

I certify that this is a copy of the authorised version of this Statutory Rule as at 3 May 2023, and that it incorporates all amendments, if any, made before and in force as at that date and any reprint changes made under any Act, in force before the commencement of the *Legislation Publication Act 1996*, authorising the reprint of Acts and statutory rules or permitted under the *Legislation Publication Act 1996* and made before 3 May 2023.

K Woodward
Acting Chief Parliamentary Counsel
Dated 25 May 2023

TASMANIA

HEALTH SERVICE ESTABLISHMENTS REGULATIONS 2021

STATUTORY RULES 2021, No. 76

CONTENTS

PART 1 – PRELIMINARY

1. Short title
2. Commencement
3. Interpretation
4. Application of regulations

PART 2 – LICENSING OF PRIVATE HOSPITALS AND DAY-PROCEDURE CENTRES

5. Classes of private hospitals and day-procedure centres
6. Licensing standards for private hospitals and day-procedure centres
7. Offences by licensees
8. Applications for licences
9. Annual licence fees
10. Transfer of licence
11. Application for annual licence
12. Requirements for routine information
13. Duty of licensee to be insured
14. Application fee for material alteration to or extension of licensed establishment

15. Late application fee for approval of material alteration to or extension of licensed establishment
16. Application fee for amendment of licence

PART 3 – DISCLOSURE OF PECUNIARY INTERESTS

17. Definition of pecuniary interest
18. Notification of pecuniary interest

PART 4 – MISCELLANEOUS

19. Director of nursing of private hospital or day-procedure centre
20. Display of licence
21. Change of ownership or control
22. Infringement notices

SCHEDULE 1 – GENERAL LICENSING STANDARDS FOR PRIVATE HOSPITALS AND DAY-PROCEDURE CENTRES

SCHEDULE 2 – ADDITIONAL LICENSING STANDARDS FOR PARTICULAR CLASSES OF PRIVATE HOSPITALS

SCHEDULE 3 – ADDITIONAL LICENSING STANDARDS FOR PRIVATE HOSPITALS AUTHORISED TO PROVIDE SPECIALISED SERVICES

SCHEDULE 4 – ADDITIONAL LICENSING STANDARDS FOR PARTICULAR CLASSES OF DAY-PROCEDURE CENTRES

SCHEDULE 5 – MEMBERSHIP AND PROCEDURES OF MEDICAL ADVISORY COMMITTEES

SCHEDULE 6 – INFRINGEMENT OFFENCES

HEALTH SERVICE ESTABLISHMENTS REGULATIONS 2021

I, the Governor in and over the State of Tasmania and its Dependencies in the Commonwealth of Australia, acting with the advice of the Executive Council, make the following regulations under the *Health Service Establishments Act 2006*.

Dated 20 September 2021.

B. BAKER
Governor

By Her Excellency's Command,

JEREMY ROCKLIFF
Minister for Health

PART 1 – PRELIMINARY

1. Short title

These regulations may be cited as the *Health Service Establishments Regulations 2021*.

2. Commencement

These regulations take effect on 28 September 2021.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 3

Part 1 – Preliminary

3. Interpretation

(1) In these regulations –

Act means the *Health Service Establishments Act 2006*;

ANZCA means the Australian and New Zealand College of Anaesthetists;

approved means approved by the Secretary, either generally or in any particular case or class of cases;

child means a person who has not attained the age of 14 years;

Commission means the Australian Commission on Safety and Quality in Health Care established by section 8 of the *National Health Reform Act 2011* of the Commonwealth;

conscious sedation has the same meaning as in *PS09 Guideline on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures* as published by the ANZCA;

dentist means a person registered under the *Health Practitioner Regulation National Law (Tasmania)* in the dentists division of the dental profession;

intrapartum means the period commencing from the onset of true labour until the

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

Part 1 – Preliminary

r. 3

delivery of the baby and placenta during childbirth;

maternity services includes –

- (a) antenatal care related to childbirth; and
- (b) intrapartum care involved in childbirth; and
- (c) surgical intervention in achieving childbirth; and
- (d) care of a mother admitted with a baby immediately following childbirth; and
- (e) postnatal care for mothers who are readmitted for treatment or management of breastfeeding or maternal complications; and
- (f) postnatal care for babies who are readmitted for treatment or management of neonatal complications.

patient's representative means –

- (a) if the patient has not attained the age of 16 years, a parent or guardian having legal custody of the patient; or
- (b) if the patient is under guardianship, the patient's guardian; or

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 3

Part 1 – Preliminary

- (c) if the patient has died, the executor or administrator of the patient's estate –

and includes any other person who, according to approved guidelines, is the patient's representative;

pecuniary interest means any one or more of the following interests:

- (a) a pecuniary interest, in respect of a licence to conduct a private hospital or day-procedure centre, which is –
 - (i) an interest as the holder of the licence or as one of the holders of the licence; or
 - (ii) an interest in any corporation (other than a public company) which is the licensee of the hospital or centre; or
 - (iii) a holding of 5% or more of the issued share capital of a public company which is the licensee of the hospital or centre;
- (b) a pecuniary interest, in respect of a licence to conduct a private hospital or day-procedure centre, in the premises at which the

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

Part 1 – Preliminary

r. 3

hospital or centre is conducted,
which is –

- (i) an interest (whether at law or in equity) in the premises at which the hospital or centre is conducted; or
 - (ii) an interest in any corporation (other than a public company) which has any interest (whether at law or in equity) in the premises at which the hospital or centre is conducted; or
 - (iii) a holding of 5% or more of the issued share capital of any public company which has any interest (whether at law or in equity) in the premises at which the hospital or centre is conducted;
- (c) a pecuniary interest in the services provided to a private hospital or day-procedure centre, which is –
- (i) an interest in any clinical or administrative services provided to the hospital or centre (other than an

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 3

Part 1 – Preliminary

interest in fees from medical or dental services provided by the person to any patient in the hospital or centre); or

(ii) an interest in any corporation (other than a public company) which has an interest in any clinical or administrative services provided to the hospital or centre; or

(iii) a holding of 5% or more of the issued share capital of any public company which has an interest in any clinical or administrative services provided to the hospital or centre;

Poisons List has the same meaning as in the *Poisons Act 1971*;

primary health care means the provision of non-urgent medical care, such as that generally provided by general practitioners;

scheduled substance means a substance that is specified in a Schedule to the Poisons List and includes any other substance that is defined by reference to any substance so specified.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

Part 1 – Preliminary

r. 3

- (2) In these regulations –
- (a) a reference to a particular class of private hospital or day-procedure centre is a reference to a private hospital or day-procedure centre that is licensed as a private hospital or day-procedure centre of that class under the Act; and
 - (b) a reference to a standard by reference to a numeral prefixed with “AS” is a reference to a standard so numbered as published by Standards Australia; and
 - (c) a reference to a standard by reference to a number prefixed with “ISO”, “BS EN ISO” or “DIN EN ISO” is a reference to a standard so numbered as published by the International Organization for Standardization; and
 - (d) a reference to a standard, code, statement or other publication includes a reference to that standard, code, statement or publication as amended or substituted from time to time; and
 - (e) a reference to ANZCA includes, if ANZCA ceases to exist, a reference to an approved successor or an approved body that carries out equivalent or similar functions to ANZCA; and
 - (f) a reference to the Commission includes, if the Commission ceases to exist, a reference to an approved successor or an approved body that carries out equivalent

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 4

Part 1 – Preliminary

or similar functions to the Commission;
and

- (g) a reference to a document published by the Commission includes, if the Commission ceases to exist, a reference to an approved document issued by an approved successor or other approved body with equivalent or similar functions.

4. Application of regulations

These regulations apply to all private hospitals and day-procedure centres that are licensed under the Act.

**PART 2 – LICENSING OF PRIVATE HOSPITALS AND
DAY-PROCEDURE CENTRES**

5. Classes of private hospitals and day-procedure centres

- (1) For the purposes of section 14 of the Act, the following classes of private hospitals are prescribed:
 - (a) general (that is, a private hospital used for a purpose other than the purposes of a surgical, maternity, rehabilitation or psychiatric class hospital);
 - (b) surgical (that is, a private hospital used for the purpose of conducting surgical operations or endoscopic procedures, other than those that would normally be conducted by a medical practitioner in his or her consulting rooms);
 - (c) maternity (that is, a private hospital used for the purpose of providing maternity services);
 - (d) rehabilitation (that is, a private hospital used for the purpose of providing long-term or specialised physical rehabilitation);
 - (e) psychiatric (that is, a private hospital used for the purpose of providing psychiatric care).

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 6

Part 2 – Licensing of Private Hospitals and Day-Procedure Centres

- (2) For the purposes of section 14 of the Act, the following classes of day-procedure centres are prescribed:
- (a) low-risk (that is, a day-procedure centre that undertakes low-risk surgical treatment that can be safely performed using conscious sedation);
 - (b) endoscopic (that is, a day-procedure centre used for the purpose of providing endoscopic treatment that involves the administration of a general anaesthetic or intravenous sedative otherwise than for the purpose of conscious sedation);
 - (c) surgical (that is, a day-procedure centre used for the purpose of providing surgical treatment that involves the administration of a general, spinal, epidural or major regional block anaesthetic, or intravenous sedative otherwise than for the purpose of conscious sedation).

