

Health Legislation Amendment Regulation (No. 2) 2017

Explanatory notes for SL 2017 No. 213

made under the

Hospital and Health Boards Act 2011
Private Health Facilities Act 1999

General Outline

Short title

Health Legislation Amendment Regulation (No. 2) 2017

Authorising law

Sections 138B and 282 of the *Hospital and Health Boards Act 2011*
Sections 10 and 151 of the *Private Health Facilities Act 1999*

Policy objectives and the reasons for them

The objectives of the *Health Legislation Amendment Regulation (No. 2) 2017* (the Amendment Regulation) are to amend:

- the *Hospital and Health Boards Regulation 2012* (HHB Regulation), to update the list of acute adult medical and surgical wards in which mandatory nurse-to-patient ratios are to apply; and
- the *Private Health Facilities Regulation 2016* (PHF Regulation) to require certain high risk surgical procedures to be performed only at licensed private health facilities.

Nurse-to-patient ratios

The *Hospital and Health Boards Act 2011* (HHB Act) provides a legislative framework for mandating minimum nurse-to-patient ratios in public sector health service facilities. Through minimum ratios, persons receiving care and treatment will benefit from improved patient safety and quality of care. In turn, this provides greater patient satisfaction and improved patient outcomes, including reduced re-admission rates and reduced post-operative mortality rates. Minimum ratios also provide safer workloads for the front-line public sector nursing and midwifery workforce, to improve recruitment and retention, staff satisfaction, and greater workforce sustainability.

The HHB Regulation currently prescribes acute adult medical, surgical and mental health wards in 27 public health facilities to which the mandatory nurse-to-patient ratios apply. The Sunshine Coast Hospital and Health Service has three hospitals prescribed for the purposes of nurse-to-patient ratios, at Caloundra, Gympie and Nambour.

The Sunshine Coast University Hospital (SCUH) commenced inpatient services in March 2017. The commission of the new SCUH has meant service changes for hospitals within the Sunshine Coast Hospital and Health Service. These changes impact on the application of mandatory nurse-to-patient ratios as Caloundra Hospital no longer has an acute adult medical ward, and the SCUH has both acute adult medical and surgical wards.

Despite it not being prescribed in regulation, the SCUH has been complying with nurse-to-patient ratios under the new service arrangements since 1 April 2017. The Amendment Regulation will ensure the compliance with mandatory nurse-to-patient ratios by the Sunshine Coast Hospital and Health Service is reflected in the HHB Regulation by prescribing the SCUH and removing the Caloundra Hospital.

Regulated surgical procedures in private health facilities

Licensed private health facilities are primarily regulated by the *Private Health Facilities Act 1999* (PHF Act) and the PHF Regulation. The PHF Act provides a framework for protecting the health and wellbeing of people receiving services at private health facilities. This is achieved by requiring compliance with a robust licensing regime, including compliance with standards to protect patient safety. The clinical and surgical procedures that must be carried out in a private health facility, and the staffing, safety and building requirements, are established and regulated by legislation, standards and related frameworks, including the Clinical Services Capability Framework.

At the time the PHF Act commenced, surgical procedures that required the administration of either heavy sedation or a general anaesthetic would have had to be performed in a private hospital or day hospital (both of which are defined as licensed private health facilities). This is because those procedures would have been captured under section 10(3)(a)(i) and (ii) of the PHF Act, which prescribe that procedures performed under general, spinal or epidural anaesthetic or with more than simple sedation must be performed in licensed private health facilities.

However, advances in medicine and changes in models of care have meant that some of these surgical procedures, such as certain liposuction and some breast augmentation, are now being performed using simple sedation or less. As such, these procedures have fallen out of the scope of the existing legislative framework and are now being performed in practitioners' rooms, which are not subject to licensing or regulation under the PHF Act. The number of procedures of this type that are being undertaken in unlicensed facilities has increased significantly in recent years.

