Health Technology Governance Policy

1. Purpose

The purpose of the *Health Technology Governance Policy* (the policy) is to specify clinical governance, safety and quality requirements for the introduction and use of health technologies within the WA health system. Health Service Providers are responsible for ensuring that health technologies are evidence-based and used safely, ethically, and in a clinically and cost-effective way.

Health technologies include procedures, diagnostic techniques and medical devices intended to prevent, diagnose or treat medical conditions, promote health or provide rehabilitation. Some health technologies (e.g. novel biological therapies and gene therapies) are complex and carry significant cost and/or service delivery implications that warrant a coordinated state-wide approach being taken to inform planning, funding and implementation in the WA health system.

This policy is a mandatory requirement for Health Service Providers under the *Clinical Governance, Safety and Quality Policy Framework* pursuant to section 26(2)(a) and (c) of the *Health Services Act 2016.*

This policy should be read in conjunction with MP 0161/21 *Procurement and Contract Management Policy* and MP 0004/16 *Procurement Development and Management System Policy*.

2. Applicability

This policy is applicable to all Health Service Providers with the exception of Health Support Services.

The requirements contained within this policy are applicable to the services purchased from contracted health entities where it is explicitly stated in the contract between the contracted health entity and the State of Western Australia or Health Service Provider. The State of Western Australia or Health Service Provider contract manager is responsible for ensuring that any obligation to comply with this policy by the contracted health entity is accurately reflected in the relevant contract and managed accordingly.

3. Policy Requirements

3.1 Responsibilities of Health Service Providers

- Health Service Providers are responsible for ensuring the safe introduction of appropriate, clinically effective health technologies.

- Health Service Providers must ensure robust governance within their processes to oversee the safety and quality requirements of health technology use, by embedding local oversight and decision-making and notifying the WA Policy Advisory Committee on Health Technology (WAPACT) when a health technology is a high-risk, high cost or highly specialised therapy.

3.2 Role of Health Service Providers' health technology committees

Health Service Providers must have local governance processes and procedures in place, either through a dedicated health technology committee or equivalent local authority, to:

- evaluate health technologies with respect to safety, efficacy and cost-effectiveness prior to introduction (information from national health technology assessment agencies or advice from the WAPACT is available for Health Service Providers to utilise if required).
- manage the safe introduction of health technologies, including monitoring, evaluating and reporting patient safety events associated with the technology or its use as per Therapeutic Goods Administration (TGA) requirements.
- ensure the use of unapproved health technologies and the off-label use of health technologies is appropriately governed and occurs within all relevant regulatory frameworks.
- ensure that staff members seeking to use a health technology hold the appropriate qualifications and credentials to competently utilise the technology and that its use is within their scope of clinical practice as per MP 0084/18 *Credentialing and Defining the Scope of Clinical Practice Policy*.
- regularly review the use of health technologies to ensure they continue to be evidenced-based and provided in a safe, ethical, and cost-effective manner.
- discontinue the use of health technologies where there is lack of evidence of effectiveness or evidence of potential harm.
- consider disinvestment in health technologies that are no longer cost-effective.

3.3 Health Service Providers to notify WAPACT of high-risk, high cost and highly specialised health technologies

Health Service Providers must notify the WAPACT of their intention to implement new or significantly extended health technologies that:

- are considered high-risk in that their long-term outcomes have not been fully assessed and still require close monitoring, or
- are highly specialised or have low anticipated case volume where centralised service delivery has potential safety and quality benefits, or
- may have statewide planning implications or significant impacts on service delivery, budget and equity of access, including all high-cost, highly specialised therapies approved for funding under the National Health Reform Agreement (NHRA) arrangements.

Advice is available from the WAPACT secretariat via WAPACT@health.wa.gov.au to clarify if a new health technology meets the above criteria.

