Day Procedure Centres Regulation 1996

[1996-407]

New South Wales

Status Information

Currency of version

Historical version for 6 December 2006 to 11 December 2007 (accessed 24 December 2024 at 5:11)

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

Provisions in force

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

Authorisation

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

File last modified 4 July 2007

Day Procedure Centres Regulation 1996

New South Wales

Contents

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Part 1 Preliminary

1 Name of Regulation

This Regulation is the *Day Procedure Centres Regulation 1996*.

2 Commencement

This Regulation commences on 1 September 1996.

3 Application

(1) This Regulation applies to and in respect of all day procedure centres.

(2) For the purposes of the definition of ***day procedure centre*** in section 3 (1) of the Act, the prescribed treatment and circumstances are as follows:

(a) 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 simple sedation,

(b) endoscopic treatment that involves the administration of a general anaesthetic or intravenous sedative otherwise than for the purpose of simple sedation,

(c) treatment that involves dialysis, haemofiltration or haemoperfusion,

(d) treatment that involves prolonged intravenous infusion of a single cytotoxic agent or sequential intravenous infusion of more than one cytotoxic agent,

(e) treatment that involves cardiac catheterisation,

(f) treatment that involves the multidisciplinary care and treatment of children who are less than 5 years of age for early childhood conditions relating to developmental, behavioural, feeding or sleeping disorders.

(3) However, the prescribed treatment and circumstances do not include the following:

(a) emergency treatment provided by a medical practitioner in circumstances that render impracticable the transfer of the patient to a hospital or day procedure

centre,

(b) dental treatment provided by a dentist in the course of the practice of dentistry.

4 Definitions

(1) In this Regulation:

admission form means an admission form referred to in clause 15.

approved means approved for the time being by the Director-General, either generally or in any particular case or class of cases.

child means a person who is under the age of 14 years.

clinical records means clinical records referred to in Schedule 1, 2 or 3.

Director-General means the Director-General of the Department of Health.

in-patient statistics form means an in-patient statistics form referred to in clause 15.

patient's representative means:

(a) if the patient is under 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

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

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

podiatrist means an accredited podiatrist within the meaning of the *Health Insurance Act 1973* of the Commonwealth.

simple sedation means a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out in such a manner:

(a) that verbal contact with the patient can be maintained throughout the period of sedation, and

(b) that the drugs and techniques used have a margin of safety wide enough to render unintended loss of consciousness unlikely.

the Act means the *Private Hospitals and Day Procedure Centres Act 1988*.

(2) In this Regulation, a reference to a particular class of day procedure centre is a

reference to a day procedure centre that is licensed as a day procedure centre of that class.

(3) In this Regulation, a reference to a Form is a reference to a Form set out in Schedule 4.

5 Notes

The explanatory note and table of contents do not form part of this Regulation.

Part 2 Licensing of day procedure centres

6 Licensing standards

(1) For the purposes of section 7 of the Act, the following standards are prescribed:

(a) for all day procedure centres—the standards specified in Schedule 1,

(b) for surgical class day procedure centres—the standards specified in Part 1 of Schedule 2,

(c) for endoscopic class day procedure centres—the standards specified in Part 2 of Schedule 2,

(d) for dialysis class day procedure centres—the standards specified in Part 3 of Schedule 2,

(e) for cytotoxic class day procedure centres—the standards specified in Part 4 of Schedule 2.

(2) For the purposes of section 7 of the Act, the additional standards specified in Part 1 of Schedule 3 are prescribed for day procedure centres authorised to provide cardiac catheterisation services.

(3) The licensee must conduct the day procedure centre in accordance with the provisions of Schedules 1, 2 and 3 applicable to the day procedure centre.

Maximum penalty: 5 penalty units.

(4) The licensee is not guilty of an offence under this clause if the licensee:

(a) was not aware of the circumstances giving rise to the alleged offence, and

(b) could not reasonably be expected to have been aware of those circumstances.

(5) A contravention of a provision of Schedule 1, 2 or 3 by any person other than the licensee does not constitute an offence under this Regulation.

7 Applications for licences

For the purposes of section 8 of the Act:

(a) the prescribed form of application is Form 1, and

(b) the prescribed application fee is $755.

8 Classes of day procedure centres

For the purposes of section 13 of the Act, the following classes of day procedure centres are prescribed:

(a) 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 simple 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 simple sedation),

(c) dialysis (that is, a day procedure centre used for the purpose of providing treatment that involves dialysis, haemofiltration or haemoperfusion),

(d) cytotoxic (that is, a day procedure centre used for the purpose of providing treatment that involves prolonged intravenous infusion of a single cytotoxic agent or sequential intravenous infusion of more than one cytotoxic agent),

(e) family care (that is, a day procedure centre used for treatment that involves the multidisciplinary care and treatment of children who are less than 5 years of age for early childhood conditions relating to developmental, behavioural, feeding or sleeping disorders).

9 Annual licence fees

For the purposes of section 17 of the Act, the prescribed annual licence fee is $1,380.

10 Transfer of licence

For the purposes of section 18 of the Act:

(a) the prescribed form of application is Form 2, and

(b) the prescribed application fee is $755.

11 Alterations or extensions

For the purposes of section 19 of the Act, the prescribed form of application is Form 3.