While local anaesthesia is mostly safe, it carries some risk of serious complications which can lead to death. Risks include allergic reactions and inappropriate use at high volume, accidental intravascular injection, or the unintentional administration of an excessive dose or rate of injection which can lead to toxicity. The concurrent use of other drugs, such as sedatives, can also mask the development of central nervous system symptoms of toxicity. A patient's reaction to local anaesthetic can be unexpected and require urgent life-saving intervention.

There are also risks associated with simple sedation. In its *Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures*, the Australian and New Zealand College of Anaesthetists warns practitioners that a person does not transition from complete consciousness to general anaesthesia in a set of discrete, well-defined stages. Instead, a person will travel through various depths of sedation as a continuum. While the effects of sedatives are known, and dosages can be carefully controlled, the reactions of patients are variable. It is relatively easy for light sedation (which is unregulated) to quickly progress to deep sedation (which is regulated).

In 2015, the New South Wales Health Care Complaints Commission (HCCC) investigated a provider of cosmetic procedures, following complaints. It was found that across a 12-month period, 33 patients who underwent breast augmentation had questionable levels of sedation used in a premises not licensed for the level of sedation used. Six of those patients suffered serious and life-threatening adverse events, including cardiac arrest, with three patients requiring resuscitation. Following the HCCC investigation, New South Wales became the first state to regulate surgical cosmetic procedures, and require the performance of certain procedures to be performed only in licensed facilities. There has been discussion at a national level, and calls by the Australian Society of Plastic Surgeons, for all other Australian jurisdictions to follow with similar regulatory measures in order to increase patient safety.

In light of the above events, the Queensland Government decided it would seek public input into possible legislative changes to provide more protection for people undergoing surgical procedures currently able to be performed outside of licensed private health facilities. The focus of this consultation was on procedures that are commonly understood to be undertaken for cosmetic reasons, but which may also be undertaken for medical reasons or a combination of both. As a result of this public consultation, it is proposed to expand the procedures currently prescribed in the PHF Act and PHF Regulation to include a specified range of high risk surgical procedures.

The surgical procedures being prescribed include those that may require more sedation than was originally intended at the commencement of the procedure. Requiring these procedures to be performed in a licensed facility creates a safer environment for sedation. Therefore, the amendments to the PHF Regulation will mean a practitioner is not limited by the location or facility as to what sedation may be used for the procedure, as all of the surgical procedures will need to be conducted in a licensed private health facility.

The policy intent is to protect the health, safety and wellbeing of patients undergoing certain high risk surgical procedures in the private health sector in Queensland. The Amendment Regulation will achieve this by requiring these procedures be carried out in licensed private health facilities that are adequately prepared with staff and equipment. The intent is to minimise the risk of adverse events, and where adverse events do occur, to limit damaging consequences by ensuring rapid and effective management of the event.

Achievement of policy objectives

Nurse-to-patient ratios

To achieve the policy objectives it is proposed to amend schedule 2A of the HHB Regulation to add acute adult medical and surgical wards at SCUH, and remove Caloundra Hospital, as public health facilities that are required to meet mandatory nurse-to-patient ratios.

Regulated surgical procedures in private health facilities

The Amendment Regulation prescribes, for section 10(3)(b)(iii) of the PHF Act, certain surgical procedures by including them in the definition of a ‘day hospital health service’. The effect is that these surgical procedures can only be performed in licensed private health facilities, regardless of the level of sedation used, and are brought back under the legislative framework of the PHF Act, the PHF Regulation and the Private Health Facilities Standards.

Members of the public seeking these procedures in Queensland will benefit from a legislative framework designed to provide a safe and effective service, with optimum professional expertise in facilities deemed fit for purpose. In addition, prescribing these surgical procedures will enable the Chief Health Officer to approve, license and inspect the private health facilities in which these procedures are being performed. This will ensure the facilities adhere to the Private Health Facilities Standards made by the Chief Health Officer under the PHF Act.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives and guiding principles of the HHB Act, which include ensuring quality and safety in the delivery of public sector health services, and the PHF Act, which provides a framework for protecting the health and wellbeing of patients receiving services at private health facilities (including day hospitals).

