Introduction to the Requirements for Haemopoietic Cellular Therapy

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for leading national improvements in the safety and quality of health care. We do this by setting standards for health care, providing best practice guidance for health professionals and helping patients understand what they can expect from their care. The Commission has released the draft Requirements for Haemopoietic Cellular Therapy (HCT) for feedback.

Background

Cellular therapies are treatments that use living cells, often from the patient (autologous) or a donor (allogeneic), to:

- help repair damaged tissues
- replace unhealthy cells
- strengthen the body's immune system to fight diseases such as cancer and blood disorders.

The Requirements for HCT aim to protect the public from harm and improve the safety and quality of cellular therapy programs. It describes a consistent framework that cellular therapy program facilities must meet to be eligible for Medicare rebates.

The updated draft requirements ensure that Australian HCT programs:

- align with international best practice.
- include safety rules for new cellular therapies
- set clear expectations for good governance, patient-centred care, safe systems, and respectful, inclusive communication that supports patients in making decisions about their care.

Development of the Haemopoietic Cellular Therapy Standard

The Commission was supported by a technical working group to develop the draft Requirements for HCT in collaboration with the **National Pathology Accreditation Advisory Council (NPAAC),** Australian, state and territory governments, consumers, practitioners, professional bodies, clinical scientists, and cellular therapy related specialists.

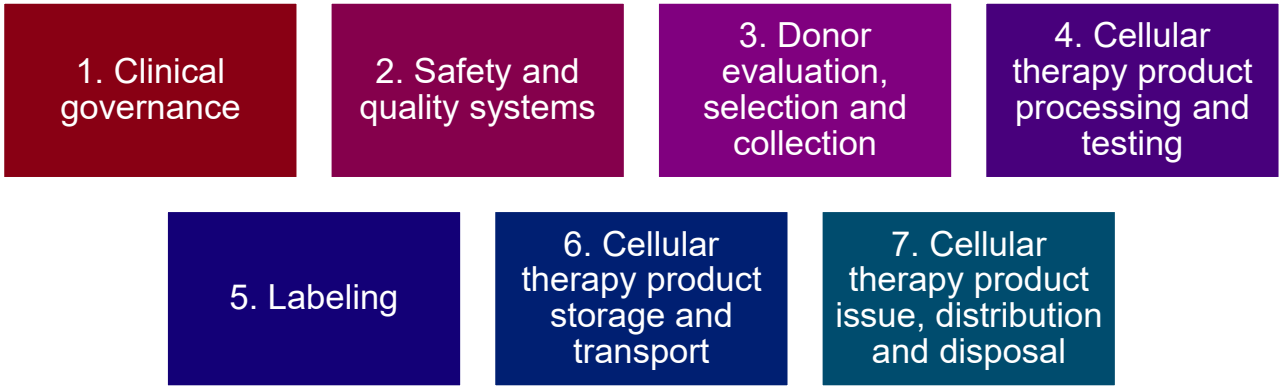
Some important requirements for consumers (such as informed consent, open disclosure, adverse events and communication) are covered in the overarching standards (Tier 2 documents) that all pathology providers have to meet. Currently this is the Requirements for Medical Pathology Services, from July 2027 this will be the National Pathology Standards. The document we are asking about is the draft HCT standard which focuses on the technical requirements for HCT.

About the Requirements for HCT

The Requirements for HCT ensure cells are:

- safely collected from a patient or a suitable donor
- carefully processed, properly stored and transported
- given to patients in a way that is safe and high quality.

There are 7 topics.



An overview of why each of the topics are in the Standards and what that means for consumers is provided in Table 1.