Prior to notifying the WAPACT, Health Service Providers must ensure the proposed health technology has been assessed and supported for implementation by their health technology committee (or equivalent local authority). Notifications to the WAPACT must be made using the *WAPACT Notification Form* and accompanied by a *Service Specifications for Highly Specialised Therapies Application*.

3.4 Health Service Providers' reporting obligations to WAPACT

Health Service Providers must provide reports to the WAPACT regarding the implementation and experience with high-risk, high cost and highly specialised therapies as specified by WAPACT (taking into consideration the nature and risk of the technology, and any other reporting requirements that are in place (e.g. reporting to clinical quality registries or related to funding under the NHRA)).

4. Compliance Monitoring

The Medicines and Technology Unit, on behalf of the System Manager, will monitor compliance with this policy by requiring Health Service Providers to report information annually using the Health Technology Governance Policy Compliance Audit Tool which includes:

- Evidence of a dedicated health technology committee, or equivalent local authority.
- Processes and procedures in place to evaluate health technologies with respect to safety, efficacy and cost-effectiveness prior to introduction, and to review health technologies for cost-effectiveness and potential disinvestment.
- Process for notification of high-risk, high cost and highly specialised therapies to WAPACT.

The Medicines and Technology Unit will request the completed audit tool by 28 February each year. The System Manager may also request additional information on health technology governance arrangements within Health Service Providers, including details of local governance processes and procedures, to ensure alignment with policy requirements.

The Medicines and Technology Unit will also ensure that Health Service Providers meet the reporting requirements and timeframes specified by the WAPACT for high-risk, high cost and highly specialised health technologies.

5. Related Documents

The following documents are mandatory pursuant to this policy:

- Health Technology Governance Policy Compliance Audit Tool (via REDCap)
- WA Policy Advisory Committee on Health Technology Notification Form
- WA Health Service Specifications for Highly Specialised Therapies Application

6. Supporting Information

The following information is not mandatory but informs and/or supports the implementation of this policy:

- Health Technology Governance Policy Compliance Audit Tool (For local internal use only-writeable PDF)
- Western Australian Highly Specialised Therapies Governance Toolkit
- Australian Government: Therapeutic Goods Administration: Understanding regulation of off-label use of medical devices
- Australian Government: Therapeutic Goods Administration: Access an unapproved therapeutic good (health practitioners)

7. Definitions

The following definition(s) are relevant to this policy.

Term	Definition
Diagnostic technique	Includes but is not limited to diagnostic imaging and testing methods, equipment, implants, interventional diagnostic procedures, genetic markers, gene-based diagnostics, tumour markers and screening tests.
Health technology	A health technology is broadly defined as a procedure, diagnostic technique or medical device intended to prevent, diagnose or treat medical conditions, promote health or provide rehabilitation. Emerging health technologies such as novel biological therapies and gene therapies are in scope of this Policy. For the purpose of this Policy, the following technologies are generally considered out of scope: • pharmaceuticals unless a device also delivers a pharmaceutical • information and communications technology (ICT), unless it is integral to the clinical application of the health technology • public health activities and programs.
Health technology committee	Health technology committees (or otherwise named) evaluate, advise and oversee the introduction of health technologies into clinical practice.
High-risk health technology	A health technology that is high risk in terms of patient safety (clinical risk) and where either: • the long-term outcomes have not yet been fully assessed and still require close monitoring • the heath technology is highly specialised and of low case volume, or • centralisation has potential safety and quality benefits.
Medical device	A medical device is any instrument, apparatus, appliance or other article that (whether used alone or in combination, and including the software necessary for its proper application): • is intended to be used in, on, or for human beings for a therapeutic purpose • does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but may be assisted in its function by such means. This includes any accessory that is intended to be used with the instrument, apparatus, appliance or other article. For the purpose of this Policy, examples of medical devices include drug delivery systems, non-diagnostic equipment, monitoring systems, therapeutic inserts (i.e. through existing body cavities), prostheses, tissue regeneration and bioengineered products used on the

