

# Licence Applications

## *Health Services Establishments Act 2006*

The object of licensing is to ensure the quality and safety of services delivered by private health service establishments through specifying the standards to be met by licence holders, and to ensure that services are provided to effectively meet the needs of Tasmanians in accordance with clinical practice guidelines and best practice standards.

All Health Service Establishments requiring licensing under the *Health Service Establishments Act 2006* are to comply with the statutory requirements specified in the *Health Service Establishments Regulations 2021*.

## Health Service Establishments Act 2006

The Department of Health (the Department) is the licensing and regulatory authority for all private sector healthcare services in Tasmania under the *Health Service Establishments Act 2006* (the Act) and the *Health Service Establishments Regulations 2021* (the Regulations).

Licensable procedures may carry significant quality and safety risks, and licensing provides for these risks to be assessed, addressed, and mitigated.

Regulation through licensing seeks to balance the business needs of the private health service industry with the health care and safety and quality needs of the public.

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.

This document provides guidance and background information on applying for a licence under the Act.

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## Which Health Service Establishments require licensing?

Under the Act, Health Service Establishments (HSE) are licensed according to the 'type' of procedure performed. The Act refers to Type A, B and C Procedures. Under section 5 of the Act:

- Premises where type A procedures are undertaken require licensing as a Private Hospital (PH),
- Premises where type B procedures but no type A procedures are undertaken require licensing as a Day-Procedure Centre (DPC) whether or not any type C procedures are undertaken, and
- Any premises where only type C procedures are undertaken do not require licensing as a PH or a DPC unless the Secretary is satisfied that, having regard to considerations of public safety and the quality of service to be provided, the premises should be licensed as a private hospital or a day-procedure centre.

Any premises where no type A, type B or type C procedures are undertaken do not require licensing as a PH or a DPC unless the Secretary is satisfied that, having regard to considerations of public safety and the quality of services to be provided, the premises should be licensed.

## What are type A, B and C procedures?

In Tasmania, licensing is determined by the type of procedures performed in a HSE. Licensable procedures under the 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.

Type A, B and C procedures are defined by the Act as:

- *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.*

Professional attention is defined in the Act as:

- *medical or surgical treatment, by or under the supervision of a registered medical practitioner, or*
- *obstetric treatment by or under the supervision of a registered medical practitioner or registered nurse with obstetric qualifications, or*
- *dental treatment by or under the supervision of a registered dental practitioner, or*
- *podiatric treatment by a registered podiatrist.*

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It is important to note that 'admitted' is not defined in the Act and in practice. DPCs in Tasmania do not 'admit' patients in the general understanding of the term. Licensing therefore focuses on the types of procedures performed in day procedure settings that require professional attention and align with the classes of day procedure centres listed below. Type B procedures are seen as procedures requiring treatment in an environment that has clinical governance systems in place, appropriately qualified clinical staff, specific clinical equipment, approved infection control procedures and practices, emergency and escalation procedures, and accreditation to the most appropriate Australian Health Services Safety and Quality Accreditation (AHSSQA) Scheme Standards for ongoing quality assurance. Type C procedures are generally low risk procedures that can safely be performed in medical practitioner's practice rooms in accordance with standard infection control practices and general safety and quality principles.

The Department 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 because the classification of procedures is frequently updated to reflect current practice as much as possible.

The Department recognises however that the assessment of some low risk/minimally invasive Type A and Type B procedures often require more information on how the procedure is performed and factors influencing the level of patient risk prior to determining the licensing requirement.

The Department seeks to avoid overregulating and therefore some procedures, despite their classification under the Rules, will not present sufficient clinical risk to warrant licensing.

The Department always meet with the HSE owner to discuss these procedures as we understand that relying on item numbers alone does not always allow comprehensive clinical assessment.

## Class of Private Hospitals

Private Hospitals (PH) can be licenced in one or more of the following classes:

- General
- Surgical
- Maternity
- Rehabilitation
- Psychiatric

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## Class of Day Procedure Centres

Day Procedure Centres (DPC) can be licenced in one of more of the following classes:

- Low risk/minimally invasive: low risk procedures that can be safely performed using conscious sedation.
- Endoscopic: providing endoscopic treatment that involves general anaesthetic or intravenous sedative other than conscious sedation.
- Surgical: surgical procedures involving general, spinal, epidural or major regional block anaesthetic or intravenous sedation other than conscious sedation.

