Health Legislation Amendment Bill (No. 3) 2025

Explanatory Notes

Short title

The short title of the Bill is the Health Legislation Amendment Bill (No. 3) 2025 (Bill).

Policy objectives and the reasons for them

The Health Legislation Amendment Bill (No. 3) 2025 (Bill) amends eight health portfolio Acts to advance the health of Queenslanders, improve governance of the health system and ensure relevant legislation operates effectively. The Bill amends the:

- *Assisted Reproductive Technology Act 2024* (ART Act) to support the implementation of the regulatory framework for assisted reproductive technology (ART) services in Queensland by clarifying provisions, promoting equitable outcomes and, where appropriate, introducing a pathway for case-by-case decision-making so the administration of the Act does not result in undue hardship;
- *Hospital and Health Boards Act 2011*, *Health and Wellbeing Queensland Act 2019*, *Pharmacy Business Ownership Act 2024*, and *Hospital Foundations Act 2018* to allow the following office holders to be removed by Governor in Council with or without grounds:
  - Hospital and Health Board (HHB) members;
  - Health and Wellbeing Queensland (HWQ) Board members and Chief Executive Officer (CEO);
  - Queensland Pharmacy Business Ownership Council (PBOC) members and CEO; and
  - Hospital Foundation Board (HFB) members;
- *Private Health Facilities Act 1999* to:
  - clarify the head of power to specify types of private health facilities that must comply with standards of accreditation to provide a mechanism for requiring facilities that provide cosmetic surgery to comply with the National Safety and Quality Cosmetic Surgery Standards (Cosmetic Surgery Standards) and support the safe delivery of cosmetic surgery in Queensland; and
  - enable a regulation to prescribe information sharing agreements with Queensland Government entities about information collected under the Act;
- *Transplantation and Anatomy Act 1979* to maximise opportunities for organ donation in cases of circulatory death by providing a clear framework for consent to be given to conduct interventions on a potential donor, before life-sustaining measures are withdrawn, to better determine suitability and matching of organs, and improve organ viability; and
- *Public Health Act 2005* to make a minor consequential amendment to require occupational respiratory diseases to be notified in accordance with proposed changes to Commonwealth legislation.

Amendments to the *Assisted Reproductive Technology Act 2024*

The ART Act was developed in response to identified issues with the self-regulation of ART providers (that is, fertility clinics) in Queensland. The Act established a state-based regulatory framework to be administered by Queensland Health, and a donor conception information register (Register) to be maintained and operated by the Registry of Births, Deaths and Marriages (RBDM). Some parts of the ART Act commenced on assent on 19 September 2024, with remaining aspects of the regulatory framework proposed to commence by proclamation on 1 March 2026.

As the ART Act represents a new legislative scheme for an industry that has previously been self-regulated in Queensland, Queensland Health has been undertaking implementation activities including ongoing consultation with affected stakeholders. These activities have identified a need to amend certain provisions of the Act to ensure it operates as intended.

Information collection and record keeping requirements

ART providers are a critical source of information about gametes (eggs or sperm) and embryos used in ART procedures, as well as information about patients who undergo ART procedures and their treatment outcomes. This information is particularly important for donor conception, where a donor-conceived person is born as a result of donor gametes. To ensure appropriate information is being collected about ART services, the ART Act requires providers to collect and keep relevant information. These provisions commenced on assent of the Act on 19 September 2024.

The information required to be collected by an ART provider under section 33 of the ART Act (Information to be collected about gamete providers) includes the gamete provider's name, residential address, phone number and email address. Additional information is required to be collected for donated gametes, such as the donor's ethnicity and physical characteristics, relevant medical history, and the sex and year of birth of the donor's existing offspring. Obtaining gametes without first collecting the required information is an offence attracting a maximum penalty of 200 penalty units. Using a gamete or embryo in an ART procedure without having collected the information is also offence. This has the effect of prohibiting an ART provider from performing an ART procedure using the relevant gamete unless all prescribed information has been collected.

Contact information

Operational issues with the information collection requirements have arisen during implementation of the ART Act. ART providers, patients, and advocacy groups have raised concerns that in instances where one piece of contact information is unable to be collected (such as a donor's email address), the ART provider is effectively prohibited from using the donor's gamete in an ART procedure. While the requirements are important to ensure adequate information is collected about gamete providers, a strict application is, in certain cases, leading to unintended and unduly harsh consequences for patients. This is particularly an issue for those patients who already have a donor-conceived child using a specific donor and who wish to expand their family.

Application of requirements to pre-commencement gametes

The information collection requirements were intended to apply to all gametes used after the Act's commencement, even if the gametes were obtained before commencement (pre-commencement gametes). As gametes may be collected years in advance of ART treatment, most of the genetic material in storage in Queensland is made up of gametes, or embryos created with gametes, obtained before the Act commenced. Ensuring appropriate information is collected before these gametes are used in future ART procedures supports the welfare and interests of those born as a result of ART and, in particular, donor-conceived people.

While Queensland Health has advised ART providers during implementation to update their policies and processes to ensure compliance with the Act for gametes or embryos already in storage, it is necessary to put the application of the information collection requirements to pre-commencement gametes beyond doubt to ensure the ART Act operates effectively. Clarification also supports operation of the ART Act's record keeping requirements, ensuring that the required information for pre-commencement gametes is kept for at least 99 years (section 36) and not be destroyed (section 37).

Application of requirements to transferred gametes

Gametes and embryos may be transferred between ART providers, including from overseas donor banks. Section 34 (Transfer between ART providers of information about gametes or embryos) of the ART Act sets out the requirements for such transfers, including that any transfer of genetic material between ART providers must include a transfer of the consents and 'other information' relating to the material. Currently, the information collection requirements at section 33(3) provide that information obtained from another ART provider under section 34 is 'taken to have been collected' under section 33(1). This is ambiguous and could lead to providers inadvertently believing they have met the information collection requirements, even where some of the required information is missing. The policy intent for transferred gametes is that:

- the recipient ART provider meets the information collection requirements before the relevant gametes or embryos are used in an ART procedure;
- the recipient provider receives all relevant information from the transferring provider; and
- if the relevant information is provided to the recipient provider when the gametes are transferred, they are taken to have satisfied the section 33(1) requirements.

Amendments to sections 33 and 34 are required to remove any potential ambiguity and ensure the application of the information collection requirements to gametes transferred between providers is clear.

Record keeping and destruction of records

Section 36 (Keeping of records) requires ART providers to keep a range of records about gametes and embryos for at least 99 years. This includes each consent of the gamete provider required under part 2, division 3 of the ART Act. These record keeping requirements do not currently reflect the full range of consent processes, including in relation to documenting modification or withdrawal of consent by a gamete provider, or consent of a person undergoing an ART procedure. To reflect the policy intent of the Act to ensure robust record keeping

obligations are in place, it is necessary to provide for additional categories of records to be kept.

To support the record keeping requirements for ART providers in section 36 of the ART Act, section 37 (Destruction of records prohibited) makes it an offence for an ART provider or other person to destroy records, unless the chief executive has approved the destruction. Clarification is required to ensure that if an ART provider ceased operating in future, the obligations to maintain records would continue.

Case-by-case chief executive approvals

There are existing powers in the ART Act for the chief executive to provide case-by-case approvals in certain circumstances, including:

- section 27 (Time limit on use of donated gametes or embryos and their disposal), which enables the chief executive to approve the use of donated gametes or embryos that are 15 years or older if satisfied there are reasonable grounds to do so;
- section 37 (Destruction of records prohibited), which allows the chief executive to authorise destruction of records on application by an ART provider, where the destruction would not adversely affect anyone.

These approval powers provide flexibility for Queensland Health to exercise discretion and limit undue hardship that may occur in the administration of the ART Act while maintaining appropriate oversight of the use of genetic material and management of records.

Implementation activities and stakeholder consultation have identified a similar need for regulatory discretion in relation to other aspects of the ART Act where the strict application of a requirement may lead to inadvertently harsh outcomes in particular cases.

Information collection approvals

As outlined above, feedback has been received from ART providers, patients and advocacy groups about the disproportionately harsh effect of the information collection requirements in particular cases where information is unable to be collected. For certain individuals, a strict application of the section 33 requirements could lead to outcomes that would be out of step with the policy intent of the Act to protect the welfare and interests of people who use ART and people who are born as a result of ART. For example, missing information about a gamete provider could, on a strict application of the information collection requirements, prohibit the use of a gamete and thereby prevent:

- a family from creating a genetic sibling for their donor-conceived child; or
- a person who had previously undergone fertility preservation treatment and created embryos using donated material, from using the embryos to have a child.

To support an appropriate balance of interests, it is necessary to provide the chief executive with the ability to approve the use of gametes on a case-by-case basis despite the information collection requirements in section 33 not being met in full, if satisfied that there are reasonable grounds for the use.

Family limit approvals

It has also been identified during implementation of the ART Act that some flexibility is required in relation to the family limit to avoid unduly harsh outcomes in particular cases.

Section 25 (Limit on number of donor-related Australian families) is a key restriction in the ART Act. It is an offence for an ART provider to use donated gametes or embryos in an ART procedure if:

- it would result in more than 10 donor-related Australian families; and
- the ART provider knew this would be the result or did not exercise due diligence to determine whether the limit would be breached.

A maximum penalty of 400 penalty units applies for non-compliance. The family limit protects donor-conceived people, particularly from the risk of consanguineous relationships and the psychosocial impacts of having many genetic siblings.

For the purposes of the family limit, a *family* is defined as a parent, their spouse (if any) and their children. Section 25(6) provides that if a person has a former spouse, the person, their former spouse and children of both parties comprise a separate family. This may disproportionately impact female same sex couples where both partners can be a birth parent. For example, a same sex couple may have a child using donor sperm. Following a breakdown of the relationship, if one of the parents wished to have a further child using the same donor, this would be treated as a separate family. If the 10-family limit had been reached, the person would be prohibited from using this donor again, despite the potential psychosocial benefits to the existing donor-conceived child of having a genetic sibling.

It is proposed to enable the chief executive to approve the use of donated genetic material beyond the 10-family limit on a case-by-case basis. In making a decision, the chief executive must consider a range of criteria and be satisfied there are reasonable grounds for the use of the material. This is intended to achieve a balance between continuing to protect the welfare and interests of donor-conceived people and avoiding unduly harsh outcomes for ART patients in individual cases.

Alignment of existing chief executive approval powers

It is intended that the new chief executive approval powers in relation to the information collection requirements and family limit be as consistent as possible with the existing chief executive approval powers in sections 27 and 37 of the Act. This is accomplished by, where practicable, aligning the terminology, decision-making criteria and processes underpinning these powers.

<u>Clarification of time limit on use of donated material</u>

Section 27 of the ART Act provides that:

- an ART provider must not use a donated gamete or donated embryo in an ART procedure if the gamete (or gamete used to create the embryo) was obtained more than 15 years before the procedure, without the written approval of the chief executive;
- the chief executive may give approval for a person to use the donated gamete or donated embryo beyond this period if satisfied there are reasonable grounds for doing so; and

- an ART provider must dispose of any donated material in their possession if they are prohibited from using it.

A maximum penalty of 100 penalty units applies for non-compliance. The intent of section 27 is to ensure that ART providers are not using older donated gametes in ART procedures without oversight by Queensland Health, as the use of donated material across long periods of time may have an impact on any future donor-conceived people born as a result.

To ensure the provision reflects the policy intent, it is necessary to clarify the application of the disposal element of section 27 to ensure the focus is on use of the material, and not storage. By way of example, a woman may be diagnosed with cancer at age 18. To preserve her ability to have children in the future, the woman may use ART to create embryos with her eggs and donor sperm. The woman may not seek to use the embryos until many years into the future. Requiring her ART provider to apply for an approval for ongoing storage of her embryos beyond 15 years or for the provider to be subject to a disposal requirement may cause undue stress to the patient. Additionally, oversight of the length of storage is not the policy intent. Instead, the policy intent is to ensure that the use of older material is appropriate, having regard to a range of considerations.

For these reasons, amendments to section 27 are required to reflect the need for Queensland Health's oversight over the use of older donated material, rather than the storage of the material. This allows the provision to better support the welfare and interests of people who use ART by ensuring that donated material does not attract a proactive requirement at the 15-year mark to either dispose of it or to seek a chief executive approval for ongoing storage. It also ensures chief executive decision-making is being applied to the appropriate aspect of 'time' for donated gametes and embryos, thereby advancing the protections under the Act.

Consent requirements

Obtaining gametes

Informed consent is an important part of healthcare. To reflect this, the ART Act requires:

- ART providers to obtain written consent before providing an ART service and to act in accordance with that consent (section 16);
- for a gamete provider who is not a donor, the ART provider to obtain written consent before using the genetic material in an ART procedure, storing the genetic material, supplying the genetic material to another person or ART provider, or exporting the genetic material from Queensland (section 17);
- for a gamete donor, the ART provider to obtain consent for use of the donor's genetic material in an ART procedure (section 18); and
- for a person undergoing an ART procedure, the ART provider to obtain their consent to undergo the procedure (section 19).

Despite these detailed consent requirements, ART providers are not specifically required to seek a gamete provider's consent for obtaining or attempting to obtain their gametes (for example, via an egg retrieval), even though this is an important step in the ART process.

Clarification of interaction of donor consent with chief executive approvals

For donors, section 18 provides that consent must also include the maximum number of families that may be created using their gametes and the maximum period for which donated genetic material may be stored, within the legislated limits imposed by sections 25 and 27 respectively. Because the Act sets maximum limits, a donor cannot consent to the use of their gametes beyond those limits.

However, the additional chief executive approval powers contemplated above are intended to provide discretion for the use of gametes beyond these limits, where required, to prevent undue hardship. Given this, there is a need to clarify the interaction between donor consent requirements and the chief executive approval powers. There may be instances where a donor would support an ART provider's application to use their gametes in an ART procedure beyond the legislated time limit or family limit, but due to the consent requirement in section 18, it is not possible for the donor to explicitly consent to the use in this way. Therefore, clarifying the interaction between sections 18, 25 and 27 ensures the Act operates as intended.

Clarification of transitional provisions

The ART Act includes transitional provisions to support the transition of the Queensland ART industry from self-regulation to the new regulatory framework.

Reflecting diverse family structures

Sections 146 and 147 of the ART Act state that despite particular requirements in the Act:

- remaining donated gametes can be used for a person to complete their family where, before commencement of the ART Act, the person was allocated donated gametes and became pregnant using some of the donated gametes in an ART procedure; and
- a remaining donated embryo can be used for a person where it was allocated for their use before commencement of the ART Act.

These provisions were designed to enable patients to continue ART treatment started before the Act commenced, including with a chosen donor, even if doing so would breach the family limit (section 25), the time limit on the use of donated gametes or embryos (section 27), or the donor consent requirements (part 2, division 3).

Section 146 of the ART Act states that a 'person' who was allocated donor gametes before commencement of the Act and had become pregnant with them, may use the remaining donor gametes in future ART procedures. This reflects the fact that the person may already have a donor-conceived child using their chosen gamete donor, and that there may be psychosocial benefits to enabling that person to have another child using the same donor. Similarly, section 147 allows a 'person' to use a donated embryo if it was allocated to them before the Act's commencement.

The wording used in section 146 could exclude some people from completing their family. This is because section 146 limits its application to only the 'person' who was pregnant previously, which excludes that person's spouse at the time the donated gametes were allocated. This creates a barrier for some couples, including a same sex couple where one partner carried the first pregnancy, and the other partner wishes to carry a subsequent pregnancy. Similarly, this could exclude a family from using a surrogate, including circumstances where they may need to use a different surrogate for the subsequent pregnancy.

The unintended exclusion means that some people would face barriers to, or be prevented from, completing their intended family using the same donor as any of their donor-conceived children or previous pregnancies.

In light of these unintended consequences, changes to the scope and operation of these transitional provisions are required to better reflect diverse family structures and enable people who had started their ART treatment before commencement of the ART Act to complete their family.

Disapplying information collection requirements for sections 146 to 148

As outlined above, sections 146 and 147 were included in the ART Act to enable patients to continue ART treatment started before the Act commenced, including with a chosen donor, even if doing so would breach the family limit (section 25), time limit on use of donated gametes or embryos (section 27), or donor consent requirements (part 2, division 3).

Section 148 (Embryo not yet used for ART procedure) provides that for an embryo that was created before commencement of the Act, but not yet used, the chief executive may approve use of the embryo even if it would breach the family limit or time limit requirements, if the chief executive has considered the relevant criteria and is satisfied that the use is reasonable. This is distinct from sections 146 and 147 as it requires chief executive approval as section 148 only requires the embryo to have been created before the Act commenced. This is a low threshold, and Queensland Health needs to ensure that embryos created before commencement ART Act were created to be used and not to circumvent the application of the requirements of the Act in the future.

As outlined above, implementation activities to support the ART Act regulatory framework have identified that the strict application of the information collection requirements may result in unnecessary hardship in particular cases where information is unable to be collected. The Bill proposes to provide the chief executive with a case-by-case discretion to address this. The transitional provisions in sections 146 to 148 require amendment to ensure that people who had started ART treatment before the commencement of the information collection requirements can continue with their treatment despite the information collection requirements not being met in full.

During development of the Act, stakeholders were broadly supportive of the information collection requirements, noting that they were already collecting relevant information. However, during implementation of the ART Act, it has become apparent that not all information, as described in the Act, was being obtained. Accordingly, to enable use of gametes or embryos by people who have already started ART treatment prior to commencement of the Act, sections 146 to 148 are proposed to recognise that use can occur despite the information collection requirements not being met.

The amended transitional provision also avoids the emotional and regulatory burden of requiring these persons who had already begun ART treatment when the Act commenced to seek an application for case-by-case approval to use donated material under section 33. In the case of embryos created but not yet used under section 148, if a section 148 application is required in relation to family limit or time limit, this approach removes the need for a further application under section 33.

Disapplying the information collection requirements for people who have already started ART treatment prior to commencement is also consistent with the approach to the family limit and time limit. This recognises that it may not be possible for people who had already started ART treatment with particular donor gametes or embryos, prior to commencement of the ART Act, to meet the requirements under the Act. It also recognises that, when applying the new regulatory scheme to an existing treatment framework, the Act needs to balance the interests of existing patients and people born as a result.

