

# Private Health Facilities Regulation 2017

[2017-483]



New South Wales

## Status Information

### Currency of version

Current version for 1 September 2023 to date (accessed 11 May 2024 at 4:26)

Legislation on this site is usually updated within 3 working days after a change to the legislation.

### Provisions in force

The provisions displayed in this version of the legislation have all commenced.

### Notes—

- **Staged repeal status**

This legislation is currently due to be automatically repealed under the [Subordinate Legislation Act 1989](#) on 1 September 2024

### Authorisation

This version of the legislation is compiled and maintained in a database of legislation by the Parliamentary Counsel's Office and published on the NSW legislation website, and is certified as the form of that legislation that is correct under section 45C of the [Interpretation Act 1987](#).

File last modified 1 September 2023

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New South Wales

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# Private Health Facilities Regulation 2017



New South Wales

## Part 1 Preliminary

### 1 Name of Regulation

This Regulation is the *Private Health Facilities Regulation 2017*.

### 2 Commencement

This Regulation commences on 1 September 2017.

**Note—**

This Regulation replaces the *Private Health Facilities Regulation 2010*, which is repealed on 1 September 2017 under section 10(2) of the *Subordinate Legislation Act 1989*.

### 3 Definitions

(1) In this Regulation—

**anaesthesia** means the administration of general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, other than—

- (a) sedation provided in connection with dental procedures, or
- (b) diagnostic imaging practice anaesthesia.

**Australasian Health Facility Guidelines** means the *Australasian Health Facility Guidelines* endorsed by the Australasian Health Infrastructure Alliance in Australia and New Zealand that commenced on 23 November 2007.

**cardiac catheterisation** means the passing of a catheter, or other instrument, through a major blood vessel and into the heart for a diagnostic or therapeutic purpose.

**chemotherapy** means intravenous treatments using one or more cytotoxic agents.

**cosmetic surgery** means—

- (a) any cosmetic surgical procedure that is intended to alter or modify a person's appearance or body and that involves anaesthesia (including a Bier block), or

- (b) any of the following surgical procedures (however described)—
- (i) abdominoplasty (tummy tuck),
  - (ii) belt lipectomy,
  - (iii) brachioplasty (armlift),
  - (iv) breast augmentation or reduction,
  - (v) buttock augmentation, reduction or lift,
  - (vi) calf implants,
  - (vii) facial implants that involve inserting an implant on the bone or surgical exposure to deep tissue,
  - (viii) fat transfer that involves the transfer of more than 2.5 litres of lipoaspirate,
  - (ix) liposuction that involves the removal of more than 2.5 litres of lipoaspirate,
  - (x) mastopexy or mastopexy augmentation,
  - (xi) necklift,
  - (xii) pectoral implants,
  - (xiii) penis augmentation,
  - (xiv) rhinoplasty (other than revision rhinoplasty),
  - (xv) superficial musculoaponeurotic system facelift (SMAS facelift),
  - (xvi) vaginoplasty or labiaplasty,

but does not include any dental procedure.

**diagnostic imaging practice anaesthesia** means the administration of general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, but only when administered—

- (a) in diagnostic imaging premises (within the meaning of the [Health Insurance Act 1973](#) of the Commonwealth) that are on the premises of a licensed anaesthesia class private health facility, and
- (b) to a patient of the private health facility, and
- (c) by a registered medical practitioner who is a member of staff of, or accredited to provide health services at, the private health facility.

**extended recovery accommodation standards** means the standards set out in

Part 2 of Schedule 3.

***gastrointestinal endoscopy*** means the use of a flexible endoscope with an internal lumen for the passage of an instrument to examine the upper or lower gastrointestinal tract.

***interventional neuroradiology*** means the passing of a catheter or other instrument through the spinal canal, the cranial cavity or through a major blood vessel, to the brain or spine.

***medical advisory committee***, in relation to a private health facility, means the medical advisory committee appointed for the facility under section 39 of the Act.

***overnight accommodation standards*** means the standards set out in Part 1 of Schedule 3.

***psychedelic-assisted therapy***—

(a) means psychotherapy involving—

- (i) the use of N, ?-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) for the treatment of post-traumatic stress disorder, or
- (ii) the use of psilocybine for the treatment of treatment-resistant depression, and

(b) does not include psychotherapy involving the use of a Schedule 9 substance authorised under the [Poisons and Therapeutic Goods Act 1966](#), section 17D.

***rapid opioid detoxification*** means the use of one or more opioid antagonists, in particular naltrexone or naloxone or a combination of the two, in a person who is physiologically dependent on opioids for the purpose of accelerating opioid withdrawal in the person and rendering the person opioid free.

***relevant health services organisation*** has the same meaning it has in the [Health Administration Act 1982](#), Part 2A.

***revision rhinoplasty*** means a rhinoplasty performed on a patient at least 12 months after an initial rhinoplasty is performed on the patient, and where each of the following circumstances applies—

- (a) the procedure requires only a local anaesthetic to be administered,
- (b) the procedure does not involve any bony structures or turbinates,
- (c) if a nasal airway is obstructed, it must only be a minor obstruction that can be corrected by the removal of mucous membrane or cartilage,
- (d) the patient has an adequate amount of skin available to perform the procedure.

**the Act** means the *Private Health Facilities Act 2007*.

**Note—**

The Act and the *Interpretation Act 1987* contain definitions and other provisions that affect the interpretation and application of this Regulation.

(2) In this Regulation, a reference to a class of private health facility is a reference to a class specified in clause 6.

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

**4 Definition of “private health facility”: prescribed services or treatments**

For the purposes of the definition of **private health facility** in section 4(1) of the Act, the following are prescribed services or treatments (irrespective of whether the person being provided with the service or treatment is admitted to the facility)—

- (a) anaesthesia,
- (b) cardiac catheterisation,
- (c) chemotherapy,
- (d) cosmetic surgery,
- (e) services or treatments relating to the care of patients injured in accidents, or those suffering from medical or other emergencies, through the provision of reception, resuscitation, medical and surgical treatment and use of life support systems,
- (f) gastrointestinal endoscopy,
- (g) interventional neuroradiology,
- (h) radiotherapy,
- (i) rapid opioid detoxification,
- (j) renal dialysis,
- (k) surgical procedures performed on patients who are administered general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, other than a surgical procedure carried out by a dentist,
- (l) psychedelic-assisted therapy.

**Note—**

The definition of **private health facility** in section 4(1) of the Act also includes certain facilities at which a person is admitted, provided with medical or surgical treatment and then discharged.

## **Part 2 Licensing of private health facilities**

### **Division 1 Classes of private health facilities**

#### **5 Licensing standards**

- (1) For the purposes of section 5 of the Act—
  - (a) the standards set out in Schedule 1 are prescribed for all private health facilities, and
  - (b) a standard specified in Schedule 2 in relation to a specified class of private health facility is prescribed for private health facilities of that class.
- (2) The licensee of a private health facility must ensure that the private health facility is conducted in accordance with the provisions of Schedules 1 and 2 applicable to the private health facility.

Maximum penalty (subclause (2)): 5 penalty units.
- (3) A licensee is not guilty of an offence under this clause if the licensee—
  - (a) was not aware of the circumstances giving rise to the alleged offence, and
  - (b) could not reasonably be expected to have been aware of those circumstances.
- (4) A contravention of a provision of Schedule 1 or 2 by any person other than the licensee does not constitute an offence under this Regulation.