6. Licensing standards for private hospitals and day-procedure centres

- (1) Private hospitals are to comply with the licensing standards specified in Schedule 1.
- (2) Surgical class private hospitals are to comply with the licensing standards specified in Part 1 of Schedule 2.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

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- (3) Maternity class private hospitals are to comply with the licensing standards specified in Part 2 of Schedule 2.
 - (4) Rehabilitation class private hospitals are to comply with the licensing standards specified in Part 3 of Schedule 2.
 - (5) Psychiatric class private hospitals are to comply with the licensing standards specified in Part 4 of Schedule 2.
 - (6) Private hospitals authorised to provide cardiac catheterisation services are to comply with the licensing standards specified in Part 1 of Schedule 3.
 - (7) Private hospitals authorised to provide emergency services are to comply with the licensing standards specified in Part 2 of Schedule 3.
 - (8) Private hospitals authorised to provide intensive care are to comply with the licensing standards specified in Part 3 of Schedule 3.
 - (9) Private hospitals authorised to provide neonatal intensive care are to comply with the licensing standards specified in Part 4 of Schedule 3.
 - (10) Day-procedure centres are to comply with the licensing standards specified in Schedule 1.
 - (11) Low-risk day-procedure centres are to comply with the licensing standards specified in Part 1 of Schedule 4.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 7

Part 2 – Licensing of Private Hospitals and Day-Procedure Centres

- (12) Surgical class day-procedure centres are to comply with the licensing standards specified in Part 2 of Schedule 4.
- (13) Endoscopic class day-procedure centres are to comply with the licensing standards specified in Part 3 of Schedule 4.
- (14) Day-procedure centres that perform electro-convulsive therapy are to comply with the licensing standards specified in Part 4 of Schedule 2.

7. Offences by licensees

A licensee of a private hospital or day-procedure centre must ensure that the provisions of these regulations and the standards specified in the Schedules to these regulations are complied with at all times in respect of the private hospital or day-procedure centre to which the licence relates.

Penalty: Fine not exceeding 5 penalty units.

8. Applications for licences

For the purposes of section 9(2)(g) of the Act, the prescribed application fee is 1 100 fee units.

9. Annual licence fees

- (1) In this regulation –

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

specialised service means a service specified
in Clause 2 of Part 4 of Schedule 1.

- (2) For the purposes of section 18 of the Act, the prescribed annual licence fee for a private hospital is the sum of –
- (a) 800 fee units; and
 - (b) 400 fee units for each class of private hospital, as specified in regulation 5(1), in respect of which the licence for the private hospital is issued; and
 - (c) 150 fee units for each specialised service authorised to be performed under the licence at the private hospital; and
 - (d) if the licence for the private hospital is endorsed to admit child patients in accordance with clause 1 of Part 4 of Schedule 1, 150 fee units; and
 - (e) if the maximum number of patients that may be accommodated overnight at any one time at the private hospital is –
 - (i) not more than 50 patients, 500 fee units; or
 - (ii) 51 patients or more, but not more than 100 patients, 700 fee units; or
 - (iii) 101 patients or more, but not more than 150 patients, 900 fee units; or

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 9

Part 2 – Licensing of Private Hospitals and Day-Procedure Centres

- (iv) 151 patients or more, but not more than 200 patients, 1 100 fee units; or
 - (v) 201 patients or more, 1 300 fee units.
- (3) For the purposes of section 18 of the Act, the prescribed annual licence fee for a day-procedure centre is the sum of –
 - (a) 500 fee units; and
 - (b) 400 fee units for each class of day-procedure centre, as specified in regulation 5(2), in respect of which the licence for the day-procedure centre is issued; and
 - (c) 150 fee units for each specialised service authorised to be performed under the licence at the day-procedure centre; and
 - (d) if the licence for the day-procedure centre is endorsed to admit child patients in accordance with clause 1 of Part 4 of Schedule 1, 150 fee units; and
 - (e) 200 fee units for each procedure room provided at the day-procedure centre, as specified on the licence in force in respect of the day-procedure centre.
- (4) For the purposes of subregulation (2)(e), the maximum number of patients that may be accommodated overnight at any one time is the number determined by the Secretary under

section 15(d) of the Act, as specified on the licence in force in respect of the private hospital.

10. Transfer of licence

For the purposes of section 19 of the Act, the prescribed application fee is –

- (a) in relation to a private hospital, 900 fee units; and
- (b) in relation to a day-procedure centre, 400 fee units.

11. Application for annual licence

On making an application for an annual licence under section 9 of the Act, the applicant must provide the Secretary with a copy of the following documents:

- (a) the director of nursing's current authority to practise;
- (b) the last annual report published by the licensee relating to the hospital.

12. Requirements for routine information

- (1) A licensee must provide the Secretary with a statement in an approved form each month providing all information, whether clinical or financial, required by the Secretary for health planning, benchmarking and reporting on performance as required by any law of the

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 13

Part 2 – Licensing of Private Hospitals and Day-Procedure Centres

Commonwealth or any authority established under any such law.

- (2) A licensee must ensure that the statement under subregulation (1) –
- (a) contains all the information necessary to complete the approved form; and
 - (b) is provided to the Secretary within 30 days after the end of the month to which the information relates.

Penalty: Fine not exceeding 5 penalty units.

13. Duty of licensee to be insured

- (1) A licensee of a private hospital or day-procedure centre must take out and maintain an approved policy of insurance, and workers' compensation insurance, in respect of the conduct of the establishment.

Penalty: Fine not exceeding 5 penalty units.

- (2) The policy of insurance is to name the licensee as the insured, and provide for –
- (a) a minimum amount of cover of \$20 000 000 for each event; and
 - (b) cover for injury, loss and damage caused by or arising from the use of diagnostic equipment or procedures involving the emission of ionising radiation; and
 - (c) cover on a claims-made basis.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

Part 2 – Licensing of Private Hospitals and Day-Procedure Centres

r. 14

- (3) The workers' compensation insurance, or any other form of approved self-insurance, is to cover any obligation or liability under the *Workers Rehabilitation and Compensation Act 1988*.

14. Application fee for material alteration to or extension of licensed establishment

For the purposes of section 20(4) of the Act, the prescribed fee is –

- (a) in relation to a private hospital, 500 fee units; and
- (b) in relation to a day-procedure centre, 330 fee units.

15. Late application fee for approval of material alteration to or extension of licensed establishment

For the purposes of section 20(10) of the Act, the prescribed late application fee is –

- (a) in relation to a private hospital, 2 550 fee units; and
- (b) in relation to a day-procedure centre, 1 200 fee units.

16. Application fee for amendment of licence

For the purposes of section 22(2)(a) of the Act, the prescribed fee is –

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 16

Part 2 – Licensing of Private Hospitals and Day-Procedure Centres

- (a) in relation to a private hospital, 1 700 fee units; and
- (b) in relation to a day-procedure centre, 800 fee units.

PART 3 – DISCLOSURE OF PECUNIARY INTERESTS

17. Definition of pecuniary interest

(1) In this Part –

partner, in respect of a person, means another person who has a personal relationship, within the meaning of the *Relationships Act 2003*, with the first-mentioned person;

relative of a practitioner means the spouse, partner, parent, child, brother or sister of the practitioner.

(2) For the purposes of section 45(4) of the Act, a practitioner is taken to have a pecuniary interest in a private hospital or day-procedure centre if the practitioner has a pecuniary interest within the meaning of these regulations.

(3) For the purposes of section 45(5) of the Act, a pecuniary interest in a private hospital or day-procedure centre of a relative of a practitioner is taken to be a pecuniary interest of the practitioner.

18. Notification of pecuniary interest

(1) For the purposes of section 45(1) of the Act, the manner in which a practitioner is to notify a person of the practitioner's pecuniary interest is –

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 18

Part 3 – Disclosure of Pecuniary Interests

- (a) by informing the person of that fact orally; and
 - (b) by giving written notice of that fact to the person; and
 - (c) by displaying a written notice of that fact at the private hospital or day-procedure centre, surgery or other premises at which the relevant advice or treatment is given or the relevant arrangements are made.
- (2) Each notification given in accordance with subregulation (1) must identify the practitioner to which it relates and must specify the nature and extent of the pecuniary interest.
- (3) The written notice referred to in subregulation (1)(c) must be clearly legible and the notice must be displayed in a prominent place.

PART 4 – MISCELLANEOUS

19. Director of nursing of private hospital or day-procedure centre

For the purposes of section 39(5)(b) of the Act, the prescribed particulars in respect of a person who carries out the duties of director of nursing are particulars of the person's current registration that gives the person authority to practise.

20. Display of licence

At all times while a private hospital or day-procedure centre is being conducted, the licensee must cause the licence (or a full-size copy of the licence) to be displayed in a prominent place in the entrance foyer of the private hospital or day-procedure centre.

Penalty: Fine not exceeding 5 penalty units.

21. Change of ownership or control

(1) In this regulation –

major shareholder, in respect of a corporation, means a shareholder whose shareholding exceeds 20% of the total shareholding in the corporation.

(2) A licensee that is a corporation must furnish to the Secretary particulars of any change in the directors or major shareholders of the

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

r. 22

Part 4 – Miscellaneous

corporation as soon as practicable after the change occurs.

Penalty: Fine not exceeding 5 penalty units.

22. Infringement notices

For the purposes of section 55A of the Act –

- (a) an offence against a provision of the Act or regulations specified in Schedule 6 is prescribed as an infringement offence; and
- (b) the penalty set out in that Schedule in respect of that infringement offence is the applicable penalty for that offence.

**SCHEDULE 1 – GENERAL LICENSING STANDARDS
FOR PRIVATE HOSPITALS AND DAY-PROCEDURE
CENTRES**

Regulation 6(1) and (10)

PART 1 – FACILITIES AND EQUIPMENT

1. Building requirements

- (1) The requirements relating to Class 9a buildings specified in the National Construction Code, within the meaning of the *Building Act 2016*, must be observed in relation to:
 - (a) private hospitals; and
 - (b) surgical class day procedure centres; and
 - (c) endoscopic class day procedure centres.
- (2) Subject to subclause (3), the requirements relating to Class 5 buildings specified in the National Construction Code, within the meaning of the *Building Act 2016*, must be observed in relation to low-risk class day procedure centres.
- (3) Despite subclause (2), the Secretary may determine, upon consideration of public safety and service quality, that a particular low-risk class day procedure centre must comply with the requirements relating to Class 9a buildings specified in the National Construction Code within the meaning of the *Building Act 2016*.