The regulatory powers within the HHB Act and the PHF Act have previously been used to prescribe the facilities in which mandatory nurse-to-patient ratios apply, and to prescribe other high risk procedures in the definition of a ‘day hospital health service’, respectively.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

Nurse-to-patient ratios

The HHB Act specifies that wards subject to minimum nurse-to-patient ratios must be prescribed in a regulation. As such, the Amendment Regulation is the only effective means of requiring compliance with mandatory nurse-to-patient ratios in acute adult medical and surgical wards at the SCUH, and removing Caloundra Hospital from having to comply following closure of its acute adult medical ward.

Regulated surgical procedures in private health facilities

The Amendment Regulation is the only effective means of protecting the health, safety and wellbeing of patients undergoing certain high risk surgical procedures in the private health sector in Queensland.

Licensed private health facilities are required to have certain staffing levels, emergency procedures, and infection control measures, as well as increased reporting requirements – all measures which ensure increased patient safety. If practitioners are not required by legislation to perform the prescribed procedures in licensed private health facilities, the identified risks remain for patient safety.

Benefits and costs of implementation

Nurse-to-patient ratios

Implementation of mandatory nurse-to-patient ratios in acute adult medical and surgical wards at the SCUH will be met within existing budget allocations. Compliance with ratios will improve safety and quality of care for patients, and provide safer workloads for the nursing workforce.

Regulated surgical procedures in private health facilities

Prescribing high risk surgical procedures in the PHF Regulation, so they may only be carried out within licensed private health facilities, will ensure the provision of safe and appropriate facilities in which these procedures may be undertaken. Doing so seeks to draw back within the regulatory framework those procedures that have, due to advances in medicine and models of care, fallen outside the regulatory framework over time. The Amendment Regulation ensures the private health facilities legislation keeps pace with changes in medical practice and techniques.

The Amendment Regulation will ensure high risk surgical procedures are regulated as part of an established inspection and enforcement regime and will require the facilities in which the procedures are undertaken to be appropriately equipped to deal with adverse events to protect the health and wellbeing of patients.

There will be no additional costs for the majority of practitioners, who are already performing the prescribed procedures on licensed premises. However, there may be compliance costs, in the form of approvals, licences and accreditation, for unlicensed facilities if the remainder of practitioners wish to continue to perform the procedures in their consulting rooms. The current costs of approvals and licences are prescribed in the PHF Regulation. For a day hospital, an approval currently costs \$1491.50 (a one-off cost) and a licence to operate costs \$1491.50 for a period of up to three years. After this, a licence renewal fee is \$670.50 for a period of up to three years (these figures are current until 30 September 2017). Licensed premises are also required to achieve accreditation by a quality assurance entity. The costs for accreditation vary according to the accrediting body and the nature of the facility. Alternatively, as is currently the choice for many practitioners, arrangements can be made to carry out the procedures at another licensed private health facility.

For patients of affected practitioners, there is potential for the costs of the prescribed surgical procedures to increase in order to cover the difference in costs between a practitioner's rooms and fees charged by a licensed private health facility, or to cover licensing and accreditation costs if practitioners choose to pass on these costs to patients. The surgical procedures being prescribed are considered elective surgery, and patients considering these procedures are made aware that the costs are generally not covered by Medicare or by private health insurance.

By way of comparison, similar regulation coming into force in New South Wales led to only one unlicensed facility applying for a licence.

Costs associated with the administration of anaesthesia are an existing obligation for these types of procedures in line with the Medical Board of Australia guidelines and the Australian and New Zealand College of Anaesthetists professional standards.

Premises licensed under the PHF Act are required to meet specific building codes such as room size and equipment required, as outlined in Queensland Development Code MP5.5. It is expected that many procedure rooms already comply with these standards.

It is recognised that practitioners may require time to comply with the Amendment Regulation, for example by making arrangements to perform the prescribed procedures in a licensed private health facility, or to take the necessary measures to upgrade their consulting rooms to a level where they may be licensed under the PHF Act. Therefore, the Amendment Regulation includes a transitional provision, which provides that the amendments relating to prescribing of surgical procedures do not apply until 1 January 2018.