12 Application for review of Director-General's decision

For the purposes of section 28 of the Act, the prescribed form of application is Form 4.

13 Chief nurse

(1) For the purposes of section 41 (1) of the Act, the prescribed qualifications to be held by a registered nurse who carries out the duties of chief nurse are:

(a) current registration on List "A" of the Register kept under the *Nurses Act 1991*, and

(b) 5 years' post-basic or post-graduate nursing experience, and

(c) 2 years' administrative experience in a position of, or more senior than that of, nursing unit manager in a hospital.

(2) For the purposes of section 41 (2) of the Act, the prescribed number of days is 7.

(3) For the purposes of section 41 (4) of the Act, the prescribed particulars in respect of a person who carries out the duties of chief nurse are particulars of the person's current authority to practise.

14 Register of patients

(1) For the purposes of section 44 (1) of the Act, the prescribed form for a register of patients is a series of forms, each form being in or to the effect of Form 5, completed in respect of each patient and maintained in strict admission date order.

(2) For the purposes of section 44 (2) (e) of the Act, the prescribed particulars to be entered in the register of patients are such of the particulars required to complete Form 5 as are relevant to a day procedure centre.

(3) For the purposes of section 44 (3) of the Act, a particular required to be entered in the register of patients must be entered by the licensee:

(a) in the case of a particular relating to the admission of a patient, at the time of admission of the patient, and

(b) in the case of a particular relating to the separation of a patient, at the time the person ceases to be a patient, and

(c) in either case:

(i) in such manner as may be directed by the senior nurse on duty at the day procedure centre at the time the particulars are obtained, and

(ii) subject to subparagraph (i), by hand or by use of an approved electronic data processing system.

15 Records

(1) In addition to the register of patients, the licensee must keep, in respect of each patient:

(a) an admission form, in the approved form, and

(b) an in-patient statistics form, in the approved form, and

(c) such other records as are referred to in Schedule 1, 2 or 3.

Maximum penalty: 5 penalty units.

(2) Such records may be kept by hand or by use of an approved electronic data processing system.

Part 3 Disclosure of pecuniary interests

16 Definition of pecuniary interest

(1) For the purposes of this Part:

pecuniary interest in a day procedure centre means any one or more of the following interests:

(a) a pecuniary interest in the licence to conduct the day procedure centre, being:

(i) an interest as the holder of the licence to conduct the day procedure centre, or as one of the holders of such a licence, or

(ii) an interest in any corporation (other than a public company) which is the licensee of the day procedure centre, or

(iii) a holding of 5 per cent or more of the issued share capital of a public company which is the licensee of the day procedure centre,

(b) a pecuniary interest in the premises on which the day procedure centre is conducted, being:

(i) an interest (whether at law or in equity) in the premises at which the day procedure 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 day procedure centre is conducted, or

(iii) a holding of 5 per cent 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 day procedure centre is conducted,

(c) a pecuniary interest in the services provided to the day procedure centre, being:

(i) an interest in any clinical or administrative services provided to the day procedure centre (other than an interest being fees from medical or dental services provided by the person to any patient in the day procedure 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 day procedure centre, or

(iii) a holding of 5 per cent or more of the issued share capital of any public company which has an interest in any clinical or administrative services provided to the day procedure centre.

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

(2) For the purposes of section 46 (4) of the Act, a practitioner has a pecuniary interest in a day procedure centre if the practitioner has a pecuniary interest within the meaning of this Part.

(3) For the purposes of section 46 (5) of the Act, a pecuniary interest in a day procedure centre of a relative of a practitioner is a pecuniary interest of the practitioner.

17 Manner in which pecuniary interest to be notified

(1) For the purposes of section 46 (1) of the Act, the manner in which a practitioner is to notify a person of the practitioner's pecuniary interest is:

(a) by telling the person of that fact by word of mouth, and

(b) by giving written notice of that fact to the person, and

(c) by displaying a written notice of that fact at the day procedure centre, surgery or other premises at which the relevant advice or treatment is given or the relevant arrangements are made.

(2) The notification 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 subclause (1) (c) must comply with the following requirements:

(a) the notice must have a surface area of at least 2 500 square centimetres,

(b) the information on the notice must be printed in plain, bold letters at least 1 centimetre high on a contrasting background,

(c) in the case of a notice displayed at a day procedure centre, the notice must be

displayed in a prominent place in the waiting room or in every room in which the practitioner to whom the notice relates attends to patients or other persons,

(d) in the case of a notice displayed at a surgery or other premises, the notice must be displayed in a prominent place.

Part 4 Miscellaneous

18 Evidentiary certificates

An officer of the Department of Health who holds an authorisation for the purposes of section 51 of the Act, being a written authorisation signed by the Director-General, is a prescribed officer for the purposes of that section.

19 Display of licence

At all times while a 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 day procedure centre.

Maximum penalty: 5 penalty units.

20 Information to be furnished with annual licence fee

(1) When paying an annual licence fee referred to in section 17 of the Act, the licensee must furnish to the Director-General:

(a) a copy of the chief nurse's current authority to practise, and

(b) a certificate in the approved form, and

(c) information in the approved form in respect of the nursing staff at the day procedure centre.

Maximum penalty: 5 penalty units.