#### **6 Classes of private health facilities**

The classes of private health facilities are as follows—

- (a) anaesthesia (being a facility licensed for the treatment of patients who are administered general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, but does not include sedation provided in connection with dental procedures),
- (b) cardiac catheterisation (being a facility licensed for any procedure involving the passing of a catheter, or other instrument, through a major blood vessel and into the heart for a diagnostic or therapeutic purpose),
- (c) cardiac surgery (being a facility licensed for surgery within, or on, the heart),
- (d) chemotherapy (being a facility licensed for intravenous treatments using one or more cytotoxic agents),
- (e) cosmetic surgery (being a facility licensed for cosmetic surgery),
- (f) emergency (being a facility licensed for the care of patients injured in accidents, or

those suffering from medical or other emergencies, through the provision of reception, resuscitation, medical and surgical treatment and use of life support systems),

- (g) gastrointestinal endoscopy (being a facility licensed for the use of a flexible endoscope with an internal lumen for the passage of an instrument to examine the upper or lower gastrointestinal tract),
- (h) intensive care (level 1 or level 2) (being a facility licensed for the observation, care and treatment of patients with life threatening or potentially life threatening illnesses, injuries or complications, from which recovery is possible, in a facility that is specially staffed and equipped for that purpose),
- (i) interventional neuroradiology (being a facility licensed for the diagnosis and treatment of diseases and conditions of the brain or spinal cord using procedures involving the passing of a catheter or other instrument through the spinal canal, the cranial cavity or through a major blood vessel, to the brain or spine),
- (j) maternity (level 1 or level 2) (being a facility licensed for maternity care, including antenatal care related to childbirth, assistance and care of a mother associated with normal childbirth, surgical intervention in achieving childbirth and assistance and care of a mother admitted to the facility immediately after childbirth),
- (k) medical (being a facility licensed for the diagnosis or treatment of admitted patients by a procedure or technique not referred to elsewhere in this clause, where the patient is admitted overnight),
- (l) mental health (being a facility licensed for the provision of mental health care to patients admitted overnight or for the provision of psychedelic-assisted therapy),
- (m) neonatal (being a facility licensed for the provision of care and treatment to a baby under the age of 28 days),
- (n) paediatric (being a facility licensed for the provision of care and treatment to admitted patients between the age of 28 days and 14 years),
- (o) radiotherapy (being a facility licensed for treatments involving the use of ionising radiation from a radioactive substance),
- (p) rapid opioid detoxification (being a facility licensed for the use of one or more opioid antagonists, in particular naltrexone or naloxone or a combination of the two, in a person who is physiologically dependent on opioids for the purpose of accelerating opioid withdrawal in the person and rendering the person opioid free),
- (q) rehabilitation (being a facility licensed for physical rehabilitation, including long-term rehabilitation and specialised physical rehabilitation where the patient is admitted overnight),

- (r) renal dialysis (being a facility licensed for the provision of haemodialysis),
- (s) surgical (being a facility licensed for surgical procedures performed on patients who are administered general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, but does not include a surgical procedure carried out by a dentist).

**Division 2 Licensing application fees and other fees**

**7 Applications for licence for private health facility**

For the purposes of section 6(2)(f) of the Act, the prescribed application fee is \$7,931 and the following particulars and documents are prescribed—

- (a) in respect of a private health facility that is a corporation (other than a corporation referred to in paragraph (b))—the extract of particulars (within the meaning of the [Corporations Act 2001](#) of the Commonwealth) for the current year, and
- (b) in respect of a private health facility that is operated by a church or religious organisation—a certificate of incorporation for the organisation or, if it is a corporation incorporated by an Act, a copy of the Act incorporating the church or organisation.

**8 Request for extension of approval in principle**

For the purposes of section 8(4) of the Act, the prescribed application fee is 4,041.

**9 Annual licence fees**

- (1) For the purposes of section 14 of the Act, the annual licence fee for a private health facility, of any class, that—
  - (a) provides for the accommodation of patients who are admitted for more than 24 hours, and
  - (b) is licensed to accommodate a number of patients within the range specified in Column 1 of the Table to this subclause,

is the fee specified opposite that range in Column 2 of that Table.

**Table**

Column 1	Column 2
Number of patients licensed to be accommodated	Licence fee
Fewer than 51	\$7,065
51-75	\$8,783
76-100	\$10,501

101-150	\$13,938
151-200	\$15,656
More than 200	\$17,374

- (2) For the purposes of section 14 of the Act, the annual licence fee for any other private health facility, of any class, is \$7,065.

#### **10 Transfer of licence**

For the purposes of section 15(3)(b) of the Act, the prescribed application fee is \$4,660.

#### **11 Alterations or extensions to private health facility**

For the purposes of section 16(2)(b) of the Act, the prescribed application fee is \$4,660.

#### **12 Amendment of licence**

For the purposes of section 17(2)(e) of the Act, the prescribed application fee is \$4,660.

#### **13 Application for review of Secretary's decision**

For the purposes of section 24(2)(b) of the Act, the prescribed application fee \$4,660.

### **Part 3 Conduct of private health facilities**

#### **13A Restriction on where cosmetic surgery may be performed**

- (1) For the purposes of section 33A(1) of the Act, cosmetic surgery is prescribed as a service or treatment that must not be performed at a private health facility unless the private health facility is a licensed cosmetic surgery class private health facility.
- (2) This clause takes effect on 17 September 2018.

#### **14 Qualifications for director of nursing of facility**

For the purposes of section 37(2) of the Act, the minimum necessary qualifications for a registered nurse to be appointed as a director of nursing at a private health facility are—

- (a) 5 years post basic or post graduate nursing experience, and
- (b) 1 year administrative experience in a position equivalent to, or more senior than, nursing unit manager in a private health facility or a public hospital.

#### **15 Register of patients**

For the purposes of section 38(4) of the Act, a particular required to be entered in the register of patients must be entered by a member of staff of the private health facility—

- (a) in the case of a particular relating to the admission of a patient—at the time of

admission of the patient to the facility, and

- (b) in the case of a particular relating to the separation of a patient—at the time the patient ceases to be a patient of the facility.

## **Part 4 Medical advisory committee**

### **16 Membership of medical advisory committee**

For the purposes of section 39(1) of the Act, the licensee of a private health facility must appoint to the medical advisory committee for the private health facility at least one medical practitioner who has no pecuniary interest in the private health facility.

## **Part 5 Serious adverse event review teams**

### **17 Reportable incident**

- (1) For the purposes of the Act, section 41, definition of **reportable incident**, a reportable incident means an incident of a type set out in Appendix D of the *Incident Management Policy* published in the Government Gazette No 292 on 30 October 2020.
- (2) If a reportable incident occurs in a private health facility, the licensee must notify the Secretary of that fact no later than 2 working days after the day of the incident.
- (3) A serious adverse event review team that is appointed under the Act, section 46 must provide an incident report in accordance with the Act, section 47 no later than 70 calendar days after the day of the incident.

### **18 Serious adverse event review**

For the purposes of the Act, section 41, definition of **serious adverse event review**, the following types of review are prescribed—

- (a) NSW Health Concise Incident Analysis set out in Appendix E of the *Incident Management Policy* published in the Government Gazette No 292 on 30 October 2020,
- (b) NSW Health Comprehensive Incident Analysis set out in Appendix F of the *Incident Management Policy* published in the Government Gazette No 292 on 30 October 2020,
- (c) *Systems Analysis of Clinical Incidents: The London Protocol*, published in August 2004 by Imperial College London.

### **18A Disclosure of information—assessor advice**

For the purposes of the Act, section 45(1)(e), the following prescribe the manner in which advice or information may be disclosed—

- (a) to obtain legal advice,

- (b) to obtain legal representation,
- (c) to notify an insurer of an incident and to provide information in relation to an insurance claim.

**18B Disclosure of information—incident reviewers**

- (1) For the purposes of the Act, section 49D, a person who is or was an incident reviewer may divulge or communicate information acquired by the person in the person's capacity as an incident reviewer if the information is divulged or communicated to a committee for the purposes of any research or investigation the committee is authorised to conduct under the [Health Administration Act 1982](#), section 23(1).
- (2) In this clause—

**committee** means a council, committee or advisory body appointed under the [Health Administration Act 1982](#), section 20 and includes the following—

- (a) Special Committee Investigating Deaths Under Anaesthesia (SCIDUA),
- (b) Collaborating Hospitals Audit of Surgical Mortality Committee (CHASM),
- (c) the NSW Maternal and Perinatal Mortality Review Committee.

**18C Notification of incidents—the Act, s 49H(g)**

- (1) A licensee of a private health facility (the **original licensee**) may notify another licensee of a private health facility about an incident if the original licensee is of the opinion the notification may assist the other licensee to perform a function under the Act, Part 4.
- (2) A licensee of a private health facility may notify a relevant health services organisation about an incident if the licensee is of the opinion the notification may assist the relevant health services organisation to perform a function under the [Health Administration Act 1982](#), Part 2A.

**18D Exchange of information—the Act, s 49H(h)**

- (1) A licensee of a private health facility (the **original licensee**) may exchange information with another licensee of a private facility if the original licensee is of the opinion the exchange of information may assist the other licensee to perform a function under the Act, Part 4.
- (2) A licensee of a private health facility may exchange information with a relevant health services organisation of an incident if the licensee is of the opinion the exchange of information may assist the relevant health services organisation to perform a function under the [Health Administration Act 1982](#), Part 2A.