Application of Act to existing matters

Other transitional provisions were included in the ART Act to clarify how the Act would apply to activities carried out or genetic material created before commencement of the Act. Existing section 144 (Application of Act to existing matters) was drafted with a view to addressing the application of the Act to the broad range of activities carried out and genetic material created before commencement.

It has been identified that due to the broad nature of section 144, it may not apply in a manner that reflects the policy intent of the ART Act in all potential cases. It is important to the effective operation of the ART Act that the transitional provisions reflect the intended application of the Act to the relevant range of activities that occurred before commencement. This is also important to ensure that there are not two classes of ART patients, and people born as a result, due to some being regulated under the Act and others not. Amendments are required to put the application of the ART Act to activities carried out before commencement beyond doubt.

Inspector powers

Part 5 of the ART Act includes investigation and enforcement provisions to support the regulatory framework. Section 69 provides that the functions of inspectors include investigating, monitoring and enforcing compliance with the Act.

To support these functions, inspectors have powers under the ART Act to require a person to:

- make available or produce for inspection a document issued or required to be kept under the Act (section 108); and
- give information to the inspector if there is a reasonable belief that an offence against the Act has been committed, and a person may be able to give information about the offence (section 111).

These powers support the regulatory activities required for the effective regulation of the ART sector, but they are limited in scope. Section 108 only applies to documents required to be kept or issued under the ART Act, and while this power may be used where there is an investigation into a falsified licence or to satisfy an inspector that the record keeping requirements are being met by an ART provider, it does not support inspectors seeking to enforce the broader functions outlined above.

Similarly, section 111 is limited to where an inspector forms a reasonable belief that an offence has been committed. Non-compliance with licence obligations, including compliance with licence conditions (section 59), improvement notices (section 62), prohibition notices (section 63) and licence suspensions (section 64), are not offences under the ART Act. The section 111 powers therefore do not permit an inspector to compel the provision of information where there

has been a potential breach of a licensing obligation, despite the licensing framework being a key component of the regulation of ART providers under the Act.

There is also no power to investigate a serious adverse event and other prescribed events notified to Queensland Health (section 61) unless the event indicates a breach of the Act, or to require documents in order to monitor compliance with the Act generally. A power to investigate such events is critical for a proactive regulatory scheme that meets the object of the Act to protect the safety and welfare of ART patients and people born as a result of ART.

Other jurisdictions' ART legislation provides for broader powers for authorised officers to request information. The ART legislation in the Australian Capital Territory, Victoria, South Australia and Western Australia permits an authorised officer to request information from a person or registered ART provider where reasonably required to monitor compliance with the relevant Act.

Reform of accreditation scheme for ART sector

It is currently a requirement of Commonwealth legislation that all ART providers must be accredited under the Reproductive Technology Accreditation Committee's (RTAC) *Code of Practice for ART Units* (RTAC Code of Practice). RTAC is a professional group of the Board of the Fertility Society of Australia and New Zealand, which is the peak body for the fertility industry.

On 13 June 2025, the regulation of the ART sector was considered at the Health Ministers' Meeting (HMM), following growing public concern over several high-profile failures by the sector. Victoria was tasked with leading a rapid review of the regulatory and accreditation environment within three months.

On 12 September 2025, HMM noted that the current industry-led accreditation is not adequate and agreed that the Australian Commission on Safety and Quality in Health Care (the Commission) should replace RTAC and provide independent accreditation for ART services against updated national standards. HMM agreed that the new accreditation requirements will be in place by January 2027.

The ART Act currently references RTAC accreditation to support the licensing framework. For example, a person may only apply for a Queensland ART licence if they have RTAC accreditation. For the purposes of the ART Act, *RTAC accreditation* is defined to include accreditation by RTAC or by another body prescribed by regulation, whether in addition to or instead of RTAC. While this definition enables another body to be prescribed as the relevant accrediting authority, the Act requires amendment to reflect the HMM decision and future-proof the legislation by removing reference to RTAC.

Terminology

The ART Act includes references to concepts in the RTAC Code of Practice to ensure consistency and alignment between the regulatory and accreditation frameworks. It also ensures Queensland Health can maintain appropriate regulatory oversight of key requirements under the RTAC Code of Practice.

Serious adverse events

The RTAC Code of Practice includes a list of serious adverse events that must be reported to RTAC by an ART provider if they occur. It includes technical and clinical matters including any event which:

- causes a significant medical or surgical condition that occurs as a result of ART treatment;
- results in the hospitalisation of a patient due to a complication of ART treatment;
- arises from a systemic failure in the validation or verification of a diagnostic test or technology that resulted in misdiagnosis or significant potential harm or loss to patients, their gametes or their embryos.

To align with this concept and ensure Queensland Health has appropriate oversight of serious adverse events, section 61 of the ART Act (Chief executive to be notified of certain events) requires ART providers to notify Queensland Health of particular events, including serious adverse events. For section 61, *serious adverse event* is currently defined, for a licensed provider, as an event that is prescribed by regulation, or by the conditions of the provider's licence, as a serious adverse event. However, the list of serious adverse events in the RTAC Code of Practice is clinical and technical in nature, making it difficult to accurately replicate in legislation.

Once the Commission is established as the relevant accrediting body, it is anticipated that any code of practice or standards issued by the Commission would continue to regulate serious adverse events. While Queensland Health does not have visibility of what these events may include in a future code or standard, it is important for the ART Act to have flexibility so that any serious adverse events under the relevant accreditation document are taken to apply for the purposes of the ART Act. It is also important that, if necessary, the accreditation document can be modified to include additional serious adverse events should all events not be captured in the new code of practice or standards.

Personnel

The RTAC Code of Practice requires ART providers to appoint personnel. This includes 'key personnel' such as a medical director, scientific director, nurse manager, and 'additional personnel' such as a clinical director, laboratory manager, and counsellor.

Key personnel are referred to in the ART Act to support the licensing framework at:

- section 57 (application for licence), which sets out information that must be included in an application for a Queensland ART licence. An application must include details of key personnel prescribed by regulation who are engaged in the provision of ART services by the applicant;
- section 61 (Chief executive to be notified of certain events), which requires licensed ART providers to provide notice to the chief executive of certain events to ensure appropriate oversight and transparency of ART services and providers. A licensed provider is required to notify Queensland Health within 21 days of a change in key personnel prescribed by regulation who are engaged in the provision of ART services by the licensed provider; and
- section 65 (Public register of licensed providers), which enables the chief executive to keep a public register of ART providers. The register may contain information including the

names of key personnel prescribed by regulation who are engaged in the provision of ART services by the licensed provider.

The reference to 'key personnel' rather than the more general term 'personnel' means that additional personnel are not currently reflected in these provisions, despite being key on-site staff members. This means that Queensland Health would not be provided with information about additional personnel employed by an ART provider as part of their licence application or have visibility of a change in additional personnel employed by the provider. As these personnel are generally on-site at clinical locations (for example, where ART laboratories are operated) they are critical to the operations of an ART provider. The RTAC Code of Practice includes detailed requirements for these additional personnel, in recognition of their central role in delivery of ART services. However, these detailed requirements may not be suitable for inclusion in a regulation for the purposes of the ART Act.

Once the Commission is established as the relevant accrediting body, it is anticipated that any code of practice or standards issued by the Commission would continue to regulate personnel, but Queensland Health does not currently have visibility about how this would be reflected in relevant accreditation documents. Flexibility is required to ensure Queensland Health can modify the application of relevant accreditation documents to the extent necessary. For example, if the Commission produced new standards that referred to staff instead of personnel, it is necessary to ensure that references in the ART Act to personnel would be taken to reflect the staffing requirements in the standards.

Application of Act to spouse of the person undergoing ART

The ART Act includes several references to a person's 'spouse' including for the purposes of defining terms, establishing a framework for a deceased person's spouse to retrieve and use their gametes, and providing for disclosure of health information by an ART provider. The term spouse is also used in the Bill in relation to the clarification of transitional provisions. 'Spouse' is not defined in the ART Act. The *Acts Interpretation Act 1954* provides that *spouse* includes de facto partner and civil partner. Where a married couple is separated but not yet divorced, they are still legally considered spouses under the *Family Law Act 1975* (Cth).

In circumstances where an ART patient has separated from their spouse, but is not yet divorced, and seeks to undergo ART using donor gametes, the application of the term 'spouse' in certain provisions in the ART Act could act as a barrier to treatment notwithstanding that the spouse's genetic material will not be used, and the spouse will have no role in the upbringing of any future child.

Section 15 (Counselling services for persons provided with ART services) makes it mandatory for an ART provider to provide counselling to a person proposing to undergo an ART procedure involving donor gametes or embryos, and their spouse (if any). A maximum penalty of 50 penalty units applies for non-compliance. Counselling services are required to be provided before the ART procedure is carried out.

In relation to donor conception, the intent of the mandatory counselling requirements is to ensure that persons involved in the life of the child to be born are aware of the implications of using donor material. If the person's spouse will not be socially involved in the life of the child and is otherwise not impacted by the donation of material, then there are no implications for them that they need counselling in relation to. Section 15 is proposed to commence by proclamation on 1 March 2026.

Section 35 (Information to be collected about persons who undergo ART procedures) sets out the information an ART provider is required to collect about a person who undergoes an ART procedure. A maximum penalty of 200 penalty units applies for non-compliance. The information required to be collected includes the full name and date of birth of any spouse of the person at the time of the procedure. The intent of section 35 is to capture relevant information about the genetic origins of the person born. This also ensures the information required to be collected for the Register is obtained by ART providers. Section 35 commenced on assent of the Act in September 2024.

Section 44 (Relevant information to be included in register) sets out the information to be included in the Register including, for the person who gave birth to a donor-conceived person as a result of an ART procedure, the full name and date of birth of any spouse of that person at the time of the procedure. A maximum penalty of 100 penalty units applies if an ART provider does not provide the Registrar with all relevant information (section 45). The intent of section 44 is to ensure sufficient information is provided to a donor-conceived person about their genetic and social origins. It may be relevant for this information to include details of the spouse of the person who gives birth to the donor-conceived person but was not intended to capture an estranged spouse who is not involved with gamete or embryo donation or in the donor-conceived person's life. Section 44 will commence by proclamation as part of establishment of the Register.

Under these provisions, the patient's ART provider would be required to provide the estranged spouse with mandatory counselling before carrying out the ART procedure and to collect the spouse's full name and date of birth. This is contrary to the policy intent of the ART Act, which is not intended be a barrier to treatment. The application of these provisions could also conflict with section 22 of the *Sex Discrimination Act 1984* (Cth) which provides that it is unlawful for a business to discriminate against a person based on the person's marital or relationship status by refusing to provide the person with goods, services or facilities they would otherwise provide.

Cross-referencing error

Section 138 of the ART Act provides that in some cases, an offence committed by an ART provider is taken to have been committed by an executive officer within the corporation if they authorised or permitted the conduct, or were knowingly concerned in the conduct. Relevant offences in relation to which executive officers may be held responsible for their role are called deemed executive liability provisions.

One of the offences that was intended to be included as a deemed executive liability provision is section 139(1). Section 139(1) prohibits a person from providing an official under the ART Act with false or misleading information. Due to a cross-referencing error, section 138 incorrectly references section 139(2) as a deemed executive liability provision even though it is not an offence.

Minor amendments to support the donor conception information register

Part 3 of the ART Act establishes the Register within RBDM. Once the Register is operational, it will hold identifying and non-identifying information about donors, donor-conceived people and the parent or parents of donor-conceived people. A primary purpose of the Register is to provide donor-conceived people, who are 16 years and older, with access to information about

their donor. This allows donor-conceived people to understand their full genetic history and potential health risks. It may also enable donor-conceived people to connect with their donor and donor-conceived siblings with mutual consent.

Section 44 of the ART Act provides the information that is included in the Register that relates to the birth of a donor-conceived person as a result of a donor conception ART procedure or a private donor conception procedure. *Relevant information* relating to the birth of a donor-conceived person is defined, for part 3, to be the information stated in section 44.

During implementation activities for the Register, it was identified that relevant information relating to the 'birth of a donor-conceived person' may not be broad enough for additional information to be prescribed in regulation. For example, it may be relevant to prescribe information relating to the death of the donor. As this does not directly relate to the 'birth of a donor-conceived person', it currently cannot be prescribed. This information could however be important for a donor-conceived person when attempting to connect with their donor or to help understand their genetic history.

Amendments to the *Hospital and Health Boards Act 2011, Health and Wellbeing Queensland Act 2019, Pharmacy Business Ownership Act 2024* and *Hospital Foundations Act 2018*

Hospital and Health Boards

The Hospital and Health Boards Act establishes 16 Hospital and Health Services (HHS) across Queensland, responsible for public health services in their geographical area, except for Children's Health Queensland, which provides statewide services.

Each HHS is managed by a Hospital and Health Board (HHB), which is made up of at least five board members appointed by the Governor in Council (on recommendation of the Minister).

HHB members have significant governance and statutory responsibilities, including setting the strategic direction of their HHS, controlling the budget and financial management of their HHS, managing the HHS land and buildings and managing HHS staff. HHB members hold an integral and fundamental role in the public health system and are appointed to oversee effective health service delivery in their local area.

Health and Wellbeing Queensland

Health and Wellbeing Queensland (HWQ) was established to improve the health and wellbeing of Queenslanders, especially focusing on reducing the burden of chronic diseases through targeting risk factors for those diseases, and reducing health inequities. HWQ is governed by the HWQ Board, which is responsible for the proper, efficient and effective performance of HWQ's functions, and deciding HWQ's objectives, strategies and policies. In 2024, HWQ administered over $55.4 million in funding to support the health system to reduce the impact of chronic disease.

The HWQ Board is made up of at least one (but not more than four) chief executives of Queensland Government departments and at least one (but not more than six) other members appointed by the Governor in Council. HWQ must also have a chief executive officer (CEO)

who is responsible for the day-to-day administration of HWQ. The HWQ CEO is appointed by the Governor in Council on recommendation of the Minister, with the approval of the HWQ Board.

Confidence in the HWQ Board members and the CEO is essential because of the work they do with government, partners and the community to support the health system and improve the health and wellbeing of Queenslanders.

Queensland Pharmacy Business Ownership Council

The Pharmacy Business Ownership Act regulates pharmacies, including who may own, or hold a material interest in, a pharmacy business. The Queensland Pharmacy Business Ownership Council (PBOC) monitors and enforces the Pharmacy Business Ownership Act.

The PBOC must consist of at least five members who are appointed by the Governor in Council, on the recommendation of the Minister. The PBOC must have a CEO who is responsible for the day-to-day administration of PBOC. The PBOC CEO is appointed by the Governor in Council on the recommendation of the Minister.

Confidence in the PBOC members and the CEO is essential in ensuring the effective regulation of pharmacy businesses to deliver safe, high-quality care to Queenslanders.

Hospital Foundations

Hospital Foundations are established to support, improve or promote an existing public sector hospital, public sector health service facility or public sector health service. For each of the 13 hospital foundations, a Hospital Foundation Board (HFB) is established as the governing body.

Each HFB is made up of at least six members who are appointed by the Governor in Council, on the recommendation of the Minister. Each Hospital Foundation must have one member who is a Board member of the relevant HHB or HWQ Board that the foundation works in conjunction with.

Each HFB must manage the hospital foundation, including by ensuring the foundation pursues its registered objects effectively and efficiently. Each HFB is also responsible for setting the strategies and policies for the management of property held by the foundation.

Removal of office holders with or without grounds

The office holders under each of these Acts play a vital role in the leadership, governance, service delivery and regulation of the public health system. Given the importance of their roles and the significant budgets and funding they administer, they are expected to uphold high standards of performance, behaviour, integrity and effectiveness.

In order to ensure office holders are upholding these standards, it is proposed to provide that they can be removed from office by the Governor in Council with or without grounds. Broader powers are considered necessary to remove an office holder if the Minister or Government has lost confidence in them. There may also be circumstances where there is a community expectation that a person should be removed from office, and the current powers are not broad enough to do so.

Amendments to the *Private Health Facilities Act 1999*

Power to prescribe standards of accreditation for facilities that provide particular health services

The Private Health Facilities Act provides a framework for protecting the health and wellbeing of patients receiving health services at private health facilities. The framework provides for the licensing of private health facilities by Queensland Health, which are referred to as private hospitals and day hospitals. In addition, the Private Health Facilities Act sets standards for the provision of health services at licensed private health facilities and provides for the compliance, monitoring and enforcement of licensing requirements.

Section 48(1)(b) of the Private Health Facilities Act provides that a licence for a private health facility must be issued on the condition that the licensee must comply with an accreditation scheme that relates to safety and quality matters and is prescribed by regulation. Section 8 of the *Private Health Facilities Regulation 2016* prescribes the Australian Health Service Safety and Quality Accreditation Scheme (AHSSQAS), incorporating the National Safety and Quality Health Service (NSQHS) Standards made by the Commission. This means that all private health facilities must comply with the NSQHS Standards to protect the public from harm and to improve the quality of health services. The NSQHS Standards include eight standards about clinical governance, preventing and controlling infections, comprehensive care, blood management, partnering with consumers, medication safety, communicating for safety, and recognising and responding to acute deterioration.

In September 2022, HMM agreed to a range of urgent actions to strengthen national regulation of cosmetic surgery. As part of these initiatives, Health Ministers asked the Commission to review licensing standards and arrangements for private health hospitals, day hospitals and clinics where cosmetic procedures are performed, and to develop national standards for the safe delivery of cosmetic procedures. In September 2023, HMM approved the National Safety and Quality Cosmetic Surgery Standards (Cosmetic Surgery Standards) and States and Territories agreed to make the necessary legislative changes to implement compliance with the standards in each jurisdiction.

The Cosmetic Surgery Standards are intended to only apply to private health facilities that provide cosmetic surgery because they contain requirements that are unique to these facilities.

While the Private Health Facilities Act requires all private health facilities to comply with the NSQHS Standards, there is no mechanism to require specific facilities that provide cosmetic surgery to comply with the Cosmetic Surgery Standards, or other standards of accreditation that are developed by the Commission or adopted by States and Territories. Compliance with the Cosmetic Surgery Standards reduces the risks to the public when undergoing cosmetic surgery at licensed private health facilities. To achieve this outcome, it is proposed to clarify the head of power about standards of accreditation in the Private Health Facilities Act.