(2) The certificate referred to in subclause (1) (b) must contain the information required to complete the approved form and (in the case of a licensee that is a corporation) must also be accompanied by the following information:

(a) the full name of the corporation,

(b) the address of the registered office of the corporation,

(c) the full name, residential address, date and place of birth and position of:

(i) each current director of the corporation, and

(ii) the principal executive officer of the corporation, and

(iii) the secretary or, if there is more than one, each secretary of the corporation,

(d) in the case of a corporation limited by shares:

(i) the types of shares and the number of shares of each type issued,

(ii) in the case of a private corporation, the full name of, and the number of shares held by, each shareholder,

(iii) in the case of a public corporation, a list of the 20 largest shareholdings and of the full names of the holders of each of those shareholdings,

(e) if the shares are held by another corporation, the name of the ultimate holding corporation.

21 Change of ownership or control

(1) A licensee that is a corporation must furnish to the Director-General, as soon as practicable after the change occurs, particulars of any change in the directors or major shareholders of the corporation.

Maximum penalty: 5 penalty units.

(2) In this clause, ***major shareholder*** of a corporation means a shareholder whose shareholding exceeds 20 per cent of the total shareholding in the corporation.

22 Information to be furnished periodically

(1) The licensee must, for each month, furnish to the Director-General a statistical statement in the approved form.

Maximum penalty: 5 penalty units.

(2) The statement must contain the information required to complete the approved form and is to be furnished to the Director-General within 14 days after the end of the month to which the information relates.

23 Repeal

(1) The *Day Procedure Centres Regulation 1990* is repealed.

(2) Any act, matter or thing which, immediately before the repeal of the *Day Procedure Centres Regulation 1990*, had effect under that Regulation continues to have effect under this Regulation.

Schedule 1 Licensing standards

(Clause 6)

Part 1 Design and construction of premises

1 Ambulance access

A day procedure centre must have adequate access for the emergency transfer of patients by ambulance.

2 Orders under the Local Government Act 1993

The licensee of a day procedure centre must ensure that notice is immediately given to the Director-General of any order made under section 124 of the *Local Government Act 1993* in relation to the premises of the day procedure centre.

Part 2 Facilities and equipment

2A Hot and warm water systems

Any hot or warm water system supplying those areas of a day procedure centre that are used by patients must be a system that has been installed in accordance with the prescribed installation requirements under section 45 of the *Public Health Act 1991*.

3 Maintenance of buildings, facilities and equipment

(1) The buildings, facilities and equipment of a day procedure centre are to be maintained in good repair and operational order.

(2) Without limiting subclause (1), a suitable maintenance program (consistent with the manufacturer's specifications, if any) must be current at all times for:

(a) all air-conditioning, heating, warming and cooling systems and appliances, and

(b) all anaesthetic, endoscopic, fluoroscopic, electrosurgical and resuscitation equipment, and

(c) all sterilising equipment, and

(d) all communication, alarm and emergency call systems, and

(e) all hot and warm water systems.

Part 3 Clinical standards

4 Medical advisory committee

(1) The licensee must appoint a medical advisory committee for the day procedure centre except where the only medical practitioners or dentists authorised to practise at the

day procedure centre are themselves the licensees.

(2) The medical advisory committee must be appointed in accordance with the approved guidelines (if any) and must consist of at least 5 persons who are each medical practitioners or dentists.

(3) The medical advisory committee is to be responsible for:

(a) advising the licensee on the accreditation of medical practitioners and dentists, and the approval of podiatrists, to provide services at the day procedure centre and on the delineation of their clinical responsibilities, and

(b) advising the licensee on matters concerning clinical practice at the day procedure centre, and

(c) advising the licensee on matters concerning patient care and safety at the day procedure centre.

(4) The medical advisory committee is to have power to co-opt other health care providers, who may include nominees or representatives of learned colleges or other relevant professional organisations.

(5) It is a function of the medical advisory committee to report to the Director-General any persistent failure by the licensee of the day procedure centre to act on the committee's advice on any of the matters referred to in subclause (3).

5 Responsibilities of health practitioners

(1) Each procedure performed at the day procedure centre is to be performed by an appropriately accredited medical practitioner or dentist or by a podiatrist.

(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 an appropriately accredited medical practitioner who is not the person performing the procedure.

(3) A medical practitioner, dentist or podiatrist is to be responsible for selecting patients suitable for treatment by the medical practitioner, dentist or podiatrist at the day procedure centre, subject to:

(a) the class or classes of the day procedure centre and the limitations (if any) on the services that may be provided there, and

(b) the clinical responsibilities of the medical practitioner, dentist or podiatrist, and

(c) the maintenance of high professional standards.

6 Quality assurance

(1) The licensee is to cause written procedures to be established for evaluating the quality of clinical service and care provided at the day procedure centre and for correcting identified problems.

(2) Such procedures are to take account of relevant external standards and programs recommended by learned colleges and other relevant professional organisations.

7 Experimental treatment

(1) Experimental treatment must not be carried out otherwise than in accordance with the document entitled *Statement on Human Experimentation* issued by the National Health and Medical Research Council.

(2) The licensee must refer any proposed new or experimental treatment to an institutional ethics committee, constituted in accordance with that Statement, and the treatment must not be carried out otherwise than in accordance with the recommendations of the committee.