## Part 6 Disclosure of pecuniary interests

### 19 Definitions

(1) For the purposes of this Part—

***pecuniary interest in a private health facility*** means any one or more of the following interests—

- (a) a pecuniary interest in the licence to conduct the private health facility, being—
  - (i) an interest as the holder of the licence to conduct the private health facility, or as one of the holders of such a licence, or
  - (ii) an interest in any corporation (other than a public company) that is the licensee of the private health facility, or
  - (iii) a holding of 5 per cent or more of the issued share capital of a public company that is the licensee of the private health facility,
- (b) a pecuniary interest in the premises on which the private health facility is conducted, being—
  - (i) an interest (whether at law or in equity) in the premises at which the private health facility is conducted, or
  - (ii) an interest in any corporation (other than a public company) that has any interest (whether at law or in equity) in the premises at which the private health facility is conducted, or
  - (iii) a holding of 5 per cent or more of the issued share capital of any public company that has any interest (whether at law or in equity) in the premises at which the private health facility is conducted,
- (c) a pecuniary interest in the services provided to the private health facility, being—
  - (i) an interest in any clinical or administrative services provided to the private health facility (other than an interest in fees from medical or dental services provided to any patient in the private health facility), or
  - (ii) an interest in any corporation (other than a public company) that has an interest in any clinical or administrative services provided to the private health facility, or
  - (iii) a holding of 5 per cent or more of the issued share capital of any public company that has an interest in any clinical or administrative services provided to the private health facility.

***relative of a practitioner*** means the spouse, de facto partner, parent, child, brother

or sister of the practitioner.

**Note—**

“De facto partner” is defined in section 21C of the [Interpretation Act 1987](#).

- (2) For the purposes of section 58(4) of the Act, a practitioner has a pecuniary interest in a private health facility if the practitioner has a pecuniary interest in that facility within the meaning of this Part or if a relative of the practitioner has such a pecuniary interest.

## **20 Manner in which pecuniary interest to be notified**

- (1) For the purposes of section 58(2) of the Act, a practitioner is to notify a person of the practitioner’s pecuniary interest—
  - (a) by a statement made by the practitioner, and
  - (b) by written notification given by the practitioner, and
  - (c) by a notice displayed at the private health facility, and
  - (d) by a notice displayed in any office or other professional premises of the practitioner.
- (2) The notification must identify the practitioner to which it relates and must specify the nature and extent of the pecuniary interest.
- (3) A notice referred to in subclause (1)(c) or (d) must comply with the following requirements—
  - (a) the notice must have a surface area of at least 2,500 square centimetres,
  - (b) the information on the notice must be printed in plain, bold letters at least 1 centimetre high on a contrasting background,
  - (c) in the case of a notice displayed at a private health facility, the notice must be displayed in a prominent place in the waiting room or in every room in which the practitioner to whom the notice relates attends to patients or other persons,
  - (d) in the case of a notice displayed at an office or other premises, the notice must be displayed in a prominent place.

## **Part 7 Miscellaneous**

### **21 Display of licence**

At all times while a private health facility is conducted, the licensee must cause the licence, the front page of the licence or a full size copy of the licence to be displayed in a prominent place in the entrance foyer of the private health facility.

Maximum penalty—5 penalty units.

## **22 Notification of Council orders**

The licensee of a private health facility must, as soon as practicable after being made aware of an order being made by a Council under section 124 of the *Local Government Act 1993* or section 121B of the *Environmental Planning and Assessment Act 1979* in relation to the premises of the facility, ensure that the Secretary is notified of the making of the order.

Maximum penalty—5 penalty units.

## **23 Information to be provided by licensees**

- (1) The licensee of a private health facility must, for each month, provide to the Ministry of Health a statistical statement in the form approved by the Secretary.

Maximum penalty—5 penalty units.

- (2) The statement must contain the information required to complete the statement in the approved form and must be provided to the Secretary within 14 days after the end of the month to which the information relates.

## **23A (Repealed)**

## **24 Savings**

- (1) Any act, matter or thing that, immediately before the repeal of the *Private Health Facilities Regulation 2010*, had effect under that Regulation, is taken to have effect under this Regulation.
- (2) The amendment to Schedule 2, clause 49 made by the *Private Health Facilities Amendment (Psychedelic-Assisted Therapy) Regulation 2023* has no effect until the day that is 3 months after the commencement of this subclause.

# **Schedule 1 Licensing standards for private health facilities generally**

(Clause 5(1)(a))

## **Part 1 Environment**

### **1 Compliance with Australasian Health Facility Guidelines**

The design of a private health facility must comply with the Australasian Health Facility Guidelines, as in force on the issue of the licence or such later date as may be specified in the licence, to the extent that those guidelines relate to the health services provided by the facility.

## **2 Compliance with Building Code of Australia**

- (1) Any part of a building comprising a private health facility must comply with the requirements of a class 9a building as defined in the *Building Code of Australia*, as in force on the issue of the licence or such later date as may be specified in the licence.
- (2) This clause does not apply in respect of any part of a private health facility that is only used to provide chemotherapy or renal dialysis class treatments to patients who are admitted and discharged as patients on the same day.

## **3 Maintenance of buildings, facilities and equipment**

- (1) All buildings, furniture, furnishings, fittings and equipment of a private health facility must be maintained in good repair and operational order.
- (2) Without limiting subclause (1), a suitable maintenance program (consistent with the manufacturer's specifications, if any) must be current for—
  - (a) all warm water systems, and
  - (b) all air-conditioning, heating, warming and cooling systems and appliances, and
  - (c) all sterilising equipment, and
  - (d) all communication, alarm and emergency call systems, and
  - (e) all biomedical equipment.

## **4 Equipment and stores**

- (1) Medical, surgical and nursing equipment, appliances and materials that are necessary for the type and level of patient care in the private health facility must be readily available at the facility.
- (2) The medical, surgical and nursing equipment, appliances and materials required to be available at a private health facility by this clause must be provided in quantities that are appropriate for the safe and effective provision of the services for which the facility is licensed.
- (3) Without limiting subclause (1), the following equipment must be readily available at a private health facility—
  - (a) resuscitation equipment, for use in advanced life support, that complies with the *Standards for Resuscitation: Clinical Practice and Education* published by the Australian Resuscitation Council and the New Zealand Resuscitation Council in June 2014, in so far as those standards are relevant to the facility, and
  - (b) in the case of a facility that admits child patients, paediatric resuscitation equipment.

## **5 Communication system**

A private health facility must have an electronic communication system in place that enables patients and staff to summon assistance from—

- (a) each bed, recovery trolley and recovery chair, and
- (b) each patient toilet, shower and bathroom.

## **6 Fire safety and emergency response**

- (1) A private health facility must have a written fire safety and emergency response policy outlining the procedures to be adopted in the event of a fire or other emergency (including contingency arrangements for the transfer of patients where necessary).
- (2) If a fire occurs in a private health facility, the licensee, as soon as practicable and regardless of whether or not the fire brigade is called to extinguish the fire—
  - (a) must notify the Secretary verbally of that fact, and
  - (b) must send to the Secretary written notice of the fact and of all relevant details of the circumstances in which the fire occurred.

## **7 Disaster planning**

A private health facility must have a written disaster response policy outlining the procedures to be followed in the event of a natural disaster or other emergency affecting the provision of services at the facility.

## **8 Back-up power supply**

A private health facility must have a back-up power supply in place that is capable of maintaining essential services, including the following—

- (a) lighting in all clinical and patient areas of the facility,
- (b) operating theatres,
- (c) life support systems.

## **9 Waste and hazardous substances**

- (1) A private health facility must have a written waste and hazardous substances policy outlining the procedures that are to be followed in relation to the handling, transport and disposal of waste and hazardous substances generated at the facility.
- (2) Without limiting subclause (1), the policy should prevent or minimise the risk of harm to the health and safety of patients, staff, the public and the environment.
- (3) A private health facility must ensure that waste and hazardous substances are

handled, transported and disposed of in accordance with the waste and hazardous substances policy.

## **10 Food services**

The licensee of a private health facility that provides for the accommodation of patients who are not discharged on the same day as they are admitted must ensure that the personal, nutritional and clinical dietary needs of each patient are assessed and satisfied, including any necessary help with feeding.