	surface of the body; non-diagnostic imaging and biomaterials; and implantable devices.
Off-label use of health technologies	The clinical use of health technologies outside of their approved indications on the Australian Register of Therapeutic Goods (ARTG). Off-label use of health technologies is a clinical decision requiring informed consent and justification that the health technology is the most appropriate option to treat the patient.
Procedure	Surgical procedures and techniques, medical interventional and therapeutic procedures, rehabilitation and other allied health techniques, modifications of existing procedures.
Staff member	Staff Member of a Health Service Provider as defined by the Health Services Act 2016, means: (a) an employee in the Health Service Provider; (b) a person engaged under a contract for services by the health service provider.
Statewide planning implications	A health technology for which planning at the state level is required. This includes health technologies for which: • the cost of the new health technology exceeds the current Health Service Provider budget allocation, or • centralisation has potential safety and quality benefits, or the potential to maximise cost effectiveness.
Unapproved health technologies	Heath technologies that are not included in the ARTG. Unapproved health technologies can be prescribed or used in Australia provided certain conditions are met.
WA health system	The WA health system is comprised of: (i) the Department; (ii) Health Service Providers (North Metropolitan Health Service, South Metropolitan Health Service, Child and Adolescent Health Service, WA Country Health Service, East Metropolitan Health Service, PathWest Laboratory Medicine WA, Quadriplegic Centre and Health Support Services); and (iii) contracted health entities, to the extent they provide health services to the State.
WA Policy Advisory Committee on Health Technology	The Western Australian Policy Advisory Committee on Health Technology (WAPACT) provides expert advice to senior health leadership to support the safe, equitable, and sustainable use of health technologies in the WA health system through robust assessments and governance considerations. WAPACT supports national health initiatives, including the National Health Reform Agreement, as they relate to health technologies.

8. Policy Contact

Enquiries relating to this policy may be directed to:
Title: Manager, Medicines and Technology Unit
Directorate: Patient Safety and Clinical Quality
Email: WAPACT@health.wa.gov.au

9. Document Control

Version	Published date	Review date	Amendment(s)
MP 0072/17	26 October 2017	October 2020	Original version
MP 0072/17 v.1.1	16 November 2017	October 2020	Minor amendment as detailed below.
• Removal of hyperlink to supporting document, in development			
MP 0072/17 v.1.2	16 November 2017	October 2020	Change of hyperlink.
MP 0072/17 v.2.0	3 February 2021	February 2024	Major Amendments as listed below.
• Inclusion of statement in the purpose section: 'Policy to be read in conjunction with the Procurement Policy Framework'. • Specified the Health Service Providers applicable to the policy and inserted Contracted Health Entities statement. • Refined and updated the policy requirements section. • Amended definition section: updated 'health technology' definition, removal of definitions: health professional and WAPACT and insertion of staff member definition.			
MP 0072/17 v.3.0	12 February 2026	February 2029	Policy review and amendments as listed below.
• Purpose section refined and updated for clarity and policy intent. • Applicability section updated. • Policy requirements section updated, refined and re-structured. • Compliance Monitoring section updated requiring Health Service Providers to use Compliance Audit Tool. • Related document: Inclusion of the Health Technology Governance Policy Compliance Audit Tool, WAPACT Health Technology Notification Form, and Service Specifications for Highly Specialised Therapies Application. • Supporting Information: Inclusion of Western Australian Highly Specialised Therapies Governance Toolkit and the Therapeutic Goods Administration's website. • Definitions section: 'Health technology' definition and 'Staff member' updated. Inclusion of 'Off Label use of health technologies', 'Unapproved health technologies', 'WA health system' and 'WA Policy Advisory Committee on Health Technology' definitions. • Policy contact: Updated to reflect policy ownership.			

Note: Mandatory policies that exceed the scheduled review date will continue to remain in effect.

10. Approval

Approval by	Rebecca Brown, Acting Director General, Department of Health
Approval date	2 October 2017

This document can be made available in alternative formats on request for a person with a disability.