Part 4 Staffing

8 Staffing

(1) The nursing staff of a day procedure centre must at all times be sufficient in number, and have appropriate experience, to perform the nursing duties necessary for the proper care of patients.

(2) The nursing staff of a day procedure centre must include persons having qualifications and experience appropriate for each class of day procedure centre specified in the licence for the centre.

(3) The licensee must cause a register to be kept in which are recorded the following particulars:

(a) the name of each person employed in nursing duties at the day procedure centre,

(b) the residential address of each such person,

(c) in respect of each such person who is a registered 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 seen by the chief nurse.

(4) The licensee must cause separate staff rosters to be prepared for the nursing and other staff of the day procedure centre and must cause written copies of the staff rosters to be kept available for inspection at the day procedure centre.

Part 5 Operational matters

9 Child patients

(1) A child must not be admitted to a day procedure centre as a patient unless the day procedure centre is approved to admit child patients and the licence is endorsed accordingly.

(2) A licensee who applies for endorsement of the licence for the purposes of this clause must indicate:

(a) the age range of children to be admitted, and

(b) the types of investigation and treatment to be performed on children, and

(c) the facilities to be provided for the treatment and care of children, and

(d) the arrangements that exist for transferring children to hospitals providing appropriate treatment and care in the event of any medical complications arising,

for consideration in determining the conditions (if any) to be endorsed on the licence.

(3) In the case of a child patient who requires special paediatric facilities or services (whether because of the child's age, general state or medical condition, because of the proposed investigation, treatment or duration of stay, or otherwise), the licensee:

(a) must arrange for a paediatric physician to be readily available for consultation at all times, and

(b) unless otherwise approved, must have a registered nurse with post-basic or post-graduate paediatric experience or qualifications on duty at all times while the child is a patient in the day procedure centre, and

(c) for neonates and children under the age of 12 months, must arrange for microchemistry to be readily available for analysis of capillary blood specimens.

(4) In the case of all child patients:

(a) the parents and guardians of the child (and any person having the care of the child) must have easy access to the child at all times except while the child is undergoing surgery, and

(b) if the child is undergoing surgery, each such person must have easy access to the child in the pre-anaesthetic and recovery areas unless, in the opinion of the attending medical practitioner, dentist or podiatrist, the presence of such persons

in those areas is detrimental to the child's welfare.

(5) A child who is less than 2 years of age must be accommodated in a cot that complies with Australian Standard 2130-1981 *entitled Metal Dropside Cots for Day Nurseries, Hospitals and Institutions (Safety Requirements)*, as published on 17 August 1981 by the Standards Association of Australia.

10 Cardiac catheterisation

Cardiac catheterisation must not be performed at a surgical class day procedure centre unless its licence authorises the provision of that service.

11 Admission and separation of patients

(1) On the admission of a patient to a 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:

(i) written information concerning the policy of the licensee in respect of the conduct of the day procedure centre, including charging for services, smoking by patients and staff and the handling of complaints about the day procedure centre, and

(ii) written information concerning the procedure for lodging a complaint.

(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 senior nurse on duty (or by some other person authorised by the chief nurse 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 clinical

record,

(c) the in-patient statistics form is, unless otherwise approved, to be submitted to the Director-General within 6 weeks after the discharge of the person to whom the record relates.

(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.

12 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 are to be used as necessary to maintain the comfort of each patient.

13 Identification of patients

(1) An identification band must be fitted around a wrist or an ankle of each patient who is to undergo general anaesthesia or intravenous sedation.

(2) The patient’s name and date of birth, and the attending medical practitioner’s name, must be indelibly and legibly written on the band.

14 Infection control

(1) The licensee must have a written infection control policy approved by the Director-General.

(2) The licensee must ensure that the day procedure centre has sufficient resources to enable the work practices of persons working in the day procedure centre to comply with that policy.

15 Hygiene

(1) Adequate facilities, equipment and stores are to be maintained for the effective cleaning and disinfection of the buildings and their fixtures and fittings.

(2) Buildings, together with their fixtures and fittings, are to be maintained in a clean and sanitary condition.

(3) Receptacles with close-fitting lids are to be provided for the collection of general refuse.

(4) General refuse is to be disposed of by the use of a service provided by the local authority or in some other approved manner.

(5) Contaminated waste is to be disposed of in accordance with the licensee's infection control policy.

16 Smoking

(1) There must be a written policy on smoking in the day procedure centre by patients and staff.

(2) The policy on smoking must provide that, if patients or staff are allowed to smoke within the day procedure centre, smoking is to be confined to designated areas that allow other patients to avoid exposure to smoke without unduly restricting their activities.

17 Injuries, transfers and deaths

(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 the day procedure centre,

(b) the transfer of a patient to a hospital as a result of any injury or iatrogenic condition,

(c) the death of any patient at a day procedure centre.

(2) As soon as practicable after such an incident occurs:

(a) details of the incident must be entered in the approved form, and in the patient's clinical record, and must be reported to the chief nurse and to the patient's medical practitioner, dentist or podiatrist, and

(b) the incident must be investigated, and the results of the investigation must be entered in the approved form, and

(c) if the patient was transferred to a hospital, details of the transfer must be entered in the approved form, and

(d) if the patient was transferred to a hospital, or the incident was life-threatening or fatal:

(i) the patient's representative or next of kin, and the Director-General, must be notified verbally of the incident, and

(ii) a copy of the completed approved form must be forwarded to the Director-General.