## **Part 2 Clinical care**

### **11 Staff qualifications and experience**

A private health facility must have—

- (a) a sufficient number of qualified and experienced staff on duty, at all times, to carry out the services provided by the facility, and
- (b) nursing staff holding qualifications and experience appropriate for the services provided by the facility, and
- (c) nursing staff that are trained in the use of the equipment, including resuscitation equipment, provided by the facility.

### **12 Clinical records and patient information**

- (1) A private health facility must have clinical records created and maintained, in respect of each patient (including each neonate) born or treated at the facility, by the appropriate staff of the facility.
- (2) If the licence of a private health facility is to be transferred, the existing licensee of the private health facility must ensure that all clinical records are made available to the new licensee for the facility.
- (3) Prior to a private health facility ceasing to operate, the licensee of the facility must make arrangements for the safe keeping of clinical records in accordance with the [Health Records and Information Privacy Act 2002](#) and must provide the Secretary with the details of the arrangements.

### **13 Infection control**

- (1) A private health facility must have a written infection control policy outlining the procedures to be followed to prevent or reduce the risk of a patient acquiring an infection while at the facility.
- (2) Without limiting subclause (1), an infection control policy must make provision for the on-going education of staff with respect to infection control.

- (3) A private health facility must ensure that the infection control policy is complied with.
- (4) All decontamination systems and processes for reusable medical devices and clinical equipment must comply with AS/NZS 4187:2003, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities* or AS/NZS 4187:2014, *Reprocessing of reusable medical devices in health service organizations*.

#### **14 Dispensaries**

The following provisions apply to any dispensary conducted at a private health facility—

- (a) the dispensary must be under the control of a pharmacist at all times,
- (b) all dispensing must be personally supervised by a pharmacist,
- (c) if the dispensary is not a pharmacy business within the meaning of the [Health Practitioner Regulation National Law \(NSW\)](#)—the functions of the dispensary are to be limited to the provision of a service to the private health facility and its patients,
- (d) the services provided by the pharmacist in control of the dispensary must include—
  - (i) the provision of all medication for patients, whether on prescription or otherwise, in a form that is suitable, as far as practicable, for direct administration or utilisation, and
  - (ii) the provision of advice on drug compatibility, possible adverse drug reactions, appropriate doses for different classes of patients and medication policy, and
  - (iii) regular inspection of drug stocks and records to ensure proper storage of medication, proper stock rotation, withdrawal of stock that is outdated or no longer required and proper recording of drug use, and
  - (iv) the establishment of written policies and procedures for the procurement, preparation, distribution and administration of medication and other therapeutic goods,
- (e) the pharmacist in control of the dispensary must make adequate provision for emergency drugs to be available to staff of the private health facility for the treatment of patients outside the normal hours of operation of the dispensary.

#### **15 Identification of patients**

Each patient or newborn at a private health facility must be easily identifiable at all times.

#### **16 Admission policies and procedures**

The licensee of a private health facility must seek and consider the advice of the medical advisory committee before making any admission policies and procedures for the facility.

## 17 Separation requirement

Each patient being separated from a private health facility must be provided with a clear explanation, in writing, of any recommendations and arrangements that have been made for follow-up care.

## 18 Transfer of patients

- (1) A private health facility must have procedures in place to transfer a patient to another private health facility or public hospital for care if—
  - (a) the facility is not authorised to provide the care that the patient requires, or
  - (b) in the event of complications arising during the treatment of the patient, the patient requires a higher level of care than is provided by the facility.
- (2) Before a patient is transferred using supported non-emergency transport, a medical practitioner or registered nurse must certify that the patient does not require an emergency ambulance service and has a low risk of deterioration during the transfer.
- (3) In this clause—

**supported non-emergency transport** has the same meaning as it has in the [Health Services Act 1997](#).

### Note—

The [Health Services Amendment \(Ambulance Services\) Act 2015](#) (the **amending Act**) amends the [Health Services Act 1997](#) to define supported non-emergency transport. However, the amending Act has not yet commenced.

## 19 Patient records to be transferred with patients

If a patient is transferred from a private health facility to another private health facility or public hospital for care, a copy of any relevant clinical records and patient information maintained under clause 12(1) of this Schedule must be transferred to the facility or hospital that is to receive the patient.

## 20 Privacy of patients

The privacy of the patients of the facility must be considered and respected by all staff of the private health facility.

# Part 3 Quality improvement

## 21 Incident and adverse clinical event management

- (1) The licensee of a private health facility must ensure that the Ministry of Health is notified about any adverse event.

- (2) A private health facility must have a written incident management system outlining the procedures to be followed in the case of an incident or adverse event.
- (3) Without limiting subclause (2), an incident management system must provide for the following—
  - (a) identification of incidents and adverse events,
  - (b) notifying the appropriate authorities about incidents and adverse events (eg the Therapeutic Goods Administration or the Health Care Complaints Commission),
  - (c) investigation of incidents and adverse events,
  - (d) management of the outcomes of any such investigation.
- (4) The licensee of a private health facility must ensure that the incident management system is complied with.
- (5) In this clause—

**adverse event** means an unintended injury to a patient, or a complication caused by the health care management of a patient, that results in a major permanent loss of function (being sensory, motor, physiological or psychological) for the patient or death of the patient.

**incident** means any unplanned event resulting in, or with the potential to cause, injury, damage or loss to a patient at a private health facility.

## 22 Complaints

- (1) A private health facility must have a written complaints policy outlining the procedure to be followed in managing and responding to complaints.
- (2) The licensee of a private health facility must ensure that patients, relatives of patients and other carers are provided with information about the procedure for making complaints, and the process for managing and responding to any complaints.
- (3) The licensee of a private health facility must ensure that the complaints policy is complied with.

## 23 Quality and outcome audits

The licensee of a private health facility must—

- (a) conduct regular audits to ensure that the facility is complying with statutory requirements as well as the facility's policies and procedures, and
- (b) conduct regular audits to monitor the effectiveness of the policies and procedures of the facility as well as clinical services and patient outcomes.

## **24 Risk assessment and safety inspections**

- (1) A private health facility must have a written risk assessment and safety inspection program outlining the procedure for carrying out risk assessments and safety inspections, including the frequency with which such assessments and inspections should be carried out.
- (2) The licensee of a private health facility must ensure that the risk assessment and safety inspection program is complied with.

## **Schedule 2 Licensing standards**

(Clause 5(1)(b))

### **Part 1 Anaesthesia class private health facilities**

#### **1 Sedation and anaesthesia**

An anaesthesia class private health facility must have the following—

- (a) anaesthetic equipment recommended by the Australian and New Zealand College of Anaesthetists in its publication *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations*,
- (b) monitoring equipment recommended by the Australian and New Zealand College of Anaesthetists in its publication *Recommendations on Monitoring During Anaesthesia*,
- (c) recovery equipment and drugs recommended by the Australian and New Zealand College of Anaesthetists in its publication *Recommendations for the Post-Anaesthesia Recovery Room*.

#### **2 Minimum staffing requirements**

An anaesthesia class private health facility must provide staff to assist an anaesthetist in accordance with the recommendations of the Australian and New Zealand College of Anaesthetists in its publication *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations*.

### **Part 2 Cardiac catheterisation class private health facilities**

#### **3 Design and construction**

A cardiac catheterisation class private health facility must comply with the *Guidelines on Support Facilities for Coronary Angiography and Percutaneous Coronary Intervention (PCI)* published by the Cardiac Society of Australia and New Zealand.

#### **4 Minimum accommodation requirements**

A cardiac catheterisation class private health facility must provide for the accommodation

of one or more of the following groups of patients—

- (a) patients who are admitted for more than 24 hours,
- (b) patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours,
- (c) patients who are admitted and discharged on the same day.

## **5 Accommodation standards**

A cardiac catheterisation class private health facility must comply with such of the following standards as are applicable to the facility—

- (a) if the facility provides for the accommodation of patients who are admitted for more than 24 hours—the overnight accommodation standards,
- (b) if the facility provides for the accommodation of patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours—the extended recovery accommodation standards.

## **Part 3 Cardiac surgery class private health facilities**

### **6 Design and construction**

A cardiac surgery class private health facility must comply with the *Guidelines for the Establishment of an Adult Cardiac Surgery Unit (CSU)* published by the Australian and New Zealand Society of Cardiac and Thoracic Surgeons.