Power to share private hospital data with other Queensland Government entities under an agreement

Sections 147(4)(g) and (6) of the Private Health Facilities Act provide that confidential information obtained under the Act may be disclosed if the chief executive believes, on reasonable grounds, that the disclosure is in the public interest. Confidential information

includes personal health information, criminal history reports or information that may damage the commercial activities of the person if disclosed.

If information is disclosed under section 147(4)(g) and (6) of the Private Health Facilities Act, a statement about the disclosure of information must be included in Queensland Health's annual report, in accordance with section 147(9) and (10) of the Act. This includes when information is shared with other Queensland Government entities. Examples of information that has previously been shared with another Queensland Government entity, as published in the annual reports of the department, includes information shared with:

- Queensland Police Service – for patients with firearm injuries in private hospitals, to assist in a strategic intelligence assessment product relating to illegal firearms in Queensland;
- Maritime Safety Queensland, Department of Transport and Main Roads – to undertake analysis of water transport injuries; and
- Department of Transport and Main Roads – to analyse clinical outcomes for patients with serious road crash injuries.

In addition, chief executive approval is required for each disclosure under section 147(6) of the Private Health Facilities Act, which creates potential delays for disclosure of the data and an administrative burden.

In contrast, section 147(4)(c) of the Private Health Facilities Act permits the disclosure of confidential information to the Commonwealth or another State under an agreement prescribed by regulation, if the chief executive is satisfied the disclosure is in the public interest. Schedule 1 of the Private Health Facilities Regulation prescribes various agreements between Queensland Health and the Commonwealth and other States and Territories to facilitate information sharing.

Section 151(1)(b) of the Hospital and Health Boards Act allows Queensland Health to disclose confidential information about public health care to a Queensland Government entity under an agreement prescribed by regulation. In addition, sections 84, 226, 228O, 244 and 279AO of the *Public Health Act 2005* also allow confidential information to be disclosed to Queensland Government entities under an agreement prescribed in a regulation.

To establish a more efficient process for information sharing with other Queensland Government entities, it is proposed to amend the Private Health Facilities Act to provide that information can be shared under an agreement prescribed by regulation, if the chief executive is satisfied that the disclosure is in the public interest. This approach also provides greater consistency with the sharing of information under the Hospital and Health Boards Act and the Public Health Act.

Amendments to the *Transplantation and Anatomy Act 1979*

Organ and tissue donation saves and improves lives, but it is only possible in around two per cent of patients who die in hospital because specific criteria must be met for organ transplantation to occur. In Queensland in 2024, only 96 people who met these criteria had their family consent to donate their organs. These donations resulted in 273 Australians receiving a transplant. Approximately 1,800 people are currently on the organ transplant waitlist in Australia, with another 14,000 people undergoing kidney dialysis who may require

a transplant in the future[1]. These figures demonstrate the importance of organ donation in circumstances where a person is a viable candidate for donation and their next of kin has provided the appropriate consents.

Further highlighting the importance of organ donation, the Australian Law Reform Commission is currently undertaking a review of human tissue laws in Australia, with the final report due to the Commonwealth Attorney-General by 16 August 2026. The terms of reference include consideration of donation and transplant of organs as well as consent arrangements. While this inquiry is ongoing, amendments to the Transplantation and Anatomy Act are required to clarify the Queensland's existing framework to maximise opportunities for organ donation.

Under the Transplantation and Anatomy Act, there are two legal definitions of death for the purposes of organ donation. First, a person may experience *brain death*, which is the irreversible cessation of all brain function of the person. Alternatively, a person may experience *circulatory death*, which is the irreversible cessation of circulation of blood in the person's body. This occurs once a person's heart stops beating and the blood stops pumping around the person's body.

Organ donation following circulatory death, while less common than donation following brain death, has steadily grown as a pathway to donation across Australia, and it is important to enhance opportunities for donation. In 2024, donation following circulatory death occurred in approximately 36 per cent of organ donations.

The Transplantation and Anatomy Act provides the legal framework for the donation of organs and tissue for use in transplantation. It provides the legal authority and consent processes that are necessary to enable donation of tissue, which includes organs for use in transplants. Under the Transplantation and Anatomy Act, a person's next of kin (referred to as the *senior available next of kin* under the Act) can consent to removal of tissue from a deceased donor.

To facilitate organ donation, certain procedures and investigations (known as 'interventions') may need to be carried out on the potential donor to determine suitability for donation, enable organ matching with suitable recipients and maintain or improve organ function and viability. These interventions may include undertaking blood tests, administering medication to prevent blood clots, or conducting x-rays. Blood tests are critical to determining the suitability of a potential donor and are carried out before other interventions.

For organ donation after brain death, these interventions are carried out post-mortem, after the certification of death is made, but while the circulation of blood and oxygen in the body of the person is being artificially maintained. As the potential donor is deceased at the time the interventions are undertaken, separate consent to the consent to tissue removal provided by the next of kin under the Act is not required.

For organ donation after circulatory death, however, the process is different. These potential donors are usually in an intensive care unit following a severe illness or injury that they are unlikely to recover from and are being maintained on life-sustaining measures. Although they do not meet the definition of brain death, their injuries or illness are such that, once life-sustaining measures have been withdrawn, the person's heart stops beating and the blood stops

[1] *Australian Donor and Transplantation Activity Report 2024,* Australian Organ and Tissue Donation and Transplantation Authority and Donate Life (25 February 2025).

pumping around their body, and they meet the definition of circulatory death under the Transplantation and Anatomy Act.

In cases of circulatory death, organ quality and viability deteriorate rapidly once life-sustaining measures are withdrawn and the person's heart stops beating. To ensure that organs remain viable for transplantation, the interventions must be carried out while the person remains legally alive and before the certification of death (known as ante-mortem). However, as the potential donor is still alive, the Transplantation and Anatomy Act does not provide a clear legislative framework for consent to be given to allow these interventions to be conducted, even if the appropriate consent to organ donation has been given by the person's next of kin.

To enhance opportunities for lifesaving and life changing organ donations, it is proposed to amend the Transplantation and Anatomy Act to provide a clear legal framework for a person's next of kin to consent to the carrying out of an ante-mortem intervention in identified cases of circulatory death.

Consequential amendment to the Public Health Act 2005

On 22 May 2024, the Commonwealth's *National Occupational Respiratory Disease Registry Act 2023* (NORDR Act) commenced, including the provisions establishing the National Occupational Respiratory Disease Registry (National Registry). To support these changes, the Public Health Act was amended on 23 September 2025, to provide that prescribed medical practitioners are required to give a notification to the Commonwealth chief medical officer under the NORDR Act.

On 3 September 2025, the Commonwealth introduced the Australian Centre for Disease Control Bill 2025, to establish the Australian Centre for Disease Control (Australian CDC) as an independent, non-corporate Commonwealth entity and to provide for the role, powers, functions and duties of the Director-General of the Australian CDC. In addition, the Commonwealth introduced legislation to amend the NORDR Act to transfer responsibility for the National Registry from the Commonwealth Chief Medical Officer to the Director-General of the Australian CDC.

A consequential amendment is needed to the Public Health Act as a result of the proposed changes to Commonwealth legislation.

Achievement of policy objectives

Amendments to the *Assisted Reproductive Technology Act 2024*

Information collection and record keeping requirements

Contact information

To address the unintended consequences of the information collection provision in section 33 of the ART Act, the Bill replaces the prescriptive requirement to collect a gamete provider's residential address, phone number and email address with a general requirement to collect contact information. *Contact information* is already defined in the Act (for the Register) to mean residential address, phone number, email address or any other way the person may be contacted. This amendment retains the policy intent to ensure adequate information is collected, while introducing flexibility to address the current challenges with collecting all three types of contact information.

There may be cases where a gamete provider does not, for example, have an email address. The amendment ensures this would not prevent a gamete from being used in a procedure, provided sufficient other contact information has been obtained. It also expands the categories of contact information that can be collected to include other ways the person can be contacted, this should ensure other means of contact information are collected where possible, and future-proof the legislation as new methods of communication are used.

Noting the importance to donor-conceived people of adequate and reliable information being collected by ART providers, Queensland Health, as the industry regulator, will set clear expectations about the minimum contact information to be collected. To monitor that this expectation is being met, Queensland Health will undertake regulatory activities targeted at information collection.

For consistency, the Bill includes equivalent amendments to section 35 (Information to be collected about persons who undergo ART procedures) and section 36 (Keeping of records), which also currently reference residential address, phone number and email address.

Application of requirements to pre-commencement gametes and transferred gametes

The Bill clarifies the application of the information collection requirements to pre-commencement gametes and gametes transferred between ART providers, to put beyond doubt that the requirements apply.

New section 149 provides that, in relation to pre-commencement gametes, the relevant information outlined in section 33(1) must be collected before an ART provider uses the gametes, or an embryo created using the gamete, in an ART procedure.

Amendments to sections 33 and 34 clarify that for transfers of gametes and embryos between ART providers, the recipient ART provider must obtain the information mentioned in section 33 before the gametes or embryos may be used in an ART procedure. Where the information required under section 33(1) has already been collected by the previous ART provider, there is no requirement for the recipient provider to re-collect or re-verify the information, where this information has been transferred to the recipient in accordance with section 34. Where the information transferred pursuant to section 34 does not meet all of the information requirements

of section 33, the recipient provider must obtain the missing information before they are permitted to use the gamete or embryo created using the gamete. As outlined below, they may also make an application to the chief executive for approval to use the gamete or embryo in narrow circumstances where strict application of the requirements would cause unnecessary hardship for individuals and families.

Record keeping and destruction of records

The Bill amends section 36 (Keeping of records) to require an ART provider to keep a record of the relevant information relating to the consent of a person.

As outlined below under 'Consent requirements', the Bill provides an additional requirement for an ART provider to obtain consent from a gamete provider before obtaining, or attempting to obtain, their gametes. To ensure a record of these consents is kept, the Bill amends the record keeping requirements to include this category of consent. Additionally, section 36 is amended to ensure records are kept about:

- notices given to an ART provider by a gamete provider who has modified or withdrawn their consent in accordance with section 20; and
- each consent of a person undergoing an ART procedure.

These additional record keeping requirements ensure that appropriate records are maintained in relation to consents received from gamete providers and patients.

The Bill also amends section 36 and section 37 to clarify that the record keeping requirements and prohibition on destruction of records apply to an individual who was previously an ART provider, in addition to a person who is currently an ART provider. This supports the policy intent of the ART Act to require records to be maintained for 99 years, ensuring records relating to ART procedures and donor conception are available for ART patients and people born as a result of ART, particularly donor-conceived people, to access during their lifetime.

Case-by-case chief executive approvals

Information collection approvals

The Bill enables the chief executive to approve the use of gametes or embryos on a case-by-case basis despite not fully complying with the information collection requirements of section 33. This discretion provides flexibility in the application of the requirements where the chief executive is satisfied that the ART provider has taken reasonable steps to collect the relevant information and that there are reasonable grounds for using the gamete or embryo.

Whether there are reasonable grounds is determined based on the individual circumstances of the application. The chief executive may consider matters including the information which has been collected by the ART provider and whether, in the circumstances, the consequences of giving, or refusing to give, the approval for the use of the gamete or embryo would be unfairly harsh for any person. The decision-making criteria ensures the chief executive considers the impact of the use of the gamete on relevant individuals, including the recipient parent/s, the donor-conceived person who could be born as a result of the procedure, any existing donor-conceived children (including within the same family as well as other families) and the donor. The chief executive will also have regard to the objects of the ART Act, including the principle

that the welfare and interests of people who are born as a result of ART are, throughout their lives, of paramount importance in the administration of the Act.

Family limit approvals

The Bill also enables the chief executive to approve the use of donated genetic material beyond the family limit on a case-by-case basis, if the chief executive is satisfied there are reasonable grounds for the use. Whether there are reasonable grounds requires the chief executive to have regard to:

- the terms of the consent given by the donor for use of the gamete, that is, the maximum number of families the donor had consented to using their gametes (for example, if they had only consented to their gametes being used to create a maximum of five families); and
- whether, in the circumstances, the consequences of giving, or refusing to give the approval to use the gamete or embryo would be unfairly harsh for any person.

In considering the application, the chief executive must also be satisfied that the donor has consented to the making of the application by the ART provider. Alternatively, if the ART provider has been unable to contact the donor, the chief executive must be satisfied that the ART provider has taken reasonable steps to contact them. Also, operationally, ART providers will be encouraged to seek the donor's views of an application when they first obtain their consent. This gives the ART provider an indication, at that point in time, of whether the donor would be supportive in the future. If a donor does not consent to the application being made, or could not be contacted, this would not automatically result in the chief executive refusing an application. It would, however, be a relevant consideration that would weigh against approving the application. This would be balanced against the other individual circumstances of the case to determine whether use of the donated material should be approved.

All decisions will include consideration of the circumstances of the individual application, differing perspectives on the family limit, and the impact of any approved use beyond the limit (including for existing and future donor-conceived people, recipient parent or parents, and the donor). Again, the chief executive will, at all times, have regard to the objects of the ART Act, including the principle that the welfare and interests of people who are born as a result of ART are, throughout their lives, of paramount importance in the administration of the Act.

This case-by-case approval process allows the chief executive to exercise discretion if presented with a particular case where the application of the 10-family limit would result in unreasonable hardship. It is anticipated that approvals would be by exception and only for cases of significant hardship where, on balance, the use is considered reasonable. It is also expected the number of cases for approval would decrease over time as the ART Act becomes embedded and practices evolve to strictly meet its requirements.

Alignment of existing chief executive approval powers

To promote consistency, the Bill aligns the terminology, decision-making criteria and processes across existing and new chief executive powers where possible.

The Bill introduces additional rigour to the existing approval power in relation to the time limit for use of donated material (section 27) by including additional and more specific decision-making criteria that align with the criteria for family limit approvals. Section 27 currently enables the chief executive to give approval to the use of a donated gamete or embryo despite

the 15-year time limit being reached, if the chief executive is satisfied there are reasonable grounds for the use. The amended chief executive approval process requires the chief executive to have regard to:

- the terms of the consent given by the donor for use of the gamete, that is, the time period consented to by the donor (for example, whether the donor only wanted their genetic material used for a five-year period); and
- whether, in the circumstances, the consequences of giving, or refusing to give, the approval to use the gamete or embryo would be unfairly harsh for any person.

Consistent with the family limit approval process, the chief executive must also be satisfied that the donor has consented to the making of the application, or if the ART provider has been unable to contact the donor, that the provider has taken reasonable steps to contact them. As with a family limit application, ART providers will be encouraged to seek the donor's views on an application for use at the outset. If a donor does not consent to the application being made, or could not be contacted, this would not automatically result in the chief executive refusing an application. It would, however, be a relevant consideration that would weigh against approving the application. This would be balanced against the other individual circumstances of the case to determine whether use of the donated material should be approved.

The Bill supports natural justice across existing and new chief executive approval powers by providing that chief executive decisions to refuse applications relating to the family limit, time limit on use, information collection requirements or destruction of records are reviewable decisions that may be subject to internal review. To ensure procedural fairness, the Bill provides that an information notice must be given to applicants as soon as practicable after a decision is made to refuse the application, and applicants may seek an internal review within 20 business days of receiving the information notice..

Clarification of time limit on use of donated material

The Bill clarifies the time limit requirements for use of donated material in section 27. The Bill provides that disposal of the donated material is required if an application to use the donated genetic material is refused by the chief executive, rather than the material proactively requiring either disposal or approval for ongoing storage at the 15-year mark. This ensures the time limit and disposal requirements, and related chief executive approval process, are clear. Queensland Health will retain oversight over any proposed use of donated gametes and embryos beyond the 15-year time limit to ensure their use is appropriate.

Consent requirements

Obtaining gametes

The Bill provides that a gamete provider's consent is required before an ART provider obtains or attempts to obtain their gametes. This ensures there is a legislated requirement for consent to be obtained in writing before an ART provider carries out this important step in the ART process. The amendment also ensures that other relevant provisions of the ART Act, including record keeping requirements, apply to consent for this step in the process. The inclusion of 'attempting to obtain' ensures, for example, that even where an egg retrieval is unsuccessful, consent is still required.

Clarification of interaction of donor consent with chief executive approvals

The Bill clarifies the relationship between the donor consent requirements in the ART Act and the chief executive approval powers relating to the family limit and time limit for use of donated material. The donor consent requirements are amended to clarify that consent is not required to the extent that a donated gamete or donated embryo is used in an ART procedure under a chief executive approval to exceed the 10-family limit or time limit on use. This ensures the chief executive powers operate as intended to provide discretion in cases of undue hardship and provide clarity to ART providers and gamete providers.

Clarification of transitional provisions

Reflecting diverse family structures

The Bill amends the transitional provisions to better reflect diverse family structures and enable people who started their ART treatment before commencement of the ART Act to complete their intended family. The amendments extend the application of section 146 and 147 to include the person's spouse at the time donated gametes or donated embryos were allocated to them, or their surrogate. The inclusion of surrogate ensures a family needing to use a surrogate can utilise a different person rather than having to use the same surrogate for each subsequent pregnancy.

Disapplying information collection requirements for sections 146 to 148

The Bill amends the transitional provisions in sections 146 and 147 of the ART Act to disapply the information collection requirements. This reflects that for people who have already started their ART treatment in accordance with sections 146 or 147, it is appropriate to enable them to continue their ART treatment despite not being able to comply in full with particular requirements in the Act. This is consistent with the original policy intent of these provisions to exclude the application of the family limit, time limit and donor consent requirements in these pre-existing cases, noting that it may not be possible to comply with requirements that were not in place at a time before the Act commenced. It also ensures that, in these circumstances, an ART provider and, by extension, patient are not required to meet the regulatory burden of having to apply for a chief executive approval to use material under section 33.

The Bill amends section 148 to enable an ART provider to apply for a patient to use an embryo that was created before commencement of the Act but has not yet been used, where the information collection requirements are not met. This reflects that it may be appropriate for such a patient to continue using embryos created prior to commencement that do not meet particular requirements in the Act, while ensuring a level of oversight by Queensland Health. This is consistent with sections 146 and 147, ensuring patient cohorts are treated equitably, and aligns with the policy intent of the transitional provisions of disapplying other requirements in the Act.

