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| Licence Application:  Clinical Governance Requirements |

# Licence Application: Clinical Governance Requirements

## Executive Summary

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* (the Act) are to comply with the statutory requirements specified in the *Health Service Establishments Regulations 2011* (the Regulations).

For clinical governance this specifically includes:

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| HSE Regs, Schedule 1, Part 2 (4) | *The licensee of a private hospital or day procedure centre is responsible for the safety of patients at the facility and the clinical governance of the facility.* |
| HSE Regs, Schedule 1, Part 2 (8) | *(1) A private hospital or day-procedure centre must have safety and quality arrangements in place that meet the requirements of the National Safety and Quality Healthcare Standard on Governance for Safety and Quality in Health Service Organisations as published by the Australian Council on Safety and Quality in Healthcare.*  *(2) In the absence of a national standard a private hospital or day-procedure centre must have safety and quality arrangements approved by the Secretary.*  *(3) These arrangements must, at a minimum, address safety and quality arrangements and their governance, clinical practice, credentialing and incident management.* |
| HSE Regs, Schedule 1, Part 2 (3) | *A licensee of a private hospital or day procedure centre must ensure that the credentials of all medical practitioners, and dentists, of the private hospital or day procedure centre are reviewed and approved in accordance with the National Standard for Credentialing and Defining the Scope of Clinical Practice as published by the Australian Council for Safety and Quality in Health Care.* |
| HSE Act, Part 5, Clause 39 | *The licensee of an establishment to which this section applies must not conduct the establishment unless –*  *(a) there is a person who carries out the duties of director of nursing of the establishment and who is responsible for the care of the patients in the establishment as prescribed by the regulations; and*  *(b) that person is a registered nurse and has such experience as the Secretary considers necessary for the proper conduct of the establishment.* |
| HSE Regs, Schedule 1, Part 2, Clauses 4 and 5.  Schedule 5 | *Clauses 4 & 5 provide statutory requirements for establishment of the Medical Advisory Committee* *and, role and functions.*  *Schedule 5 further outlines requirements for the Medical Advisory Committee regarding membership and procedures.* |
| HSE Regs, Schedule 1, Part 4, Clauses 10 | *(1) (a) any injury requiring medical attention that is sustained by a patient as a result of any accident at a private hospital or day procedure centre*  *(b) the transfer of a patient to another hospital as a result of an injury or iatrogenic condition*  *(c) the death of any patient at a private hospital or day procedure centre*  *(d) an incident classified as a sentinel event by the Australian Commission on Safety and Quality in Healthcare.*  *(2) As soon as practicable after any such incident occurs –*  *(a) details of the incident must be entered in an approved form ("the incident form") in the patient’s clinical record and must be reported to the director of nursing and to the patient’s medical practitioner and*  *(b) the incident must be investigated by the medical advisory committee and the results of the investigation must be entered in the incident form and*  *(c) if the patient was transferred to another hospital, details of the transfer must be entered in the incident form and*  *(d) if the patient was transferred to another hospital, or the incident was life threatening or fatal –*  *(i) the Secretary and the patient’s representative or next of kin must be notified orally of the incident and*  *(ii) a copy of the incident form must be forwarded to the Secretary.* |

This document provides guidance to ensure appropriate documented evidence regarding the health service’s governance arrangements is provided to support the licensing process.

The health service must ensure that the safety and quality requirements underpinning clinical governance are supported with policies, procedures and other applicable documentation.

The policies and procedures will be developed by the applicant, in collaboration with the Regulation Unit, to ensure all they are inclusive of the statutory safety and quality requirements.

These requirements include infection prevention and control; management and reporting of injuries, transfers, death and other sentinel events; feedback and complaints management; and clinical practice.

During development, changes to documents may be required and additional documents requested, depending on the individual service. A recommendation to issue a licence under the Act will be put forward to the Secretary for approval when all documentation has been successfully completed.

## Clinical Governance Requirements

Health service establishments must have in place a number of documents that outline and support the clinical governance processes for the establishment. The documents need to be provided to the Regulation Unit as part of the application process.

**Mandatory Requirements:**

**Policy and Procedures**

* Adverse Events Reporting and Management policy and procedure (see Regulations Schedule 1, Part 4 (10))
* Staff Incident and Occupational Health and Safety Management policy and procedure
* Feedback and Complaints Management policy and procedure
* Open Disclosure Policy

**Medical Advisory Committee (MAC)**

* Terms of Reference – including proper reference to the statutory responsibilities of a MAC under the HSE Regs
* List of MAC Members, qualifications and contact details, commencement date
* Process for credentialing health care practitioners and defining their scope of practice

**Workforce**

* Statement of duties for key clinical staff including responsibilities, delegations and reporting lines (ie: Director of Nursing)
* Evidence of a structured orientation program for new staff

**Clinical Practice**

* Operational polices/procedures specific to the clinical practice of the service (see Appendix 1 and 2 below)
* Incident management and reporting and logging system
* Mechanisms to identify patients ‘at risk of harm’ ie: admission criteria
* Management of deteriorating patient and escalation of care i.e.: transfer protocol to higher level care