### **7 Concurrent licensing**

A cardiac surgery class private health facility must also be licensed as an intensive care (level 2) class private health facility.

### **8 Minimum operating requirements**

A cardiac surgery class private health facility that carries out open heart surgery must have at least two independent operating rooms that are equipped to carry out cardiac surgery class procedures.

### **9 Minimum accommodation requirements**

A cardiac surgery class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

### **10 Accommodation standards**

A cardiac surgery class private health facility must comply with the overnight accommodation standards.

## **Part 4 Chemotherapy class private health facilities**

### **11 Design and construction**

Any part of a building comprising a chemotherapy class private health facility must comply with the requirements of a class 5 building as defined in the *Building Code of Australia*, as in force on the issue of the licence for the private health facility or on such later date as may be specified in the licence.

### **12 Conduct of chemotherapy class private health facilities**

A chemotherapy class private health facility must have—

- (a) written policies and procedures for—
  - (i) the provision of information and counselling to patients and their relatives, and
  - (ii) the admission and discharge of patients, including continuing care and review, and
  - (iii) the management of side effects, and
  - (iv) access to relevant specialists for consultation, and
- (b) a written policy on the provision of chemotherapy services as part of a multi-disciplinary approach to patient care, that includes specific provisions for consultation, referral and links to other relevant services for the patient, such as radiation oncology, surgical services, clinical haematology, palliative care and clinical support services, and
- (c) sufficient appropriate practitioners for the services provided, including medical oncologists, haematologists, specialist nurses and other relevant specialists for consultation.

### **13 Antineoplastic drugs**

- (1) Antineoplastic drugs administered at a chemotherapy class private health facility must be prepared from a cytotoxic drug cabinet—
  - (a) that complies with AS 2567-2002 *Laminar flow cytotoxic drug safety cabinets*, and
  - (b) that is in a room that complies with AS 2639-1994, *Laminar flow cytotoxic drug safety cabinets—Installation and use*.
- (2) A chemotherapy class private health facility must ensure that the clinical record for each patient who receives an antineoplastic drug includes—
  - (a) a written treatment plan based on the assessment of the patient, and
  - (b) a signed record of the patient's consent to the treatment, and

(c) the details of the antineoplastic drugs, and the dose of the drugs, prescribed for and administered to the patient.

(3) A chemotherapy class private health facility must comply with the *Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy* published by the Clinical Oncological Society of Australia in November 2008.

(4) The medical advisory committee of a chemotherapy class private health facility must include a specialist oncologist or a consultant physician trained in oncology when matters relating to antineoplastic drugs are discussed.

#### **14 Review of certain treatment**

(1) A chemotherapy class private health facility must ensure that the prescription or administration of antineoplastic drugs that are outside the scope of normal clinical practices or protocols are regularly and independently reviewed and audited.

(2) In this clause, **independent**, in relation to a review or audit, means a review or audit that is conducted by—

(a) at least one oncologist, and

(b) persons who are independent of the treating clinician (whether or not the persons are independent of the facility).

#### **15 Minimum accommodation requirements**

A chemotherapy class private health facility must provide for the accommodation of one or more of the following groups of patients—

(a) patients who are admitted for more than 24 hours,

(b) patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours,

(c) patients who are admitted and discharged on the same day.

#### **16 Accommodation standards**

A chemotherapy class private health facility must comply with such of the following standards as are applicable to the facility—

(a) if the facility provides for the accommodation of patients who are admitted for more than 24 hours—the overnight accommodation standards,

(b) if the facility provides for the accommodation of patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours—the extended recovery accommodation standards.

## **17 Transitional provision**

- (1) The licensing standards prescribed by this Part have effect on and from 1 January 2018.
- (2) The licensing standards prescribed by Part 4 (Chemotherapy class private health facilities) of Schedule 2 (Licensing standards) to the *Private Health Facilities Regulation 2010* continue to have effect until the end of 31 December 2017.

## **Part 5 Cosmetic surgery class private health facilities**

### **18 Application of certain standards**

- (1) A cosmetic surgery class private health facility must comply with the anaesthesia standards listed in Part 1 of this Schedule.
- (2) Clauses 81–85 of this Schedule apply to a cosmetic surgery class private health facility in the same way as they apply to a surgical class private health facility. For that purpose, references in those clauses to a surgical procedure or surgical class procedure are to be construed as references to cosmetic surgery.
- (3) A cosmetic surgery class private health facility is not required to comply with subclause (1) to the extent that it carries out either of the following surgical procedures without anaesthesia but is, however, required to comply with the *Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures* published by the Australian and New Zealand College of Anaesthetists—
  - (a) fat transfer that involves the transfer of more than 2.5 litres of lipoaspirate,
  - (b) liposuction that involves the removal of more than 2.5 litres of lipoaspirate.

## **Part 6 Emergency class private health facilities**

### **19 Design of emergency area**

Any part of an emergency class private health facility that is used for the provision of emergency treatment must be designed for the reception, assessment, stabilisation, treatment and transfer of patients.

### **20 Staffing**

An emergency class private health facility must—

- (a) have an appropriately qualified and experienced medical practitioner appointed as director of the emergency service, and
- (b) have appropriately qualified specialists available on call at all times, and

- (c) have a sufficient number of appropriately trained and experienced staff on duty at all times, and
- (d) be open to receive patients at all times.

## **21 Triage of patients**

An emergency class private health facility must have arrangements for the triage of a patient to be carried out at the time of the patient's arrival by appropriately experienced clinical staff.

## **22 Policies and procedures**

An emergency class private health facility must have written policies and procedures for—

- (a) the co-ordination of services with other private health facilities and public hospitals in the same or adjacent areas, and
- (b) the integration of the emergency services with the other clinical and educational programs carried on at the facility, and
- (c) the safe movement of patients in any part of the facility that is used for the provision of emergency class procedures, and
- (d) the review of care plans for patients.

## **23 Transfer of patients**

An emergency class private health facility must have—

- (a) effective communication arrangements with the Ambulance Service of New South Wales, and
- (b) written procedures for the transfer of patients requiring a higher level of care than is provided by the facility.

## **24 Clinical records**

- (1) An emergency class private health facility must have a clinical record for each patient at the facility.
- (2) Without limiting subclause (1), a clinical record must include the following—
  - (a) the date and time of the patient's arrival,
  - (b) details of the patient's presenting symptoms and condition,
  - (c) the triage category allocated at the time of first assessment,
  - (d) details of significant clinical, laboratory and radiological findings,

- (e) accurate details of the treatment (if any) provided to the patient,
- (f) details of any follow-up directions given to the patient prior to the patient's departure,
- (g) the date and time of the patient's departure,
- (h) the identity and signature of the attending medical officer.

## **25 Minimum accommodation requirements**

An emergency class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

## **Part 7 Gastrointestinal endoscopy class private health facilities**

### **26 Compliance with guidelines**

A gastrointestinal endoscopy class private health facility must comply with *Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures* published by the Australian and New Zealand College of Anaesthetists.

### **27 Disinfection of endoscopes**

Endoscopes used at a gastrointestinal endoscopy class private health facility must be disinfected by the use of an automatic endoscope reprocessor or otherwise in accordance with the manufacturer's instructions in an area with atmospheric extraction facilities that is adjacent to the procedure room in which the endoscope is to be used.

### **28 Reprocessing of other equipment**

- (1) Instruments and other equipment used at a gastrointestinal endoscopy class private health facility must be decontaminated, cleaned and reprocessed in accordance with AS/NZS 4187:2003, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities* or AS/NZS 4187:2014, *Reprocessing of reusable medical devices in health services organizations*.
- (2) Without limiting subclause (1), the decontamination, cleaning and reprocessing of equipment and instruments used in the facility must be carried out by a staff member who has appropriate training and experience.

### **29 Minimum accommodation requirements**

A gastrointestinal endoscopy class private health facility must provide for the accommodation of one or more of the following groups of patients—

- (a) patients who are admitted for more than 24 hours,

- (b) patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours,
- (c) patients who are admitted and discharged on the same day.

### **30 Accommodation standards**

A gastrointestinal endoscopy class private health facility must comply with such of the following standards as are applicable to the facility—

- (a) if the facility provides for the accommodation of patients who are admitted for more than 24 hours—the overnight accommodation standards,
- (b) if the facility provides for the accommodation of patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours—the extended recovery accommodation standards.