18 Fire safety and emergency evacuation

(1) The licensee must have a written policy outlining the procedures to be adopted in the event of fire or other emergency (including contingency arrangements for the transfer of patients where necessary).

(2) The licensee must ensure that all staff, immediately on commencing employment at the day procedure centre, are instructed in the procedures (including emergency evacuation procedures) to be adopted in the event of fire or other emergency.

(3) An evacuation diagram must be displayed at each nurses' station and at each exit to the day procedure centre.

(4) The licensee must appoint a member of staff to be the fire safety officer for the day procedure centre and must ensure that the fire safety officer is provided with appropriate fire safety training.

(5) All of the staff of a day procedure centre are to participate in an evacuation exercise at least once every 6 months.

(6) All of the staff of a day procedure centre must attend fire safety training, provided by New South Wales Fire Brigades or by some other recognised fire safety training organisation, at least once every year.

(7) A record of each such fire safety training, showing the name of each person attending and signed by the training officer for the fire safety training organisation, must be maintained.

(8) If a fire occurs in a day procedure centre, the licensee, as soon as practicable and regardless of whether or not the fire brigade has been called to extinguish the fire:

(a) must notify the Director-General verbally of the fact, and

(b) must send to the Director-General written notice of the fact and of all the relevant details of the circumstances in which the fire occurred.

19 Storage of non-prescription drugs

(1) In this clause:

drug of addiction means a substance specified in Schedule 8 of the Poisons List under the *Poisons and Therapeutic Goods Act 1966*.

non-prescription drug means a medication that is not a restricted substance or a drug of addiction.

restricted substance means a substance specified in Schedule 4 of the Poisons List under the *Poisons and Therapeutic Goods Act 1966*.

(2) Non-prescription drugs must be stored in accordance with such of the requirements of the regulations under the *Poisons and Therapeutic Goods Act 1966* as relate to the storage of restricted substances in hospitals.

Part 6 Clinical records

20 Application of Part

This Part applies 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.

21 Clinical records

(1) A record of the medical condition of each patient in a day procedure centre, and of all medical, nursing and other care provided to each such patient, is to be maintained by an entry in a patient clinical record system made by the appropriate medical, nursing or other health care provider.

(2) Without limiting subclause (1), a patient's clinical record must include the following:

(a) the patient's admission form,

(b) the patient's medical history, and the results of any physical examination, that may be contained in any referral document,

(c) any medical consultation reports,

(d) a record of any medication administered,

(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, dental or podiatric treatment is necessary,

(i) consent or request forms, if applicable,

(j) if a medical, surgical or other procedure has been performed:

(i) in a case where anaesthesia has been employed—the anaesthetic record (which must comply with the recommendations of the Australian and New Zealand College of Anaesthetists in its publication *The Anaesthetic Record*),

(ii) the procedure report, including the pre-procedural and post-procedural diagnoses, and a description of the findings, technique used and tissue removed or altered,

(iii) in a case where tissue or body fluid has been removed—a pathological report on the tissue or body fluid,

(iv) in a case where the procedure has involved surgery—a record of the swab, sponge and instrument count,

(v) the post-procedural recovery record,

(k) a discharge statement, completed by the medical practitioner, dentist or podiatrist attending the patient, that specifies the main 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, dental or podiatric treatment must identify the medical practitioner, dentist or podiatrist by whom that treatment was provided.

(4) A discharge statement referred to in subclause (2) (k) must be completed prior to the patient's discharge unless verbal discharge instructions are given, in which case the statement must be completed within 48 hours after the patient's discharge.

22 Retention of records

(1) The register of patients, together with the patient's clinical records, are to be retained as follows:

(a) the register of patients must be kept indefinitely,

(b) clinical records relating to patients aged 18 years or over at the date of last separation must be kept for at least 7 years from the date of last separation,

(c) clinical records relating to patients aged under 18 years 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 day procedure centre is transferred to another person.

(3) If the licence for the day procedure centre is surrendered or cancelled, the licensee must deal with the register and records in accordance with the instructions of the Director-General.

(4) Unless otherwise approved, the register and records are to be kept at the day procedure centre.

23 Patient's right of access to clinical records

(1) A patient or the patient's representative may, by written application to the licensee, request access to the patient's clinical record.

(2) The licensee must, as soon as practicable after receipt of such an application, make the clinical record available to:

(a) the patient or the patient's representative, or

(b) a person nominated by the patient or patient's representative.

(3) However, the licensee may refuse a request by a patient or by the patient's representative for access to the patient's clinical record:

(a) if the medical practitioner, dentist or podiatrist 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 clinical record.

24 Manner of providing access

(1) Access to a clinical 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 clinical 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 clinical record, the information may be provided by the medical practitioner, dentist or podiatrist in charge of the patient's care or, subject to the advice of that medical practitioner, dentist or podiatrist, by a medical practitioner or registered nurse on the staff of the day procedure centre.

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

(5) The licensee may charge a fee (not exceeding the relevant fee, if any, determined by the Director-General) to cover the licensee's costs of complying with this clause.