These amendments remove the need for the ART provider to apply for multiple approvals from Queensland Health. For example, a person's provider may apply to use an embryo under section 148 due to the family limit having been reached, but because they are also missing a piece of information such the donor's place of birth, they would then also have to make a section 33 application to use the material. This is an unjustifiable hurdle when the application is unlikely to be refused by the chief executive given a section 148 decision has already approved use.

Sections 146 to 148 are also amended to clarify the intent of the transitional provisions in relation to consent and withdrawal of consent.

The current provisions state that the consent provisions under part 2, division 3 are disapplied for the purposes of people who had started their ART treatment before commencement of the Act. The amendments clarify that this was intended to disapply section 18(2) specifically, which provides for donor consent in relation to the family limit and time limit, noting that part 2, division 3 of the Act contains a range of consent requirements which are not all relevant to donated material.

The current provisions also state that the ART provider may use the remaining donated material (or, in the case of section 148, that the chief executive may authorise the use of the embryo) even though the donor has not consented under part 2, division 3, unless the donor has previously consented but withdraws that consent under part 2, division 3. The intent was to ensure that an ART provider does not seek to override explicit withdrawal of consent by a donor, either before or after commencement of the Act. The Bill clarifies this by providing that an ART provider may use donated material despite section 18(2), unless the donor has withdrawn their consent under section 20 of the ART Act (Withdrawal or variation of consent) or has otherwise withdrawn the consent by clearly communicating it to the ART provider, whether or not in writing.

Application of Act to existing matters

The Bill inserts additional transitional provisions to support the effective operation of the ART Act by specifying in greater detail how the Act applies to activities carried out, or to genetic material collected or created before commencement of the Act. These provisions outline the intended operation of certain key requirements for matters initiated before the Act commenced and will prevail over the existing section 144 to the extent of any inconsistency.

Section 145 (Licensing of existing ART providers) is amended to clarify which provisions of the ART Act are relevant for the purpose of deeming an ART provider to be a licensed provider during the initial licensing assessment period.

New section 145A (Licensed providers' notification of particular events that happened before commencement—new s 61) clarifies that ART providers must notify the chief executive of serious adverse events that occur prior to the commencement of section 61, if the ART provider becomes aware of the event after the commencement of section 61.

New section 145B (Donor-related Australian families—new section 25) clarifies that for the purpose of calculating the number of families for the family limit, it does not matter whether the person was born before or after the commencement of the family limit requirement.

New section 145C (Time limits on use of existing donated gametes and embryos—new s 27) clarifies the application of the time limit on use of donated material under section 27 to existing donated gametes and donated embryos used in an ART procedure after commencement of the requirement.

New section 145D (Record-keeping—s 36) clarifies the application of the record keeping requirements in section 36, to provide that if, before commencement of the requirements on 19 September 2024, an ART provider collected information mentioned in part 2, division 6, that the record keeping requirements apply to the information.

New section 145E (Disclosure of health information—s 38) clarifies the relevant parties who may have health information disclosed to them by an ART provider, including donor-conceived people and donor-conceived siblings born as a result of an ART procedure that was carried out before the commencement of section 38.

New section 149 (Use of particular gametes obtained before 19 September 2024—collection of information) clarifies, as outlined above, that the relevant information required under section 33(1) must be collected in relation to pre-commencement gametes before an ART provider uses the gametes, or an embryo created using the gamete, in an ART procedure.

The Bill also inserts a transitional regulation-making power which provides that a regulation may make a provision about a matter for which the ART Act does not provide or sufficiently provide. This ensures that any further issues identified throughout the implementation of the ART Act can be addressed in a timely manner. The transitional regulation-making power and any regulation made under it will expire two years from when the power commences.

Inspector powers

The Bill supports the effective operation of the regulatory framework by amending the investigation powers in the ART Act to enable inspectors to seek information from persons in a broader range of circumstances than currently provided for in part 5 of the Act.

The Bill amends section 111 to enable an inspector to require a person to give information if they reasonably believe:

- a person may be able to give information about a licensed provider's compliance with the Act; and
- the information is necessary for the inspector to perform their function to investigate, monitor and enforce compliance with the Act under section 69(a).

The amended power enables an inspector to give notice to a person to provide the information by a stated reasonable time, to inform any compliance action that may be required.

The amendment ensures Queensland Health has appropriate regulatory powers to compel the provision of information, consistent with the functions of inspectors detailed under section 69 of the Act to investigate, monitor and enforce compliance with the ART Act. This supports effective monitoring and compliance activities, consistent with community expectations of how regulation of the ART sector should operate.

Ensuring inspectors under the ART Act can compel information to monitor compliance with the Act and investigate serious adverse events reflects the policy intent of the legislative scheme. It also brings Queensland in line with other Australian jurisdictions, securing a full range of scalable compliance and enforcement powers.

Reform of accreditation scheme for ART sector

To reflect the HMM decision to replace RTAC as the accrediting authority for the ART industry from January 2027, the Bill removes references to RTAC accreditation and inserts references to *prescribed accreditation*. This provides for accreditation by the relevant accrediting body prescribed by regulation. A regulation is intended to be made to support the

ART Act. The regulation will prescribe RTAC as the relevant accrediting body until the Commission commences as the accrediting body in January 2027.

Terminology

The Bill amends the Act to update key terms and ensure alignment with the RTAC Code of Practice or a future code of practice and/or standards published by the Commission once it is stood up as the accrediting body in 2027.

Serious adverse event

The Bill amends the definition of *serious adverse event* in the ART Act to refer to serious adverse events identified in the accreditation standard. *Accreditation standard* is defined as a document that provides for matters in relation to prescribed accreditation and approved by regulation, with or without modification. Noting the changes to the accreditation of ART services agreed to by HMM in September 2025, this enables the RTAC Code of Practice to be prescribed as the accreditation standard for the Act while RTAC is still the relevant accrediting body, with a view to prescribing a future code or standard once the Commission is stood up as the accrediting body.

Referring directly to serious adverse events identified in the accreditation standard ensures transparency by requiring any events notified to RTAC or the Commission to also be notified to Queensland Health. This also ensures consistency between the accreditation and regulatory schemes by avoiding differently worded but likely corresponding serious adverse events to be listed in two authoritative schemes (code or standards and the ART Act).

Personnel

The Bill broadens current references in the Act to 'key personnel' to include additional personnel, by referring generally to 'personnel' within the meaning of the accreditation standard. This change reflects the important on-site role of additional personnel, who are generally the staff managing day-to-day operations in ART clinics. This supports the licensing framework by enabling Queensland Health to have more visibility of staffing by providers.

This amendment does not impact ART providers' staffing requirements, which are governed by the accreditation framework. It is a requirement under the RTAC Code of Practice for providers to appoint key personnel and additional personnel. The Code of Practice sets out detailed requirements for the functions and qualifications of all personnel, against which providers are audited. The amendments have the effect that, in addition to providing information to Queensland Health about key personnel engaged in the provision of ART services, ART providers are also required to provide information about additional personnel they appoint.

As noted above, it is intended to prescribe the RTAC Code of Practice by regulation with a view to prescribing a new code or standard by the Commission once the Commission is stood up as the accrediting body.

Application of Act to spouse of the person undergoing ART

The Bill amends sections 15, 35 and 44 to provide that a spouse for these provisions excludes a spouse from whom the person has separated and is living separately and apart. Targeted

amendments to these penalty provisions that would otherwise prevent a person from undergoing an ART procedure without their estranged spouse's involvement will ensure the provisions operate as intended and do not conflict with the Sex Discrimination Act.

Cross-referencing error

The Bill amends section 138 to make a minor correction to include section 139(1) of the ART Act as a deemed executive liability provision. This enables Queensland Health to hold executive officers accountable if they play a role in providing false or misleading information.

Minor amendments to support the donor conception information register

The Bill amends part 3 to broaden what is considered relevant information for the purposes of including information for the Register. This ensures the information does not need to relate directly to the 'birth of a donor-conceived person' and enables further information to be prescribed by regulation. It supports the policy intent that the Register can hold the range of information needed to support access to genetic, health and relational information for donors, donor-conceived people and the parent/s of donor-conceived people.

Amendments to the *Hospital and Health Boards Act 2011, Health and Wellbeing Queensland Act 2019, Pharmacy Business Ownership Act 2024* and *Hospital Foundations Act 2018*

The Bill amends the Hospital and Health Boards Act, Health and Wellbeing Queensland Act, Pharmacy Business Ownership Act and Hospital Foundations Act to provide that the Governor in Council can remove the following office holders for any reason, including for no reason:

- HHB members under the Hospital and Health Boards Act;
- HWQ Board members and CEO under the Health and Wellbeing Queensland Act;
- PBOC members and CEO under the Pharmacy Business Ownership Act; and
- HFB members under the Hospital Foundations Act.

The Bill also includes transitional provisions so that the power applies to existing office holders appointed before commencement. As the power is given to the Governor in Council, a proposal to remove an office holder requires consultation across Government, which provides a safeguard to ensure the power is exercised appropriately.

These Acts already provide external circumstances which result in office holders being disqualified from office or allow for office holders to be removed. These circumstances include the person being insolvent, disqualified from managing a corporation, or convicted of an indictable offence. The Bill makes the external circumstances, that result in an office holder being disqualified, consistent across each of the Acts.

The Bill also makes other minor and technical amendments to improve consistency across the Acts, including ensuring each Act has provisions allowing the Minister to appoint acting members if there is a vacancy.

Amendments to the *Private Health Facilities Act 1999*

Power to prescribe standards of accreditation for facilities that provide particular health services

The Bill amends the Private Health Facilities Act to clarify that a regulation can be made to prescribe a standard of accreditation that must be complied with for all health services, or a type of health service, provided at a private health facility. This provides a mechanism to require facilities that provide cosmetic surgery to comply with the Cosmetic Surgery Standards, in addition to the NSQHS Standards. The proposed amendment also provides flexibility if future standards of accreditation are developed or agreed to be applied or implemented for specific private health facilities.

Separate amendments to the Private Health Facilities Regulation are required to prescribe that licensees that provide cosmetic surgery services must comply with the Cosmetic Surgery Standards. The Private Health Facilities Regulation will continue to require all licensees to comply with the NSQHS Standards.

Section 3(2) of the Private Health Facilities Regulation already lists a significant number of cosmetic surgery procedures that must be performed in a licensed private health facility, including abdominoplasty, breast augmentation or reduction, facelift, facial implants and rhinoplasty. The definition of what constitutes 'cosmetic surgery' for the purposes of applying the Cosmetic Surgery Standards will be included in future amendments to the regulation. Stakeholders and industry will be separately consulted about the definition of what will constitute 'cosmetic surgery' as part of the process for making those changes.

Power to share private hospital data with other Queensland Government entities under an agreement

The Bill amends the Private Health Facilities Act to provide that information can be shared with Queensland Government entities under an agreement prescribed by regulation, if the chief executive is satisfied that the disclosure is in the public interest. This creates a more efficient process for sharing information with other Queensland Government entities and provides greater consistency with how information can be disclosed with the Commonwealth and other States under the Private Health Facilities Act.

The approach in the Bill is consistent with how information is shared with Queensland Government entities under the Hospital and Health Boards Act and Public Health Act. If a relevant agreement is prescribed, information could be shared about both public and private health care with other Queensland Government entities at the same time.

Amendments to the *Transplantation and Anatomy Act 1979*

The Bill amends the Transplantation and Anatomy Act to provide authority for consent to be given for ante-mortem interventions to be undertaken on a potential donor to support organ donation following circulatory death.

The Bill provides that for a child, or an adult with impaired capacity, the person's next of kin (known as the *senior available next of kin* in the Transplantation and Anatomy Act) can give consent to the carrying out of an ante-mortem intervention.

Before consent to an ante-mortem intervention can be given, the potential donor must be in hospital and a lawful decision to withdraw or withhold life-sustaining measures must have already been made and not revoked. A lawful decision may include, in the case of a child, a decision by a parent or guardian and, in the case of an adult who does not have capacity, a decision under the relevant laws relating to withholding or withdrawing life-sustaining measures.

It is critical to note that the decision to withdraw or withhold life-sustaining measures must come before—and be wholly separate from—any subsequent discussion or decision about organ donation or ante-mortem interventions. The consent process for organ donation is already established under the Transplantation and Anatomy Act in relation to consent to donation of tissue after death, which includes organs for transplantation.

Once consent to withdraw or withhold life-sustaining measures has been given, the Bill provides that the designated officer for the hospital is required to authorise, in writing, the carrying out of ante-mortem interventions if the next of kin has consented, in writing, to the carrying out of the ante-mortem intervention and that consent has not been revoked. Under the Transplantation and Anatomy Act, a designated officer is the medical superintendent of a hospital, a nominated medical practitioner, or officers appointed by the person or body in charge of a hospital. The designated officer is already required to authorise removal of the donated tissue once consent has been received from the next of kin.

Importantly, the designated officer is not a member of the person's treating team and is independent of any discussions and decision-making regarding withholding or withdrawing life-sustaining measures, ante-mortem interventions or organ donation.

Blood tests are critical to determining suitability for organ donation and are usually done before other ante-mortem interventions are undertaken. The taking of blood is time critical as it is often the first step to determine whether someone is suitable to be an organ donor. As such, the Bill excludes removing blood from the body of a living person for the purpose of determining tissue donation viability as an ante-mortem intervention. This is to ensure blood tests do not need the separate written authorisation by the designated officer before they are undertaken, as a designated officer is not always readily available to provide the written authorisation required at short notice.

As such, the Bill amends part 2, division 4 of the Transplantation and Anatomy Act to provide that in the case of an adult with impaired capacity, or a child, the senior available next of kin can consent, in writing, to the removal of blood for the purposes of determining tissue donation viability. As blood tests are considered routine and non-invasive, the consent by the next of kin is considered sufficient authority and does not require the designated officer to separately authorise it.

The Bill also provides administrative processes required to document the consent and authorisation to conduct ante-mortem interventions and includes provisions in relation to the giving of oral consent when written consent is not reasonably practicable.

Consequential amendment to the *Public Health Act 2005*

The Bill amends the references to the Commonwealth chief medical officer in the Public Health Act, to refer to a person to whom notifications must be made under the NORDR Act. This approach provides for continued notification under the current NORDR Act, and also ensures

that, if the changes to Commonwealth legislation pass and the Australian CDC is established, notifications will be made to the Australian CDC from 1 January 2026.

Alternative ways of achieving policy objectives

Amendments to the *Assisted Reproductive Technology Act 2024*

There are no alternatives to amending the ART Act in order to achieve improvements to the regulatory framework. The amendments support the effective regulation of ART services in Queensland and avoid unintended outcomes.

Amendments to the *Hospital and Health Boards Act 2011, Health and Wellbeing Queensland Act 2019, Pharmacy Business Ownership Act 2024* and *Hospital Foundations Act 2018*

An alternative way of achieving the policy objective is to rely on section 25(1)(b)(i) of the Acts Interpretation Act, which provides that the Governor in Council can remove or suspend, at any time, a person appointed to the office. However, the proposed approach makes it clear that the Governor in Council can remove the person for any reason or none, which provides transparency for office holders and the public. The amendment also supports efforts to ensure office holders uphold high standards of performance, behaviour, integrity and effectiveness in their roles as leaders of the public health system.

Amendments to the *Private Health Facilities Act 1999*

Power to prescribe standards of accreditation for facilities that provide particular health services

There are no alternatives to amending the Private Health Facilities Act other than amending the current head of power. The amendments ensure there is an appropriate mechanism to require facilities that provide cosmetic surgery procedures to comply with the Cosmetic Surgery Standards.

Power to share private hospital data with other Queensland Government entities under an agreement

There are no alternatives to amending the Private Health Facilities Act to ensure that information can be shared with Queensland Government entities under an agreement prescribed by regulation. The amendments provide consistency with the way information under the Act is shared with other Queensland Government entities, and with the Commonwealth and other States. In addition, the amendments provide consistency with the way private health information is shared with Queensland Government entities with the process that is provided for in the Hospital and Health Boards Act and Public Health Act.

Amendments to the *Transplantation and Anatomy Act 1979*

There are no alternatives to amending the Transplantation and Anatomy Act. Without the amendments, there will continue to be no legislative framework to facilitate consent to ante-mortem interventions to be undertaken to support organ donation following circulatory death.

This will result in continued uncertainty and missed opportunities for lifesaving and life-improving transplants.

Consequential amendment to the *Public Health Act 2005*

There are no alternatives to amending the Public Health Act. The amendments provide for the continued notification under the current NORDR Act and ensure that notifications will be made to the Australian CDC if the proposed Commonwealth legislation passes.

Estimated cost for government implementation

The amendments either have no financial implications or will be implemented within existing resources.

Consistency with fundamental legislative principles

The amendments included in the Bill are generally consistent with fundamental legislative principles in the *Legislative Standards Act 1992*. However, the amendments may impact on particular principles. The potential departures from fundamental legislative principles are discussed below. All departures have been carefully considered and their potential impacts have been minimised to the extent possible.

Whether the legislation has sufficient regard to the rights and liberties of individuals (Legislative Standards Act, s 4(2)(a))

Does the legislation make rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review?

Section 4(3)(a) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation makes rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review.

Assisted Reproductive Technology Act

The Bill provides new and amended administrative powers for the chief executive to support the operation and administration of the ART Act. These powers are sufficiently defined and subject to appropriate review, as outlined below.

The Bill provides the chief executive with new powers to approve, on reasonable grounds, the use of donated gametes and embryos despite the requirements in section 25 (10 donor-related families) and section 33 (information collection requirements). Where practicable, the Bill aligns these new chief executive approval powers with the existing chief executive approval powers in section 27 (Time limit on use of donated gametes or embryos and their disposal) and section 37 (Destruction of records prohibited) of the ART Act, for example by providing consistent terminology, decision-making criteria and processes.

The new chief executive approval powers provide limited flexibility in the application of the 10-family limit and information collection requirements to ensure their intent is upheld while

preventing any undue hardship or unintended outcomes that may occur in individual cases if the requirements were strictly adhered to. It is anticipated that the chief executive approval process may be relevant in circumstances such as an individual or couple who would be prohibited from using a gamete donor due to an inability to obtain a specific piece of information, despite already having a donor-conceived child from the same donor. In relation to the family limit, discretion may be exercised by the chief executive where, for example, following the breakdown of a relationship, a person who wishes to access the same donor as their existing donor-conceived children is prevented from doing so, as they would now constitute a separate *family* under the ART Act and have exceeded the family limit.