**Non-clinical Practice**

* Procedures for recording and evaluating the quality of non-clinical services (ie: contracted services) provided at the health service and for correcting any identified problems

**Please Note:**

All policies and procedure must:

* Reflect where necessary the statutory requirements of the HSE Act and HSE Regs
* Be consistent with the National Safety and Quality Healthcare Standards published by the Australian Commission on Safety and Quality in Healthcare
* Include relevant external standards and programs recommended by learned colleges and other relevant professional organisations
* Be endorsed by the relevant clinical governance body of the establishment (ie: MAC or Board of Directors)
* Include a date of effect and revision date

## Resources

*Health Service Establishments Act 2006* and *Health Service Establishments Regulations 2011*

http://www.legislation.tas.gov.au

Australian Commission for Safety and Quality in Healthcare (ACSQHC)

http://www.safetyandquality.gov.au/

Australian Charter of Healthcare Rights

https://www.safetyandquality.gov.au/publications/using-the-australian-charter-of-healthcare-rights-2/

Open Disclosure

https://www.safetyandquality.gov.au/our-work/open-disclosure/

Review by Peers: A guide to professional, clinical and administrative processes

https://www.safetyandquality.gov.au/wp-content/uploads/2012/01/37358-Review-by-Peers1.pdf

Standard for Credentialing and Defining the Scope of Clinical Practice https://www.safetyandquality.gov.au/our-work/credentialling/

## Appendix 1 - Applicant Checklist

| **Document Name** | **Statutory Requirement / Required for accreditation / other** | **Included in application (yes/no)** |
| --- | --- | --- |
| **Governance and Quality Improvement Systems** | | |
| Clinical Governance plan relevant to the facility | Required for accreditation to Standard 1 |  |
| Documented vision, mission and strategic objectives | Required for accreditation to Standard 1 |  |
| Organisational chart | Required for accreditation to Standard 1 |  |
| Risk register and Management Plan | Required for accreditation to Standard 1 |  |
| Quality Improvement Plan – Activities (clinical and non-clinical) | Required for accreditation to Standard 1 |  |
| Plan and policy in the event of a fire or other emergency evacuation | Required for accreditation to Standard 1 |  |
| Consumer engagement plan and tools | Required for accreditation to Standard 1 |  |
| Medical Advisory Committee with Terms of Reference | **Statutory requirement** |  |
| Credentialing Health Practitioners and defining their scope of practice – plan and process (including checking professional registration requirements) | **Statutory requirement** |  |
| Workforce Statement of Duties, including responsibilities, delegations, reporting lines | **Statutory requirement** |  |
| Strategies for communicating with the clinical and non-clinical workforce i.e.: monthly staff meetings | Required for accreditation to Standard 1 |  |
| Staff performance management policy and program | Required for accreditation to Standard 1 |  |
| Staff orientation manual / program | **Statutory requirement** |  |
| Staff education and training policy & program – i.e.: annual competencies | Required for accreditation to Standard 1 |  |
| **Clinical Practice** | | |
| Mechanisms in place to identify patients at increased risk of harm; complexity / out of scope for service capability i.e.: admission criteria | In accordance with best practice, clinical care standards and service scope |  |
| **Incident and Complaints Management** | | |
| Clinical operational policies/ procedures/ guidelines/ pathways supported by best practice, applicable to the practice setting | **Specific policies depending on service will be required for safety and quality** (refer to Appendix 2) |  |
| Systems, processes and policies to manage deteriorating patient and escalation of care to higher level | In accordance with best practice, clinical care standards, and service scope |  |
| Incident management system | **Statutory requirement** |  |
| Policies and procedures regarding adverse event reporting and management | **Statutory requirement** |  |
| Feedback and Complaints Management system supported by policy and processes | **Statutory requirement** (Regulations, Sch 1, Part 4, 4(1)(i)) |  |
| Open disclosure process based on the national open disclosure standard, and clinical workforce training | Required for accreditation to Standard 1 |  |
| **Patient Rights and Engagement** | | |
| Patient charter of rights policies and practices consistent with the current national charter of healthcare rights | Required for accreditation to Standard 1 |  |

## Appendix 2

Please complete this table indicating the policies, procedures, guidelines, protocols, checklists that the service will need to develop and provide prior to the service commencing, and forward a copy to the Regulation Unit. Please add addition lines as necessary.

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| **Clinical Practice Policies** | **To Draft** | **Complete** |
| *ie: Patient transfer to higher level service – Communication Policy* |  |  |
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| **Clinical Practice Procedures** | **To Draft** | **Complete** |
| *ie: Bone Marrow Biopsy – Patient preparation and equipment - Procedure* |  |  |
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| **Clinical Practice Guidelines** | **To Draft** | **Complete** |
| *ie: Guidelines for care of patient post xxx procedure* |  |  |
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| **Clinical Practice Protocols** | **To Draft** | **Complete** |
| *ie:Provision of any standing orders* |  |  |
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| **Clinical Practice Checklists** | **To Draft** | **Complete** |
| *ie: Emergency Trolley checklist* |  |  |
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