a particular health profession and therefore would not apply to relevant health practitioners who do not practice in that health profession.

### Part 1 Preliminary

#### 1 Definitions

(1) In this Schedule:

*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.

**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,
- (f) any other procedure during which a patient's skin is penetrated, cut or otherwise rendered non-intact,
- (g) any other treatment of a wound.

**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 relevant health practitioner who is assisting in performing a procedure in the same way

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as they apply to a relevant health practitioner who is actually performing the procedure.

## **Part 2 General standards applying to relevant health practitioners**

### **2 General precautions and aseptic techniques**

- (1) Precautions must be taken to avoid direct exposure to a patient's blood or body substance.
- (2) The requirement in subclause (1) applies regardless of whether there is any perceived risk of infection.
- (3) Aseptic techniques must be used in the course of complying with the requirements of this Schedule.

### **3 Hand and skin cleaning**

- (1) A relevant health practitioner, other than a pharmacist, must clean the health practitioner's hands:
  - (a) immediately before and after any direct patient care, and
  - (b) immediately after handling blood or body substances.
- (2) A pharmacist must clean the pharmacist's hands:
  - (a) immediately before and after performing an invasive procedure, and
  - (b) immediately before and after performing a procedure during which direct contact is anticipated or occurs with a patient's blood or body substances, mucous membranes or non-intact skin, and
  - (c) immediately after handling blood or body substances.
- (3) Subclauses (1) and (2) do not apply in circumstances in which treatment is required to be performed urgently and cleaning facilities are not readily available.
- (4) Hands may be cleaned by:
  - (a) using washing facilities involving water and a soap or antiseptic, or
  - (b) using non-water cleansers or antiseptics.
- (5) 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.

- (6) 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 a procedure where direct contact is anticipated with a patient's blood or body substances, 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) Subclause (4) does not affect 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 or suspected by the relevant health practitioner to have an infectious disease if the disease is capable of being transmitted by the airborne or droplet route.
- (3) If the disease is tuberculosis, the mask must be a particulate mask that is capable of filtering to 0.3µm.

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- (4) If a mask is required to be worn, it must be worn and fitted in accordance with the manufacturer's instructions.
  - (5) A mask must be discarded once it has been worn and it must not be used again.
  - (6) In cases where protective eye wear is required to be worn, it must be worn and fitted in accordance with the manufacturer's instructions.
  - (7) 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 relevant health practitioner and any other person.
- (2) However, the requirement in subclause (1) does not apply if, in any case involving an invasive procedure, the proper conduct of the procedure would be adversely affected.
- (3) A puncture resistant tray must be used to transfer sharps.
- (4) 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 relevant health practitioner is performing a procedure in which the needle is required to be bent.
- (5) A needle must not be bent after it is contaminated with blood or body substances.
- (6) If 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) a single handed technique or forceps, or a suitable protective guard designed for the purpose, must be used.
- (7) Reusable sharps must, immediately after being used, be placed in a puncture resistant container specially kept for that purpose and labelled as such.
- (8) 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.

**Note.** The disposal of clinical waste is regulated by the *Protection of the Environment Operations Act 1997* and the regulations under that Act.

- (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 relevant health practitioners**

### **9 Sterile medications and solutions**

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

### **10 Anaesthetic apparatus**

- (1) 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.
- (2) 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) if 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

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- (d) if 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 Respiratory equipment**

- (1) Respiratory equipment that is designed for single use must be discarded once it is used.
- (2) Any other respiratory equipment must be cleaned and disinfected after each time the equipment is used.

**12 Invasive procedures**

- (1) If 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**

**13 Cleaning of instruments and equipment**

- (1) An instrument or equipment that comes into contact with intact skin must be cleaned before it is used.
- (2) An 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, for 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) An 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, for an office-based practice, AS/NZS 4815.

**15 Sterilisation of instruments and equipment**

- (1) An 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, for 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, for an office-based practice, Table 7.1 Performance Testing, Monitoring, Calibration and Maintenance of Sterilizers of AS/NZS 4815.

