Information Sheet

Day Procedure Centres providing Aesthetic Treatments

Health Services Establishments Act 2006

Department of **Health**

Tasmanian Government

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.

Health Services 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.

Full details of the HSE Act and HSE Regulations can be found here:

HSE Act (www.legislation.tas.gov.au/view/whole/html/inforce/current/act-2006-017)

HSE Regulations (www.legislation.tas.gov.au/view/html/inforce/current/sr-2021-076)

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. 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.

Type A procedure means a procedure involving professional attention normally requiring admitted overnight hospital stay.

Type B procedure means a procedure involving professional attention normally requiring admitted hospital treatment that does not include part of an overnight stay.

Type C procedure means a procedure involving professional attention that does not normally require admitted hospital treatment.

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.

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.

Facilities and Equipment

Schedule 1 part 1 of the HSE Regulations states that Low-Risk Class Day Procedure Centres must be a building classification of 5 as specified in the National Construction Code, within the meaning of the Building Act 2016 (unless the Secretary determines that for public safety and quality it must be a class 9a building). 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 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.

Aesthetic Treatments as clients/patients remain ambulatory and do not require sedation.

The building/treatment rooms would also 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):

  a) One wash basin for each 10, or part 10 employees; and

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

- Sanitary facilities

  Sanitary facilities for customers must be provided and must include not less than-

  a) One water closet; and
  b) One wash basin

- 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—

  c) an evacuation plan for all clients/patients and members of staff at the health service establishment is prepared; and
  d) 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
  e) all staff are trained in its implementation

- 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

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

  a) kept in a proper state of repair and maintained in good working order; and
  b) kept in a clean and hygienic condition.

- 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 – *Reprocessing of reusable medical devices in health service organisations* and AS/NZ 4815:2006 – *Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*.

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.

Clinical Standards

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* (https://www.safetyandquality.gov.au/standards/primary-and-community-healthcare).

Initial assessment by the accrediting agency should occur within 10 working days from the date of licence issue as per *Advisory AS18/02 Interim Accreditation for newly established health service organisations* (https://www.safetyandquality.gov.au/sites/default/files/2019-06/as18_02_interim_accreditation_for_newly_established_health_service_organisations.pdf)

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.

The *Nursing and Midwifery Board of Australia - Position statement on nurses and cosmetic medical procedures (nursingmidwiferyboard.gov.au)* provides further guidance.

Medical Advisory Committee

A Medical Advisory Committee must be in place and 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).

*(*https://www.safetyandquality.gov.au/sites/default/files/migrated/National-Model-Clinical-Governance-Framework.pdf)

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

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.

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 be measured. (https://www.health.tas.gov.au/publications/professional-practice-and-regulatory-requirements-privately-practicing-registered-nurses-cosmetic-injectables-industry)

Completing an application for licensing

There are five parts to the application. Each part must 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. Applications which are not complete or do not provide all the required information for assessment, will be returned to the applicant for resubmission. Partially complete applications will not be accepted.

Part A

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

Part B

Part B gathers information on the proposed service.

Part C

Part C details all the documents which must be included to demonstrate corporate governance of the service.

Part D

Part D details all the policy and procedure needed to be included with the application.

It includes 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 review submitted policies and procedures to ensure they meet the statutory safety and quality requirements. If they do not meet the requirements, they will be returned to the applicant for revision.

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.

Part E

Must be completed by the applicant.

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.

How much does the licence application cost?

The cost of a new licence application is prescribed within the HSE Regulations and is set at 1100 fee units.

The up-to-date fee unit amount can be found here:

Fee Units | Treasury and Finance Tasmania (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.

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).

Questions and further information

For all questions, or further information about Licensing, please contact the Regulation, Licensing and Accreditation Unit on 6166 3856 | hselicensing@health.tas.gov.au

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