



Health

**Cosmetic Surgery and The
Private Health Facilities Act 2007:
The Regulation of Facilities
Carrying Out Cosmetic Surgery**

DISCUSSION PAPER

Cosmetic Surgery and the Private Health Facility Act and Regulation

Cosmetic surgery in NSW

Recently there have been increased concerns about the safety and regulation of cosmetic surgery in NSW and Australia. Cosmetic surgery can be carried out by different medical practitioners, from specialist plastic surgeons to general practitioners. The types of cosmetic procedures have grown over the years and there is an array of different procedures available, from eyelid surgery to face lifts to breast enlargement to penile extension. Further, procedures that in the past would have been undertaken in a hospital under general anaesthesia are, in some cases, now undertaken in cosmetic clinics using local anaesthetic or conscious sedation. There have also been a number of reported cases of serious incidents, including cardiac arrests, arising in relation to cosmetic surgery. In light of these changes and concerns, it is pertinent to consider whether the current regulation of cosmetic surgery is safe and appropriate.

Regulation of cosmetic surgery in NSW

There are 2 main levels of regulation in NSW that can apply to cosmetic surgery:

- Those that apply to the practitioner involved in cosmetic surgery, and
- Those that apply to the facilities where cosmetic surgery is carried out.

In respect of regulation at the practitioner level, all medical practitioners and other registered health practitioners must be registered under the Health Practitioner Regulation National Law (NSW) and comply with the standards and guidelines issued by the relevant health professional Board of Australia, such as the Medical Board of Australia. These professional standards and guidelines will apply to all registered health practitioners involved in cosmetic surgery.

However, it is recognised that some procedures cannot be safely carried out in a medical practitioner's room and that additional regulation is required. As such, at the facility level, some health or medical clinics where practitioners work are subject to additional regulation. In NSW, private health facilities that meet specific requirements are subject to licensing under the Private Health Facilities Act 2007 and the Private Health Facilities Regulation 2010. The Act has 18 classes of private health facilities, including a surgical class and an anaesthesia class.

Facilities that perform procedures falling within any of these classes must be licensed under the Act and comply with the standards set out in the Regulation. These standards are aimed at protecting patients and relate to the safety of the premises (such as complying with the relevant sections of the Building Code of Australia) and clinical care and patient safety (such as having procedures for the transfer of patients who require higher levels of care,

minimum staffing requirements and appropriate equipment). While the Private Health Facilities Act provides extensive regulation in respect of licensed facilities, it only applies to facilities that carry out procedures that fit within one of the 18 classes of private health facilities.

With respect to cosmetic surgery, not all facilities that carry out these procedures are licensed under the Private Health Facilities Act. There is no specific class of “cosmetic surgery”. While there is a surgical class and anaesthesia class, the definition of these classes require procedures to involve the use of general, epidural or major regional anaesthetic or sedation resulting in more than conscious sedation. Many of the cosmetic surgical procedures that are currently carried out do not use general, epidural or major regional anaesthetic or sedation resulting in more than conscious sedation. Rather, many cosmetic surgical procedures, such as breast augmentation, may be carried out under conscious sedation or local anaesthetic.

This means that while the medical practitioners performing cosmetic procedures are subject to relevant standards and guidelines issued by the Medical Board of Australia, the facilities carrying out the procedures are not always subject to the standards required by the Private Health Facilities Act and Regulation.

The paper considers whether the current regulation of facilities carrying out cosmetic surgery is appropriate and raises the question of whether there should be a specific class of cosmetic surgery in the Private Health Facilities Act and Regulation. It is noted that broader issues relating to the regulation of medical practitioners carrying out cosmetic surgery is also currently under consideration by the Medical Board of Australia¹.

Questions for consideration

- 1) Is the current regulation of facilities carrying out cosmetic surgery appropriate?

Should cosmetic surgery be a new class of private health facilities?

The Ministry is considering whether facilities carrying out cosmetic surgery should be required to be licensed under the Private Health Facilities Act. Licensing such facilities will help ensure that appropriate standards in relation to the safety of the premises and clinical care apply to such clinics.

However, it is important that the Ministry only regulates in this area where there is a public health and safety risk that can only be appropriately mitigated by way of requiring facilities to be licensed. Some cosmetic surgical procedures, for example minor surgical procedures

¹ The Medical Board of Australia recently released a discussion paper to canvass a range of issues relating to cosmetic procedures. While submissions have closed (and the Board is considering the submissions received, a copy of the discussion paper can be found at <http://www.medicalboard.gov.au/News/Past-Consultations.aspx>.

such as a mole removal for cosmetic reasons, are likely to be able to be safely carried out in a medical practitioner's room. On the other hand, it may be more appropriate for major surgical procedures, such as breast augmentation, to only be carried out in licensed private health facilities.