2. Sterilisation of equipment and instruments

- (1) All equipment and instruments must be sterilised in accordance with the AS/NZS 4187:2014 – Reprocessing of reusable medical devices in health service organisations and AS/NZ 4815:2006 – Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment.
- (2) In addition to subclause (1), the following standards must also be complied with, if applicable:
 - (a) BS EN ISO 15883-1:2009 Washer-disinfectors – Part 1: General requirements, terms and definitions and tests;
 - (b) BS EN ISO 15883-2:2009 Washer-disinfectors – Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc;
 - (c) ISO 17664:2004 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices;
 - (d) ISO/TS 15883-5:2021 – Washer-disinfectors – Part 5: Performance

requirements and test method criteria for demonstrating cleaning efficacy;

- (e) BS EN ISO 11140-1:2014 – Sterilization of health care products – Chemical indicators – Part 1: General requirements.

- (3) There is to be calibration and regular testing of sterilising and processing equipment.

PART 2 – CLINICAL STANDARDS

1. Objects of this Part

The objects of this Part are to ensure that –

- (a) there will be a rigorous assessment of credentials –
 - (i) on appointment of senior medical practitioners; and
 - (ii) on appointment of dentists at a day-procedure centre; and
- (b) credentials are approved for specific activities or procedures; and
- (c) all credentials are reviewed and approved at specific intervals.

2. Accreditation

- (1) A licensee of a private hospital or day-procedure centre must ensure that –

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (a) the private hospital or day-procedure centre is granted accreditation by an approved industry body –
 - (i) subject to subparagraph (ii), if the private hospital or day-procedure centre is established on or after the commencement of the *Health Service Establishments Amendment Regulations 2019*, within 18 months after it commences its functions; or
 - (ii) despite subparagraph (i), if –
 - (A) the private hospital or day-procedure centre is established on or after the commencement of the *Health Service Establishments Amendment Regulations 2019*; and
 - (B) an advisory issued by the Commission in respect of accreditation applies to the private hospital or day-procedure centre and specifies a time period within which the hospital or centre is to be granted accreditation –

within the time period so specified in the advisory; and

- (b) the accreditation continues in force.
- (2) Proof of accreditation must be provided to the Secretary together with a copy of any accreditation report issued in relation to that accreditation by the approved industry body.
- (3) If at any time there is no accreditation for a private hospital or day-procedure centre, its licence is taken to be cancelled.

3. Review and approval of staff credentials

A licensee of a private hospital or day-procedure centre must ensure that the credentials of all medical practitioners, and dentists, of the private hospital or day-procedure centre are reviewed and approved in accordance with the *Standard for Credentialling and Defining the Scope of Clinical Practice: A National Standard for credentialling and defining the scope of clinical practice of medical practitioners, for use in public and private hospitals* as published by the Australian Council for Safety and Quality in Health Care, as amended or substituted by the Commission.

4. Medical advisory committee

- (1) The licensee of a private hospital or day-procedure centre must appoint a medical advisory committee for the establishment.
- (2) The Secretary may approve alternative arrangements for a establishment to those

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

specified in subclause (1) if the licensee of the establishment –

- (a) applies to the Secretary in writing for approval of the alternative arrangements; and
 - (b) proves, to the satisfaction of the Secretary, that the proposed alternative arrangements will fulfil the functions and responsibilities of a medical advisory committee as set out in this Part.
- (3) The medical advisory committee is to be responsible for advising the licensee on –
- (a) the accreditation of practitioners necessary to provide services at the establishment and the delineation of their clinical responsibilities; and
 - (b) matters concerning clinical practice at the establishment; and
 - (c) matters concerning the care and safety of patients at the establishment; and
 - (d) any other matter relating to the safety and quality of services at the establishment.
- (4) The medical advisory committee must, as soon as is reasonably practicable, report to the Secretary any repeated failure by the licensee of the establishment to act on the advice given under subclause (3) if the failure is likely to adversely impact on the health or safety of patients or staff.

- (5) The licensee of a private hospital or day-procedure centre must, as soon as is reasonably practicable, notify the Secretary in writing of –
- (a) the name, contact details and qualifications of each person who becomes a member of the medical advisory committee for the establishment; and
 - (b) the date on which each such person becomes a member, or ceases to be a member, of the medical advisory committee.
- (6) Despite this section, the licensee of a private hospital or day-procedure centre is responsible for the safety of patients at the establishment and the clinical governance of the establishment.

5. Functions of medical advisory committee

The functions of a medical advisory committee are –

- (a) to review and approve selection reports for the appointment of senior medical practitioners and dentists; and
- (b) to review the credentials of medical practitioners and dentists in the private hospital or day-procedure centre; and
- (c) to assess and recommend to the licensee the appropriate scope of clinical practice for medical practitioners and dentists at

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- the private hospital or day-procedure centre; and
- (d) to ascertain and certify that a medical practitioner is qualified, and competent, to carry out requested services in the hospital and to evaluate any matter relating to the scope of clinical practice of a medical practitioner or dentist; and
 - (e) to review regularly and recommend to the licensee any variations considered necessary or desirable to the credentials or scope of clinical practice of medical practitioners and dentists practising in the private hospital or day-procedure centre; and
 - (f) to advise the licensee on an application to perform an approved procedure following relevant training and in particular any procedure or technique not previously performed in the private hospital or day-procedure centre; and
 - (g) to communicate as may be necessary or appropriate with any other committee declared by the Minister under section 4(1) of the *Health Act 1997* to be an approved quality assurance committee for the purposes of that Act in respect of any matter relevant to the functions of the committee; and
 - (h) to provide advice on policies or procedures in relation to reporting and

infection control, safety and quality arrangements and incident management; and

- (i) to perform any other functions specified by the Secretary or licensee.

6. Membership and procedures of medical advisory committees

Schedule 5 has effect with respect to the membership and procedures of medical advisory committees.

7. Responsibilities of medical practitioners and dentists

- (1) Each procedure performed at a private hospital or day-procedure centre is to be performed by an appropriately accredited medical practitioner or dentist who is granted clinical privileges to provide services at the hospital or day-procedure centre.
- (2) If a procedure involves the administration of a general, spinal, epidural, major field block or large field infiltration anaesthetic or intravenous sedative, the patient is to be attended throughout the procedure by a second appropriately accredited medical practitioner.
- (3) A medical practitioner or dentist is responsible for selecting patients suitable for treatment at the private hospital or day-procedure centre by the practitioner or dentist, taking into account –

sch. 1

- (a) the class or classes of the private hospital or day-procedure centre and the limitations (if any) on the services that may be provided in it; and
 - (b) the clinical responsibilities of the medical practitioner or dentist; and
 - (c) the maintenance of high professional standards.
- (4) A medical practitioner or dentist is to have his or her credentials reviewed and approved during each period of 5 years in accordance with the *Standard for Credentialling and Defining the Scope of Clinical Practice: A National Standard for credentialling and defining the scope of clinical practice of medical practitioners, for use in public and private hospitals* as published by the Australian Council for Safety and Quality in Health Care, as amended or substituted by the Commission.

8. Safety and quality standards

- (1) A private hospital or day-procedure centre must have safety and quality arrangements in place that meet the requirements of the *National Model Clinical Governance Framework* as published by the Commission.
- (2) In the absence of a national standard, a private hospital or day-procedure centre must have safety and quality arrangements approved by the Secretary.

- (3) These arrangements must, at a minimum, address safety and quality arrangements and their governance, clinical practice, credentialling and incident management.

9. Research with human participants

- (1) Any research with human participants carried out at a private hospital or day-procedure centre must be in accordance with the *National Statement on Ethical Conduct in Human Research (National Statement)* issued by the National Health and Medical Research Council in 2007.
- (2) The licensee of a private hospital or day-procedure centre –
 - (a) must refer any research with human participants to a human research ethics committee (HREC), constituted in accordance with the National Statement, of the private hospital or day-procedure centre; and
 - (b) must not carry out the research otherwise than in accordance with the recommendations of that HREC and the *National Clinical Trials Governance Framework* as published by the Commission.

10. Identification of patients

Patient identification practices at a private hospital or day-procedure centre must be carried out in accordance with the requirements of –

- (a) the *Specifications for a standard patient identification band* as published by the Commission; and
- (b) AS 4846:2014 – Person and provider identification in healthcare.

PART 3 – STAFFING

1. Staffing

- (1) The licensee of a private hospital or day-procedure centre must ensure that –
 - (a) the director of the establishment is appropriately qualified by education, training and experience; and
 - (b) there are documented policies which reflect current knowledge and practice to ensure the health and safety of the staff; and
 - (c) sufficient qualified nursing staff are employed to adequately and safely meet the needs of patients.
- (2) The nursing staff must include persons having qualifications and experience appropriate for each class of private hospital or day-procedure

centre specified in the licence for the private hospital or day-procedure centre.

- (3) A register is to be kept in which are recorded the following particulars:
- (a) the name of each person employed in nursing duties in the private hospital or day-procedure centre;
 - (b) the residential address of each such person;
 - (c) in respect of each such person who is a registered nurse or enrolled nurse –
 - (i) the person's nursing qualifications; and
 - (ii) the number and expiry date shown on the person's current authority to practise; and
 - (iii) a statement that the person's current authority to practise has been produced to the director of nursing.
- (4) The licensee must give documented and dated job descriptions to each staff member on appointment which specify at least the following:
- (a) the qualifications required for the position;
 - (b) the lines of authority;

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (c) the accountability functions and responsibilities;
 - (d) the frequency and type of staff performance appraisals;
 - (e) the terms and conditions of service.
- (5) Confidential personnel records are to be maintained for each member of staff.
- (6) A structured orientation program is to be provided to introduce new staff to the service and relevant aspects of the establishment and aims and to prepare them for their role and responsibilities.