(6) The Director-General may determine a scale of fees generally, or a fee payable in a particular case, in relation to a licensee's costs of complying with this clause.

25 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 clinical record, the licensee:

(a) must inform the patient or patient's representative in writing of the reason for the refusal and of any rights of appeal that may exist in relation to the refusal, and

(b) must include in the patient's clinical 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 Director-General against a decision of the licensee to refuse access to the patient's clinical record.

(3) The Director-General 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 clinical record under such conditions as the Director-General may direct.

(4) A determination made by the Director-General is to be conveyed in writing to the licensee and retained in the clinical record of the patient to whom it relates.

26 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 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 clinical records must be stored in a secure place to which unauthorised persons are not to be permitted to have access.

Schedule 2 Additional licensing standards for particular classes of day procedure centre

(Clause 6)

Part 1 Surgical class day procedure centres

1 Equipment in surgical class day procedure centres

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 by the Australian and New Zealand College of Anaesthetists in its publication *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites*,

(e) monitoring equipment recommended by the Australian and New Zealand College of Anaesthetists in its publication *Monitoring During Anaesthesia*,

(f) recovery equipment and drugs recommended by the Australian and New Zealand College of Anaesthetists in its publication *Guidelines for the Care of Patients Recovering from Anaesthesia Related to Day Surgery*.

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 to assist an anaesthetist in accordance with the recommendations of the Australian and New Zealand College of Anaesthetists in its publication *Minimum Assistance Required for the Safe Conduct of Anaesthesia*.

Part 2 Endoscopic class day procedure centres

4 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 by the Australian and New Zealand College of Anaesthetists in its publication *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites*,

(e) monitoring equipment recommended by the Australian and New Zealand College of Anaesthetists in its publication *Monitoring During Anaesthesia*,

(f) recovery equipment and drugs recommended by the Australian and New Zealand College of Anaesthetists in its publication *Guidelines for the Care of Patients Recovering from Anaesthesia Related to Day Surgery*.

5 Staffing

Staff are to be provided to assist an anaesthetist in accordance with the recommendations of the Australian and New Zealand College of Anaesthetists in its publication *Minimum Assistance Required for the Safe Conduct of Anaesthesia*.

Part 3 Dialysis class day procedure centres

6 Definitions

In this Part:

continuous ambulatory peritoneal dialysis means the form of peritoneal dialysis in which dialysing fluid is run into the abdominal cavity, left for some hours, drained out and replaced with fresh fluid.

dialysis means the procedure for the removal of certain elements from the blood or lymph by virtue of the difference in their rate of diffusion through an external semipermeable membrane or, in the case of peritoneal dialysis, through the peritoneum.

haemodialysis means the process by which certain molecules are removed from circulating blood of uraemic patients by diffusion through a semipermeable membrane.

haemofiltration means the extracorporeal process by which the fluid and solute composition of blood and body fluids can be corrected by a combination of ultrafiltration and convective solute loss and dilution with physiologic saline solution.

haemoperfusion means the removal of substances from the blood by passage through a column containing a substance over the surface of which the blood passes and comes into contact before leaving the column and returning to the patient.

peritoneal dialysis means the process by which dialysing fluid is instilled into the abdominal cavity, left for a period of time, then drained.

7 Medical advisory committee

The medical advisory committee of a dialysis class day procedure centre must be joined by a specialist nephrologist or a consultant renal physician trained in dialysis, haemofiltration and haemoperfusion techniques when matters relating to dialysis, haemofiltration or haemoperfusion are being discussed.

8 Design and construction

Dialysis, haemofiltration or haemoperfusion services must not be provided otherwise than in and from a unit which:

(a) is air-conditioned and of adequate size for the functions performed, and

(b) has a reception and waiting area, and

(c) has rooms for consultation and examination, and

(d) has access to patient change facilities, and

(e) has access to patient toilets, and

(f) has a clean utility room, and

(g) has access to a dirty utility room, and

(h) has a soundproof area for the reverse osmosis unit, and

(i) is located close to a station for nurses and technicians, and

(j) has access to pathology services, and

(k) has access to an appropriately qualified and trained specialist for the insertion of vascular access catheters, and

(l) has a fully equipped cardiac arrest trolley.

9 Conduct of dialysis, haemofiltration and haemoperfusion units

A unit for dialysis, haemofiltration or haemoperfusion:

(a) must have a written policy in relation to all of the following matters:

(i) the provision of information and counselling to patients and their relatives,

(ii) admission, discharge and review of care,

(iii) the maintenance and replacement of all medical equipment associated with dialysis, haemofiltration and haemoperfusion,

(iv) the management of cardiac arrest, and

(b) must have sufficient and appropriately trained and experienced staff, including a program director and visiting medical officers and consultants, and

(c) must have appropriate specialists available on call at all times, and

(d) must have procedures for other specialists to be readily available for consultation, and

(e) must have access to trained dialysis, haemofiltration and haemoperfusion technicians at all times, and

(f) must have contingency arrangements for the transfer of patients, if appropriate, to a hospital providing a higher level of care in the event of complications.

10 Clinical records

The clinical record of a patient admitted for dialysis, haemofiltration or haemoperfusion in a day procedure centre must include a record of the dialysis, haemofiltration or haemoperfusion.