The Bill appropriately defines these administrative powers by expressly outlining the factors the chief executive must take into account in making a decision to approve use. These criteria are directly relevant to whether, in the circumstances, the consequences of giving, or refusing to give, the approval would be 'unfairly harsh' for any person. This is a legal standard that requires a careful balancing of the welfare and interests of the parties involved, and of the objects and paramount principle of the ART Act.

Additional decision-making criteria is introduced in relation to the time limit on use of donated material to align with the criteria for the family limit. Currently, the chief executive may give an approval under section 27 if the chief executive is satisfied there are reasonable grounds for doing so. The Bill includes additional and more specific decision-making criteria to align with the family limit criteria. This ensures that decisions made in relation to these approval applications are appropriately defined and limited by setting out the criteria the chief executive must be satisfied of to approve use of the gametes.

Further supporting the rights and liberties of individuals, the Bill establishes the right for applicants under part 2 to seek internal review where a decision has been made to refuse the application. This process establishes a greater degree of procedural fairness by ensuring that applicants are provided notice in relation to decisions to refuse applications and may seek internal review if required.

Decisions to approve the use of a gamete or embryo despite the requirements in section 25, 27 or 33, or to approve destruction of records under section 37, are not considered appropriate for external review. This is because of the complex clinical, ethical and regulatory factors involved in such a decision and the need for the decision-maker to balance competing considerations and the interests of a range of individuals. For this reason, it is appropriate that the chief executive, as regulator of ART services, determine whether an approval is warranted in the circumstances, and that review be limited to internal review.

To support transparency of and promote confidence in this decision-making, Queensland Health will also publish the number of applications received against each chief executive approval provision and overall outcomes. This reporting will be available on the Queensland Health website and will be kept updated at regular intervals.

Is the legislation consistent with principles of natural justice?

Section 4(3)(b) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation is consistent with principles of natural justice.

Amendments to the Hospital and Health Boards Act, Health and Wellbeing Queensland Act, Pharmacy Business Ownership Act and Hospital Foundations Act

Under the amendments in the Bill, the Governor in Council is able to remove certain statutory office holders for any reason or none. Although the Bill permits an office holder to be removed without grounds, it is expected that procedural fairness and natural justice would ordinarily be observed, such as by giving the person notice of the proposed action and an opportunity to be heard. As such, it is considered the Bill is consistent with this fundamental legislative principle.

The approach in the Bill is not unique and other Queensland legislation allows for office holders to be removed for any reason or none, including:

- Legal Aid Board members under section 51(3) of the *Legal Aid Queensland Act 1997*;
- Queensland Rail Transit Authority Board members under section 20(2) of the *Queensland Rail Transit Authority Act 2013*;
- Director and deputy directors of Forensic Science Queensland under sections 10 and 14D(2) of the *Forensic Science Queensland Act 2024*;
- Forensic Science Queensland Advisory Council members under section 34(2) of the Forensic Science Queensland Act;
- Gold Coast Waterways Authority Board members under section 50 of the *Gold Coast Waterways Authority Act 2012*;
- Board of directors of Stadiums Queensland under section 17 of the *Major Sports Facilities Act 2001*;
- Members of the Queensland Art Gallery Board of Trustees under section 10 of the *Queensland Art Gallery Act 1987*;
- CEO of the National Injury Insurance Agency, Queensland under section 82 of the *National Injury Insurance Scheme (Queensland) Act 2016*; and
- Community board members of the Parole Board Queensland under section 226(2) of the *Corrective Services Act 2006*.

Assisted Reproductive Technology Act

The Bill aligns the terminology, decision-making criteria and processes where possible across the new and existing chief executive approval powers under part 2 of the ART Act. To ensure the principles of natural justice are upheld, the Bill makes amendments to provide that a decision to refuse an application relating to the family limit, time limit on use, information collection requirements or destruction of records may be subject to internal review. The Bill provides that an information notice must be given to the applicant as soon as practicable after a decision is made to refuse the application, and that an applicant has 20 business days from receiving the information notice to seek an internal review of the decision.

Once an application for internal review is received in accordance with section 122, a reviewer holding a more senior office than the original decision-maker must conduct an internal review and determine whether to confirm the decision, amend the decision or substitute another decision. The internal review must conclude within 20 business days of the application being received, unless a longer review period is agreed to by the chief executive and the applicant.

This process supports natural justice by ensuring that applicants are provided an adequate opportunity to present their case in relation to a decision.

The Bill provides that internal review decisions in relation to the chief executive decisions under part 2 is not subject to external review. This is appropriate as these decisions require complex consideration of a broad range of matters and will be directly informed by expert advice which represents the interests and perspectives of impacted parties. For example, a decision-maker may be supported by medical practitioners experienced in ethics, counsellors, advocacy groups representing cohorts with lived experience, and other specialists. Given the complex nature of these decisions and the specific subject matter expertise required to strike a balance between competing interests and perspectives, limiting the review process to internal review is considered appropriate and justified. It achieves natural justice by ensuring applicants have a right of review without placing an excessive burden on the tribunal system to undertake external reviews of these complex decision-making processes.

Does the legislation provide appropriate protection against self-incrimination?

Section 4(3)(f) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation provides adequate protection against self-incrimination.

Assisted Reproductive Technology Act

The amendment to section 111 (Power to require information) broadens the existing inspector power which requires a person to give an inspector information where there is a reasonable belief an offence against the Act has been committed. The Bill enables an inspector to request information, by notice given to the person, where a person may be able to give information about a licensed provider's compliance with the ART Act and the information is necessary to support the inspector's function under section 69(2) of the Act to investigate, monitor and enforce compliance with the Act.

Former parliamentary committees have found that it may be justifiable to abrogate the privilege against self-incrimination in instances where Parliament considers the public interest is elevated over individual interests (for example, where it is more important to determine the facts of a matter). Also, in *Pyneboard Proprietary Limited v Trade Practices Commission* (1983) 152 CLR 328, Mason A-CJ and Wilson and Dawson JJ observed that privilege may be abrogated:

> … when the object of imposing the obligation [for example, answering questions or producing documents] is to ensure the full investigation in the public interest of matters involving the possible commission of offences which lie peculiarly within the knowledge of persons who cannot reasonably be expected to make their knowledge available otherwise than under a statutory obligation.

The information sought in the section is required to determine, for example, whether a licensing condition has been breached (section 59); whether an improvement notice, prohibition notice or suspension has been complied with (sections 62 – 64); where a serious adverse event has been notified to the chief executive (section 61) which requires investigation; and to support monitoring of compliance with the Act generally. This may include information tending to incriminate the person but that is peculiarly within the knowledge of the person. However, it is

a reasonable excuse under section 112 (Offence to contravene information requirement) for the person not to provide this information if it would tend to incriminate them.

The information sought by the chief executive is necessary for the effective regulation of ART providers. In particular, the information may be relevant to key aspects of the licensing scheme, including whether the person is complying with licensing conditions and relevant notices, which could also speak to whether they should continue to hold a licence and are operating safely. The information is also necessary where a serious adverse event or other event has been notified to the chief executive under section 61 which requires investigation by the regulator. This power is considered necessary and justified as without it, inspectors will not have sufficient powers to support their functions under section 69 of the Act to investigate, monitor and enforce compliance with the Act. Under the current Act, inspectors would only be able to exercise these powers in the circumstances described via consent, which in a healthcare environment is highly complex, owing to the various parties from whom consent is required, and can result in the potential for patient harm to go unactioned in a timely manner because of a process frustrated by delays in consent. It is untenable to delay action in favour of consent when the safety and welfare of patients and persons born as a result could be impacted.

Section 112 provides that a person of whom a requirement is made under section 111 must comply with the requirement unless they have a reasonable excuse. A maximum penalty of 50 penalty units applies for non-compliance with this requirement. While the amendment broadens the existing inspector powers and increase the circumstances in which information may be required from an ART provider, section 112(2) provides enduring protection and states that self-incrimination is a reasonable excuse for an individual not to give information required by an inspector under section 111.

Does the legislation adversely affect rights and liberties, or impose obligations, retrospectively?

Section 4(3)(g) of the Legislative Standards Act provides that whether legislation has sufficient regard to rights and liberties of individuals depends on whether the legislation adversely affects rights and liberties, or imposes obligations, retrospectively.

Assisted Reproductive Technology Act

The Bill clarifies that the information collection requirements in section 33 apply to pre-commencement gametes (that is, gametes obtained by ART providers prior to commencement of the Act). This supports the policy intent of ensuring information is collected about all gametes used in ART procedures and that appropriate records are maintained by ART providers.

Gametes are often obtained well in advance of the procedure they will be used in. Most of the genetic material in storage in Queensland is made up of gametes, or embryos created with gametes, obtained before the ART Act commenced. Donated gametes are also often obtained through overseas donor banks. Currently, section 33(5) provides that it is an offence to use a gamete or embryo without having collected the information required under section 33. This requirement was intended to apply to *use* of all gametes following commencement of the Act, regardless of when the gametes were *obtained*, including gametes obtained prior to commencement of the ART Act.

The Bill inserts new section 149 to put beyond doubt the application of section 33 to pre-commencement gametes. Section 149 clarifies that pre-commencement gametes may be used in an ART procedure where the provider has met the information collection requirements before the gametes were obtained, where the ART provider has collected any outstanding information and has met the information collection requirements prior to using the material, or where the chief executive has approved use under new section 39C.

While this provision could be seen to impose retrospective obligations, the effect of section 149 for gametes already in storage prior to commencement of the information collection provisions is that ART providers must collect the relevant information before the material may be used in an ART procedure. The provision does not impose a retrospective requirement to have already collected the information prior to commencement of section 33, but clarifies that for all gametes in storage, the requirement to collect relevant information before the gamete is used applies equally, with prospective effect. Where existing information relating to pre-commencement gametes does not meet the information collection requirements, ART providers are required to obtain the information before the material may be used in future ART procedures.

Clause 45 inserts a transitional regulation-making power. The power provides that a regulation may make provision about a matter for which this Act does not provide or sufficiently provide. This may be seen as a breach of section 4(3)(g) of the Legislative Standards Act as it provides a head of power for a transitional regulation, which may have retrospective operation. This is appropriate as the retrospective operation can only be to a day that is not earlier than the day on which the section commences. The transitional regulation-power is also limited. The power and any transitional regulation made will expire two years after the commencement of the section. Although the Bill already provides for a range of transitional issues, it is possible that unanticipated matters may arise given the complexity of the ART Act and transitioning to the new regulatory regime from a previously self-regulated industry. The inclusion of such a power ensures that any transitional issues that have not been identified during the drafting of the provisions can be quickly addressed to ensure individuals' rights are not adversely affected.

A similar transitional provision has been included in a range of other Acts, including repealed section 282 of the *Medicines and Poisons Act 2019*, repealed section 86 of the *Ambulance Service Act 1991*, and repealed section 202 of the *Transport Operations (Road Use Management) Act* 1995.

Amendments to the Hospital and Health Boards Act, Health and Wellbeing Queensland Act, Pharmacy Business Ownership Act and Hospital Foundations Act

The Bill includes transitional provisions to clarify that whether an office holder was appointed before or after the amendments commence, the person may be removed from office by the Governor in Council for any reason or none. This could potentially be considered to affect the rights of current office holders retrospectively. This impact could be significant for office holders that may have made housing or employment decisions to allow them to accept the appointment.

However, this approach is considered necessary to ensure that all office holders, regardless of when they were appointed, are treated the same and are subject to the same powers of removal. For example, if two members of a board were appointed at different times, one before commencement and one after commencement, if the transitional provisions were not included,

different grounds for removal would apply to them, which could result in them being subject to different outcomes. Also, the amendments only apply after commencement of the Bill and it is common practice to include transitional provisions to clarify the application of new powers. Given the importance of the roles of the office holders, it is considered appropriate for all office holders to be subject to the same powers of removal from office.

Does the legislation in all other respects have sufficient regard to the rights and liberties of individuals?

The list of examples in the Legislative Standards Act is not exhaustive of the issues relevant to deciding whether legislation has sufficient regard to the rights and liberties of individuals. Further considerations include whether the legislation infringes on the privacy of individuals, unduly restricts ordinary activities (including the right to conduct business without interference) and whether the penalties imposed by legislation are proportionate and relevant to the actions to which the penalties are applied.

Does the legislation infringe on the right to privacy?

The Scrutiny of Legislation Committee has noted that the right to privacy is relevant to whether legislation has sufficient regard to the rights and liberties of individuals. The Bill contains provisions that may be seen to affect the privacy of individuals, namely the amendments to section 33 of the ART Act relating to collection of personal and confidential information of gamete providers, and the amendment to the Private Health Facilities Act to enable improved process for information sharing with other Queensland Government entities.

Assisted Reproductive Technology Act

The amendment of section 33 and insertion of new section 149 do not introduce any new powers to collect information. Instead, the Bill clarifies the application of existing requirements, including in relation to pre-commencement gametes. Broadly, the requirements in section 33 are considered justified as they support the operation of the ART Act by ensuring appropriate records are collected. ART providers are a crucial source of information about gametes and embryos used in ART procedures (including donated gametes and embryos), patients who have used ART services and outcomes of treatment. Good record keeping and data reporting are an integral part of ART clinical practice.

Adequate safeguards are also in place. The ART Act includes specific offences for failing to collect or keep records in accordance with the requirements of the legislation, which are commensurate with the possible impacts. There are also penalties in the Act for destroying records or providing false and misleading information or documents.

Private Health Facilities Act – information sharing

The amendment to section 147 of the Private Health Facilities Act make the existing process for information sharing with other Queensland Government entities more efficient, by providing for information to be shared under an agreement prescribed by regulation. Information sharing with other Queensland Government entities can already be authorised in accordance with section 147(4)(g) and (6) if the chief executive believes on reasonable grounds that the disclosure is in the public interest, but authorisation must be sought for each individual disclosure.

The amendment in the Bill facilitates a consistent approach to sharing of health care information by Queensland Health with other Queensland Government entities by aligning the approach that applies to data about public and private health care. The amendment authorises information to be shared under an agreement prescribed by regulation. This means public and private health information could be shared with another State Government entity under a single agreement. Providing comprehensive data is expected to assist other Queensland Government entities to conduct a thorough analysis of relevant issues for which the data is provided.

Disclosure of confidential information is only be permitted where the chief executive is satisfied it is in the public interest, and it must be disclosed in accordance with the terms of the prescribed agreement.

This approach also brings the process for information sharing with Queensland Government entities into line with the existing process under section 147(4)(c) of the Private Health Facilities Act permitting the disclosure of confidential information by the chief executive to the Commonwealth or another State (or an entity of the Commonwealth or another State) under an agreement prescribed by regulation. The amendment is also consistent with the process under section 151(1)(b) of the Hospital and Health Boards Act, which allows Queensland Health to disclose confidential information about public health care to a Queensland Government entity under an agreement prescribed by regulation, and with various provisions allowing confidential information to be disclosed to Queensland Government entities in the Public Health Act (including sections 84, 226, 228O, 244 and 279AO).

It is considered that appropriate safeguards are in place. Confidential information is only permitted to be shared if the chief executive is satisfied the disclosure is in the public interest, and in accordance with the terms of the prescribed agreement. Also, prescribed agreements for the disclosure of information are drafted to ensure that they contain appropriate obligations for continued compliance with the *Information Privacy Act 2009* and the Queensland privacy principles. This approach ensures that confidential and personal information is stored, handled, accessed, amended, managed, transferred, used and disclosed appropriately. With these safeguards in place, the disclosure of information is considered to have appropriate regard to the rights and liberties of persons whose information is shared.

The amendment strikes an appropriate balance between the rights and liberties of individuals by ensuring limits on the disclosure of private hospital data, and the benefits to the broader community of enabling the sharing of information with Queensland Government entities to assist with analysis of health care data.

Does the legislation unduly restrict ordinary activities (including the right to conduct business without interference)?

Legislation should not, without sufficient justification, unduly restrict ordinary activities. Regulation of business is an intervention in the right to conduct business in the way in which the persons involved consider appropriate.

Private Health Facilities Act – Power to prescribe standards of accreditation for facilities that provide particular health services

The Private Health Facilities Act provides the statutory framework for protecting the health and wellbeing of patients receiving health services at private health facilities. To hold a licence for a private health facility, the licensee must comply with the AHSSQAS and the NSQHS Standards. The NSQHS Standards apply to all health services provided at private hospitals and day hospitals.

The Bill amends the Private Health Facilities Act to clarify that a regulation can be made to prescribe a standard of accreditation that must be complied with for all health services or a type of health service provided at a private health facility. This provides a mechanism to require private health facilities that provide cosmetic surgery procedures to comply with the Cosmetic Surgery Standards. This potentially restricts the ordinary activities of these businesses.

The Cosmetic Surgery Standards were developed by the Commission in response to an agreement by HMM in September 2022 to strengthen national regulation of cosmetic surgery.

Cosmetic surgery involves specific safety and quality risks that are unique to the cosmetic surgery sector. The Commission states that cosmetic surgery has seen exponential growth in recent years and that, if not delivered to acceptable safety and quality standards, there can be severe consequences for patient health outcomes.

The Cosmetic Surgery Standards are intended to apply only to private health facilities that provide cosmetic surgery. They require facilities to address the specific safety and quality risks inherent to cosmetic surgery procedures and reduce the potential for harm to members of the public undergoing cosmetic surgery. The restriction on private health facilities that perform cosmetic surgery procedures to require them to comply with the Cosmetic Surgery Standards is considered justified given the intent to protect the public from harm and improve the quality of cosmetic surgery in Australia.

The Cosmetic Surgery Standards were developed to align in structure and intent to the NSQHS Standards. A licensed private health facility that provides cosmetic surgery services will continue to be required to comply with the NSQHS Standards, plus additional actions under the cosmetic surgery module. This will allow facilities to be assessed for compliance against both the NSQHS Standards and Cosmetic Surgery Standards in a single accreditation assessment, which will reduce the compliance burden for businesses.

Does the legislation balance the rights of individuals and the rights of the community appropriately?