The major risks associated with cosmetic surgery relate to:

- The use of anaesthesia or sedation, including risks related to over-sedation under-sedation, risk of inadvertent administration of a toxic dose of local anaesthesia, and allergic reactions to the sedation/anaesthesia; and
- The inherent risks attached to certain procedures, regardless of what level of anaesthesia or sedation is used. For example, breast augmentation/reduction surgery carries risk of significant haemorrhage and liposuction carries risks relating to fat embolism and haemorrhage. Other risks can include infection, nerve damage, formation of seromas and excessive scarring.

Where the risks are high, there are concerns that the risks cannot be adequately managed by way of the guidelines that apply to registered medical practitioners alone. Rather, there are good grounds to consider that private health facility licensing is required to manage these serious risks. Further, in relation to the use of sedation, any practitioner carrying out a surgical procedure, whether low risk or high risk, that involves the use of sedation should comply with appropriate standards and guidelines, such as the *Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures*, which are put out by the Australian and New Zealand College of Anaesthetists.² These guidelines note that in undertaking techniques using conscious sedation, there should be a *margin of safety that is wide enough to render loss of consciousness unlikely*. However, if there is a real risk of loss of consciousness, the Ministry preliminary considers that the procedure should only be carried out in a licensed facility.

Licensing facilities carrying out such cosmetic surgery would ensure that facilities would have to comply with wide ranging standards that relate to both the safety of the premises and clinical care. Importantly, licensing would require facilities to be Building Code of Australia compliant and have appropriate policies relating to fire. Patients undergoing major surgical procedures will generally not be ambulatory for periods of time and therefore it is essential that appropriate fire safety requirements are in place to ensure patients can be safely evacuated in cases of fire. Licensing will also require facilities to have appropriate policies regarding transferring patients who require a higher level of care. Where patients are undergoing cosmetic surgery that carry significant risks, appropriate transfer policies can help ensure that there are adequate processes in place to ensure that patients are transferred to appropriate facilities should the risks of the procedure eventuate. Further,

² See <http://www.anzca.edu.au/resources/professional-documents/pdfs/ps09-2014-guidelines-on-sedation-and-or-analgesia-for-diagnostic-and-interventional-medical-dental-or-surgical-procedures.pdf>

licensing standards can help ensure that facilities carrying out major cosmetic surgical procedures met minimum staffing requirements necessary to ensure safe care and have appropriate anaesthesia equipment.

Guidelines issued by the Medical Board of Australia, which focus on individual practitioners and not the facilities, are not developed to address these issues. However, the standards required of licensed facilities under the Private Health Facilities Act have been developed to address these risks.

Accordingly, the Ministry is considering the need to provide further regulatory oversight in this area by creating a new class of private health facilities of “cosmetic surgery”. However, a key issue with creating a “cosmetic surgery” class is ensuring that the class is properly defined to ensure that high risk procedures are appropriately captured in the definition while not including low risk surgical procedures that can be safely carried out in unlicensed premises. To that end, a possible definition of the new class is a facility that is licensed to:

- Undertake cosmetic surgery, being any surgical procedure (other than a dental procedure³) that is intended to alter or modify a person’s appearance or body, and
 - that involves the administration of a general , epidural, spinal or major regional anaesthetic (including Biers Block) or sedation resulting in more than conscious sedation; OR
 - that involves one of the following procedures (however named): breast augmentation/reduction, mastopexy or mastopexy augmentation, buttock augmentation/reduction/lift, pectoral implants, penis augmentation, abdominoplasty (tummy tuck), liposuction, belt lipectomy, large volume fat transfer, brachioplasty (arm lift), rhinoplasty, facelift, neck lift, facial implants, lower eyelid blepharoplasty, canthoplasty.

This definition focuses on the use of anaesthesia and sedation and certain types of specific procedures. The procedures listed are high risk procedures that are preliminarily considered should only be undertaken in a licensed facility regardless of the level of anaesthesia or sedation that is used. This is due to:

- the risk of the procedure itself (eg the significant risk of haemorrhage associated with a breast augmentation), or
- in cases where conscious sedation and/or local anaesthetic are intended to be used, the increased risk that higher doses of anaesthetic agents will in fact be used due to the level of patient discomfort generated by the procedure itself (which may result in increased doses of doses of sedatives and/or local anaesthesia such that deep sedation or local anaesthetic toxicity may occur inadvertently).