## **Part 8 Intensive care (level 1 or level 2) class private health facility**

### **31 Staffing**

An intensive care (level 1 or level 2) class private health facility must have—

- (a) a medical practitioner with appropriate qualifications appointed as director of the unit, the appropriate qualifications being (in the case of an intensive care (level 2) class private health facility) a recognised post-graduate qualification in intensive care, and
- (b) in the case of an intensive care (level 1) class private health facility—a medical practitioner on duty at the private health facility at all times, with priority for attendance on patients in the intensive care unit, and
- (c) in the case of an intensive care (level 2) class private health facility—a medical practitioner with an appropriate level of experience present in the unit at all times, and
- (d) sufficient nursing staff on duty at all times, being—
  - (i) a nursing staff to patient ratio of at least 1:1 for all critically ill patients, and
  - (ii) in the case of an intensive care (level 2) class private health facility—at least 50% of whom are registered nurses with intensive care certification.

### **32 Minimum operating requirements**

An intensive care (level 1 or level 2) class private health facility must comply with the requirements of the *Minimum Standards for Intensive Care Units* published by the College of Intensive Care Medicine of Australia and New Zealand.

### **33 Minimum accommodation requirements**

An intensive care (level 1 or level 2) class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

### **34 Accommodation standards**

An intensive care (level 1 or level 2) class private health facility must comply with the overnight accommodation standards.

## **Part 9 Interventional neuroradiology class private health facility**

### **35 Minimum accommodation requirements**

An interventional neuroradiology class private health facility must provide for the accommodation of one or more of the following groups of patients—

- (a) patients who are admitted for more than 24 hours,
- (b) patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours,
- (c) patients who are admitted and discharged on the same day.

### **36 Accommodation standards**

An interventional neuroradiology class private health facility must comply with such of the following standards as are applicable to the facility—

- (a) if the facility provides for the accommodation of patients who are admitted for more than 24 hours—the overnight accommodation standards,
- (b) if the facility provides for the accommodation of patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours—the extended recovery accommodation standards.

## **Part 10 Maternity (level 1 or level 2) class private health facility**

### **36A Definition**

In this Part—

***Birth on Country demonstration facility*** means a maternity (level 1) class private health facility that has an agreement with the local health district serving the area in which the facility is located for—

- (a) support for the delivery of maternity care within the facility, and
- (b) the transfer and admission of patients to a hospital operated by the local health district.

### **36B One Birthing on Country demonstration facility**

- (1) A Birthing on Country demonstration facility must only be located in the area served by Illawarra Shoalhaven Local Health District.
- (2) Illawarra Shoalhaven Local Health District must not enter into an agreement with more than 1 Birthing on Country demonstration facility.

### **37 Term of pregnancy**

- (1) A maternity class private health facility must not admit a patient for maternity class procedures—
  - (a) in the case of a maternity (level 1) class private health facility—prior to 37 weeks completed gestation, or
  - (b) in the case of a maternity (level 2) class private health facility—prior to 34 weeks completed gestation.
- (2) Despite subclause (1), a maternity (level 2) class private health facility may admit a patient for maternity class procedures prior to 34 weeks completed gestation, but not prior to 32 weeks completed gestation, if the licence for the facility is subject to a relevant condition and the facility is also licensed as a neonatal class private health facility.
- (3) In this clause, **relevant condition** means a condition to the effect that the private health facility must have support services, infrastructure and staff with appropriate clinical expertise that, in the opinion of the Secretary, are appropriate for the provision of maternity class procedures to patients who have completed between 32 and 34 weeks gestation.

### **38 Normal risk pregnancies**

- (1) A maternity (level 1 or level 2) class private health facility must have support services, infrastructure and staff with appropriate clinical expertise to provide care for normal risk pregnancies, including the following—
  - (a) obstetricians, anaesthetists and a paediatrician on call at all times,
  - (b) a medical practitioner at the facility at all times,
  - (c) experienced midwives on duty at all times,
  - (d) established links with clinical nurse consultants or clinical nurse educators in midwifery and neonatal nursing.
- (2) Subclause (1)(b) and (c) do not apply to a Birthing on Country demonstration facility.

### **39 Moderate risk pregnancies**

- (1) A maternity (level 1) class private health facility must not admit a maternity patient with a moderate risk pregnancy.
- (2) A maternity (level 2) class private health facility must not admit a maternity patient with a moderate risk pregnancy unless—
  - (a) the medical advisory committee is satisfied that the facility is able to provide appropriate care for a patient having regard to any risk factors relevant to the patient, and
  - (b) the facility has appropriate support services and infrastructure and has staff with clinical expertise relevant to the risk factors of particular patients, including—
    - (i) obstetricians, anaesthetists and a paediatrician on call at all times, and
    - (ii) a medical practitioner at the facility at all times, and
    - (iii) experienced midwives on duty at all times, and
    - (iv) established links with clinical nurse consultants or clinical nurse educators in midwifery and neonatal nursing, and
    - (v) a special care nursery.

### **40 Accommodation of neonates**

A maternity (level 1 or level 2) class private health facility must have appropriate accommodation and procedures for the management of healthy neonates and neonates with minimal complications.

### **41 Patient transfer policy**

- (1) A maternity (level 1 or level 2) class private health facility must have procedures in place that provide for the transfer of patients requiring a higher level of care than is provided by the facility.
- (2) Without limiting subclause (1), the facility must have procedures in place for the transfer of a patient in premature labour.
- (3) Without limiting subclause (1), procedures for the transfer of neonates must provide for the resuscitation and stabilisation of neonates prior to their transfer.
- (4) The procedures referred to in subclause (1) must be reviewed at least every 3 years and must be submitted to the medical advisory committee for approval and comment.
- (5) In this clause—

***premature labour***, in relation to a patient, means a patient who is in labour but has

not completed the number of weeks gestation required for admission to the private health facility.

#### **42 Birth register**

- (1) A maternity class private health facility must maintain a birth register that records the details of every child born at the facility.
- (2) Without limiting subclause (1), the birth register must contain the following—
  - (a) the mother's full name and clinical record number,
  - (b) the date and time of the child's birth,
  - (c) the sex of the child,
  - (d) whether the child was born alive,
  - (e) the method of delivery,
  - (f) the name of any midwives or medical practitioners present at the birth.
- (3) A maternity class private health facility must retain a child's record on the birth register for at least 25 years after the birth of the child.

#### **43 Minimum accommodation requirements**

A maternity class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

#### **44 Accommodation standards**

A maternity class private health facility must comply with the overnight accommodation standards.

#### **44A Additional requirements for Birthing on Country demonstration facility**

- (1) A Birthing on Country demonstration facility must—
  - (a) have an endorsed midwife on duty at the facility at all times while a patient is admitted to the facility for maternity care, and
  - (b) have at least 1 additional endorsed midwife on call at all times, and
  - (c) have a written policy for the delivery of a Birthing on Country model of maternity care, and
  - (d) have a written policy, developed having regard to the Ministry of Health guideline *Maternity and Neonatal Service Capability* published on 20 May 2022, that addresses the following—

- (i) clinical governance, including competence and credentialling of staff,
- (ii) quality and safety processes,
- (iii) service requirements, including consultation, escalation, transfer and education, and
- (e) comply with the *National Midwifery Guidelines for Consultation and Referral*, 4th edition, published by the Australian College of Midwives, and
- (f) ensure all midwives providing services at the facility have skills and experience in the following—
  - (i) the repair of perineal tears, other than third and fourth degree perineal tears,
  - (ii) the management of obstetric emergencies and neonatal emergencies.

(2) In this clause—

**endorsed midwife** means a midwife whose registration is endorsed under the [Health Practitioner Regulation National Law \(NSW\)](#), section 94.

**perineal tear** and **third and fourth degree perineal tear** have the same meaning as in the *Third and Fourth Degree Perineal Tears Clinical Care Standard*, published by the Australian Commission on Safety and Quality in Health Care in April 2021.

#### **44B Modification of Schedule 1 for Birthing on Country demonstration facility**

For a Birthing on Country demonstration facility—

- (a) a reference in Schedule 1, clause 11 to nursing staff is to be read as a reference to midwifery staff, and
- (b) a reference in Schedule 1, clause 18 to a registered nurse is to be read as a reference to a midwife practising at the Birthing on Country demonstration facility.