Transplantation and Anatomy Act

The Bill amends the Transplantation and Anatomy Act to authorise a person's next of kin to consent to ante-mortem interventions being undertaken on a potential donor to support organ donation following circulatory death. Ante-mortem interventions are intended to assist with determining patient suitability for donation, facilitating organ matching with suitable recipients and maintaining or improving organ function and viability for the benefit of the recipient.

These provisions may be considered to impact on the rights and liberties of individuals who are subject to ante-mortem interventions as they provide for a person's next of kin to consent to medical procedures in circumstances where the person the subject of the medical treatment is unable to consent. However, there are existing safeguards in the Transplantation and Anatomy Act to ensure the person's next of kin, in order of priority, are able to consent to the removal of tissue from the body of the deceased person and that their consent to tissue donation after death is not in opposition to the person's own objections to their tissue being donated.

Further, section 22 of the Act, which deals with tissue donation following death, provides for the following accountability measures:

- the designated officer, who is the medical superintendent of a hospital, or a nominated medical practitioner appointed under the Act, is required to make reasonable enquiries into whether the person had objected to the removal after death of tissue from their body over their lifetime;
- the fact that the consent or communication was given and the details of it must be documented in writing by the designated officer;
- reasonable attempts must be made by the designated officer to have the consent confirmed in writing by the senior available next of kin; and
- the designated officer has responsibility for ensuring that the senior available next of kin's written consent, or written confirmation of the senior available next of kin's oral consent or communication, is placed on the hospital records relating to the deceased person, as soon as practicable.

Consent for ante-mortem interventions would only be sought after a lawful decision to withdraw life-sustaining measures has been made and where the person's next of kin gives consent to organ donation. Further, the amendments provide for similar accountability measures as set out in section 22. In particular, the designated officer of a hospital must separately authorise the carrying out of an ante-mortem intervention (excluding blood tests) and the consent must be in writing. As outlined above, consent and authorisation are also separately required for removal of tissue from the body of the deceased person under section 22 of the Transplantation and Anatomy Act. Importantly, the designated officer is not a member of the potential donor's medical team and is independent of any discussions and decision-making regarding withholding or withdrawing life-sustaining measures, ante-mortem interventions or organ donation.

<u>Abrogation of established statute law rights and liberties must be justified</u>

Amendments to the Hospital and Health Boards Act

The Bill inserts new section 25A into the Hospital and Health Boards Act, which provides the criteria for when a HHB member is disqualified from becoming or continuing as a HHB member. The disqualification criteria includes when the member has a conviction for an indictable offence or an offence against the Hospital and Health Boards Act. The disqualification criteria does not exclude spent convictions.

The *Criminal Law (Rehabilitation of Offenders) Act 1986* provides a scheme to support the rehabilitation of persons convicted of offences. Providing that a person is disqualified from becoming or continuing as a HHB member, including because of a spent conviction, may be

considered a breach of the fundamental legislative principle as a possible abrogation of established statute law.

The disqualification criteria in new section 25A of the Hospital and Health Boards Act are based on the grounds for removal that were previously included in section 28 of the Hospital and Health Boards Act, which are omitted by the Bill. Section 28 currently provides a basis for removal from office including if a person has a 'spent conviction'. The disqualification criteria in new section 25A is consistent with the existing approach in section 28.

HHB members hold important positions of public trust. They are responsible for overseeing significant service delivery of the health system and are responsible for significant budgets and funding. Given their important leadership role in the health system, it is considered that spent convictions should not be excluded. Therefore, the potential breach of this fundamental legislative principle is considered justified.

Whether the legislation has sufficient regard to the institution of Parliament (Legislative Standards Act, s 4(2)(b))

Does the legislation sufficiently subject the exercise of a delegated legislative only in appropriate cases and to appropriate persons?

Section 4(4)(a) of the Legislative Standards Act states that whether legislation has sufficient regard to the institution of Parliament depends on whether the legislation allows for the delegation of legislative power only in appropriate cases and to appropriate persons.

The Bill includes several regulation-making powers:

- the amendment to the ART Act to remove reference to RTAC accreditation and refer to prescribed accreditation by a body prescribed by regulation;
- the amendment to the ART Act to provide for an *accreditation standard* to be prescribed by Regulation, with or without modification, to support the interpretation of certain key terms;
- a regulation-making power for transitional matters that are not adequately addressed within the ART Act;
- the amendment to the Private Health Facilities Act to provide a mechanism to require private health facilities providing cosmetic surgery procedures to comply with the Cosmetic Surgery Standards; and
- the amendment to the Private Health Facilities Act to enable information sharing with other Queensland Government entities through an agreement prescribed by regulation.

These provisions are considered to have sufficient regard to the institution of Parliament given:

- the matters to be prescribed are consistent with the policy objectives and purpose of the relevant legislation;
- the matters to be prescribed are technical in nature and relate to operational and clinical aspects of the relevant legislation;

- the regulation-making powers allows the Government to respond promptly and flexibly if changes are needed to the relevant frameworks in future, ensuring they can be managed appropriately. For example:
  - prescribing matters by regulation provides some flexibility for Queensland Health to be able to update requirements relating to technical and clinical matters, such as additional agreements with other Queensland Government entities;
  - prescribing an accrediting body and accreditation standard by regulation to support the ART Act is considered appropriate noting the shifting accreditation landscape and the need for flexibility to ensure the national accreditation framework continues to be accurately reflected in the Act; and
  - the inclusion in the ART Act amendments of a transitional regulation-making power is considered appropriate given the complexity of establishing a regulatory framework for an industry that was previously self-regulated and the possibility that unanticipated matters will be identified that require timely action.

Does the legislation sufficiently subject the exercise of a delegated legislative power to the scrutiny of the Legislative Assembly?

Section 4(4)(b) of the Legislative Standards Act provides that whether legislation has sufficient regard to the institution of Parliament depends on whether the Bill sufficiently subjects the exercise of a delegated legislative power to the scrutiny of the Legislative Assembly.

Assisted Reproductive Technology Act

The Bill provides that a regulation may prescribe an external document for the purpose of defining or describing relevant terms in the ART Act. These provisions potentially impact on the fundamental legislative principle that legislation must have sufficient regard to the institution of Parliament.

RTAC currently accredits providers against the RTAC Code of Practice. The Code of Practice sets criteria against which ART providers are audited in order to maintain their accreditation.

The ART Act currently provides for key personnel to be prescribed by regulation for the purposes of an ART provider applying for a licence (section 57) or notifying the chief executive of certain events (section 61), and for the purposes of the chief executive publishing information on the public register of ART providers (section 65).

The RTAC Code of Practice outlines personnel requirements which are audited annually. 'Key personnel' are listed to include a Medical Director, a Scientific Director, a Nurse Manager, a Counselling Manager/Senior Counsellor and a Quality Manager/Coordinator, however titled. ART providers are required to keep these roles filled at all times and where someone vacates a role it must be filled within 30 days. If an ART provider does not maintain suitably qualified persons in these roles, it is taken to be a major non-conformance and the provider can lose their RTAC accreditation. The RTAC Code of Practice also lists 'additional personnel' to be the Clinical Director, Laboratory Manager/Supervisor, Nurse Unit Manager/Senior Nurse and Counsellor. While key personnel are generally offsite, the additional personnel must be onsite at the ART clinic.

The Bill establishes that for the purpose of licence applications under section 57, events to be notified to the chief executive under section 61, and the operation of the public register of licensed providers under section 65, the terms 'personnel' and 'serious adverse event' are to be interpreted based on their meaning within the *accreditation standard* prescribed by regulation, with or without modifications.

The RTAC Code of Practice is intended to be prescribed by Regulation for this purpose. Although RTAC is currently the sole accrediting body recognised in Australia, this amendment ensures that an equivalent code or standard from a future accrediting body may be prescribed. This ensures the regulatory framework can respond flexibly when the Commission is established as the accrediting authority for ART providers from 2027 and providers are accredited against updated national standards. Requiring that these terms be interpreted in alignment with their meaning in the *accreditation standard* is considered justified noting it would not be suitable to include detailed, technical and clinical matters in legislation. It is also considered justified noting the changing accreditation landscape and the need to ensure the ART Act continues to reflect the requirements in the relevant accreditation code or standard.

Establishing that the term 'personnel' is to be interpreted within its meaning in the *accreditation standard* to be prescribed by regulation, with or without modifications, is justified considering that ART providers are already accustomed to these concepts noting RTAC's accreditation role, and that defining by reference to the accreditation standard ensures alignment between the accreditation scheme and ART Act. It is also justified given the detailed, technical role descriptions and requirements contained in the RTAC Code of Practice for personnel, which are not suitable for inclusion in legislation.

Similarly, the RTAC Code of Practice sets out adverse event reporting requirements for ART providers, including that ART providers need to report any serious adverse events to RTAC. The RTAC Code of Practice provides a detailed list of serious adverse events, including specific medical or surgical conditions that meet the threshold of a serious adverse event.

Section 61 of the ART Act (Chief executive to be notified of certain events) sets out events ART providers must notify the chief executive of and the time in which they must do so. This is intended to ensure the chief executive has appropriate oversight of ART services and providers and can respond to any issues as necessary. Section 61(1), table, item 1 provides that an ART provider must give the chief executive notice of a serious adverse event related to the ART services provided by the licensed provider, within 7 days. Section 61(3) defines *serious adverse event* as an event that is prescribed by regulation, or by the conditions of the provider's licence, as a serious adverse event.

As outlined in the explanatory notes to the Assisted Reproductive Technology Bill 2024, the policy intent of the notifiable event reporting in section 61 was to align the serious adverse event category with the list of serious adverse events in the RTAC Code of Practice, noting that ART providers are familiar with this process and to ensure that Queensland Health is notified of the same events as RTAC.

Requiring serious adverse events identified in the *accreditation standard* prescribed by regulation, with or without modifications, to be notified by an ART provider to Queensland Health is justified. This ensures there is consistency between the RTAC Code of Practice (or a future equivalent code of practice or standards) and the ART Act's regulatory framework,

which supports the operation of the ART Act while removing the need to prescribe clinical, technical information in regulation.

The Bill also provides that the accreditation standard may be prescribed by regulation with modifications. This assists with ensuring that the regulatory framework can respond flexibly to future change, including when the Commission is established as the accrediting authority for ART providers.

'Serious adverse events' and 'personnel' are key concepts within the RTAC Code of Practice. While these concepts are critical to ART accreditation, there is scope for terminology to shift throughout the development of any new accreditation framework. The ability to approve an accreditation standard with modifications is considered justified as it ensures that the ART Act continues to operate as intended even if a future accrediting authority uses different terminology.

In order to make a regulation to provide for an accreditation standard, the Minister is required to be satisfied that the document prescribed as the accreditation standard, including any modifications to the document, provides for the matters mentioned in section 57(2)(b)(iv), 61(1) and (3), and 65(2)(d). This ensures that the prescribed document, and any modifications to it, continue to provide for matters relating to serious adverse events and personnel, as intended.

Amendment of an Act only by another Act (Henry VIII clauses)

Section 4(4)(c) of the Legislative Standards Act states that whether legislation has sufficient regard to the institution of Parliament depends on whether the legislation authorises the amendment of an Act only by another Act.

Assisted Reproductive Technology Act

Clause 45 of the Bill provides that a regulation may make provision about a matter for which the ART Act does not provide or sufficiently provide. The transitional regulation may have retrospective operation to the day the section commences.

Although the ART Act has existing transitional provisions with further transitional matters addressed through the Bill, it is possible that unanticipated matters may arise given the complexity of transitioning to the ART Act's regulatory framework. The inclusion of this regulation-making power is justified as it ensures that if any further transitional issues arise throughout the implementation of the ART Act, these issues can be addressed in a timely manner. It is common practice to include a transitional regulation-making power in complex legislative schemes.

This transitional regulation-making power and any regulation made under it will expire two years from when the power commences. Transitional regulation-making powers and transitional regulations often expire after one year. However, for the ART Act, two years is considered necessary to accommodate the staged implementation of the regulatory framework.

Principles underlying a parliamentary democracy based on the rule of law

Although not specifically enumerated in the Legislative Standards Act, an important aspect of a parliamentary democracy is the appropriate diffusion of power and responsibility.

The Bill includes amendments to the Hospital and Health Boards Act, Health and Wellbeing Queensland Act, Pharmacy Business Ownership Act and Hospital Foundations Act to enable the Governor in Council to remove certain statutory office holders for any reason or none. This could be perceived as potentially compromising the independent performance of these office holders.

Allowing the Governor in Council to remove a person for any reason or none is necessary to achieve the purpose of ensuring high standards of performance, behaviour, integrity and effectiveness. The amendment provides an avenue for ensuring these officers are effective in the important leadership roles they hold in the public health system. Furthermore, any decision by Governor in Council to remove an office holder would need to have regard to the *Anti-Discrimination Act 1991*, which includes protections against discrimination for political activities and beliefs, and the Human Rights Act.

Further, as outline above, the removal powers in the Bill are not unique, as other Queensland legislation allows for office holders to be removed for any reason or none.

Consultation

In August 2025, Queensland Health published a consultation paper on the amendments to the ART Act, Transplantation and Anatomy Act and Private Health Facilities Act and sought stakeholder feedback for a two-week period. Relevant stakeholders for each amendment were notified and a draft version of the ART Act and Transplantation and Anatomy Act amendments were also made available. Stakeholders consulted included ART providers, organisations and individuals representing the interests of donor-conceived individuals, health consumers, regulators, legal stakeholders, hospitals and organisations involved with organ and tissue donation, the Public Advocate and Public Guardian, licensees of private health facilities and stakeholders in the cosmetic surgery industry.

No external consultation was undertaken on the amendments to the Hospital and Health Boards Act, Health and Wellbeing Queensland Act, Pharmacy Business Ownership Act or Hospital Foundations Act as the amendments relate to internal Government processes. There was also no external consultation on the amendment to the Public Health Act due to the minor and consequential nature of the amendment.

The main areas of feedback are outlined below.

Amendments to the *Assisted Reproductive Technology Act 2024*

Overall, stakeholders were supportive of the amendments to the ART Act, including Rainbow Families, Monash IVF, Virtus Health, the Office of the Health Ombudsman and Queensland Nurses and Midwives' Union (QNMU).

ART providers and other stakeholders were broadly supportive of the information collection amendments. One provider queried the amendments to section 33 to remove the reference to

information transferred between ART providers under section 34 as being 'taken to have been collected' under section 33 when the provider seeks to use the gamete or embryo. Their concern was that they would be required to re-collect or re-verify the information provided by the transferring provider under section 34. The amendments are not intended to require providers to re-collect or re-verify information transferred to the recipient under section 34 if the information aligns with information required under section 33(1). If information under section 33 is missing, then the recipient ART provider must attempt to collect the information or would need to apply for chief executive approval to use the gamete or embryo without the information. The amendments ensure the information collection requirements operate effectively and support the objects of the Act.

Donor-conceived advocates expressed concern about the amendment to replace the existing information collection requirements to collect a gamete provider's residential address, phone number and email address with a requirement to obtain *contact information*, noting a preference for legislated minimum requirements. A donor-conceived person further expressed concern that the amendment would result in a weakening of the requirements and could disadvantage donor-conceived people. Queensland Health considers that this amendment provides an appropriate degree of flexibility in relation to the contact information to be collected, while continuing to require a minimum standard of information. Queensland Health will also set clear expectations about minimum information collection standards and undertake regulatory activities targeted at information collection. These activities seek to ensure the interests of donor-conceived people are upheld by recognising the unique and important role ART providers hold in obtaining information about the genetic origin of people born from ART. Additionally, contact information collected under section 33 is, in part, being obtained for the Register. The Register only requires contact information, as defined, be provided so the amendment ensures consistency across the Act of the information required to be collected.

A number of stakeholders, including Rainbow Families, Health Consumers Queensland (HCQ), and Assisted Reproductive Technology Families Australia (ARTFA), noted support for the introduction of case-by-case chief executive approval powers relating to the family limit and information collection requirements. In relation to approval for information collection, Queensland Donor Conceived People (QDCP) commented that an approval should never be granted where no contact information has been recorded and that any decision to approve the use of donated material must be guided by a clear commitment to the best interests of donor-conceived individuals. QDCP noted support for exceeding the 10-family limit in principle but noted that exceptions should only be granted in rare, well-justified cases.

Queensland Health considers that the chief executive approval processes enable case-by-case flexibility if presented with a particular case where the application of the ART Act could result in unreasonable hardship. Any decision to grant an approval will include consideration of a range of matters, including the differing interests and perspectives of and potential impacts on existing and future donor-conceived people, recipient parent/s and the donor, as well as the overarching objects of the Act. To support transparency of and promote confidence in this decision-making, Queensland Health will also publish the number of applications received against each chief executive approval provision and overall outcomes. This reporting will be available on a Queensland Health website and will be kept updated at regular intervals.

QDCP, ARTFA and the Australian and New Zealand Infertility Counsellors Association expressed a range of concerns in relation to amendments relating to donor consent and the interaction with chief executive approval processes. QDCP and the Australian and New

Zealand Infertility Counsellors Association considered that any express lack of consent from a donor should not be overridden. ARTFA, on the other hand, were of the view that donor consent should not have to be sought in support of a chief executive application as proposed by the Bill, on the basis that the donor could refuse and obstruct use of the donated material. Queensland Health considers that the amendments appropriately balance the complex considerations relating to consent. The Bill ensures that the interaction between donor consent and the chief executive approval process is clear and operates as intended. Further, the donor's express consent is a relevant consideration in any chief executive decision-making, as this forms part of balancing the potential unduly harsh outcomes for various parties that are critical to the decision.

HCQ and QNMU raised concerns about the amendments to update key terms in the ART Act and ensure alignment with the accreditation framework. A concern was raised by HCQ regarding whether the amendments, by not specifically identifying RTAC as the relevant body for the purposes of the accreditation framework, would allow for a document by another accrediting body perceived as not equivalent to RTAC to be prescribed. Concerns were raised by HCQ and QNMU regarding the amendments to reference 'personnel' instead of 'key personnel' and whether this would dilute the roles of key ART staff. Queensland Health considers that the amendments future-proof the ART Act to reflect the HMM recommendation to replace RTAC as the accrediting body for ART providers. The amendments to update references to key personnel do not impact on ART providers' staffing requirements, which are governed by the accreditation framework. The amendments have the effect that in addition to providing information to Queensland Health about key personnel engaged in the provision of ART services, ART providers are also required to provide information about additional personnel appointed by providers. This ensures Queensland Health has visibility of staffing arrangements within ART clinics, which is important in relation to the additional personnel seeking to be captured by this change in terminology, as it is usually these roles that are on-site in ART clinics managing their day-to-day operations.