³ Dental procedures are currently excluded from the anaesthesia and surgical class under the Private Health Facilities Regulation 2010

However, there may be additional procedures that should be captured within the definition to ensure that, regardless of the level of anaesthesia/sedation used, the procedures can only be carried out in licensed premises. The Ministry would like to hear submissions on whether other procedures, particularly vaginoplasty and calf implants, should be specifically included in the definition.

The Ministry does recognise that there are issues with the above definition which relies, in part, on specific procedures undertaken. This is because the names of procedures may change and/or new cosmetic surgical procedures are likely to be undertaken in the future. Therefore the definition will need to be constantly under review and is likely to change over time. A definition based on the use of anaesthesia/sedation only could be used to define the cosmetic surgery class. However, there are also issues associated with relying only on the use of anaesthesia or sedation in the definition. For example, if the level of anaesthesia or sedation in the definition is set too high (such as only applying to general anaesthesia or more than conscious sedation), then procedures that carry serious risks regardless of the level of anaesthesia or sedation used will not be captured. On the other hand, if the level of anaesthesia or sedation in the definition is set too low, then the definition will capture a range of low risk procedures that can safely be carried out in a medical practitioner's room.

As a preliminary view, the Ministry considers that a definition that relies both on the use of anaesthesia or sedation and specific procedures, as outlined above, is preferable. However, the Ministry would like to hear submissions on whether the above definition is appropriate, or if there are alternative ways to define the cosmetic surgery class. However, in considering any definition, it is important to ensure that the definition only covers those areas where the risks associated with the procedure can only be adequately mitigated by way of requiring the facility to be licensed. That is, the definition should not cover low risk cosmetic surgical procedures that can be safely carried out in a medical practitioner's room.

In order to assist the Ministry in considering these issues, feedback is sought on the questions below.

Questions for consideration

- 2) Should a new class of "cosmetic surgery" be included in the Private Health Facilities Act and Regulation, requiring cosmetic surgery to only be undertaken in a licensed private health facility (or a public hospital)?
- 3) If so, is the following definition appropriate:
Cosmetic surgery is any surgical procedure (other than a dental procedure) that is intended to alter or modify a person's appearance or body, and
 - a. *that involves the administration of a general, epidural, spinal or major regional anaesthetic (including Bier's Block) or sedation resulting in more than conscious sedation; or*
 - b. *that involves one of the following procedures (however named): breast*

augmentation/reduction, mastopexy or mastopexy augmentation, buttock augmentation/reduction/lift, pectoral implants, penis augmentation, abdominoplasty (tummy tuck,) liposuction, belt lipectomy, large volume fat transfer, brachioplasty (arm lift), rhinoplasty, facelift, neck lift, facial implants, lower eyelid blepharoplasty or canthoplasty.

- 4) Are there any other procedures, such as vaginoplasty or calf implants, that should be included in the definition so that such procedures should only be carried out in a licensed private health facility (or public hospital)?
- 5) If the definition is not appropriate, how should the cosmetic surgery class be defined?

What standards should apply to a cosmetic surgery class of private health facilities?

If it is decided that cosmetic surgery should be licensed under the Private Health Facilities Act, the secondary issue is what standards should apply to such facilities carrying out cosmetic surgery.

All private health facilities are required to comply with the standards set out in Schedule 1 of the Private Health Facilities Regulation. In the main, the standards in Schedule 1 relate to the safety of premises and general clinical care issues, such as requiring buildings to be compliant with the Building Code of Australia, have appropriate fire safety procedures and requiring facilities to have appropriate policies to transfer patients needing a higher level of care. In addition, specific standards that apply to individual classes of private health facilities are then found in Schedule 2 of the Regulation. A copy of the standards in Schedule 1 are attached.

The Ministry's preliminary view is that if cosmetic surgery will form a new class of private health facilities, such facilities should be required to comply with the same standards as currently apply to the surgical and anaesthesia class (in addition to the general standards found in Schedule 1). A summary of these standards are set out below:

The anaesthesia class standards:

- Require facilities to have and maintain appropriate anaesthetic equipment in line with the Australian and New Zealand College of Anaesthetists' publication *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and other Anaesthetising Locations*; and
- Set minimum staffing requirements in line with the Australian and New Zealand College of Anaesthetists' publication *Recommendations on Minimum Facilities for*

Safe Administration of Anaesthesia in Operating Suites and other Anaesthetising Locations.

