

# Day Procedure Centres providing Aesthetic Treatments

## *Health Services Establishments Act 2006*

Certain cosmetic injectables are classified as Schedule 4 (S4) substances under the *Poisons Act 1971* (Poisons Act), which means that they can only be possessed and supplied by authorised healthcare professionals.

Privately Practising Registered Nurses (PPRN) can apply for authorisation from the Minister for Health under Section 25A of the Poisons Act, so they can legally possess and supply S4 medications if they oversee a Day Procedure Centre (DPC). The DPC must first be approved by the Secretary of the Department of Health.

An approved DPC is one that is licensed under the *Health Service Establishments Act 2006* (HSE Act).

This document provides guidance for facilities providing Aesthetic Treatments who are considering applying for a licence under the HSE Act.

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## Introduction

### What is the Health Service Establishments Act 2006?

The HSE Act requires that all private Health Service Establishments (HSE) in Tasmania performing licensable procedures are licensed.

Licensing provides an assurance that private health service establishments in Tasmania are providing safe, quality services, in circumstances where the public are unable to obtain this assurance for themselves. Quality and safety standards are determined and audited in accordance with licensing standards and accreditation requirements.

The Department of Health (DoH) is the responsible entity for administering the HSE Act and the [Health Service Establishments Regulations 2021](#) (HSE Regulations).

It is important to note that the licence relates to the physical building, not to the healthcare professional performing the procedure.

The Licensee is responsible for ensuring procedures are being performed by qualified healthcare professional/s in an appropriate setting that is safe, with the right equipment and processes in place to ensure the delivery of safe, high quality health care for the Tasmanian people.

### What are licensable procedures?

In Tasmania, licensing is determined by the type of procedures performed in a HSE. Licensable procedures under the HSE Act are defined as Type A, B, and C, which is based on the Australian Government classification of procedures for private health insurance Default Table Benefit purposes. Section 5 of the HSE Act requires all establishments performing Type A and/or Type B procedures to be licensed. Any HSE where only Type C procedures are undertaken does not require licensing unless, having regard to public safety and the quality of the service to be provided, the Department's Secretary considers that they should hold a licence.

The DoH primarily takes guidance about procedure types by reference to the specific Medical Benefits Schedule (MBS) item number listings, found in the definitions and schedules sections of the *Private Health Insurance (Benefit Requirements) Rules 2011*. This reference point was adopted partly because the classification of procedures is frequently updated to reflect current practice as much as possible.

### I don't perform Type A or B procedures, why do I need to be licensed?

There is no requirement under the HSE Act for an establishment providing Aesthetic Treatments to be licensed.

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However, if a PPRN is working independently, without a medical practitioner on site, to provide cosmetic injectables, they may **voluntarily** choose to apply for a licence under the HSE Act.

Certain cosmetic injectables are classified as Schedule 4 (S4) substances in the Poisons Act, which means that they can only be possessed and supplied by authorised healthcare professionals.

A registered nurse may possess, offer, or agree to supply, dispense, and administer an S4 substance if they are authorised to do so in writing by the Minister for Health under section 25A of the Poisons Act.

A PPRN can apply for authorisation from the Minister for Health if they oversee a DPC. The DPC must first be approved by the Secretary of the Department of Health.

An approved DPC is one that is licensed under the HSE Act.

Therefore, obtaining a Licence under the HSE Act allows the PPRN to apply for authorisation under 25A of the Poisons Act, thus providing a legal pathway for the PPRN to supply S4 substances for cosmetic injectables.

## Requirements for Licensing

Facilities providing Aesthetic Treatments who **choose** to apply for a licence under the HSE Act must be able to comply with the statutory requirements specified in the HSE Regulations.

Applicants should **carefully consider** whether they can meet the following elements before applying for a licence. If the following cannot be evidenced, it is unlikely that the application will be successful.

### I. Facilities and Equipment

Schedule 1 part 1 of the HSE Regulations states that the construction of Class 9a buildings specified in the National Construction Code, within the meaning of the Building Act 2016, must be observed in respect of a private hospital or day-procedure centre. This is to ensure that licensed HSEs meet National Construction Code (NCC) requirements in relation to health, safety and amenity, including access for people with disability.

The NCC includes several mandatory Performance Requirements however the NCC allows for some flexibility for achieving compliance by allowing a range of building solutions. Compliance with the relevant performance requirements of the NCC can be achieved by complying with the relevant 'deemed-to-satisfy' requirements for the NCC.

The Building Occupancy Certificate will state the building class. This should be obtained by the Applicant from the building owner and submitted with the application form.