### **Part 11 Medical class private health facility**

#### **45 Minimum accommodation requirements**

A medical class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

#### **46 Accommodation standards**

A medical class private health facility must comply with the overnight accommodation standards.

## **Part 12 Mental health class private health facility**

### **47 Design and construction**

- (1) Any part of a mental health class private health facility that is used for the provision of mental health class treatments must be designed to meet the needs of mentally ill and mentally disordered persons (within the meaning of the [Mental Health Act 2007](#)) with—
  - (a) suitable arrangements for patient safety and protection, and
  - (b) areas for observation of patients, and
  - (c) accommodation providing personal privacy, consistent with the treatment being provided.
- (2) If electro convulsive therapy is to be administered at the private health facility the facility must have treatment and recovery areas set aside for that purpose.

### **48 Concurrent licensing**

A mental health class private health facility, at which electro convulsive therapy is to be administered, must also be licensed as an anaesthesia class private health facility.

### **49 Conduct of mental health class private health facilities**

A mental health class private health facility must have—

- (a) a written policy on the provision of psychiatric services, including a statement of the private health facility's philosophy of service, and
- (b) written policies and procedures for—
  - (i) supporting the functions of the Mental Health Review Tribunal constituted under the [Mental Health Act 2007](#), and
  - (ii) supporting the functions of official visitors, authorised officers and welfare officers, and
  - (iii) supporting the administration of the [Guardianship Act 1987](#), and
  - (iv) the management of patients' trust funds, and
- (c) clear, written criteria and assessment procedures for the admission of both inpatients and outpatients to psychiatric programs and psychedelic-assisted therapy, and
- (d) a written treatment plan for each patient that—
  - (i) is based on the assessment of that patient, and

- (ii) includes provision for discharge, continuing care and review, and
- (e) access at all times to a psychiatrist, and
- (f) access to a general practitioner and relevant specialists for consultation, and
- (g) sufficient registered nurses with appropriate psychiatric qualifications or experience on duty at all times.

## **50 Telephone access**

A mental health class private health facility must provide at least one telephone, on each floor of the facility that is used for the provision of mental health class treatments, for the use of patients and their next of kin for both incoming and outgoing calls.

## **51 Visiting hours**

- (1) Patients in a mental health class private health facility must be allowed to receive visitors at any reasonable time.
- (2) However, a medical practitioner or the senior nurse on duty may, if necessary for the care of a patient—
  - (a) restrict the hours for visiting a patient and, if necessary, other patients in the same ward, and
  - (b) restrict the number of persons who may visit the patient at any one time.

## **52 Minimum accommodation requirements**

A mental health class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

## **53 Accommodation standards**

A mental health class private health facility must comply with the overnight accommodation standards.

### **53A Psychedelic-assisted therapy**

- (1) Notice must be given to the Secretary at least 7 days before psychedelic-assisted therapy is first provided at a mental health class private health facility.
- (2) Staff of a mental health class private health facility must, when providing psychedelic-assisted therapy, consider the memorandum *Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression* issued by the Royal Australian and New Zealand College of Psychiatrists in June 2023.
- (3) The licensee of a mental health class private health facility at which psychedelic-assisted therapy is provided must, for each period of 6 months commencing when the

therapy is first provided at the facility, give to the Secretary a statement of information relating to each patient to whom the therapy has been provided during the period.

(4) The statement must be—

- (a) in the form approved by the Secretary, and
- (b) given to the Secretary within 14 days after the end of the period of 6 months to which the information relates.

## **Part 13 Neonatal class private health facility**

### **54 Accommodation of neonates**

A neonatal class private health facility must have appropriate accommodation and procedures for the management of healthy neonates, neonates with minimal complications and convalescing neonates, including an intensive care nursery.

### **55 Transfer of neonates**

- (1) A neonatal class private health facility must have a written neonate transfer policy that outlines the procedures to be followed for the transfer of patients requiring a higher level of care than is provided by the facility.
- (2) Without limiting subclause (1), procedures for the transfer of neonates must provide for the resuscitation and stabilisation of neonates prior to their transfer.
- (3) The procedures referred to in subclause (1) must be reviewed at least every 3 years and must be submitted to the medical advisory committee for approval and comment.

### **56 Minimum accommodation requirements**

A neonatal class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

### **57 Accommodation standards**

A neonatal class private health facility must comply with the overnight accommodation standards.

## **Part 14 Paediatric class private health facilities**

### **58 Admission policy**

- (1) A paediatric class private health facility must have a written policy for determining whether a person may be admitted to the facility for the purpose of receiving paediatric class procedures.

- (2) The policy referred to in subclause (1) must make provision for the following—
  - (a) the age of patients who may be admitted to the facility,
  - (b) the types of procedures that may be performed on, and treatments that may be given to, paediatric patients,
  - (c) the maximum period for which a paediatric patient may be admitted,
  - (d) the maximum number of paediatric patients who may be admitted to the facility at any one time,
  - (e) the facilities that are available for the treatment and care of paediatric patients.
- (3) The policy referred to in subclause (1) must be reviewed at least every 3 years and must be submitted to the medical advisory committee for approval and comment.

#### **59 Visitor policy**

A paediatric class private health facility must have a written visitor policy that—

- (a) allows any person having the care of a paediatric patient to have access to the paediatric patient at all times, except while the patient is undergoing surgery, and
- (b) while the paediatric patient is undergoing surgery—allows any person having the care of a paediatric patient to have access to the patient while the patient is in pre-anaesthesia or recovery unless, in the opinion of the medical practitioner responsible for the treatment of the patient, it would not be in the best interests of the patient, and
- (c) ensures that resources are made available to allow any person having the care of a paediatric patient to remain at the private health facility during the patient's stay at the facility.

#### **60 Patient transfers**

- (1) A paediatric class private health facility must have procedures in place that provide for the transfer of patients who require care or treatment that is not provided by the facility.
- (2) The procedures referred to in subclause (1), must be reviewed at least every 3 years and must be submitted to the medical advisory committee for approval and comment.

#### **61 Minimum operating requirements**

A paediatric class private health facility must, at all times during which a paediatric patient is admitted to the facility—

- (a) have a paediatric physician available for consultation, and

- (b) have a registered nurse on duty at the facility who has appropriate paediatric experience or qualifications, and
- (c) in respect of any paediatric patient who is under 12 months of age—have microchemistry available for analysis of capillary blood specimens.

## **62 Minimum accommodation requirements**

A paediatric class private health facility must provide for the accommodation of one or more of the following groups of patients—

- (a) patients who are admitted for more than 24 hours,
- (b) patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours,
- (c) patients who are admitted and discharged on the same day.

## **63 Accommodation standards**

A paediatric class private health facility must comply with such of the following standards as are applicable to the facility—

- (a) if the facility provides for the accommodation of patients who are admitted for more than 24 hours—the overnight accommodation standards,
- (b) if the facility provides for the accommodation of patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours—the extended recovery accommodation standards.

# **Part 15 Radiotherapy class private health facility**

## **64 Conduct of radiotherapy class private health facilities**

A radiotherapy class private health facility—

- (a) must maintain its radiotherapy equipment in good working order and maintain a system for independent dosimetry auditing of linear accelerators, and
- (b) must have a written policy on the provision of radiotherapy services as part of a multi-disciplinary approach to patient care, that includes specific provisions for consultation, referral and links to other relevant services for the patient, such as medical oncology, surgical services, clinical haematology, palliative care and clinical support services, and
- (c) must have sufficient appropriate practitioners for the services provided, including radiation therapists, radiation oncologists, medical physicists and other relevant specialists for consultation.

## **65 Minimum accommodation requirements**

A radiotherapy class private health facility must provide for the accommodation of one or more of the following groups of patients—

- (a) patients who are admitted for more than 24 hours,
- (b) patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours,
- (c) patients who are admitted and discharged on the same day.

## **66 Accommodation standards**

A radiotherapy class private health facility must comply with such of the following standards as are applicable to the facility—

- (a) if the facility provides for the accommodation of patients who are admitted for more than 24 hours—the overnight accommodation standards,
- (b) if the facility provides for the accommodation of patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours—the extended recovery accommodation standards.