Part 4 Cytotoxic class day procedure centres

11 Definition

In this Part:

cytotoxic agent means a substance that has the effect of destroying, damaging or inhibiting the proliferation of cells within the human body.

12 Medical advisory committee

The medical advisory committee of a cytotoxic class day procedure centre must be joined by a specialist oncologist or a consultant physician trained in oncology when matters relating to cytotoxic agents are being discussed.

13 Design and construction

Cytotoxic agents must not be administered otherwise than in and from a unit which:

(a) is air-conditioned and of adequate size for the functions performed, and

(b) has a reception and waiting area, and

(c) has rooms for consultation, examination and (where necessary) patient isolation, and

(d) has access to patient toilets, and

(e) has a clean utility room, and

(f) has access to a dirty utility room, and

(g) has access to pathology services and an oncology pharmacist, and

(h) if cytotoxic drugs are prepared at the day procedure centre, has a cytotoxic drug cabinet:

(i) that complies with the Australian Standard AS 2567–1994 *entitled Laminar flow cytotoxic drug safety cabinets*, as published by the Standards Association of Australia, and

(ii) that is heated in a room that complies with Australian Standard AS 2639–1994 *entitled Laminar flow cytotoxic drug safety cabinets—Installation and use*, as published by the Standards Association of Australia.

14 Administration of cytotoxic agents

A unit for the administration of cytotoxic agents:

(a) must have a written policy in relation to all of the following matters:

(i) the provision of information and counselling to patients and their relatives,

(ii) admission, discharge and review of care,

(iii) procedures for other specialists to be readily available for consultation,

(iv) pre-treatment investigations to be undertaken before each treatment is administered,

(v) the management of the extravasation of cytotoxic drugs,

(vi) the management of side effects,

(vii) the disposal of cytotoxic waste,

(viii) procedures for attending to spills of cytotoxic materials, and

(b) must have sufficient and appropriately trained and experienced staff, including a program director and visiting medical officers and consultants, and

(c) must have appropriate specialists available on call at all times, and

(d) must have contingency arrangements for the transfer of patients, if appropriate, to a hospital providing a higher level of care in the event of complications, and

(e) must have a suitably equipped resuscitation trolley.

15 Clinical records

The clinical record of a patient admitted for the administration of cytotoxic agents in a day procedure centre must include:

(a) a record of the administration of cytotoxic agents and any other medication administered as part of the treatment plan, and

(b) home care plans.

Schedule 3 Additional licensing standards for day procedure centres authorised to provide cardiac catheterisation services

(Clause 6)

1 Definition

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 day procedure centre 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 Planning and location

(1) Cardiac catheterisation services must be performed in a separate unit which:

(a) is dedicated, as a cardiac catheterisation unit, to the performance of those services, and

(b) is air-conditioned and adequate in size for the services performed, and

(c) is so located as to allow quick access, when those services are performed, to a cardiac care unit or intensive care unit located in a nearby hospital, and

(d) has an emergency call system linked to at least one of those units, and

(e) is close to a staff station, and

(f) includes a short-term recovery area that has accommodation for at least 2 trolleys from each procedure room in the unit, and

(g) has a scrub up area, and

(h) has a clean utility room with a refrigerator for the storage of drugs, and

(i) has access to a central sterilising supply service (unless only sterile disposable equipment is used in the unit), and

(j) has access to facilities for linen and general storage, and

(k) has access to facilities near the unit for recording images of cardiac catheterisation services, and

(l) has access to a dirty utility room, staff change rooms and staff toilets, all of which are near the unit.

(2) If the cardiac catheterisation services performed are therapeutic, the day procedure centre must have immediate access to a cardiac care unit or intensive care unit from which the transfer of a patient to a theatre equipped and staffed for open heart surgery can be completed within 30 minutes.

(3) When therapeutic cardiac catheterisation services are performed, the day procedure centre must have access to a readily available, suitably equipped ambulance.

4 Conduct of cardiac catheterisation unit

A day procedure centre authorised to provide cardiac catheterisation services:

(a) must have a written policy in relation to all 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 day procedure centre, 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 a nearby hospital that provides a higher level of medical service, and

(b) must have a written policy that details the quality assurance programs established by the day procedure centre 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) must have contingency arrangements with a nearby hospital capable of performing open heart surgery for the transfer of patients in an emergency.

5 Retention of clinical records

The films or other archival media on which a cardiac catheterisation procedure is recorded must be kept for at least 3 years from the date when the procedure was carried out.

6 Identification of patients

(1) An identification band must be fitted around a wrist or an ankle of each cardiac catheterisation patient.

(2) The patient’s name and date of birth, and the attending medical practitioner’s name, must be indelibly and legibly written on the band.

7 Medical, surgical and nursing equipment

Each procedure room in a cardiac catheterisation unit must have its own resuscitation

equipment including a defibrillator.

Schedule 4 Forms

Form 1 Application for licence for a day procedure centre

(Clause 7)

(*Private Hospitals and Day Procedure Centres Act 1988*)

I/We, ...

(*full name of applicant[s]*)

date of birth: ..... place of birth: .....
of .....