Consistency with fundamental legislative principles

The Amendment Regulation is consistent with fundamental legislative principles.

Consultation

Nurse-to-patient ratios

The proposal to require acute adult medical and surgical wards at SCUH to comply with mandatory nurse-to-patient ratios, and remove Caloundra Hospital from having to comply, was discussed at the meeting of the Ratios Implementation Working Group (RIWG) on 2 August 2017. The membership of RIWG comprises representatives from Hospital and Health Services, the Queensland Nurses and Midwives' Union and Queensland Health. The RIWG supports the making of the Amendment Regulation.

Regulated surgical procedures in private health facilities

The amendments to the PHF Regulation were developed following the Government's decision to publicly consult on whether legislative changes should be considered to provide more protection for people undergoing certain surgical procedures in the private health sector in Queensland.

The public consultation process was undertaken from 20 March 2017 to 14 April 2017, consisting of responses made via a consultation form to a discussion paper, *Regulation of certain cosmetic surgical procedures under the Private Health Facilities Act 1999*, and responses to an online poll. The discussion paper and poll were published on the Queensland Government's 'Get Involved' website, and the discussion paper was also provided directly to professional medical associations for targeted consultation.

Responses to the discussion paper were received from 24 respondents, including seven professional medical associations and the Queensland Health Ombudsman. In addition, three responses to the online poll were received. The responses showed overwhelming support for amending private health facilities legislation to require certain surgical procedures to be conducted only in licensed private health facilities.

The discussion paper proposed a list of surgical procedures, which was based on a prescribed list in New South Wales legislation. Respondents were asked to comment on whether this list was adequate, whether some procedures should be removed from the list, or whether additional procedures should be included.

A small number of respondents to the discussion paper recommended that up to eight procedures be removed from the proposed list of prescribed surgical procedures. These procedures were: breast augmentation, breast enhancement, liposuction involving the removal of >2.5 litres of lipoaspirate, necklift, rhinoplasty (non-surgical), vaginoplasty or labiaplasty, penis augmentation and facial implants. With the exception of rhinoplasty, vaginoplasty or labiaplasty and penis augmentation, respondents did not provide rationale to support the removal of these procedures.

Feedback was provided that rhinoplasty, vaginoplasty or labiaplasty and penis augmentation can be performed using non-surgical techniques, and as such should be removed from the list. As a result of this feedback, it was necessary to provide clarity and address confusion about the extent of the proposed amendments, so the Amendment Regulation makes it clear that the prescribed procedures are those performed *surgically*. This means any of the prescribed procedures that are performed only using non-surgical techniques, such as threads or laser, will not be subject to the new licensing requirements.

Respondents also suggested that additional procedures be included in the proposed list of prescribed surgical procedures. These procedures were: blepharoplasty (eyelid surgery); all facelifts; liposuction and fat transfer >250ml; surgery involving the penetration of the orbit (the cavity in the skull that contains the eye); meloplasty (surgery of the cheek); otoplasty (to repair or reconstruct ears, such as 'bat ears'); scalp reduction; body contouring; liposculpture; abdominal etching; other genital aesthetic procedures, such as monsplasty (pubic lift); other limb implants (bicep, tricep, deltoid, thigh/hip); all procedures conducted under IV sedation; and dental procedures.

An expert advisory panel was convened by the Department of Health to consider stakeholder feedback on the proposed list of procedures, including suggested additions to the list. The expert advisory panel comprised representatives from the Australian Society of Plastic Surgeons, the Australasian College of Cosmetic Surgery and the Australian Medical Association Queensland.

For each of the additional procedures that were suggested for inclusion in the prescribed list, advice was sought from the expert advisory panel about the safety of carrying out these procedures in practitioners' rooms and whether they should be performed only in a licensed facility. A specialist oculoplastic surgeon was consulted specifically about blepharoplasty, who advised that this procedure could safely be conducted in rooms.