## **67 Transitional provision**

- (1) The licensing standards prescribed by this Part have effect on and from 1 January 2018.
- (2) The licensing standards prescribed by Part 14 (Radiotherapy class private health facility) of Schedule 2 (Licensing standards) to the [Private Health Facilities Regulation 2010](#) continue to have effect until the end of 31 December 2017.

# **Part 16 Rapid opioid detoxification class private health facility**

## **68 Guidelines**

A rapid opioid detoxification class private health facility must comply with the *Rapid Opioid Detoxification—Guidelines* published by the Ministry of Health on 21 July 2011.

## **69 Transfer of patients**

- (1) A rapid opioid detoxification class private health facility must have access to an intensive care (level 1 or level 2) class private health facility (whether in the same, or another, private health facility) or a public hospital, to which a patient may be transferred for intensive care in less than 30 minutes.
- (2) A rapid opioid detoxification class private health facility that is not also licensed in the intensive care (level 1 or level 2) class must have written procedures in place that

provide for the transfer of a patient in less than 30 minutes to an intensive care (level 1 or level 2) class private health facility or a public hospital if the patient requires a higher level of care than that provided at the facility.

- (3) If the intensive care class private health facility is not in the private health facility in which rapid opioid detoxification class procedures are carried out, the rapid opioid detoxification class private health facility must have a suitably equipped vehicle available for the transfer of patients to the intensive care class facility at all times during which any such procedure is performed.

## **70 Minimum accommodation requirements**

A rapid opioid detoxification class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

## **71 Accommodation standards**

A rapid opioid detoxification class private health facility must comply with the overnight accommodation standards.

## **72 Minimum staffing requirements**

- (1) A rapid opioid detoxification class private health facility—
  - (a) must have a medical practitioner on staff or on call at all times who has experience in opioid treatment and in the management of detoxification (including severe withdrawal management), and
  - (b) must have a medical practitioner on duty for the first 4 hours following the carrying out of any induction procedure on any patient, and
  - (c) must have a medical practitioner on duty or on call between 4 and 48 hours following the carrying out of any induction procedure on any patient.
- (2) A rapid opioid detoxification class private health facility must have sufficient nursing staff on duty at all times, including—
  - (a) a nursing staff to patient ratio of at least 1:2 in the first 8 hours following the carrying out of any induction procedure on any patient, and
  - (b) a nursing staff to patient ratio of at least 1:4 between 8 hours and 24 hours following the carrying out of any induction procedure on any patient.

# **Part 17 Rehabilitation class private health facilities**

## **73 Conduct of facility**

A rehabilitation class private health facility—

- (a) must have a written policy on the provision of rehabilitation services, including—
  - (i) a statement of the private health facility's philosophy of service, and
  - (ii) details of the liaison to be established with community based services to ensure continuity and co-ordination of care, and
- (b) must have clear, written criteria and assessment procedures for the admission of both inpatients and outpatients to rehabilitation programs, and
- (c) must have a written rehabilitation plan for each patient that—
  - (i) is based on an assessment of the patient, and
  - (ii) states the needs and limitations of the patient and the goals of the rehabilitation plan, and
  - (iii) is prepared by a multi-disciplinary team with the active participation of the family of the patient, and
  - (iv) includes provision for discharge, continuing care and review, and
- (d) must have procedures for regularly evaluating the progress of each patient against the written rehabilitation plan, and
- (e) must have a formal and planned discharge procedure, and
- (f) must provide for regular case management meetings, involving the treating medical practitioner and appropriate therapists, to review individual rehabilitation plans, and
- (g) must have specialists for consultation, and
- (h) must have sufficient appropriate therapists for the services provided, and
- (i) must have sufficient registered nurses with appropriate rehabilitation qualifications or experience on duty at all times, and
- (j) if patients with brain impairment are being treated, must have access for the services of a neuropsychologist, and
- (k) if patients with chronic pain are being treated, must have access to the services of a clinical psychologist.

#### **74 Clinical records**

The clinical record of a patient in a rehabilitation class private health facility must include—

- (a) a clear statement by the treating medical practitioner giving details of the reason for the administration of, and the perceived need for, rehabilitation that is consistent with

the admission policy, and

- (b) a rehabilitation plan based on the assessment of the patient, and
- (c) a record of each evaluation of the patient's progress, and
- (d) a discharge plan.

#### **75 Minimum accommodation requirements**

A rehabilitation class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours.

#### **76 Accommodation standards**

A rehabilitation class private health facility must comply with the overnight accommodation standards.

### **Part 18 Renal dialysis class private health facilities**

#### **77 Design and construction**

Any part of a building providing renal dialysis class services must comply with the requirements of a class 5 building as defined in the *Building Code of Australia*, as in force on the issue of the licence for the private health facility or on such later date as may be specified in the licence.

#### **78 Minimum accommodation requirements**

A renal dialysis class private health facility must provide for the accommodation of one or more of the following groups of patients—

- (a) patients who are admitted for more than 24 hours,
- (b) patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours,
- (c) patients who are admitted and discharged on the same day.

#### **79 Accommodation standards**

A renal dialysis class private health facility must comply with such of the following standards that are applicable to the facility—

- (a) if the facility provides for the accommodation of patients who are admitted for more than 24 hours—the overnight accommodation standards,
- (b) if the facility provides for the accommodation of patients who are not discharged on the day that they are admitted, but are admitted for not more than 24 hours—the extended recovery accommodation standards.

## **Part 19 Surgical class private health facility**

### **80 Concurrent licensing**

A surgical class private health facility must also be licensed as an anaesthesia class private health facility.

### **81 Procedure register**

- (1) A surgical class private health facility must have a procedure register that records the details of every surgical procedure that is carried out at the facility.
- (2) Without limiting subclause (1), the procedure register must contain the following—
  - (a) the patient's full name and medical record number,
  - (b) the name of the procedure,
  - (c) the name of any surgeon, surgical assistant and anaesthetist involved in the procedure,
  - (d) the name of the scrub nurse involved in the procedure,
  - (e) the anaesthetic administered,
  - (f) the date, time and place of the procedure.

### **82 Clinical records**

- (1) A surgical class private health facility must have a clinical record for each patient at the facility on whom a surgical class procedure is carried out.
- (2) Without limiting subclause (1), a clinical record must include the following—
  - (a) in a case where anaesthesia has been employed—the anaesthetic record, which must comply with the recommendations of the Australian and New Zealand College of Anaesthetists in its publication *The Anaesthesia Record: Recommendations on the Recording of an Episode of Anaesthesia Care* published in 2006,
  - (b) the procedural report, including pre-procedural and post-procedural diagnoses, and a description of the findings, technique used and tissue removed or altered,
  - (c) in a case where tissue or body fluid was removed—a pathological report on the tissue or body fluid,
  - (d) a record of the swab, sponge and instrument count,
  - (e) the post-procedural recovery record.

### **83 Specialist equipment**

A surgical class private health facility must have the following equipment available in each room in which a surgical class procedure is carried out—

- (a) adequate equipment and instruments for elective use,
- (b) sterile instrument sets available for emergency procedures.

### **84 Minimum accommodation requirements**

A surgical class private health facility must provide for the accommodation of one or more of the following groups of patients—

- (a) patients who are admitted for more than 24 hours,
- (b) patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours,
- (c) patients who are admitted and discharged on the same day.

### **85 Accommodation standards**

A surgical class private health facility must comply with such of the following standards as are applicable to the facility—

- (a) if the facility provides for the accommodation of patients who are admitted for more than 24 hours—the overnight accommodation standards,
- (b) if the facility provides for the accommodation of patients who are not discharged on the same day that they are admitted, but are admitted for not more than 24 hours—the extended recovery accommodation standards.

## **Schedule 3 Accommodation standards**

(Clause 3(1))

### **Part 1 Overnight accommodation standards**

#### **1 Compliance with guidelines**

Any part of a private health facility that is used to accommodate patients for more than 24 hours must meet the requirements for an inpatient accommodation unit under the Australasian Health Facility Guidelines as in force on the issue of the licence for the facility, or on such later date as may be specified on the licence.

### **Part 2 Extended recovery accommodation standards**

#### **2 Admission criteria**

- (1) A private health facility must have a written policy for determining whether a person

may be admitted as a patient of the facility.

- (2) The policy referred to in subclause (1) must be reviewed at least every 3 years and must be submitted to the medical advisory committee for approval and comment.
- (3) A private health facility must not admit a patient otherwise than in accordance with the admission policy.