The surgical class standards:

- Require appropriate record keeping requirements in respect of the surgical procedure performed;
- Require facilities to have appropriate surgical equipment in each surgical room; and
- Require facilities to comply with the relevant day or overnight accommodation standards.

A copy of the standards that apply to the anaesthesia and surgical classes are attached.

While applying the anaesthesia and surgical standards, in addition to the standards set out in Schedule 1, to the cosmetic surgery class is considered preliminarily appropriate, the Ministry is keen to hear submissions as whether any amendments to these standards are required or whether any additional standard should be imposed on the cosmetic surgery class (if that class is created). For example, the cosmetic surgery class could be required to comply with the standards set out in the Agency for Clinical Excellence's *Minimum Standards for Safe Procedural Sedation*.⁴ These standards set out standards of care that apply pre-procedure, intra-procedure and post-procedure, including appropriately assessing risk and having appropriate staff to assist in the procedure.

Questions for consideration

- 6) If a new class of cosmetic surgery is created under the Private Health Facility Regulation, should the standards currently applying to the anaesthesia and surgical class apply to the cosmetic surgery class (in addition to the standards set out in Schedule 1)?
- 7) Should there be any amendment to these standards as they apply to the cosmetic surgery class?
- 8) Should additional standards, for example compliance with the Agency for Clinical Excellence's *Minimum Standards for Safe Procedural Sedation*, be imposed on the cosmetic surgery class?

Submissions

The Ministry of Health would like to hear submissions on the issues raised in this paper. Any submissions on this paper should be sent to:

⁴http://www.aci.health.nsw.gov.au/_data/assets/pdf_file/0006/218580/Minimum_Standards_for_Safe_Procedural_Sedation_Project_-_Final_-_updated_June_2015.PDF

Legal and Legislative Services Branch
NSW Ministry of Health
Locked Bag 961
NORTH SYDNEY 2059

Submissions may also be made via email to legalmail@doh.health.nsw.gov.au. Submissions must be received by **29 January 2016**.

Individuals and organisations should be aware that generally submissions made in respect of the Discussion Paper may be made publically available under the Government Information (Public Access) Act 2009. The Ministry of Health, in considering its response to the Discussion Paper, may also circulate submissions for further comment to other interested parties or to publish parts of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be stated clearly and marked.

Private Health Facilities Regulation 2010

Schedule 1 Licensing standards for private health facilities generally

(Clause 4 (1) (a))

Division 1 Environment

1 Compliance with Australasian Health Facility Guidelines

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

2 Compliance with Building Code of Australia

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

3 Regular risk assessment and safety inspection program

- (1) A private health facility must have a written risk assessment and safety inspection program for the assessment of risks and hazards in the private health facility.
- (2) Without limiting subclause (1), a risk assessment and safety inspection program must include:
 - (a) a process for carrying out risk assessments and safety inspections, and
 - (b) a timetable for carrying out those assessments and inspections.
- (3) A private health facility must ensure that risk assessments and safety inspections are carried out in accordance with the risk assessment and safety inspection program.

4 Maintenance of buildings, facilities and equipment

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

5 Equipment and stores

- (1) Medical, surgical and nursing equipment, appliances and materials that are necessary for the type and level of patient care in the private health facility must be readily available at the facility.
- (2) Without limiting subclause (1), the following equipment must be readily available at a private health facility:
 - (a) resuscitation equipment, for use in advanced life support, that complies with the *Standards for Resuscitation: Clinical Practice and Education* published by the Australian Resuscitation Council and the Australian College of Critical Care Nurses in March 2008, in so far as those standards are relevant to the facility, and
 - (b) in the case of a facility that admits child patients, paediatric resuscitation equipment.
- (3) The medical, surgical and nursing equipment, appliances and materials required to be available at a private health facility by this clause must be provided in quantities that are appropriate for the safe and effective provision of the services for which the facility is licensed.

6 Communication system

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

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

7 Fire safety and emergency response

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

8 Disaster planning

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

9 Back-up power supply

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

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

10 Waste and hazardous substances

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

11 Food services

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

Division 2 Clinical care

12 Staff qualifications and experience

A private health facility must have:

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

13 Clinical records and patient information

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

14 Infection control

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

- (4) All decontamination systems and processes for reusable medical devices and clinical equipment must comply with AS/NZS 4187:2003, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*.