PART 4 – OPERATIONAL MATTERS

1. Child patients

- (1) A child must not be admitted to a private hospital or day-procedure centre as a patient unless the establishment is approved to admit child patients and the licence is endorsed accordingly.
- (2) A licensee who applies for an endorsement of the licence for the purposes of this clause must state in the application –
- (a) the age range of children to be admitted; and
 - (b) the types of investigations and treatments to be performed on children; and

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (c) the maximum duration of stay of children; and
- (d) the maximum number of children to be accommodated at any one time; and
- (e) the facilities to be provided for the treatment and care of children; and
- (f) the arrangements that exist for transferring children to hospitals providing appropriate treatment and care in the event of any medical complications arising –

and each of those matters is to be taken into consideration in determining the conditions (if any) attached to the endorsement of the licence.

- (3) In the case of a child patient who requires special paediatric facilities or services (whether owing to the child's age, general state or medical condition, the proposed investigation, treatment or duration of stay, or otherwise), the licensee must –
 - (a) arrange for a specialist paediatrician, or a medical practitioner with relevant experience in paediatrics and child health who is approved by the Secretary, to be readily available for consultation at all times; and
 - (b) unless an exemption is granted by the Secretary, have a registered nurse with post-basic or post-graduate paediatric experience or qualifications on duty at all

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- times while the child is a patient in the establishment; and
- (c) for neonates and children under the age of 12 months, arrange for microchemistry to be readily performed as required for analysis of capillary blood specimens.
- (4) In the case of a child patient, the parents and guardians of the child (and any person having the care of the child) must –
- (a) have easy access to the child at all times except while the child is undergoing surgery; and
 - (b) if the child is undergoing surgery, have easy access to the child in the pre-anaesthetic and recovery areas unless, in the opinion of the attending medical practitioner or dentist, the presence of such persons in these areas is detrimental to the child's welfare; and
 - (c) unless otherwise exempted by the Secretary, have access to facilities to enable such a person to remain with the child throughout the period of admission.
- (5) A child who is less than 2 years of age must be accommodated in a cot that complies with AS 2130 – Cots for day nursery, hospital and institutional use - Safety requirements.

2. Specialised hospital services

The following specialised services must not be performed at a private hospital or day-procedure centre unless its licence specifically authorises the performance of that service:

- (a) coronary angioplasty, in its various forms, cardiac valvuloplasty or radiofrequency catheter ablation;
- (b) all forms of cardiac surgery;
- (c) emergency department;
- (d) intensive care;
- (e) renal dialysis, haemofiltration or haemoperfusion;
- (f) maternity services;
- (g) neonatal intensive care;
- (h) services to a patient who a medical practitioner has reason to believe is suffering from severe mental illness;
- (i) tertiary vascular procedures;
- (j) neurosurgery;
- (k) nuclear medicine;
- (l) radiation therapy.

3. Patient programs

The licensee of a private hospital or day-procedure centre must ensure that the pursuit of cultural and religious interests of patients is not unnecessarily obstructed by staff of the private hospital or day-procedure centre.

4. Admission and separation of patients

- (1) On the admission of a patient to a private hospital or day-procedure centre –
 - (a) a record of the patient's personal particulars and reason for admission must be made; and
 - (b) the attention of the patient or a person responsible for the patient must be drawn to the existence of, and the patient or person responsible must be given a copy of –
 - (i) written information concerning the policy of the licensee in respect of the conduct of the private hospital or day-procedure centre, including charging for services, smoking by patients and staff and the handling of complaints about the establishment; and
 - (ii) written information concerning the procedure for lodging a complaint.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (2) On a person's ceasing to be a patient (whether by discharge, transfer or death), a summary is to be made of the person's personal and clinical particulars, together with the reasons for the person's so ceasing to be a patient.
- (3) The records referred to in this clause are to be made –
 - (a) in the register of patients; and
 - (b) in the admission form for the patient concerned; and
 - (c) in the in-patient statistics form for the patient concerned.
- (4) On completion of the admission details and again on completion of the separation details, the records are to be signed by the director of nursing (or by another person authorised by the director of nursing for that purpose) and are to be dealt with as follows:
 - (a) the register of patients form is to be retained in a loose-leaf file with all other completed register of patients forms;
 - (b) the admission form is to be retained as the front sheet of the patient's health record;
 - (c) the in-patient statistics form is, unless otherwise approved, to be submitted to the Secretary within 6 weeks after the person, to whom the record relates, ceases to be a patient.

sch. 1

- (5) A patient is not to be discharged from a day-procedure centre until the patient has recovered sufficiently so as no longer to require regular nursing observation.
- (6) A patient who has undergone general anaesthesia or intravenous sedation is not to be discharged from a day-procedure centre except on the advice of a medical practitioner.

5. Quality assurance

- (1) The licensee of a private hospital or day-procedure centre must ensure written procedures are established for evaluating and recording the quality of non-clinical services provided at the private hospital or day-procedure centre and for correcting any identified problems.
- (2) Procedures established under subclause (1) must be consistent with the *National Safety and Quality Health Service Standards* published by the Commission.
- (3) The procedures are to take account of other relevant external standards and programs recommended by learned colleges and other relevant professional organisations.
- (4) In addition to the procedures established under this clause, there is to be a Quality Activities Plan for the establishment which must include the evaluation of clinical and non-clinical areas.
- (5) Quality activities of contracted services are to be consistent with the policies of the establishment.

6. Patient cleanliness and comfort

- (1) All practicable measures (including the prompt removal and replacement of soiled clothing and linen) must be taken to keep each patient clean and comfortable at all times.
- (2) Heating and cooling facilities must be used as necessary to maintain the comfort of each patient.

7. Medication safety

- (1) The licensee of a private hospital or day-procedure centre must ensure that the storage, handling and distribution of scheduled substances at that private hospital or day-procedure centre is in accordance with –
 - (a) guidelines, codes and standards of practice for the distribution of medicines in Australian hospitals published by the Society of Hospital Pharmacists of Australia; and
 - (b) the *Poisons Act 1971*.
- (2) The licensee of a private hospital or day-procedure centre must ensure that there is an active establishment-wide medication safety program in place for the hospital or day-procedure centre that includes –
 - (a) policy and procedures to ensure safety in storage, handling and distribution of medication that are relevant to the

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

establishment and based on current national and State guidelines and legislation; and

- (b) appropriate education and training programs to enable staff to implement those policies and procedures; and
 - (c) provision for the oversight of staff in implementing those policies and procedures; and
 - (d) a “monitor and review” process, that is consistent with the *National Safety and Quality Health Service Medication Safety Standard* as published by the Commission, to monitor and evaluate processes through performing audits of compliance with policies, procedures and protocols for the handling, storage and distribution of medication.
- (3) The licensee must ensure that the private hospital or day-procedure centre is provided with sufficient resources to enable staff to comply with the medication safety program referred to in subclause (2).

8. Infection control

- (1) The licensee of a private hospital or day-procedure centre must ensure that there is an approved written infection control policy in place for the hospital or day-procedure centre.

- (2) The licensee of a private hospital or day-procedure centre must ensure that infection control precautions are implemented –
 - (a) in accordance with the requirements of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* published by the Australian Government National Health and Medical Research Council; and
 - (b) as recommended by the Tasmanian Infection Prevention and Control Unit.

- (3) The licensee of a private hospital or day-procedure centre must ensure that there is an active establishment-wide infection control program in place for the private hospital or day-procedure centre that –
 - (a) is consistent with any National Safety and Quality Health Service Standard on infection control published by the Commission; and
 - (b) includes –
 - (i) a risk management policy to minimise the risk of infection to the staff and patients of the establishment; and
 - (ii) policies and procedures to prevent and control infection that are relevant to the establishment and based on current national or State guidelines; and

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (iii) appropriate education and training programs to enable staff to implement those policies and procedures; and
 - (iv) provision for the oversight of staff in implementing those policies and procedures; and
 - (v) a “monitor and review” process (such as the use of logbooks or completion of checklists during care provision) to ensure correct implementation of those policies and procedures; and
 - (vi) provision for the oversight of surveillance of specific organisms that pose a risk of infection to the establishment; and
 - (vii) antimicrobial stewardship initiatives run in conjunction with a pharmacy.
- (4) The licensee must ensure that the private hospital or day-procedure centre is provided with sufficient resources to enable staff to comply with the infection control program referred to in subclause (3).

9. Hygiene

- (1) The licensee of a private hospital or day-procedure centre must ensure that adequate facilities, equipment and stores are maintained

for the effective cleaning and disinfection of the buildings and their fixtures and fittings.

- (2) The licensee must ensure that the buildings of a private hospital or day-procedure centre, together with their fixtures and fittings, are maintained in a clean and sanitary condition.
- (3) Without limiting subclause (2) –
 - (a) all furniture, furnishings, fittings, bedsteads and bedding must be kept in a clean and sanitary condition; and
 - (b) eating, drinking or cooking utensils or food storage containers which are cracked, chipped, scored, stained or defective must not be used; and
 - (c) each bed-pan, commode-pan, urinal vessel, wash basin and vomit bowl must be sanitised after each use; and
 - (d) each tooth mug, denture container and sputum mug must, while in use, be sanitised at least once every 24 hours; and
 - (e) all floors and walls in a building on the premises are to be kept clean.
- (4) All necessary measures must be taken –
 - (a) to exclude flies and other vermin from a private hospital or day-procedure centre; and

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (b) to destroy any flies or other vermin that are within a private hospital or day-procedure centre.
- (5) A pan sluice, macerator or flusher-sanitiser (but not a toilet facility) must be used for disposal of the contents of bed-pans, commode-pans and urinal vessels.
- (6) Receptacles with close-fitting lids must be provided for the collection of general refuse.
- (7) General refuse must be disposed of by the use of a service provided by a local authority or in some other suitable manner.
- (8) Contaminated waste must be disposed of in accordance with the licensee's infection control policy.
- (9) The grounds of a private hospital or day-procedure centre must be kept in a clean, tidy and safe condition.
- (10) Clinical waste disposal must –
 - (a) be in accordance with the waste requirements of AS 3816:2018 – Management of clinical and related wastes; and
 - (b) comply with the requirements of any approved management method in force in accordance with the *Environmental Management and Pollution Control (Waste Management) Regulations 2020*.