## **Schedule 2      Records kept by medical practitioners and medical corporations in relation to patients**

(Clauses 7 (1) and 8 (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 medical practitioner who provides the medical treatment or other medical services to the patient that is relevant to the patient's 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 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 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 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, if any, given to the patient,
  - (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 medical treatment (including any medical or surgical procedure) proposed by the 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 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) An abbreviation or shorthand expression may be used in a record only if the abbreviation or expression is 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 medical practitioner or medical corporation must not alter a record, or cause or permit another person to alter a record, in a way that obliterates, obscures or renders 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 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 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 medical practitioner ensures the record is made and kept in accordance with this Schedule.

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## Schedule 3      Equipment and publications required for pharmacy premises

(Clause 13 (1) (e) (i) and (f))

### 1      Equipment

- a refrigerator manufactured (either exclusively or principally) for the purpose of storage of vaccines
- a dispensing balance
- heavy duty scales, capable of weighing up to 1 kg and a set of metric weights compatible for use with those scales or an electronic scale capable of weighing up to 1 kg in increments of no more than 50 mg
- a 200 mL dispensing measure
- a 100 mL dispensing measure
- a 10 mL dispensing measure
- a 5 mL dispensing measure
- a funnel
- 2 mortars and pestles (at least 1 of the mortars and pestles being made of glass)
- a stirring rod
- 2 spatulas
- an ointment slab
- a tablet counting tray

### 2      Publications

- the *Poisons and Therapeutic Goods Act 1966* and the regulations under that Act
- the Poisons List proclaimed under section 8 of the *Poisons and Therapeutic Goods Act 1966* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch)
- the Law and this Regulation
- the Price Information Code of Practice
- the latest editions, and all published amendments or supplements to those editions, of:
  - (a) *MIMS Annual* or *Drugs on Disk* or *AusDI* or another publication approved by the Pharmacy Council for the purposes of this paragraph, and

- (b) *Martindale—The Extra Pharmacopoeia* or *AusDI* or *Micromedex* or another publication approved by the Pharmacy Council for the purposes of this paragraph, and
- (c) *Australian Pharmaceutical Formulary and Handbook* (also known as *APF*) or another publication approved by the Pharmacy Council for the purposes of this paragraph, and
- (d) *Australian Medicines Handbook* (also known as *AMH*) or the *Pharmacy Self Care Cards* published by the Pharmaceutical Society of Australia or another publication approved by the Pharmacy Council for the purposes of this paragraph.

**Note.** Clause 6 of Schedule 7 of the Law provides that a reference to an Act or instrument extends to the Act or instrument as in force for the time being. Section 69 of the *Interpretation Act 1987* makes provision for how a reference to a publication that is not an Act or instrument is to be construed.

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## Schedule 4 Publications required for professional services room premises

(Clause 14 (1) (e))

the *Poisons and Therapeutic Goods Act 1966* and the regulations under that Act the Poisons List proclaimed under section 8 of the *Poisons and Therapeutic Goods Act 1966* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch)

the Law and this Regulation

the latest editions, and all published amendments or supplements to those editions, of:

- (a) *MIMS Annual* or *Drugs on Disk* or *AusDI* or another publication approved by the Pharmacy Council for the purposes of this paragraph, and
- (b) *Martindale—The Extra Pharmacopoeia* or *AusDI* or *Micromedex* or another publication approved by the Pharmacy Council for the purposes of this paragraph, and
- (c) *Australian Pharmaceutical Formulary and Handbook* (also known as *APF*) or another publication approved by the Pharmacy Council for the purposes of this paragraph, and
- (d) *Australian Medicines Handbook* (also known as *AMH*) or the *Pharmacy Self Care Cards* published by the Pharmaceutical Society of Australia or another publication approved by the Pharmacy Council for the purposes of this paragraph.

**Note.** Clause 6 of Schedule 7 of the Law provides that a reference to an Act or instrument extends to the Act or instrument as in force for the time being. Section 69 of the *Interpretation Act 1987* makes provision for how a reference to a publication that is not an Act or instrument is to be construed.