15 Dispensaries

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

- (a) the dispensary must be under the control of a pharmacist at all times,
- (b) all dispensing must be personally supervised by a pharmacist,
- (c) the dispensary must comply with the standards prescribed by the regulations under the *Pharmacy Practice Act 2006* for or with respect to the safe and competent delivery of pharmacy services,
- (d) if the dispensary is not a pharmacy business within the meaning of the *Pharmacy Practice Act 2006*—the functions of the dispensary are to be limited to the provision of a service to the private health facility and its patients,
- (e) the services provided by the pharmacist in control of the dispensary must include:
 - (i) the provision of all medication for patients, whether on prescription or otherwise, in a form that is suitable, as far as practicable, for direct administration or utilisation, and
 - (ii) the provision of advice on drug compatibility, possible adverse drug reactions, appropriate doses for different classes of patients and medication policy, and
 - (iii) regular inspection of drug stocks and records to ensure proper storage of medication, proper stock rotation, withdrawal of stock that is outdated or no longer required and proper recording of drug use, and
- (iv) the establishment of written policies and procedures on the procurement, preparation, distribution and administration of medication and other therapeutic goods,
- (f) the pharmacist in control of the dispensary must make adequate provision for emergency drugs to be available to staff of the private health facility for the treatment of patients outside the normal hours of operation of the dispensary.

16 Identification of patients

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

17 Admission and separation

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

18 Transfer of patients

A private health facility must have procedures in place to transfer a patient to another private health facility or public hospital for care if:

- (a) the facility is not authorised to provide the care that the patient requires, or
- (b) in the event of complications arising during the treatment of the patient, the patient requires a higher level of care than is provided by the facility.

19 Patient records to be transferred with patients

If a patient is transferred from a private health facility to another private health facility or public hospital for care, a copy of any relevant clinical records and patient information maintained under clause 13 (1) of this Schedule must be transferred to the facility or hospital that is to receive the patient.

20 Privacy of patients

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

Division 3 Quality improvement

21 Incident and adverse event management

- (1) A private health facility must have a written incident management system outlining the procedures to be followed in the case of an incident or adverse event.
- (2) Without limiting subclause (1), an incident management system must provide for the following:
 - (a) identification of incidents and adverse events,
 - (b) notifying the Department about adverse events,
 - (c) investigation of incidents and adverse events,
 - (d) management of the outcomes of any such investigation.
- (3) A private health facility must ensure that the incident management system is complied with.
- (4) In this clause:

adverse event means an unintended injury to a patient, or a complication caused by the health care management of a patient, that results in disability, death of the patient or a prolonged hospital stay by the patient.

incident means any unplanned event resulting in, or that is likely to cause, injury or damage to a patient at a private health facility.

22 Complaints

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

23 Compliance audits

The licensee of a private health facility must conduct regular audits to ensure that the facility is complying with statutory requirements as well as the facility's policies and procedures.

24 Outcome audits

The licensee of a private health facility must ensure that regular audits are conducted to monitor the effectiveness of the policies and procedures of the facility as well as clinical services and patient outcomes.

Schedule 2: Licensing standards

(Clause 4 (1) (b))

Part 1: Anaesthesia class private health facilities

1 Sedation and anaesthesia

An anaesthesia class private health facility must have the following:

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

2 Minimum staffing requirements

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

Part 18: Surgical class private health facility

75 Concurrent licensing

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

76 Procedure register

- (1) A surgical class private health facility must have a procedure register that records the details of every surgical procedure that is carried out at the facility.
- (2) Without limiting subclause (1), the procedure register must contain the following:
 - (a) the patient's full name, gender, date of birth and clinical record number,
 - (b) the date, time and place that the surgical procedure was carried out,
 - (c) the name of the procedure,
 - (d) the name of any surgeon, surgeon's assistant, anaesthetist and scrub nurse involved in the procedure,
 - (e) the anaesthetic administered,
 - (f) the nature, and identification number, of any prosthesis used during the procedure,
 - (g) details of any complications arising during the procedure.

77 Clinical records

- (1) A surgical class private health facility must have a clinical record for each patient at the facility on whom a surgical class procedure is carried out.

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

78 Specialist equipment

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

- (a) an electrosurgical unit,
- (b) adequate instruments for elective use,
- (c) sterile instrument sets available for emergency procedures.

79 Minimum accommodation requirements

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

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

80 Accommodation standards

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

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