- (11) A housekeeping program, which includes the following, must be in place for a private hospital or day-procedure centre:
- (a) guidelines for routine and special-purpose cleaning procedures;
 - (b) a system for storage of equipment and use of housekeeping and cleaning materials.

10. Injuries, transfers, deaths and other sentinel events

- (1) This clause applies to the following incidents:
- (a) any injury requiring medical attention that is sustained by a patient as a result of any accident at a private hospital or day-procedure centre;
 - (b) the transfer of a patient to another hospital as a result of an injury or iatrogenic condition;
 - (c) the death of any patient at a private hospital or day-procedure centre;
 - (d) an incident classified as a sentinel event by the Commission.
- (2) As soon as practicable after any such incident occurs –
- (a) details of the incident must be entered in an approved form (*the incident form*) in the patient's health record and must be

sch. 1

- reported to the director of nursing and to the patient's medical practitioner; and
- (b) the incident must be investigated by the medical advisory committee and the results of the investigation must be entered in the incident form; and
 - (c) if the patient was transferred to another hospital, details of the transfer must be entered in the incident form; and
 - (d) if the patient was transferred to another hospital, or the incident was life-threatening or fatal –
 - (i) the Secretary and the patient's representative or next of kin must be notified orally of the incident; and
 - (ii) a copy of the incident form must be forwarded to the Secretary.

11. Fire safety and emergency evacuation

If a fire occurs in a private hospital or day-procedure centre, the licensee, as soon as practicable and whether or not the fire brigade has been called to extinguish the fire –

- (a) must notify the Secretary orally of the fact; and
- (b) must provide the Secretary with written notice of the fact and of all the relevant

details of the circumstances in which the fire occurred.

PART 5 – HEALTH RECORDS

1. Application of Part

The application of this Part extends to a former patient, and to the records relating to a former patient, in the same way as it applies to a patient and to the records relating to a patient.

2. Health records

- (1) A record is to be kept of the medical condition of each patient in a private hospital or day-procedure centre and a record of all medical, nursing and other care provided to the patient must be maintained by an entry in a patient health record system made by the appropriate medical, nursing or other health care provider.
- (2) Without limiting subclause (1), the health record of a patient is to include the following:
 - (a) the patient's admission form;
 - (b) the patient's medical history and results of any physical examination, which may be contained in any referral document;
 - (c) any medical consultation reports;
 - (d) a record of any medication administered;

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (e) a record of allergies and other factors requiring special consideration;
- (f) reports of all laboratory tests performed;
- (g) reports of all X-ray and other medical imaging examinations performed;
- (h) the name of any person whose consent to the carrying out of medical or dental treatment is necessary;
- (i) consent or request forms, if applicable;
- (j) if a medical, surgical or other procedure has been performed;
- (k) in a case where anaesthesia has been employed, the anaesthetic record (which must comply with the recommendations of *PS06 Guideline on the anaesthesia record* as published by the ANZCA);
- (l) the procedure report, including the pre-procedural and post-procedural diagnoses, and a description of the findings, technique used and tissue removed or altered;
- (m) in a case where tissue or body fluid has been removed, any pathological report on the tissue or body fluid;
- (n) in a case where the procedure has involved surgery, a record of the swab, sponge and instrument count;
- (o) the post-procedural recovery record;

- (p) a discharge statement, completed by the medical practitioner or dentist attending the patient, that specifies any major procedures performed, the final diagnosis, the patient's condition and recommendations and arrangements for the patient's future care.
- (3) Any records relating to medical or dental treatment are to identify the medical practitioner or dentist by whom that treatment was provided.
- (4) A discharge statement referred to in subclause (2)(p) must be completed before the patient's discharge unless discharge instructions are given orally, in which case the statement must be completed within 48 hours after the patient's discharge.

3. Retention of records

- (1) The register of patients, together with the patients' health records, must be retained as follows:
 - (a) the register of patients must be kept indefinitely;
 - (b) health records relating to patients (other than maternity patients) of 18 or more years of age at the date of last separation must be kept for 7 years from the date of last separation;
 - (c) health records relating to patients (other than maternity patients) of less than 18

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

years of age at the date of last separation must be kept until the patient to whom the record relates attains, or would have attained, the age of 25 years.

- (2) The documents referred to in subclause (1) must be given to the transferee if the licence for the private hospital or day-procedure centre is transferred to another person.
- (3) If the licence for the private hospital or day-procedure centre is surrendered or cancelled, the licensee must deal with the register and records in accordance with the instructions of the Secretary.
- (4) Unless an exemption is granted by the Secretary, the register and records are to be kept at the private hospital or day-procedure centre.

4. Patient's right of access to health records

- (1) A patient or the patient's representative may, by written application to the licensee, request access to the patient's health record.
- (2) The licensee must, as soon as practicable after the receipt of such an application, make the health record available to –
 - (a) the patient or the patient's representative;
or
 - (b) a person nominated by the patient or the patient's representative.

- (3) The licensee may refuse a request by a patient or by the patient's representative for access to the patient's health record –
 - (a) if the medical practitioner or dentist in charge of the patient's care advises that the request should be refused; and
 - (b) if the licensee is satisfied that access by the patient or representative would be prejudicial to the patient's physical or mental health.
- (4) An application under this clause is to be retained in the patient's health record.

5. Manner of providing access

- (1) Access to a health record may be given by making the record available for inspection or by providing a copy of the record, as specified by the applicant.
- (2) If a person to whom access to a health record is given so requests, the person must be given assistance in the interpretation of the record (including any test results, findings and comments contained in the record) by a person qualified to do so.
- (3) If a patient or the patient's representative requests particular clinical information (such as test results or details of past treatment) rather than access to the patient's health record, the information may be provided by the medical practitioner or dentist in charge of the patient's

care or, subject to the advice of that medical practitioner or dentist, by a medical practitioner or registered nurse on the staff of the private hospital or day-procedure centre.

- (4) If a patient or the patient's representative disagrees with information contained in the patient's health record, the licensee must, on request by the patient or patient's representative, attach the patient's or patient's representative's own comments in the form of an addendum to the record.

6. Procedure on refusal of request for access

- (1) If the licensee refuses a request by a patient or by the patient's representative for access to the patient's health record, the licensee –
 - (a) must inform the patient or representative in writing of the reason for the refusal and of any rights of appeal that may exist in respect of the refusal; and
 - (b) must include in the patient's health record a written note of the refusal and the reason given for the refusal.
- (2) A patient or the patient's representative may appeal in writing to the Secretary against a decision of the licensee to refuse access to the patient's health record.
- (3) The Secretary may, in determining such an appeal –

- (a) confirm the decision of the licensee; or
 - (b) direct that the licensee grant the patient or the patient's representative access to the patient's health record under such conditions as the Secretary may direct.
- (4) A determination made by the Secretary is to be given in writing to the licensee and retained in the health record of the patient to whom it relates.

7. Confidentiality of records

- (1) The licensee must ensure that, except as provided by this clause, personal information concerning a patient is not released from the private hospital or day-procedure centre except with the consent of the patient or the patient's representative or with other lawful excuse.
- (2) Subclause (1) does not affect the operation of any other law requiring, prohibiting or restricting the release of any such information.
- (3) All health records must be stored in a secure place to which unauthorised persons are not permitted access.

**PART 6 – ADDITIONAL REQUIREMENTS FOR
PRIVATE HOSPITALS**

1. Beds

- (1) A suitable hospital-type bed must be provided for each patient other than a patient required under clause 1(5) of Part 4 of this Schedule to be accommodated in a cot.
- (2) This clause does not apply to a psychiatric or rehabilitation ward if a suitable bed of domestic type is provided for each patient in the place of a hospital-type bed.
- (3) The beds are to be comfortable, safe and in a good state of repair with due regard for the comfort and safety of all patients.

2. Other bedroom furniture

- (1) For each bed, there must be provided at least one bedside locker, situated within easy reach of the bed, and having a top surface which has rounded corners and is washable and impervious to liquids.
- (2) For each bed, there must be available an overbed table which –
 - (a) is of adjustable height; and
 - (b) is of safe design and robust construction; and

- (c) has washable surfaces impervious to liquids.
- (3) At least one chair with arms must be provided for each bed and must be made of materials that facilitate the chair being kept clean and hygienic.
- (4) At least one wardrobe of suitable size must be provided for each bed for the storage of the clothes of the patient occupying the bed.
- (5) Individual draw screens must be provided for each bed in each multiple-bed ward to provide privacy for patients and each such draw screen –
 - (a) must be of suitable, washable, fire-resistant materials; and
 - (b) must be suspended from strong overhead tracking.

3. Furnishing and equipping of lounge areas

Lounge areas for patients must be furnished with an adequate number of appropriate chairs.

4. Medical, surgical and nursing equipment

- (1) Medical, surgical and nursing equipment, appliances and materials that are necessary for the type and level of patient care in the private hospital must be provided and properly maintained.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (2) Without limiting subclause (1), the following equipment must be provided in a private hospital:
- (a) a resuscitation trolley containing a complete set of adult resuscitation and monitoring equipment in each of the following areas:
 - (i) each ward area supervised from a single nurse station;
 - (ii) in a private hospital approved to provide intensive care, the intensive care area;
 - (b) if the private hospital is approved to admit child patients, a resuscitation trolley containing a complete set of paediatric resuscitation and monitoring equipment (suitable for the various age ranges of children approved to be admitted) in the children's ward area;
 - (c) oxygen and suction facilities at appropriate locations.

