Introduction of new Medical Devices or Procedures within Tasmanian Private Health Service Establishments

Advisory Notice 4/20 March 2020

Requirements for health services change over time. New innovations, technologies and treatments become available, enabling establishments to build clinical services to meet consumer demands, and improve care delivery for efficiencies and effectiveness.

In order to ensure that clinical governance underpinning safety and quality are in place, the licensee of a private health service establishment must inform the Department of Health's Regulation, Licensing and Accreditation Unit (RLA Unit) and discuss any proposed new medical device or interventions which may vary or increase the clinical risk profile of procedures undertaken at the establishment.

A Medical Device is –

(a) any instrument, apparatus, appliance, material or other article (whether used alone in in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one of more of the following:

i. Diagnosis, prevention, monitoring, treatment or alleviation of disease

ii. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap

iii. Investigation, replacement or modification of the anatomy or of a physiological process

iv. Control of conception

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(b) An accessory to such an instrument, apparatus, appliance, material or other article.

(Therapeutic Goods Act 1989)

A Therapeutic Intervention is – a procedure involving invasive contact with the patient by a health clinician or health service provider.

1 Purpose

- To ensure the new medical device, or new therapeutic intervention is within the current scope of the health service establishment's (HSE) licence.
- To assess the HSE's capacity to meet legislative, regulatory and approved national, professional or clinical standards regarding the proposed implementation of the new medical device or therapeutic intervention.
- To ensure the HSE's licensee has considered the clinical governance required to underpin safety and quality; and that any risks for the patient, health care workforce and the organisation have been thoroughly considered and mitigated; and
- To assure the Secretary of the Department of Health, the Minister for Health, and the general public that the private HSEs are providing access to safe, effective, high quality clinical care that is regulated through the Australian Department of Health's Therapeutic Goods Administration (TGA), approved through the Tasmanian Department of Health's Regulation, Licensing and Accreditation (RLA) Unit's processes, and accredited to the National Safety and Quality Health Service (NSQHS) Standards.

The RLA Unit staff can provide advice to the licensee of a private HSE regarding the introduction of a new medical device or therapeutic interventions, as required.

New therapeutic procedures, technologies or treatments which are experimental in nature and require introduction within a research framework will NOT be considered for implementation within a private HSE.

2 Process

2.1 The licensee of the HSE must advise the Manager of the RLA Unit of the proposed new therapy, including the introduction of a new device or implementation of a new therapeutic intervention, before any new procedures are undertaken.

2.2 If the Manager of the RLA Unit considers that the proposed new therapy may vary or increase the clinical risk profile of the HSE, the licensee must provide the following information to the RLA Unit for review and to ensure compliance with regulatory obligations for safety and quality, before any new procedures are undertaken:

2.2.1 The purpose for the proposed new therapeutic intervention/device, name of the device, manufacturer's information and contact, and information on the registration of the device with the Australian Register of Therapeutic Goods (ARTG)

2.2.2 any impact that the introduction of the new therapeutic intervention/device may have on public health services, to support the current demand for clinical services or where higher level services may be required for emergency management

2.2.3 where same/similar services involving the new therapeutic intervention/device is currently provided in the public health system

2.2.4 any impact on the healthcare workforce due to implementation of the new therapeutic intervention/device; and

2.2.5 formal audit is required and should be included for every new therapeutic intervention until such time that the new service is fully implemented. The HSE should determine periodic reporting data to be provided to the Department of Health as evidence of ongoing safety and quality.

2.2.6 Clinical Governance requirements including but not limited to those **listed below:**

Systems and Processes	***Alignment with NSQHS Standard 1***	***Suggested evidence***
An implementation plan for the new therapy or therapeutic device	Action 1.5	• Copy of the Implementation Plan
Assessment and identification of risks for patients and staff with identification of where new policies and procedures may be required	Actions 1.7 and 1.10	• Copy of the Risk Assessment • List of HSE's revised policies, procedures, guidelines, protocols, flow-charts • Provision of new policy documents
Consumer engagement	Action 1.13	• Patient admission information regarding the intervention/device for awareness and to inform consent • Discharge information for patients • PROMs audit data tool • Feedback / complaints process
Identification of diversity and high-risk groups	Action 1.15	• Revised HSE's Admission policy with specific inclusions/exclusions for the health service establishment
Assessment of workforce education, training and competency needs for implementation, use of equipment, ongoing safety and quality requirements	Action 1.20	• Education and training plan • Ongoing competency requirements • Evidence of training /education attendance records
Identification of specific requirements for credentialing of clinicians performing the new therapeutic intervention or using the new device	Action 1.23	• Evidence of: - credentialing of clinicians - proctoring, specific training undertaken - education attendance records
Provision of evidence-based care	Action 1.27	• Evidence of: - consultation with other providers, including from interstate or international jurisdictions who have provided the same or similar procedures - Health Technical Assessment (ie: best practice guidelines, clinical pathways, decision support tools) - Incorporation of ACSQHC's clinical standards and professional college guidelines into policy documents and practice - Provision of clinical audit tools
Processes for variation in clinical practice and health outcomes for quality assurance	Action 1.28	• Provision of data collection audit tools (ie: Morbidity Audit, PROMs) • Participation in clinical quality registries

3 Questions and further information

For all questions or further information, visit www.dhhs.tas.gov.au/privatehealthregulation or contact 6166 3856 or hselicensing@health.tas.gov.au