Amendments to the *Private Health Facilities Act 1999*

Stakeholders were generally supportive of the amendments to the Private Health Facilities Act to clarify the head of power to require facilities to comply with standards of accreditation, including the Australian Health Practitioner Regulation Agency, Australian Medical Association Queensland, Australasian College of Cosmetic Surgery and Medicine, Australian Society of Plastic Surgeons, Certification Partner Global (Aust) Pty Ltd, Day Hospitals Australia, HCQ and QNMU.

Some stakeholders advocated that facilities that already comply with the NHQHS Standards for surgical procedures should not have to comply with additional standards of accreditation that specifically relate to cosmetic surgery. However, HMM considered there are additional risk factors for patients undertaking cosmetic surgery that warrant specific accreditation requirements for undertaking this type of procedure. Some stakeholders also provided feedback on particular elements of the Cosmetic Surgery Standards. The relevant stakeholder feedback was passed on to the Commission for development of additional guidance material for implementation of the standards and consideration of future improvements to the standards.

Amendments to the *Transplantation and Anatomy Act 1979*

Overall, stakeholders were supportive of the amendments to the Transplantation and Anatomy Act, commenting that clarifying consent around ante-mortem interventions would benefit Queenslanders who require life-saving organ transplants. While overall supportive, key stakeholders such as DonateLife Queensland (DLQ) and the Australian Organ and Tissue Authority =raised issues for consideration.

Both DLQ and the Australian Organ and Tissue Authority were concerned that prescribing specific ante-mortem interventions by regulation could limit the opportunities for organ donation in the future if a new clinical practice in relation to ante-mortem interventions was developed. These stakeholders considered that a narrow definition of *ante-mortem intervention* could lead to arbitrary and confusing distinctions about what qualifies as an ante-mortem intervention, noting it is a clinical decision and should not be prescribed in legislation. The Bill has been amended to adopt this feedback and includes a broader definition of *ante-mortem intervention*.

DLQ also highlighted that blood tests are essential and time-critical and must be conducted as soon as possible once the decision to withdraw life-sustaining measures is made and the person has been identified as a potential donor. The results of the blood tests often inform additional conversations about donation and are critical in determining whether a person is a potential donor. Accordingly, DLQ expressed concern that requiring the separate authorisation of the designated officer following consent by the next of kin in relation to routine blood tests could delay the donation process and ultimately, lead to fewer donations. The Bill has been amended to adopt this feedback by providing a separate provision in relation to blood tests which excludes blood tests as an ante-mortem intervention for the purposes of determining tissue donation viability. In effect, this means that a blood test can be undertaken following consent from the senior available next of kin and that is sufficient authority for the blood test to be undertaken.

Consistency with legislation of other jurisdictions

Amendments to the *Assisted Reproductive Technology Act 2024*

The majority of other Australian jurisdictions have state-based legislation in place to regulate the provision of ART services.

Amendments to the *Private Health Facilities Act 1999*

All other jurisdictions have agreed to make the necessary legislative changes to implement the Cosmetic Surgery Standards.

Amendments to the *Transplantation and Anatomy Act 1979*

New South Wales[2] and Victoria[3] have a framework for consent to ante-mortem interventions being undertaken established in their legislation relating to organ donation. The amendments bring Queensland in line with these jurisdictions.

[2] *Human Tissue Act 1983* (NSW)
[3] *Human Tissue Act 1982* (Victoria)

Notes on provisions

Part 1 Preliminary

Short Title

Clause 1 provides that the short title of the Act is the *Health Legislation Amendment Act (No. 3) 2025*.

Commencement

Clause 2 provides for the commencement of certain provisions.

Clause 2(1) provides that the following provisions commence immediately after the commencement of the *Assisted Reproductive Technology Act 2024*, section 12 –

- Sections 4 to 14;
- Sections 21 to 25;
- Sections 28 to 32;
- Sections 34 to 45;
- Sections 46(1) and (2).

Clause 2(2) provides that sections 15(2) and sections 16 to 20 commence immediately after the commencement of the *Assisted Reproductive Technology Act 2024*, section 42.

Clause 2(3) provides that sections 77 and 78 commence on a day to be fixed by proclamation.

Part 2 Amendment of Assisted Reproductive Technology Act 2024

Act amended

Clause 3 states that this part amends the *Assisted Reproductive Technology Act 2024* (ART Act).

Amendment of s 15 (Counselling services for persons provided with ART services)

Clause 4 amends section 15 to clarify the application of the ART Act's counselling requirements where a person proposing to undergo an ART procedure has a legal spouse from whom they are separated.

Clause 4(1) omits the words 'and to any spouse of that person' from section 15(2)(a).

Clause 4(2) inserts a new section 15(2)(aa) to state that an ART provider must provide counselling services under section 15 to a spouse of the person proposing to undergo a procedure that uses donated gametes or a donated embryo, other than a spouse from whom the person is separated and is living separately and apart.

Clause 4(3) renumbers section 15(2)(aa) and (b) as section 15(2)(b) and (c)

Clause 4(4) omits current section 15(3) and inserts a new section 15(3) to provide if a person proposes to undergo an ART procedure that does not use donates gametes or a donated embryo, the ART provider must make counselling services available to the person and to a spouse of the person, other than a spouse from whom the person is separated and is living separately and apart. The maximum penalty for non-compliance is 25 penalty units.

Insertion of new s 16A

Clause 5 inserts new section 16A (Consent required for obtaining, or attempting to obtain, gamete).

New section 16A(1) provides that the consent of a gamete provider is required for obtaining, or attempting to obtain, a gamete from the gamete provider for use in an ART procedure or for storage to use in an ART procedure.

New section 16A(2) provides that the consent of a gamete provider is not required for anything that is authorised under division 5. Part 2, division 5 of the ART Act relates to the retrieval and use of gametes from deceased or unresponsive persons.

New section 16A(3) provides that the consent of a child includes the consent of a parent of the child or a person who has parental responsibility for the child. This supports the provision of an ART service to a child where that is permitted under section 23 (ART services for child prohibited), for example, for fertility preservation.

New section 16A(4) provides that a reference to a gamete provider in section 16A includes, in relation to an attempt to obtain a gamete, a reference to the individual who would have been the gamete provider had the attempt been successful. This is intended to ensure, for example, that even where an egg retrieval is unsuccessful, consent of the gamete provider is still required.

Amendment of s 18 (Consent of gamete provider in case of donated gametes or donated embryos)

Clause 6 amends section 18 to ensure the consent requirements relating to gamete providers in the case of donated gametes or donated embryos operate as intended.

Clause 6(1) clarifies the consent requirement in section 18(2)(b) relating to the time limit for use in section 27, by removing reference to the period for which the donated gametes or donated embryos may be stored for use and replacing it with reference to the period during which the donated gametes or donated embryos may be used in an ART procedure. This is a consequential change to support the clarification of the policy intent of section 27 achieved by clause 8.

Clause 6(2) inserts new section 18(3A) to provide that section 18(1), which states that ART providers must obtain consent from gamete providers before using donated gametes or donated embryos in an ART procedure, does not apply to the extent a donated gamete or donated embryo is used in an ART procedure under an approval of the chief executive given, for the purpose of section 25(2) or 27(1), under section 39B (see clauses 7, 8 and 14).

New section 18(3A) confirms the interaction between the donor consent requirements and the chief executive approval powers provided for in new part 2, division 8 of the ART Act (clause 14). These approval powers are intended to provide discretion for the use of gametes beyond the family limit and time limit requirements referenced in section 18. As a result, the interaction with the consent requirements needs to be made clear as a donor cannot consent to a family limit or time limit for use beyond the maximum limits permitted under the ART Act. Therefore, the intent is to disapply these consent requirements if a chief executive approval is granted.

Clause 6(3) renumbers section 18(3A) and (4) as section 18(4) and (5).

Amendment of s 25 (Limit on number of donor-related Australian families)

Clause 7 inserts new subsection 25(1A).

New subsection (1A) provides that section 25(1), which establishes that an ART provider must not use donated material if it would result in more than 10 donor-related Australian families, does not apply if the ART provider has the approval of the chief executive under new section 39B (clause 14) to use the donated gamete or donated embryo in the ART procedure. As donated material cannot be used if it would exceed the 10-family limit, the interaction between the family limit and chief executive approval needs to be made clear. Therefore, the intent is to disapply the 10-family limit if a chief executive approval is granted.

Clause 7(2) renumbers section 25(1A) to (6) as section 25(2) to (7).

Amendment of s 27 (Time limit on use of donated gametes or embryos and their disposal)

Clause 8 amends section 27 to ensure the time limit on use of donated material requirements operate as intended.

Clause 8(1) aligns the time limit requirements with the chief executive approval process in new section 39B by omitting reference to ‘written approval of the chief executive’ and replacing it with reference to ‘approval of the chief executive given, for the purposes of this subsection, under section 39B’. This supports the intention that material that would exceed the time limit for use (15 years) can only be used in an ART procedure where a chief executive approval is granted.

Clause 8(2) omits current section 27(2) and (3) and inserts new section 27(2) and (3) to clarify the operation of the disposal requirement.

New section 27(2) provides that the ART provider must dispose of the donated gamete or donated embryo within the period mentioned in subsection (3), if:

- the chief executive has decided under section 39B(2) to refuse to approve the use of the donated gamete or donated embryo in the ART procedure (the *refusal decision*); and
- either:
  - the period for applying for internal review of the refusal decision under section 122 (Requirements for application for internal review) has ended and no application for internal review has been made; or

- an application for internal review of the refusal decision has been made under section 122 and the chief executive has decided under section 123 (Internal review) to confirm the refusal decision.

The maximum penalty for failure to dispose of the donated material within the period mentioned in subsection (3) is 100 penalty units.

New section 27(3) provides that for subsection (2), the period within which the ART provider must dispose of the donated gamete or donated embryo is as soon as practicable after the end of the period of 90 days starting on:

- if section 27(2)(b)(i) applies, the day the ART provider is given an information notice for the refusal decision under new section 39B(3); or
- if subsection (2)(b)(ii) applies, the day the ART provider is given a notice under section 123(1)(c)(i) of the chief executive's decision on the internal review of the refusal decision.

The effect of these changes is to clarify the application of the disposal element of section 27. The disposal requirement is linked to a refusal to permit use rather than the period for which the material is stored. The intent is to ensure the chief executive retains authority over decisions to use older donated material rather than making decisions about how long that material can be stored for. The changes to section 27 support the protection of existing, if any, and future donor-conceived people, by ensuring, for example, the donor is alive and there is not too great an age gap between donor-conceived siblings.

Amendment of s 33 (Information to be collected about gamete providers)

Clause 9 amends section 33, which sets out information collection requirements for ART providers seeking to obtain or use gametes.

Clause 9(1) amends section 33(1)(a)(ii) to replace the requirement to collect a gamete provider's 'residential address, phone number and email address' with a requirement to collect their 'contact information'.

The definition of *contact information*, which was previously in part 3 to support the Register, is inserted in schedule 1 (Dictionary) by clause 46 to apply across the ART Act. *Contact information*, for a person, means the person's residential address, phone number or email address or any other way the person may be contacted. The amendment of section 33(1)(a)(ii) addresses the current challenges with collecting prescriptive forms of contact information, while retaining the policy intent to ensure adequate information is collected about gamete providers, and where donor material is used, that the information is available for inclusion in the Register.

Clause 9(2) omits section 33(3) to support the clarification of the interaction of section 33 with section 34 (Transfer between ART providers of information about gametes or embryos).

Current section 33(3) provides that information obtained from another ART provider under section 34 is 'taken to have been collected' under section 33(1). This is ambiguous and could lead to providers inadvertently believing they have met the information collection requirements, even where some of the required information is missing. It is necessary to

remove any potential ambiguity and ensure the application of the information collection requirements to gametes transferred between providers is clear.

The policy intent for transferred gametes is that:

- the recipient ART provider meets the information collection requirements before the relevant gametes or embryos are used in an ART procedure;
- the recipient provider receives all relevant information from the transferring provider; and
- if the relevant information is provided to the recipient provider when the gametes are transferred, they are taken to have satisfied the section 33(1) requirements to the extent the information meets section 33(1). Where the information from the transferring provider is deficient, the recipient provider will need to attempt to collect the missing information before they are permitted to use the gamete or embryo or make an application for a chief executive approval under new section 39C.

Clause 9(3) amends section 33(5) to replace the reference to information collected 'under' subsection (1) with reference to the information 'mentioned in' subsection (1). The effect of this change is to put beyond doubt that the requirement not to use a gamete or embryo in an ART procedure without having first collected the relevant information applies regardless of when the gamete was obtained or embryo was created, including if this occurred prior to section 33 commencing on 19 September 2024. It also confirms the prospective application of the information collection requirement, meaning a provider cannot use the gamete or embryo without satisfying section 33(1) regardless of whether the information was obtained at the time the gamete was obtained, unless they have a new section 39C approval.

Clause 9(4) inserts new subsections 33(6) and (7).

New section 33(6) provides that section 33(4) does not apply if the ART provider has the approval of the chief executive given under section 39C to use the gamete or embryo for the ART procedure. This has the effect of enabling use of a gamete or embryo despite the information collection requirements in section 33(1) not being met in full, if the chief executive has approved the use.

New section 33(7) clarifies that section 33 is not limited by, and does not limit, section 34. This further supports clarification of the interaction between sections 33 and 34.

A note is inserted below new section 33(7) to provide that new section 149 (Use of particular gametes obtained before 19 September 2024—collection of information) is relevant for the application of section 33 to gametes obtained before 19 September 2024. This supports the intent of the Bill to put the application of the information collection requirements to pre-commencement gametes beyond doubt to ensure the ART Act operates effectively.

Clause 9(5) renumbers section 33(4) to (7) to section 33(3) to (6).

Amendment of s 34 (Transfer between ART providers of information about gametes or embryos)

Clause 10 amends section 34, which sets out the requirements that apply when an ART provider supplies gametes or embryos to another provider, or receives gametes or embryos from another provider, to clarify the interaction with the requirements in section 33.

Clause 10(1) omits references in section 34(2)(a) and (b) to 'consents and other information' and replaces them with reference to 'information mentioned in subsection (3)'.

Clause 10(2) inserts new subsection (3) to provide that for subsection 2(a) and (b), the information is:

- the information mentioned in section 33(1) in relation to the gametes or gametes used to create the embryos; and
- any other consents or information in relation to the gametes or embryos.

The effect of these changes is to make it clearer that the information provided during a transfer of gametes or embryos from one ART provider to another must, at a minimum, include all information required under section 33(1) of the ART Act, all consents, and any other additional information relevant to the material, for example, infectious disease screening or genetic testing results.

Amendment of s 35 (Information to be collected about persons who undergo ART procedures)

Clause 11 amends section 35, which sets out the information that ART providers must collect about persons who undergo ART procedures.

Clause 11(1) amends section 35(1)(b) to replace the reference to 'residential address, phone number and email address' with 'contact information'. This aligns the contact information requirements relating to a person who undergoes an ART procedure with the requirements in section 33 relating to gamete providers.

Clause 11(2) amends section 35(1)(d) by omitting the reference to 'any spouse of the person at the time of the procedure' and replacing it with reference to 'a spouse of the person at the time of the procedure, other than a spouse from whom, at that time, the person is separated and is living separately and apart'.

Amendment of s 36 (Keeping of records)

Clause 12 amends section 36, which sets out the records ART providers are required to keep, to provide for additional categories of records to be kept.

Clause 12(1) inserts new section 36(2A) to provide that an ART provider must keep a record of:

- each consent of a person under section 16A for attempting to obtain a gamete from the person; and

- a notice given to the ART provider by a gamete provider under section 20(2) modifying or withdrawing a consent of the gamete provider under part 2, division 3 of the ART Act.

Clause 12(2) inserts new section 36(3)(c) to provide that, in relation to information about ART procedures, an ART provider must also keep record of each consent of a person collected under part 2, division 3 undergoing the ART procedures mentioned in that division.

The intent of these new record keeping requirements is to ensure ART providers keep all consents obtained from gamete providers or persons undergoing ART procedures. These consents are an essential part of the clinical record. The inclusion of these additional consents in the record keeping requirements will ensure they are available for 99 years consistent with other records required to be kept under section 36 of the ART Act.

Clause 12(3) amends section 36(4)(b) to replace the reference to 'name, residential address, phone number and email address' with 'name and contact information'. This aligns the record keeping requirements relating to a person who gave birth as a result of an ART procedure with the information collection requirements in sections 33 and 35 (clause 9 and 11).

Clause 12(4) inserts new section 36(7) to clarify that a reference in section 36 to an ART provider includes a reference to a person who was an ART provider. The effect of this change is to ensure that if an ART provider ceased operating in future, the obligations to maintain records would continue. As access to records about ART patients and procedures is a pillar of the ART Act, it is essential that this obligation remains even when a provider stops operating, for example, if a providers sells their business or entirely ceases trading. It would be expected that any sale of an existing business that is subject to a record keeping obligation under the ART Act would include provision for the ongoing maintenance of records already collected by the outgoing provider.

Clause 12(5) renumbers section 36(2A) to (7) as section 36(3) to (8).

Amendment of s 37 (Destruction of records prohibited)

Clause 13 amends section 37 to support alignment of the case-by-case chief executive approvals across the ART Act.

Clause 13(1) amends section 37(2) to replace reference to authorisation by the chief executive with reference to 'approval'. This aligns the terminology used across the chief executive approval provisions.

Clause 13(2) amends section 37(3) to replace 'authorise' with 'give approval for'. This clarifies that written approval is needed from the chief executive to destroy a record.

Clause 13(3) inserts new sections 37(4) and (5).

New section 37(4) provides the chief executive must give the applicant an information notice for the decision, as soon as practicable after deciding to refuse to approve an application for approval to destroy a record under subsection (3). This supports natural justice by providing that chief executive decisions to refuse applications under part 2 of the ART Act are reviewable decisions that may be subject to internal review.