## Specialised Services

In addition to the class, PHs and DPCs can also be licenced to provide specific specialised services<sup>1</sup>. These services include (but due to advances in technology are not limited to):

- coronary diagnostic and interventional procedures, all forms of cardiac surgery
- emergency department
- intensive care
- renal dialysis, haemofiltration or haemoperfusion
- maternity services
- neonatal intensive care
- services to a patient who a medical practitioner has reason to believe is suffering from severe mental illness
- tertiary vascular procedures
- neurosurgery
- nuclear medicine, and
- radiation therapy.

Some specialised hospital services have defined requirements under the Act while others do not because clinical technologies advance at a fast pace. Guiding Principles are therefore established by the Regulation, Licensing and Accreditation (RLA) Unit through consultation with subject matter experts and published to ensure the provision of safe clinical care within private HSEs seeking to provide specialised services where specific licensing requirements have not been prescribed within the Regulations.

If your application includes a specialised service where there are approved Guiding Principles, the RLA Unit will provide these.

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<sup>1</sup> Regulation Schedule I, Part 4 (2), *Health Service Establishments Regulations 2021*

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

## Building requirements

Schedule 1 part 1 of the 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 Hospital / Day Procedure Centre isn't built yet. When should the licence application be submitted? (Approval In Principle)

The application should be submitted when the building plans are being developed. The licence will be considered as an 'Approval In Principle' (AIP). An AIP remains effective for a period of one year from the date of issue, which allows time for the building work to be completed, the necessary policies and procedures to be developed and staff recruitment and training to take place.

If there is a delay, an extension to the AIP can be requested in writing (prior to the AIP expiry date).

[Click here to see the application process.](#)

### The Health Service Establishment is already operating. What happens now? (Temporary Licence)

To continue to perform Type A and B procedures, a licence must be applied for under the Act. Type C procedures can be performed without a licence.

Under the Act, there are several requirements which must be met for an application to be properly assessed and determined. The Department recognises that it can take some time for an establishment to compile all the evidence required to demonstrate compliance to the Act.

There is provision under the Act for a temporary licence to be issued whilst an application is being determined. This means that Establishments where licensable procedures are performed, can apply

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for a temporary licence to be able to continue performing said procedures before the final licence application determination is made.

[Click here to see the application process.](#)

## The Health Service Establishment is new, but it will operate in an existing building. When should the licence be applied for?

The application should be submitted before the HSE is intending to open (please refer to [How long does it take to process an application?](#)).

[Click here to see the application process.](#)

## 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
- 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 patient's clinical deterioration; feedback and complaints management; and ensuring the delivery of safe clinical practice.

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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

### **Part 3 - Accreditation**

All licensed PHs and DPCs are required to be accredited. PHs must be accredited to the [National Safety and Quality Health Service \(NSQHS\) Standards](#) developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC).

However, this is not always appropriate for DPCs that are classed as low risk/minimally invasive. Accreditation to the [National Safety and Quality Health Service Standards for Primary and Community Healthcare Services](#) may be a more appropriate accreditation.

The information on the procedures intended to be performed in the facility provided in Part I of the application will determine what class the health service will be licensed as. The RLA Unit can provide advice on which accreditation is required.

#### **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 16 August 2022 this equates to \$1870. 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 patients are treated and the number of beds/treatment rooms

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

The Department 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'm not sure whether my HSE requires licensing?

Please contact the Regulation, Licensing and Accreditation Unit on 6166 3856 | [hslicensing@health.tas.gov.au](mailto:hslicensing@health.tas.gov.au). We are happy to discuss with you whether your HSE meets the requirements for licensing. There is no cost for advice.

## How does the Department make its decision on whether a licence is required?

The priority of the Department is to ensure the safety and quality of clinical care provision for the Tasmanian population. The focus is to ensure that the procedures provided can be safely performed in an appropriate setting.

The Department assesses each licence application on an individual basis, taking into consideration:

- the safety and quality systems in place
- the physical environment of the HSE (the building, rooms, and equipment)
- accreditations already in place
- the procedures being performed

Where necessary, and before making a decision, relevant and expert clinical advice is sought on the procedures, and the setting in which they can be safely performed in consultation with professional colleges and subject matter experts.

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Periodically the Department also performs environmental scans of unlicensed private HSEs for a defined clinical service or sector in Tasmania to assess whether licensing is required under the Act. Please see the information sheet – Environmental scans for further information

## What's the benefit of licensing?

Licensing ensures the procedures can be performed in an appropriate setting that is safe, with the right equipment, procedure, and qualified workforce to ensure the delivery of safe, high quality health care for the Tasmanian people.

Holding a Licence provides assurance to the patients and customers of the HSE that it provides safe, quality services. This is especially important in circumstances where the public are unable to obtain this assurance for themselves.

Licensing also allows business to expand, providing additional services in line with their licence specifications. In addition, they can tender for Department of Health contracts and expand their service offering.

## 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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