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If the building is a Class 5 or 6, it may also be suitable for licensing an establishment providing Aesthetic Treatments as clients/patients remain ambulatory and do not require sedation. However, the building/treatment rooms would need to satisfy the following:

Sanitary and other facilities	
Washbasins	The area in which procedures are performed must be provided with (either in the room itself or close so that they can access the treatment room without opening doors): <ul style="list-style-type: none"> <li>a) One wash basin for each 10, or part 10 employees; and</li> <li>b) An adequate supply of hot and cold water controlled by foot operated or other suitable means which allows the use of a tap without hand contact</li> </ul>
Sanitary facilities	Sanitary facilities for customers must be provided and must include not less than- <ul style="list-style-type: none"> <li>a) One water closet; and</li> <li>b) One wash basin</li> </ul>
Prevention of scalding	Every bath, shower and hand basin used by clients/patients is installed with a system or mechanism to avoid the risk of scalding by controlling the outlet temperature of hot water.
Emergency access	
Evacuation plan	A health service establishment must ensure that— <ul style="list-style-type: none"> <li>a) an evacuation plan for all clients/patients and members of staff at the health service establishment is prepared; and</li> <li>b) the evacuation plan is displayed in a prominent position at the entrance foyer or reception area of the health service establishment and in each common room, recreational or rest area or other place where client/patient care is provided; and</li> <li>c) all staff are trained in its implementation.</li> </ul>
Emergency lifts	If applicable, at least one emergency lift must be installed in a building in which client/patient care areas are located at a level that does not have direct egress to a road or open space.
Emergency services access	In the event that a client/patient needs to be carried out by stretcher, there needs to be enough space in corridors / doorways for the stretchers to have access:  Ferno 26T Ambulance Stretcher – 55cm

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Premises	
Cleanliness	Premises must be a clean and hygienic condition.
State of repair	Premises must be in a proper state of repair.
Health & Safety	Premises must be kept free of hazards or the accumulation of materials which may become offensive, injurious to health or likely to facilitate the outbreak of fire.
Equipment	
Suitability	All facilities, equipment, furnishings and fittings at the health service establishment are suitable for the kind or kinds of health services being provided by the health service establishment.
Cleanliness and state of repair	All facilities, equipment, furnishings and fittings at the health service establishment are <ul style="list-style-type: none"> <li>(a) kept in a proper state of repair and maintained in good working order; and</li> <li>(b) kept in a clean and hygienic condition.</li> </ul>
Locked cabinet	Suitable storage must be in place for S4 substances to allow them to be locked securely away. This includes S4 substances that require cold chain management.
Treatment bed	Suitable treatment bed / chair / trolley must be available for clients/patients to align with treatments provided and recovery.
Infection Prevention and Control	
Sterilisation of equipment and instruments	If the establishment does its own sterilisation, all equipment and instruments must be sterilised in accordance with the AS/NZS 4187:2014 – <i>Reprocessing of reusable medical devices in health service organisations</i> and AS/NZ 4815:2006 – <i>Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment.</i>

As part of the licence application process the Regulation, Licensing and Accreditation (RLA) Unit may request that a Building Surveyor is engaged to assess and provide a report as to the suitability of the building's intended use, having regard to the requirements in the HSE Regulations. This will be at the applicant's expense.

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## 2. Clinical Standards

### Accreditation

Once licensed under the HSE Act, the establishment must gain accreditation under the [National Safety and Quality Health Service Standards for Primary and Community Healthcare Services](#).

### Guiding Principles

The *Guiding Principles for Private Day Procedure Centres providing Aesthetic Treatments* has been implemented by the RLA Unit through consultation with subject matter experts and published to ensure the provision of safe clinical care.

Guiding Principles are used as part of the RLA Unit Auditing Program to assess compliance of the health service establishment against the HSE Act and the HSE Regulations, respective licence conditions and applicable clinical standards.

Licensed DPCs providing Aesthetic Treatments must adhere to them.

### Medical Advisory Committee

A Medical Advisory Committee must be put in place that is responsible for matters concerning:

- Clinical practice at the establishment
- Safety and care of the clients/patients
- Safety and Quality of services provided, and
- Investigating adverse events, incidents and complaints.

It should include, as a minimum, a medical practitioner, a consumer representative, and an independent representative (not connected to the establishment in any way).

Minutes and actions must be maintained and must be provided to the RLA Unit on request.

### Safety and Quality Standards

The applicant must be able to demonstrate how their establishment meets the [National Model Clinical Governance Framework](#) as published by the Australian Commission on Safety and Quality in Health Care (ACSQHC).