The panel agreed that solid body implants present a risk as they are foreign objects introduced into the body, and recommended that a more comprehensive list of implant procedures than the New South Wales list be prescribed in the PHF Regulation. Therefore, in addition to calf and pectoral implants, the Amendment Regulation prescribes biceps, triceps and deltoid implants. The panel also recommended the inclusion of monsplasty because the procedure is often performed in conjunction with labiaplasty, as the need for it can become apparent at that time (labiaplasty is included in the list of prescribed procedures).

Given discussions, a decision was made to lower the listed volume of lipoaspirate transferred during a fat transfer procedure from that prescribed in the New South Wales legislation. Because of safety concerns, where more than 500 millilitres of lipoaspirate is transferred in a fat transfer procedure the procedure must be carried out in a licensed private health facility. Consultation on the legislative changes to the PHF Regulation has been supported by other consultation processes, including:

- advocacy from the Australian Society of Plastic Surgeons for greater regulation of cosmetic surgery; and
- public consultation by the Medical Board of Australia prior to releasing its *Guidance to Practitioners Undertaking Cosmetic Medical and Surgical Procedures*, which showed clear support for guidelines and gave a strong indication that anything other than statutory regulation would not effectively protect consumers.

In addition, the Amendment Regulation closely mirrors the New South Wales legislation, which was developed following consultation with many of the same stakeholders (given the national reach of colleges, boards and facility operators).

Notes on provisions

Part 1 Preliminary

Short title

Clause 1 provides the short title of the *Health Legislation Amendment Regulation (No. 2) 2017*.

Part 2 Amendment of Hospital and Health Boards Regulation 2012

Regulation amended

Clause 2 provides that part 2 amends the *Hospital and Health Boards Regulation 2012*.

Amendment of sch 2A (Wards subject to minimum nurse-to-patient and midwife-to-patient ratios)

Clause 3(1) amends schedule 2A to omit the entry for Caloundra Hospital. As Caloundra Hospital no longer has an acute adult medical ward, it is no longer subject to the requirement to comply with mandatory nurse-to-patient ratios.

Clause 3(2) inserts an entry for the new Sunshine Coast University Hospital acute adult medical and surgical wards. This will ensure those wards comply with the mandatory nurse-to-patient ratio requirements under the *Hospital and Health Boards Act 2011*.

Part 3 Amendment of Private Health Facilities Regulation 2016

Regulation amended

Clause 4 provides that part 3 amends the *Private Health Facilities Regulation 2016*.

Amendment of s 3 (Day hospital health services)

Clause 5 amends section 3 to insert a new subsection (2) to add a list of surgical procedures that are considered a health service within the meaning of a *day hospital health service*. The effect of this amendment is that those procedures will be regulated under the *Private Health Facilities Act 1999*, meaning they can only be conducted in a licensed private health facility.

The procedures are:

- abdominoplasty;
- belt lipectomy;
- biceps implants;
- brachioplasty;

- breast augmentation or reduction;
- buttock augmentation, reduction or lift;
- calf implants;
- deltoid implants;
- facelift, other than a mini-lift that does not involve the superficial musculoaponeurotic system (SMAS);
- facial implants that involve—
 - inserting an implant on the bone; or
 - surgical exposure to deep tissue;
- fat transfer of more than 500 millilitres of lipoaspirate;
- labiaplasty;
- liposuction that involves removing more than 2.5 litres of lipoaspirate;
- mastopexy or mastopexy augmentation;
- monsplasty;
- neck lift;
- pectoral implants;
- penis augmentation;
- rhinoplasty;
- triceps implants; and
- vaginoplasty.

Insertion of new s 12

Clause 6 inserts new section 12 – a transitional provision to provide that new section 3(2) will not apply until 1 January 2018.

This will give practitioners sufficient time to arrange to perform the prescribed procedures in a licensed private health facility, or to take the necessary measures to upgrade their consulting rooms to a level where they may be licensed under the *Private Health Facilities Act 1999*.