(*address of applicant[s]*)

apply for a licence for a day procedure centre of the following class[es]
.....
The day procedure centre will be known as
.....

(*proposed name*)

and will be situated at
.....

(*proposed location*)

The range of procedures proposed to be carried out include the following:
.....

(*proposed procedures*)

The forms of anaesthetic and sedation to be used include the following:
.....

(*proposed anaesthetic and sedation*)

The applicant[s] is/are/will be
* owner[s]
* lessee[s]
of the day procedure centre.

**Delete whichever is not applicable*

I/We attach the following information:

(1) In the case of an application by a corporation:

(a) a copy of the certificate of incorporation,

(b) the address of the registered office of the corporation,

(c) the full name, date and place of birth, residential address and position of:

(i) each current director of the corporation,

(ii) the principal executive officer of the corporation,

(iii) the secretary or, if there is more than one, each secretary of the corporation,

(d) in the case of a corporation limited by shares:

(i) the types of shares and the number of shares of each type issued,

(ii) in the case of a private corporation—the full name of, and the number of shares of each type held by,

each shareholder,

(iii) in the case of a public corporation—a list of the 20 largest shareholdings and of the full names of the holders of each of those shareholdings,

(e) if the shares are held by another corporation, the name of the ultimate holding corporation.

(2) If the day procedure centre is leased, a copy of the lease.

(3) If the day procedure centre is proposed to be leased, a description of the proposed lease arrangements.

I/We also enclose the prescribed application fee.

.....	.....
(*Print name*)	(*Signature*)
.....	.....
(*Position*)	(*Date*)

Form 2 Application for transfer of licence for a day procedure centre

(Clause 10)

(*Private Hospitals and Day Procedure Centres Act 1988*)

I/We, ...

(*full name of applicant[s]*)

date of birth: ..... place of birth: .....
of .....

(*address of applicant[s]*)

apply for a transfer to me/us of the licence for the day procedure centre known as .....

(*name of day procedure centre*)

at .....

(*address of day procedure centre*)

The applicant[s] is/are/will be
* owner[s]
* lessee[s]
of the day procedure centre.

**Delete whichever is not applicable*

I/We attach the following information:

(1) In the case of an application by a corporation:

(a) a copy of the certificate of incorporation,

(b) the address of the registered office of the corporation,

(c) the full name, date and place of birth, residential address and position of:

(i) each current director of the corporation,

(ii) the principal executive officer of the corporation,

(iii) the secretary or, if there is more than one, each secretary of the corporation,

(d) in the case of a corporation limited by shares:

(i) the types of shares and the number of shares of each type issued,

(ii) in the case of a private corporation—the full name of, and the number of shares of each type held by, each shareholder,

(iii) in the case of a public corporation—a list of the 20 largest shareholdings and of the full names of the holders of each of those shareholdings,

(e) if the shares are held by another corporation, the name of the ultimate holding corporation.

(2) If the day procedure centre is leased, a copy of the lease.

(3) If the day procedure centre is proposed to be leased, a description of the proposed lease arrangements.

I/We also enclose the prescribed application fee.

....

(*Print name*) (*Signature*)

....

(*Position*) (*Date*)

TO BE COMPLETED BY CURRENT LICENSEE

I/We agree to the transfer of the licence to the abovenamed applicant(s).

....

(*Print name*) (*Signature*)

....

(*Position*) (*Date*)

Form 3 Application for approval to alter or extend a licensed day procedure centre

(Clause 11)

(*Private Hospitals and Day Procedure Centres Act 1988*)

I/We, ...

(*name of licensee*)

of .....

(*address of licensee*)

being the holder of the licence (No. .....) for the day procedure centre known as .....

(*name of day procedure centre*)

at .....

(*address of day procedure centre*)

apply for approval to alter or extend the day procedure centre.

I/We attach the following documents:

(1) Two copies of a site plan of the day procedure centre, drawn to scale and showing the lot number and deposited plan number or other relevant particulars that identify the site.

(2) Two copies of sketch plans of the day procedure centre, drawn to a scale of 1:100 and showing the dimensions of each part of the day procedure centre and the use to which each part is to be put (the proposed alterations or extensions to the day procedure centre are shown by distinctive colouring or cross-hatching).

.....	.....
(*Print name*)	(*Signature*)
.....	.....
(*Position*)	(*Date*)

Form 4 Application for review of Director-General's decision

(Clause 12)

(*Private Hospitals and Day Procedure Centres Act 1988*)

I/We, ...

(*name of applicant*)

of .....

(*address of applicant*)

apply for a review of the decision of the Director-General to:

.....

(*nature of decision*)

I/We enclose a copy of the Director-General's letter notifying the decision.

The grounds for my/our request for review are as follows:

.....
.....
.....

I/We understand that this application will be referred to a Committee of Review, which may make such investigation as it considers necessary in relation to this application before reporting to you. I/We agree, for this purpose, to allow any member of the Committee access to documentation, staff and patients, as judged necessary by the Committee. I/We also agree to relevant documentation held by the Department of Health being made available to members of the Committee for the purposes of its investigation.

.....	.....
(*Print name*)	(*Signature*)
.....	.....
(*Position*)	(*Date*)

Form 5 Register of patients

(Clause 14)

(*Private Hospitals and Day Procedure Centres Act 1988*)