5. Staffing

- (1) Sufficient staff with appropriate qualifications must be provided in a private hospital to ensure that allied health services necessary for good patient care are provided.
- (2) Sufficient domestic and maintenance staff or services to carry out the cooking, cleaning,

laundering, maintenance and other duties necessary for the proper conduct of the private hospital must be provided.

- (3) The licensee of a private hospital must cause staff rosters to be prepared for the nursing and other staff of the private hospital and must cause written copies of the staff rosters to be kept available for inspection at the private hospital.

6. Identification of patients

- (1) The licensee of a private hospital must ensure that there is a system in place in the private hospital that complies with the accepted standards in the Australian health sector –
 - (a) to correctly establish the identity of each patient; and
 - (b) to verify the identity of each patient; and
 - (c) to ensure that records pertaining to the patient are correctly matched to that patient.
- (2) The licensee of a private hospital must ensure that an identification band used to identify a patient of the private hospital complies with clause 10 of Part 2 of this Schedule.

7. Notification of missing patients

If a patient appears to be missing from a private hospital, the patient's representative or next of kin, the patient's medical practitioner and a

police officer must immediately be informed of that fact.

8. Health records

In addition to the requirements of regulation 6, private hospital medical records must also include –

- (a) a record of planned nursing management, including all other treatment and diet orders; and
- (b) progress notes including –
 - (i) a current principal diagnosis and other significant diagnoses; and
 - (ii) a daily record of all medical and nursing care given in respect of the patient's medical, physical, psychological and social needs and responses.

9. Visiting hours

Patients in a private hospital must be allowed to receive visitors at any reasonable time but a medical practitioner or the senior nurse on duty may, if necessary for the care of a patient –

- (a) restrict the hours for visiting the 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.

10. Storage, preparation and serving of food

- (1) In this regulation –

kitchen, in a private hospital, means a kitchen of that hospital that is responsible for the majority of food that is stored, prepared, cooked or distributed in respect of staff and patients.

- (2) A kitchen in a private hospital must be used solely for the purposes of –
 - (a) storing, preparing, cooking and distributing food; and
 - (b) washing dishes and utensils used in connection with the storage, preparation, cooking or serving of food.
- (3) An area of a private hospital, other than a kitchen, must not be used for the purposes specified in subclause (2), except that –
 - (a) a servery may be used for the preparation of beverages and light snacks; and
 - (b) a scullery may be used for washing dishes and utensils.
- (4) Laundry and waste (other than kitchen waste) must not be taken through a kitchen.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (5) Meals at a private hospital must be prepared and served –
- (a) in accordance with a planned menu of at least one week; and
 - (b) in sufficient variety, quality and quantity –
 - (i) to be attractive and palatable to, and edible by, patients; and
 - (ii) to provide the dietary allowances recommended in the *Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes*, as issued by the National Health and Medical Research Council in 2006.
- (6) Any special diet prescribed or requested for a patient by the medical practitioner or dentist in charge of the patient's care must be provided.

11. Overcrowding

- (1) Unless otherwise approved, a patient must not be lodged in any part of a private hospital other than a ward.
- (2) If in an emergency the number of patients in a ward exceeds the number of patients specified in the licence in respect of that ward, the licensee of the private hospital must, as soon as practicable –

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 1

- (a) cause the excess patient or patients to be removed from that ward; and
- (b) notify the Secretary orally of the fact; and
- (c) send to the Secretary notice in writing of the fact and of all the relevant details of the circumstances in which it occurred.

**SCHEDULE 2 – ADDITIONAL LICENSING
STANDARDS FOR PARTICULAR CLASSES OF
PRIVATE HOSPITALS**

Regulation 6(2), (3), (4) and (5)

PART 1 – SURGICAL HOSPITALS

1. Support services

A surgical class private hospital is to have access to basic pharmaceutical, anaesthetic, pathology and medical imaging services within a period of time appropriate to clinical need.

2. Staffing

Staff are to be provided in a surgical class private hospital to give adequate assistance to an anaesthetist in accordance with –

- (a) the recommendations contained in the *PS09 Guideline on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures* as published by the ANZCA; and
- (b) the *Standards for Perioperative Nursing Australia, Volume 2: Professional Standards* as published by the Australian College of Perioperative Nurses.

3. Identification of patients

- (1) An identification band is to be fitted around a wrist or an ankle of each surgical patient admitted to a private hospital.
- (2) The patient's name and date of birth and the attending medical practitioner's name are to be written indelibly and legibly on the band.

4. Medical, surgical and nursing equipment

- (1) The following equipment is to be provided in the operating suite of a surgical class private hospital:
 - (a) an electrosurgical unit for each operating room;
 - (b) adequate instrument sets for elective use;
 - (c) sterile instrument sets available for emergency procedures;
 - (d) anaesthetic equipment and facilities recommended in the *PS55 Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations* as published by the ANZCA;
 - (e) monitoring equipment recommended in the *PS18 Guideline on monitoring during anaesthesia* as published by the ANZCA;
 - (f) recovery equipment, facilities and scheduled substances recommended in

the *PS04 Statement on the post-anaesthesia care unit* as published by the ANZCA.

- (2) Equipment, facilities and substances referred to in subclause (1)(e) and (f) are also to be in accordance with the *Standards for Perioperative Nursing Australia, Volume 1: Clinical Standards* and *Standards for Perioperative Nursing Australia, Volume 2: Professional Standards* as published by the Australian College of Perioperative Nurses.

PART 2 – MATERNITY HOSPITALS

1. Medical advisory committee

The medical advisory committee of a maternity class private hospital is to include at least one specialist obstetrician.

2. Conduct of maternity class private hospitals

A maternity class private hospital –

- (a) is to have an approved policy in respect of the following matters:
- (i) the private hospital's criteria for admission to maternity services;
 - (ii) normal childbirth and the criteria for interventions to assist birth;
 - (iii) breastfeeding;

- (iv) rooming-in;
 - (v) the accommodation by the private hospital of the individual needs of patients and their families;
 - (vi) the numbers and qualifications of medical practitioners and nursing staff available to the private hospital and the numbers of any such staff on duty for each shift;
 - (vii) the quality assurance programs established by the private hospital;
 - (viii) provision made by the private hospital for the transfer of patients to another hospital providing a higher level of medical service; and
- (b) is to have an obstetrician, an anaesthetist and a paediatrician on close call at all times; and
 - (c) is to have a suitable number of midwives on duty at all times; and
 - (d) is to have contingency arrangements in case of an emergency for the transfer of mothers and babies to a hospital that is capable of providing a higher level of care.

3. Health records

- (1) The health record of a baby in a maternity class private hospital is to include the childbirth labour record if obstetric childbirth has occurred.
- (2) Despite clause 3(1)(c) of Part 5 of Schedule 1, a baby's health record is to be retained for at least 30 years after the date of the baby's separation from the private hospital.

4. Record of births

- (1) Details of the birth of a baby (whether live or stillborn) born in a private hospital or admitted to a private hospital as a newborn baby (otherwise than by transfer from another hospital) is to be recorded in an approved form.
- (2) The record is to be signed –
 - (a) by the medical practitioner or midwife attending the birth; or
 - (b) by the director of nursing or a person authorised by the director of nursing for the time being for that purpose.
- (3) Copies of the record are to be distributed as follows:
 - (a) the first copy is to be retained at the private hospital with the mother's health record;
 - (b) the second copy, unless otherwise approved, is to be forwarded to the

Secretary within 6 weeks after the separation of the mother or baby from the private hospital, whichever occurs first;

- (c) the third copy is to be made available to the local child health nurse, but only with the consent of the mother;
- (d) other copies of the record are to be forwarded to the mother's referring medical practitioner and consulting specialist (if any), unless the mother objects.

5. Identification of patients

- (1) An identification band is to be fitted around a wrist or an ankle of each maternity patient and baby admitted to, or born in, a private hospital.
- (2) The patient's name and date of birth and the attending medical practitioner's name are to be written indelibly and legibly on the patient's band.
- (3) The baby's name and date of birth and the attending medical practitioner's name are to be written indelibly and legibly on the baby's band.

6. Furnishing of wards

Each maternity ward in a maternity class private hospital is to have one bassinette for each maternity bed and one reserve bassinette for each 10 (or portion of 10) maternity beds.

7. Medical, surgical and nursing equipment

The delivery suite of a maternity class private hospital is to be equipped in accordance with the recommendations contained in the *PS55 Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations* as published by the ANZCA.

PART 3 – REHABILITATION HOSPITALS

1. Medical advisory committee

There is to be a medical advisory committee of a rehabilitation class private hospital which is to include at least one specialist in rehabilitation medicine.

2. Conduct of rehabilitation class private hospitals

A rehabilitation class private hospital –

- (a) is to have a written policy on the provision of rehabilitation services, including –
 - (i) a statement of the private hospital’s philosophy of service; and
 - (ii) details of the liaison to be established with community-based services to ensure

- continuity and coordination of care; and
- (b) is to have clear, written criteria and assessment procedures for the admission of both inpatients and outpatients to rehabilitation programs; and
 - (c) is to have a written rehabilitation plan for each patient that –
 - (i) is based on the assessment of that 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 patient and the family of the patient; and
 - (iv) includes provision for discharge, continuing care and review; and
 - (d) is to have procedures for regularly evaluating the progress of each patient having regard to the written rehabilitation plan; and
 - (e) is to have a formal and planned discharge procedure; and
 - (f) is to have regular case management meetings, involving the treating medical practitioner and appropriate therapists, to

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 2

- review individual rehabilitation plans;
and
- (g) is to have access to specialists for consultation; and
- (h) is to have sufficient appropriate therapists for the services provided; and
- (i) is to 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, is to have access to the services of a neuropsychologist; and
- (k) if patients with chronic pain are being treated, is to have access to the services of a clinical psychologist.