A feedback and complaints process must be in place, with evidence of review and quality improvements implemented from the feedback/complaints.

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## Emergency response

Systems and processes must be in place should the client/patient have an adverse event / incident. The applicant must be able to demonstrate how:

- The client/patient would be treated and by whom
- The client/patient would be monitored and by whom
- Emergency response would be called (Ambulance Tasmania) and by whom

Consideration must be given to how an adverse event would be managed by a sole practitioner, working independently, with no other workers within the licenced facility to ensure quality care and safety of the patient for best outcomes.

A documented risk assessment must be completed, and risk register maintained.

## 3. Staffing

Staff working within the establishment must be appropriately trained for the roles they are required to perform. PPRNs must have the appropriate qualifications in aesthetic treatments or have had significant education, training and experience to perform the clinical procedures. Evidence of qualifications and/or education, training and experience as part of the licence application.

The [Professional Practice and Regulatory Requirements - Privately Practicing Registered Nurses - Cosmetic Injectables Industry](#) outlines the requirements to demonstrate ongoing competence, safe practice and compliance professionally, and in accordance with the Tasmanian legislation. It also outlines an audit framework against which compliance will also be measured in line with licensing requirements.

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## Completing an application for licensing

There are three parts to the application. Each part needs to be completed to the best of the applicant's knowledge. There may be some parts where further collaboration or clarification on how this applies to individual services is needed from the RLA Unit.

### Part 1

Part 1 gathers information about the business, the procedures that are proposed to be performed, the staffing and corporate governance arrangements and the building. Part 1 includes:

- Form 1 – New Licence Application
- Form 1A – Director's Statutory Declaration
- Form 1B – Conviction Check Consent Form - Licensee

All forms must be completed.

### Part 2

Part 2 gathers information on the clinical governance arrangements of the service. The health service must ensure that the safety and quality requirements underpinning clinical governance are supported with policies, procedures, and other applicable documentation.

Sometimes new policies and procedures need to be developed by the applicant (or existing policy and procedures revised). The RLA Unit provide guidance and support to ensure the policies and procedures meet the statutory safety and quality requirements.

These requirements include infection prevention and control; medication safety; management and reporting of clinical incidents, processes for recognising and responding to client's/patient's clinical deterioration; feedback and complaints management; and ensuring the delivery of safe clinical practice.

During development, changes to documents may be required and additional documents requested, depending on the individual service. The RLA Unit will provide assistance and advice on additional documents as appropriate.

Part 2 includes:

- Form 2 – Clinical Governance Requirements
- Form 2A – Infection Prevention & Control Requirements

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### Part 3 - Accreditation

All licensed DPCs are required to be accredited.

DPCs that are classed as low risk/minimally invasive may request to be accredited under the [National Safety and Quality Health Service Standards for Primary and Community Healthcare Services](#).

#### **Disclaimer**

Assessment and review of documents provided by the licence applicant will be undertaken by the RLA Unit prior to a determination being made on the application by the Secretary. The initial documents provided do not necessarily have to reflect the final package as some changes may be required to ensure the statutory requirements are met. The RLA Unit will work through this process with the applicant once the application package has been submitted.

### How much does the licence application cost?

The cost of a new licence application is prescribed within the *Health Service Establishments Regulations 2021* (the Regulations) and is set at 1100 fee units.

As at 4 May 2022 this equates to \$1815. The up-to-date fee unit amount can be found here: <https://www.treasury.tas.gov.au/economy/economic-policy-and-reform/fee-units>

There is also an annual renewal fee payable by 31 December each year. The renewal fee is dependent on the licence class/es and type of establishment, any specialised services, whether child client/patients are treated and the number of beds/treatment rooms

### How long does it take to process an application?

The DoH aim to process all applications within 12 weeks. However, this is very much dependent on the complexity of the HSE, the procedures to be performed and if some level of accreditation is already in place or not.

If a large number of policy and procedures need to be developed, the licence application process can take significantly longer.

### I am a franchisee of a larger organisation. Who is responsible for the licence?

The licence will be in the business name and therefore the licensee is normally the business/company owner (ABN/ACN).

Even if you are a franchisee, it is your business, and you will solely be named on the licence (in line with the details you complete on the application form).

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## Questions and further information

For all questions, or further information about Licensing, please contact the Regulation, Licensing and Accreditation Unit on 6166 3856 | [hslicensing@health.tas.gov.au](mailto:hslicensing@health.tas.gov.au)

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