Table 1 What each topic means for your care

Topic	Why it is in the requirements?	What do HCT programs need to do?	What does this mean for you?
1. Clinical Governance	To outline where the responsibilities and accountabilities for treatments are. To ensure everybody knows who is responsible for your care.	Ensure a well-led, accountable team delivers high-quality care that respects your needs, culture, and background. Document roles, responsibilities, and processes.	This means you always know who is responsible for your care and there is a clear line of accountability to address any feedback or complaints.
2. Safety and Quality systems	To describe the systems needed for a HCT program to prevent errors, manage risks and	Facilities must have systems to: • identify and manage risks to patients • respond to and learn from incidents	This means there are controls in place to make sure: • the facility environment is safe

Topic	Why it is in the requirements?	What do HCT programs need to do?	What does this mean for you?
	be transparent if issues occur.	• be open and honest if something goes wrong (open disclosure).	• there are processes for infection prevention • your data and samples are secure • products (cells) are tracked at every step (full traceability) • if something goes wrong, the service must investigate what happened, learn from it, and make improvements to help prevent it happening again.
3. Donor evaluation, selection and collection	To make sure the safety of both the donor and the person receiving the cells is prioritised and is protected. Whether you are a donor or recipient, this ensures: • donors are safe and suitable • risks of infection or complications are minimised.	Carefully and independently checking donor suitability by checking for infections and reviewing their overall health before they can donate. Facilities must make sure that before donating, every donor gives their informed consent. This means they have been clearly told what is involved, the risks and what to expect in a format that is accessible and understandable to them with the opportunity to ask questions.	This means the donors are safe and suitable. If you are receiving cells, you can have confidence that the donor has been carefully assessed and that appropriate testing has been completed to minimise risks to your health. If you are the donor, it means you must have the information you need to consent to collection, understand the risks and experience high-quality care.
4. Cellular therapy product processing and testing	To make sure the cells used in your treatment are carefully prepared, tested, and checked to ensure they are safe and effective.	After collection, the cells are carefully processed and tested in a laboratory to confirm they meet quality and safety requirements before they can be used.	This means the cells used in transplants have been thoroughly checked. Outcomes (like engraftment success) are monitored and reviewed.
5. Labelling	This section is in the standard to outline the safeguards needed to make sure you receive the correct cells and treatment.	Each cellular therapy product is given a unique identifier and label so it can be matched to the correct donor and patient throughout every stage of care It is how staff can make sure, that the cells they have in front of them are definitely the right ones.	This means the cells are always correctly matched to you, the donor and your records. At every step someone checks the label and confirms it still matches and there is a written record of every movement of the cells

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			and when and how they were transported. If a question is ever raised, your care team can trace the cells back through every step.
6. Cellular therapy product storage and transport	This section is in the standard to make sure cells are protected from damage during storage and movement.	Cells are stored at exact temperatures and monitored 24 hours a day. When cells need to travel between clinics, they are moved in special containers that keep them at the right temperature, with back up plans in case of delays.	This means the cells are protected including overnight, weekends and while being transported. This reduces the risk of the cells being damaged, lost, or becoming unsuitable for treatment during storage or transport
7. Cellular therapy product issue, distribution and disposal	This section is in the standard to make sure the right cells reach the right person, they are safe and unwanted cells are disposed or stored properly.	Before your cells are released for use, staff check that they meet all safety requirements and that they are matched to the correct patient. If cells are no longer needed, there are clear rules about how they are safely disposed of. Everything must be documented and patients must be informed about treatment and testing.	This means there are checks in place right up until treatment is given, helping ensure the correct cells are provided to the correct patient at the correct time

Have your say

The Commission is seeking consumer feedback through an online survey.

Following the consultation, the Commission will:

- analyse the feedback with the National Pathology Accreditation Advisory Council (NPAAC) and the Human Haemopoietic Progenitor Cells Working Group (HHPCWG)
- finalise the *Requirements for Cellular Therapy Products (7th Edition)* for release in 2027.

For more information

For more information on how the Commission is making health care safe for consumers, please visit Consumers | Australian Commission on Safety and Quality in Health Care

For more information about your healthcare rights, go to the Australian Charter of Healthcare Rights.

For more information on Pathology Standards, please go to Pathology Standards | Australian Commission on Safety and Quality in Health Care.