3. Health records

The health record of a patient in a rehabilitation class private hospital is to include –

- (a) a clear statement by the treating medical practitioner giving details of the reason for admission and the perceived need for rehabilitation which 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.

PART 4 – PSYCHIATRIC HOSPITALS

1. Medical advisory committee

There is to be a medical advisory committee for a psychiatric class private hospital which is to include at least one psychiatrist.

2. Conduct of psychiatric class private hospitals

A psychiatric class private hospital –

- (a) is to have a written policy on the provision of psychiatric services, including a statement of the private hospital's philosophy of service; and
- (b) is to have a written policy and procedure for –
 - (i) supporting the functions of the Mental Health Tribunal established under the *Mental Health Act 2013*; and
 - (ii) supporting the functions of Official Visitors and mental health officers within the meaning of the *Mental Health Act 2013* and other welfare officers

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 2

- lawfully permitted to visit the private hospital; and
 - (iii) supporting the administration of the *Guardianship and Administration Act 1995*; and
 - (iv) if electro-convulsive therapy is administered in the private hospital, the administration of that therapy; and
 - (v) the management of patients' trust funds; and
- (c) is to have clear, written criteria and assessment procedures for the admission of both inpatients and outpatients to psychiatric programs; and
- (d) is to have 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) is to have access at all times to a psychiatrist; and
- (f) is to have access to a general practitioner and relevant specialists for consultation; and
- (g) is to have sufficient registered nurses with appropriate psychiatric

qualifications or experience on duty at all times.

3. Health records

The health record of a patient in a psychiatric class private hospital is to include –

- (a) a clear statement of the reason for admission, consistent with the admission policy; and
- (b) a treatment 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.

4. ECT equipment

The equipment and scheduled substances provided in areas in which electro-convulsive therapy is administered are to comply with recommendations contained in the *PS55 Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations* as published by the ANZCA.

**SCHEDULE 3 – ADDITIONAL LICENSING
STANDARDS FOR PRIVATE HOSPITALS
AUTHORISED TO PROVIDE SPECIALISED
SERVICES**

Regulation 6(6), (7), (8) and (9)

PART 1 – CARDIAC CATHETERISATION

1. Interpretation

In this Part –

cardiac catheterisation means the procedure of passing a catheter (or other instrument) through a major blood vessel to the heart for a diagnostic or therapeutic purpose.

2. Medical advisory committee

The medical advisory committee of a private hospital authorised to provide cardiac catheterisation services is to include a cardiologist trained in cardiac catheterisation techniques, and an anaesthetist experienced in cardiac procedures, while matters relating to cardiac catheterisation are being discussed.

3. Conduct of cardiac catheterisation unit

- (1) Coronary angioplasty may be performed only on –

- (a) patients who would not be expected to require cardiac surgery regardless of the outcome of the angioplasty; or
 - (b) patients for whom there is a low risk of requiring urgent cardiac bypass surgery.
- (2) Emergency coronary angioplasty may be performed in a private hospital only in a case of –
- (a) cardiogenic shock; or
 - (b) acute myocardial infarction, where thrombolytic therapy is relatively contraindicated, or found to be ineffective; or
 - (c) acute myocardial infarction where the coronary artery anatomy is known and the lesion is suitable for angioplasty.
- (3) A patient requiring emergency coronary angioplasty may not be transferred from another hospital to the private hospital and must be transferred to the nearest public hospital with a cardiac catheterisation unit that can undertake emergency procedures.
- (4) Patients for whom there is a high or moderate risk of requiring urgent coronary artery bypass surgery, including patients who would require ambulance standby or cardiac surgery operating theatre standby, are to be transferred to the nearest public hospital with a cardiac catheterisation unit that can undertake emergency procedures.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 3

- (5) Angioplasty may be performed at a private hospital only by a cardiologist who has performed, in the previous 12 months, at least the number of angioplasty procedures recommended in the *Position Statement on Performance of, and Support Facilities for, a Primary Percutaneous Coronary Intervention Service* issued by the Cardiac Society of Australia and New Zealand.
- (6) Morbidity records on a person having coronary angioplasty at the private hospital are to be provided to the Secretary in an approved form and the records are to be provided in respect of each year before 31 March in the following year or at any other time when requested by the Secretary.
- (7) A private hospital authorised to provide cardiac catheterisation services –
 - (a) must have a written policy in respect of each of the following matters:
 - (i) the criteria for the admission of patients to cardiac catheterisation;
 - (ii) the program of care for patients following cardiac catheterisation;
 - (iii) the numbers and qualifications of medical practitioners and nursing staff available to the private hospital and the numbers of any such staff on duty for each shift;

- (iv) the qualifications of those practitioners and staff;
- (v) the provision made for the transfer of patients to another hospital that provides a higher level of medical service; and
- (b) must have a written policy giving full details of the quality assurance procedures established by the private hospital concerning cardiac catheterisation services; and
- (c) must have a suitable number of appropriate staff, including a specialist director of cardiac catheterisation services, registered nursing staff with relevant experience and allied health staff; and
- (d) must have an in-patient orientation and education program; and
- (e) if the private hospital is not authorised to carry out open heart surgery, must have contingency arrangements with a nearby hospital capable of performing open heart surgery for the transfer of patients in an emergency.

4. Retention of health records

The films or other archival media on which a cardiac catheterisation procedure is recorded

must be kept for at least 3 years after the date of the procedure.

5. Identification of patients

- (1) An identification band must be fitted around a wrist or an ankle of a cardiac catheterisation patient admitted to a private hospital.
- (2) The patient's name and date of birth and the attending medical practitioner's name must be written indelibly and legibly on the band.

6. Medical, surgical and nursing equipment

Each procedure room in a cardiac catheterisation unit must have facilities and equipment as recommended in the *PS09 Guideline on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures* as published by the ANZCA.

PART 2 – EMERGENCY SERVICES

1. Interpretation

In this Part –

emergency service means a service for the care of persons injured in accidents, or for those suffering from medical or other emergencies, through the provision of reception, resuscitation, medical and

surgical facilities and life support systems.

2. Conduct of emergency service

A private hospital approved to provide an emergency service must have –

- (a) a written policy relating to each of the following matters:
 - (i) the coordination of the service with other emergency services in the same district as the private hospital;
 - (ii) the integration of the emergency service with the clinical and educational activities of the private hospital;
 - (iii) the admission and discharge of patients and the review of the care provided to patients;
 - (iv) the provision of information and counselling to relatives and friends of patients; and
- (b) an appropriately qualified and experienced medical practitioner appointed as director of the emergency service; and
- (c) arrangements for appropriate specialists to be available on close call at all times; and

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 3

- (d) sufficient appropriately trained and experienced staff on duty and immediately available at all times; and
- (e) an effective system of triage which separates patients needing emergency services from patients needing primary health care; and
- (f) arrangements for the provision of primary health care in appropriate cases; and
- (g) contingency arrangements for the transfer of patients by retrieval teams to a hospital providing a higher level of care if needed.

3. Health records

The private hospital's health record for each emergency patient must include –

- (a) the date and time of arrival and separation; and
- (b) a description of significant clinical, laboratory and radiological findings; and
- (c) accurate details of any treatment provided; and
- (d) the identity and signature of the attending medical officer.

4. Medical and nursing equipment

An emergency service must have the following equipment and scheduled substances:

- (a) suitable monitors and ventilators;
- (b) resuscitation and diagnostic equipment and scheduled substances, adequate for the planned maximum numbers of child and adult patients who may be undergoing examination or treatment by the service at any one time.

PART 3 – INTENSIVE CARE

1. Interpretation

In this Part –

intensive care means 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 separate intensive care unit that is specially staffed and equipped for that purpose.

2. Medical advisory committee

When matters relating to intensive care are being considered, the medical advisory committee of a private hospital authorised to provide intensive care must include a medical practitioner with experience in intensive care.

3. Conduct of intensive care unit

Intensive care services provide by a private hospital must comply with the *Minimum Standards for Intensive Care Units* as published by the College of Intensive Care Medicine of Australia and New Zealand.

4. Identification of patients

- (1) An identification band must be fitted around a wrist or an ankle of each patient admitted to an intensive care unit of a private hospital.
- (2) The patient's name and date of birth and the attending medical practitioner's name must be written indelibly and legibly on the band.

5. Medical, surgical and nursing equipment

An intensive care unit must have the following equipment:

- (a) ventilators;
- (b) hand ventilating assemblies;
- (c) suction apparatus;
- (d) airway access equipment, including bronchoscopic equipment;
- (e) vascular access equipment;
- (f) dialysis equipment;

- (g) monitoring equipment, both non-invasive and invasive;
- (h) defibrillation and pacing equipment;
- (i) equipment to control patients' temperatures;
- (j) chest drainage equipment;
- (k) infusion and specialised pumps;
- (l) transport monitoring equipment;
- (m) specialised intensive care beds.

PART 4 – NEONATAL INTENSIVE CARE

1. Interpretation

In this Part –

neonatal intensive care means life support, monitoring and care for newly born children suffering from life-threatening prematurity, illness or disability at birth or post-birth complications.

2. Medical advisory committee

When matters relating to neonatal intensive care are being considered, the medical advisory committee of a private hospital authorised to provide neonatal intensive care must include a specialist paediatrician with neonatal experience.

3. Conduct of a neonatal intensive care unit

A private hospital authorised to provide neonatal intensive care must have –

- (a) a written policy in respect of each of the following matters:
 - (i) the private hospital's criteria for admission to the neonatal intensive care unit;
 - (ii) the care of children admitted for neonatal intensive care;
 - (iii) the numbers and qualifications of medical practitioners and nursing staff available to the private hospital and the numbers of any such staff on duty for each shift;
 - (iv) the quality assurance programs established by the private hospital;
 - (v) provision made by the private hospital for the transfer of patients to another hospital providing a higher level of care; and
- (b) a specialist paediatrician or paediatric registrar on close call at all times, or a resident medical officer on duty at all times and a specialist paediatrician or paediatric registrar on call at all times; and

- (c) a sufficient number of registered nurses, a majority of whom are specially trained and permanently attached to the unit, on duty in the neonatal intensive care unit at all times; and
- (d) contingency arrangements for the transfer of patients to a hospital providing a higher level of neonatal intensive care in an emergency.

4. Identification of patients

- (1) An identification band must be fitted around a wrist and an ankle of each neonatal intensive care patient admitted to a private hospital.
- (2) The patient's name and date of birth and the attending practitioner's name must be written indelibly and legibly on the band.

5. Medical, surgical and nursing equipment

A neonatal intensive care unit must have the following equipment:

- (a) at least one-half of the approved number of cots fitted as humidicribs;
- (b) cardio-respiratory monitoring equipment for each cot;
- (c) sufficient intravenous fluid therapy equipment;
- (d) sufficient tube feeding equipment;

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 3

- (e) sufficient phototherapy equipment;
- (f) a resuscitation trolley containing a complete set of paediatric resuscitation and monitoring equipment.

**SCHEDULE 4 – ADDITIONAL LICENSING
STANDARDS FOR PARTICULAR CLASSES OF DAY-
PROCEDURE CENTRES**

Regulation 6(11), (12) and (13)

**PART 1 – LOW-RISK CLASS DAY-PROCEDURE
CENTRES**

**1. Procedures to be undertaken in a low-risk class
day-procedure centre**

All procedures to be undertaken in a low-risk
class day-procedure centre must be –

- (a) capable of being safely performed under
local anaesthetic, conscious sedation or
analgesia in accordance with *PS09
Guideline on sedation and/or analgesia
for diagnostic and interventional
medical, dental or surgical procedures* as
published by the ANZCA; and
- (b) approved by the Secretary, taking into
account appropriate clinical advice.

2. Health records

In a case where conscious sedation, or analgesia,
or both, have been employed, the health record
of a patient of a low-risk class day-procedure
centre must include a procedure record which is
to comply with the recommendations contained
in *PS06 Guideline on the anaesthesia record* as
published by the ANZCA.

3. Staffing

Staff are to be provided in a low-risk class day-procedure centre to give adequate assistance to a proceduralist in accordance with the recommendations contained in the *PS09 Guideline on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures* as published by the ANZCA.

4. Medication and equipment in low-risk class day-procedure centre

- (1) A low-risk class day-procedure centre is to be provided with the anaesthetic medication, clinical care and monitoring equipment recommended in the *PS09 Guideline on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures* as published by the ANZCA.
- (2) The medication and equipment referred to in subclause (1) is to be available at all times while the low-risk day-procedure centre is in use.
- (3) There is to be calibration and regular testing of sterilising and processing equipment.

PART 2 – SURGICAL CLASS DAY-PROCEDURE CENTRES

1. Equipment in surgical class day-procedure centres

- (1) The following equipment is to be provided in a surgical class day-procedure centre and is to be available at all times while the day-procedure centre is in use:
 - (a) an electrosurgical unit;
 - (b) adequate instrument sets for elective use;
 - (c) sterile instrument sets available for emergency procedures;
 - (d) anaesthetic equipment recommended in the *PS55 Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations* as published by the ANZCA;
 - (e) monitoring equipment recommended in the *PS18 Guideline on monitoring during anaesthesia* as published by the ANZCA;
 - (f) recovery equipment and scheduled substances recommended in the *PS04 Statement on the post-anaesthesia care unit* as published by the ANZCA.
- (2) The nursing staff of a surgical class day-procedure centre must comply with the requirements in the *PS15 Guideline for the*

perioperative care of patients selected for day stay procedures as published by the ANZCA.

2. Pathology and radiography services

A surgical class day-procedure centre must have access to basic pathology and radiography services within a period of time appropriate to clinical need.

3. Staffing

Staff are to be provided in a surgical class day-procedure centre to assist an anaesthetist in accordance with the recommendations of the *PS09 Guideline on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures* as published by the ANZCA.

PART 3 – ENDOSCOPIC CLASS DAY-PROCEDURE CENTRES

1. Equipment in endoscopic class day-procedure centres

The following equipment is to be provided in an endoscopic class day-procedure centre and is to be available at all times while the day-procedure centre is in use:

- (a) a sufficient number of colonoscopes and endoscopes;

- (b) fluoroscopic facilities, if appropriate;
- (c) an electrosurgical unit;
- (d) anaesthetic equipment recommended in the *PS55 Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations* as published by the ANZCA;
- (e) monitoring equipment recommended in the *PS18 Guideline on monitoring during anaesthesia* as published by the ANZCA;
- (f) recovery equipment and scheduled substances recommended in the *PS04 Statement on the post-anaesthesia care unit* as published by the ANZCA.

2. Staffing

Staff are to be provided in an endoscopic class day-procedure centre to assist an anaesthetist in accordance with the recommendations of the *PS09 Guideline on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures* as published by the ANZCA.

**SCHEDULE 5 – MEMBERSHIP AND PROCEDURES
OF MEDICAL ADVISORY COMMITTEES**

Clause 6 of Part 2 of Schedule 1

1. Membership

- (1) Unless otherwise approved by the Secretary, a medical advisory committee is to consist of at least 5 medical practitioners.
- (2) The Secretary may approve a committee as a medical advisory committee that does not comply with the requirements of subclause (1) if the Secretary thinks fit to do so, after taking into account the relevant establishment and the treatment performed.
- (3) Despite subclauses (1) and (2), a medical advisory committee must include one member who has no pecuniary interest in the establishment.
- (4) In addition to the members specified in subclauses (1) and (2), the medical advisory committee may include nominees or representatives of other health care providers, academic institutions or other relevant professional organisations.

2. Procedure of medical advisory committee

- (1) The medical advisory committee is to meet as often as is necessary to effectively perform its responsibilities and functions.

- (2) A medical advisory committee may co-opt any person having any desirable expertise but any such person is not entitled to vote.
- (3) A medical advisory committee is to review at least once in each period of 5 years the credentials and scope of clinical practice of each medical practitioner and dentist appointed to the private hospital or day-procedure centre.
- (4) A member must not participate in any deliberation or decision of the committee in respect of a practitioner if grounds might exist for a reasonable apprehension that the member might not bring a fair and unbiased mind to the issue before the committee.
- (5) In the circumstances referred to in subclause (4), the member concerned must declare the facts of the matter to the chairperson who must then decide whether or not the member should participate in any deliberation or decision of the committee.
- (6) A decision of the committee is to be subject to appeal as follows:
 - (a) in the first place the committee is to review its own decision;
 - (b) if the decision is unchanged, any person aggrieved by the committee's decision may appeal to the appeals committee, established for the purpose by the private hospital or day-procedure centre, which may either confirm or overturn the original decision.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 5

- (7) A quorum of the committee is to consist of a majority of the members, one of whom must be the chairperson or his or her nominee.
- (8) If the clinical director is not able to attend the meeting, he or she must provide comments in writing on the relevant matter.
- (9) The scope of clinical practice of any medical practitioner or dentist is to be determined by reference to his or her credentials and any recommendation of a selection committee appointed for the purpose.
- (10) If the Secretary is satisfied that, owing to special circumstances, the committee as constituted in accordance with this Schedule –
 - (a) may be perceived to be biased in respect of any issue to be determined; or
 - (b) is otherwise unsuitable to determine any issue –

the membership of the committee may instead consist of not less than 5 and not more than 9 persons appointed by the Secretary for the purposes of considering and determining that issue.

3. Procedural fairness

The medical advisory committee is to observe the rules of procedural fairness.

4. Voting

A decision of the medical advisory committee is to be determined by a majority of the members present and voting and, if the votes on any matter before the committee are equal, the matter is to be determined in the negative.

5. Record of decisions

The medical advisory committee must keep a record of all its decisions including the reasons and evidence on which they are based.

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

sch. 6

SCHEDULE 6 – INFRINGEMENT OFFENCES

Regulation 22

	Provision of Act or regulations	Penalty units
1.	Section 21(2)	5
2.	Section 22(5)	0.5
3.	Section 32	40
4.	Section 33(1)	50
5.	Section 34(1)	25
6.	Section 37(1)	6
7.	Section 38(1)	4
8.	Section 39(2)	2
9.	Section 39(4)	0.5
10.	Section 40(1)	0.3
11.	Section 41	4
12.	Section 42(4)	1
13.	Section 48	3
14.	Section 49	6.5
15.	Section 54	8
16.	Regulation 12(2)	0.5
17.	Regulation 20	0.5
18.	Regulation 21	0.5

Health Service Establishments Regulations 2021
Statutory Rules 2021, No. 76

Printed and numbered in accordance with the *Rules Publication Act 1953*.

Notified in the *Gazette* on 24 September 2021.

These regulations are administered in the Department of Health.

NOTES

The foregoing text of the *Health Service Establishments Regulations 2021* comprises those instruments as indicated in the following table. Any reprint changes made under any Act, in force before the commencement of the *Legislation Publication Act 1996*, authorising the reprint of Acts and statutory rules or permitted under the *Legislation Publication Act 1996* and made before 3 May 2023 are not specifically referred to in the following table of amendments.

Citation	Serial Number	Date of commencement
¹ <i>Health Service Establishments Regulations 2021</i>	S.R. 2021, No. 76	28.9.2021
<i>Health Service Establishments Amendment Regulations 2023</i>	S.R. 2023, No. 14	3.5.2023

¹Expiry 24 September 2031 - Subordinate Legislation Act 1992

TABLE OF AMENDMENTS

Provision affected	How affected
Part 1 of Schedule 1	Amended by S.R. 2023, No. 14