New section 37(5) clarifies that a reference in section 37 to an ART provider includes a reference to a person who was an ART provider. The effect of this change is to ensure that if an ART provider ceased operating in future, the prohibition on the destruction of records would continue. This is essential as a prohibition against destruction of ART records is a pillar of the ART Act and this obligation needs to remain even when a provider stops operating, for example, because they sell their business or entirely cease trading.

Insertion of new pt 2, div 8

Clause 14 inserts new part 2, division 8 (Chief executive's approval to use particular gametes or embryos) which provides for the chief executive's approval to use particular gametes or embryos.

New section 39A (Purpose of division) provides that the purpose of new division 8 is to enable the chief executive to give an ART provider approval to use a gamete or embryo in an ART procedure even though:

- for a donated gamete or donated embryo:
  - the use of the donated gamete or donated embryo would result in more than 10 donor-related Australian families; or
  - the donated gamete, or a gamete used to create the donated embryo, was obtained from the gamete provider more than 15 years before the ART procedure; or
- for any gamete or embryo—the ART provider has not collected the information mentioned in section 33(1) in relation to the gamete or a gamete used to create the embryo.

New section 39B (Chief executive may approve use of particular donated gamete or donated embryo—ss 25 and 27) sets out the chief executive approval requirements relating to use of donated gametes or embryos despite the family limit or time limit for use.

New section 39B(1) provides that this section applies for the purposes of section 25(2) or 27(1).

New section 39B(2) provides that the chief executive may, on application by an ART provider, approve the use of a donated gamete or donated embryo in an ART procedure if the chief executive is satisfied that:

- either:
  - the gamete provider, or the gamete provider from whom a gamete used to create the embryo was obtained, has consented to the making of the application by the ART provider; or
  - the ART provider has been unable to contact the gamete provider mentioned in section 39B(2)(a)(i) despite taking reasonable steps to do so; and
- there are reasonable grounds for using the donated gamete or donated embryo in the ART procedure, having regard to:
  - the terms of the consent given by the gamete provider for the use of the gamete, to the extent the consent relates to the provision mentioned in subsection (1) that is the subject of the application; and

- whether, in the circumstances, the consequences of giving, or refusing to give, the approval to use the gamete or embryo would be unfairly harsh for any person.

The intent of new part 2, division 8 is to:

- introduce the ability for the chief executive to make a case-by-case decision to approve use of donated gametes or embryos despite the 10-family limit already having been reached; and
- align the decision-making criteria and process for the purposes of chief executive approval to use donated gametes or embryos despite the time limit on use, which was previously set out in section 27, noting the considerations that must be taken into account for use of donated material despite the family limit or time limit are the same.

In considering whether approval or refusal would be unfairly harsh for 'any person', the chief executive will not consider the impacts on every person who may be affected by the decision. People who may be involved in the decision in an ancillary capacity, such as the patient's treating clinician, will not be considered as part of the assessment of the impacts of the decision. Conversely, the impact on existing donor-conceived children and donor-related Australian families would be considered in the decision-making.

New section 39B(3) provides the chief executive must give the applicant an information notice for the decision, as soon as practicable after deciding to refuse an application to use a donated gamete or donated embryo under subsection (2). This supports natural justice by providing that chief executive decisions to refuse applications under part 2 of the ART Act are reviewable decisions that may be subject to internal review.

New section 39C (Chief executive may approve use of other particular gamete or embryo—s 33) sets out the chief executive approval requirements for use of a gamete or embryo despite the information collection requirements in section 33 not being met in full.

New section 39C(1) provides that this section applies for the purposes of section 33(5).

New section 39C(2) provides that the chief executive may, on application by an ART provider, approve the use of a gamete or embryo in an ART procedure if the chief executive is satisfied:

- the ART provider has taken reasonable steps to collect the information mentioned in section 33(1) in relation to the gamete or a gamete used to create the embryo; and
- there are reasonable grounds for using the gamete or embryo, having regard to:
  - the information the ART provider has collected; and
  - whether, in the circumstances, the consequences of giving, or refusing to give, the approval would be unfairly harsh for any person.

In considering whether approval or refusal would be unfairly harsh for 'any person', the chief executive will not consider the impacts on every person who may be affected by the decision. People who may be involved in the decision in an ancillary capacity, such as the patient's treating clinician, will not be considered as part of the assessment of the impacts of the decision. Conversely, the impact on existing donor-conceived children and donor-related Australian families would be considered in the decision-making.

New section 39C(3) provides that if the chief executive decides to approve an application to use a gamete or embryo under subsection (2), the applicant and any other ART provider whom the gamete or embryo is supplied:

- may use the gamete or embryo despite section 33(4); and
- is taken to have complied with section 33(1) in relation to the gamete, or a gamete used to create the embryo.

Extending the approval to any other ART provider to whom the gamete or embryo is supplied is intended to limit the regulatory burden on the patient and new or subsequent ART providers, if the patient changes providers. In these circumstances, there is no requirement for the subsequent provider to make a further application for use, when use has already been approved by the chief executive.

New section 39C(4) provides that if the chief executive refuses to approve an application to use a gamete or embryo under subsection (2), they must give the applicant an information notice about the decision, as soon as practicable after making the decision. This supports natural justice by providing that chief executive decisions to refuse applications under part 2 of the ART Act will be reviewable decisions that may be subject to internal review.

Amendment of s 40 (Definitions for part)

Clause 15 amends section 40 to omit the definition of *contact information* from the definitions for part 3 (Donor conception information register). As the term has been inserted throughout part 2 of the Act, the definition is inserted into schedule 1 by clause 46.

Clause 15(2) amends the definition of *relevant information* to refer to the information in section 44(1).

Amendment of s 41 (Information relating to donor-conceived persons to which part applies)

Clause 16 removes reference to 'relating to donor-conceived persons' from the heading of section 41. This makes the new heading of section 41 'Information to which part applies'.

Clause 16(2) amends section 41 to provide that part 3 (Donor conception information register) applies to information in relation to a donor-conceived person.

This provides consistent language throughout part 3.

Amendment of s 44 (Relevant information to be included in register)

Clause 17 amends section 44 which outlines the relevant information that is to be included in the Register.

Clause 17(1) replaces current section 44(1) to provide that the information mentioned in section 44(2) (the *relevant information*), in relation to a donor-conceived person, that is provided to the Registrar is the information that is to be included in the Register.

This clarifies that the Register can hold the range of information needed to support access to genetic, health and relational information for donors, donor-conceived people and the parent/s of donor-conceived people.

Clause 17(2) omits current section 44(2)(i) and inserts a new section 44(2)(i) which provides that the full name and date of birth of the person who gave birth to the donor-conceived person as a result of the procedure and a spouse of the person at the time of the procedure, other than a spouse form whom, at that time, the person was separated and was living separately and apart, is relevant information for the purposes of the Register.

Amendment of s 45 (Mandatory provision of information by ART providers)

Clause 18 amends section 45(1) to replace reference to 'relating to the birth of a donor-conceived person born' with 'in relation to a donor-conceived person born'.

Amendment of s 46 (Mandatory provision of historical information)

Clause 19 amends section 46(1)(a) to replace reference to 'relates to the birth of a donor-conceived person' with 'is information in relation to a donor-conceived person born'.

Amendment of s 47 (Voluntary provision of information by parties to private donor conception procedures)

Clause 20 amends section 47(1) to replace reference to 'relating to the birth of a donor-conceived person' with 'in relation to a donor-conceived person born'.

Insertion of new s 56A

Clause 21 inserts new section 56A (Meaning of *accreditation standard*).

New section 56A(1) provides that the *accreditation standard* is a document that:

- provides for matters in relation to prescribed accreditation; and
- is approved by regulation for this paragraph, with or without modifications.

New section 56A(2) provides that the Minister may recommend to the Governor in Council the making of a regulation under subsection (1) only if the Minister is satisfied the document, including any modifications, provides for the following matters:

- persons who are personnel for sections 57(2)(b)(iv), 61(1) and 65(2)(d);
- events that are serious adverse events for section 61.

The inclusion of this new term in the ART Act supports the licensing framework by ensuring the national accreditation framework and related documents can be approved for the purposes of the ART Act. This is important in a sector where there can be changes made to the accreditation framework and requirements. The amendments support the longevity of the ART Act, enabling it to continue to operate effectively while responding to sector changes.

The requirement for the Minister to be satisfied the accreditation standard provides for the matters mentioned above ensures that any accreditation standard approved by regulation

appropriately provides for serious adverse events and personnel for the purposes of the ART Act. Additionally, permitting an accreditation standard to be prescribed with or without modification enables matters not covered by an accreditation standard that are essential to the ART Act to be included in the Regulation so as not to frustrate or undermine the operation of the ART Act.

Amendment of s 57 (Application for licence)

Clause 22 amends section 57(1)(a) to replace reference to 'RTAC accreditation' with 'prescribed accreditation'.

Clause 22(2) amends section 57(2)(b)(iv) to replace reference to 'any other key personnel prescribed by regulation' with 'the name of each of the personnel, within the meaning of the accreditation standard'.

The effect of these changes is to reflect the HMM decision to replace RTAC as the accrediting authority for the ART industry by referring to an accreditation body prescribed by regulation and to ensure that a licensing application includes information about all relevant personnel employed by an ART provider. This also future proofs the ART Act in case there are any further changes to the accreditation framework.

Amendment of s 61 (Chief executive to be notified of certain events)

Clause 23 amends section 61 to update the requirements for notification of certain events.

Clause 23(1) amends section 61(1), table, items 2 and 3, column 1, to replace reference to 'RTAC accreditation' with 'prescribed accreditation'.

Clause 23(2) amends section 61(1), table, item 8, column 1, to replace reference to 'any other key personnel prescribed by regulation' with broader reference to 'any of the personnel, within the meaning of the accreditation standard'.

Clause 23(3) amends section 61(3), definition of *serious adverse event,* to replace reference to 'prescribed by regulation' with 'identified in the accreditation standard'. The effect of this change is to enable serious adverse events, within the meaning of the relevant accreditation document, to inform notification requirements for the purposes of the ART Act.

Amendment of s 64 (Cancellation or suspension of licence)

Clause 24 amends section 64(1)(a) to replace reference to 'RTAC accreditation' with 'prescribed accreditation'.

Amendment of s 65 (Public register of licensed providers)

Clause 25 amends section 65(2)(d) to replace reference to 'names of any other key personnel prescribed by regulation' with reference to the 'name of each of the personnel, within the meaning of the accreditation standard'.

Clause 25(2) replaces current section 65(2)(e). New section 65(2)(e) provides that the public register may also contain the date of expiry of the prescribed accreditation of the licensed provider.

Amendment of s 111 (Power to require information)

Clause 26 inserts new section 111(1A) to provide that the section also applies if an inspector reasonably believes:

- a person may be able to give information (*compliance information*) about a licensed provider's compliance with this Act; and
- the compliance information is necessary for the inspector to perform the inspector's function mentioned in section 69(a).

New section 111(1A) ensures that the power to require information extends to monitoring compliance with the ART Act, which is a key function of an inspector under section 69 of the ART Act. The amendments to section 111 support the establishment of a proactive regulatory scheme that seeks to protect the welfare and interests of users of ART and people born from ART. The new section is intended to support a range of monitoring activities including to:

- monitor compliance with a provider's licence conditions;
- investigate serious adverse events that do not amount to a breach of the ART Act;
- undertake a schedule of intelligence-led monitoring activities targeting key areas of the ART Act, for example, a desktop review of compliance with consent or information collection requirements.

Clause 26(2) replaces section 111(2)(a) to provide that the inspector may require the person to give either information related to the offence mentioned in subsection (1); or the compliance information mentioned in subsection (2)(a).

Clause 26(3) amends section 111(2)(b) to replace reference to 'paragraph (a)' with 'paragraph (a)(i) or (ii)'.

Clause 26(4) renumbers section 111(1A) to (3) as section 111(2) to (4).

Amendment of s 112 (Offence to contravene information requirement)

Clause 27 amends section 112(1) by replacing reference to 'section 111(2)' with 'section 111(3)'.

Amendment of s 119 (Definitions for part)

Clause 28 amends section 119, which provides definitions for part 6 of the Act (Review of decisions and appeals).

Clause 28(1) inserts a definition for *part 2 decision*, to mean:

- a decision to refuse to approve an application for approval to use a gamete or embryo under section 39B(2) or 39C(2); or

- a decision to refuse to approve an application for approval to destroy a record under section 37(3).

Clause 28(2) amends the current definition of *reviewable decision* to provide that a part 2 decision is a reviewable decision for the purposes of the ART Act.

Clause 28(3) renumbers the definition of *reviewable decision*, paragraphs (aa) to (e) as paragraphs (a) to (f).

The effect of this change is to enable chief executive decisions to refuse applications relating to the family limit, time limit on use, information collection requirements or destruction of records to be reviewable decisions that may be subject to internal review. This promotes natural justice by offering an additional pathway for these decisions to be reviewed. It will also ensure independence, by providing for the reviewer to be different and at a higher level than the original decision-maker.

Replacement of s 120 (Review process must start with internal review)

Clause 29 replaces current section 120 to set out the review process for reviewable decisions.

New section 120(1) provides that a part 2 decision is subject to internal review only. The intent of limiting the review to internal review is due to the highly specialised and clinical nature of the decision-making, which is best managed by decision-makers with a higher degree of familiarity with the ART Act and ART sector. Additionally, there could be the potential for a considerable number of decisions under these sections and the impact of these in terms of throughput to an external review body such as QCAT is unknowable.

New section 120(2) provides that any other reviewable decision may consist of internal review under division 2; and if the internal review decision has been made, or is taken to have been made, under division 2, the review can go for an external review by QCAT under division 4.

Amendment of s 123 (Internal review)

Clause 30 amends the current requirements under section 123(1)(a) to (c) to amend the process the chief executive must follow after receiving an application for internal review of a reviewable decision.

New section 123(1) provides that the chief executive must review the reviewable decision; decide to confirm or amend the reviewable decision, or substitute another decision for the reviewable decision; and give the affected person for the reviewable decision notice of the chief executive's decision under section 123(1)(b) (if the reviewable decision is a part 2 decision) or otherwise, a QCAT information notice for the chief executive's decision under section 123(1)(b).

Clause 30(2) amends sections 123(3), (4) and (5) to remove any reference to the term 'original' in each of the subsections. This change aligns the term 'reviewable decision' with the definition in section 119 of the ART Act.

Amendment of s 124 (QCAT may stay operation of reviewable decision)

Clause 31 omits section 124(1) and inserts new sections 124(1) and 124(1A).

New section 124(1) provides that section 124 applies in relation to a reviewable decision that is not a part 2 decision.

New section 124(1A) provides that an affected person for the reviewable decision may apply to QCAT, as provided under the *Queensland Civil and Administrative Tribunal Act 2009* (QCAT Act), for a stay of the operation of the decision.

Clause 31(2) renumbers sections 124(1A) to (5) as section 124(2) to (6).

Replacement of s 125 (Applying for QCAT external review)

Clause 32 replaces section 125. New section 125(1) provides that section 125 applies if an affected person for a reviewable decision is required to be given a QCAT information notice under section 123(1)(c)(ii) for an internal review decision.

New section 125(2) provides that the affected person may apply to QCAT, as provided for under the QCAT Act, for a review of the internal review decision.

New section 125 also includes a note that section 56 also provides for a QCAT external review of certain decisions of the Registrar under part 3.

Amendment of s 138 (Executive officer may be taken to have committed offence against deemed executive liability provision)

Clause 33 amends section 138(4), definition of *deemed executive liability provision*, paragraph (c) to replace an erroneous reference to ‘section 139(2)’ with reference to ‘section 139(1)’.

The effect of this change is to correct a cross-referencing error to enable Queensland Health to hold executive officers accountable if they play a role in providing false or misleading information.

Insertion of new pt 9, div 1, hdg

Clause 34 inserts a new heading ‘Division 1 Transitional provisions commencing on 19 September 2024’ before section 144.

Insertion of new pt 9, div 2, hdg

Clause 35 inserts a new heading ‘Division 2 Other transitional provisions for Act No. 46 of 2024’ after section 144.

Insertion of new pt 9, div 2, sdiv 1

Clause 36 inserts new part 9, division 2, subdivision 1 (Preliminary).

New section 144B (Definitions for division) provides relevant definitions for the division.

Future ART procedure is defined to mean, for a person mentioned in new section 146(1)(a)(i) or 147(1)(a), an ART procedure carried out after the commencement of this section for the any of the following persons:

- the person;
- the person who, at the relevant time, was the person's spouse;
- a surrogate of the person;
- a surrogate of the person who, at the relevant time, was the person's spouse.

This definition supports the equitable application of the transitional provisions in sections 146 and 147 beyond the 'person' who had become pregnant or been allocated a donated embryo before commencement.

New, is defined, in relation to a provision of the Act, to mean the provision as in force from the commencement. This supports interpretation of the transitional provisions.

The meaning of *relevant time* is defined in new section 144C(3).

New section 144C (Particular references to spouses) provides the application of particular references to spouses in new sections 146 and 147.

New section 144C(1) provides that new section 144C applies in relation to a person mentioned in new section 146(1)(a)(i) or 147(1)(a) if, at the relevant time, the person and the person's spouse were separated and were living separately and apart.

New section 144C(2) provides that for this division, the spouse is taken not to have been a spouse of the person at the relevant time.

New section 144C(3) provides that, for the purpose of new section 144C(1), *relevant time* means:

- for a person mentioned in new section 146(1)(a)(i), the time when an ART provider allocated donated gametes for use by the person in ART procedures, as mentioned in that section; or
- for a person mentioned in new section 147(1)(a), the time when an ART provider allocated a donated embryo for use by the person in ART procedures as mentioned in that section.

Insertion of new pt 9, div 2, sdiv 2, hdg

Clause 37 inserts new part 9, division 2, subdivision 2 (Licensing).

Amendment of s 145 (Licensing of existing ART providers)

Clause 38 replaces section 145(2) and inserts new section 145(3).

New section 145(2) provides that new subsection (3) applies to an ART provider if the ART provider provided ART services immediately before the commencement of section 12 and the ART provider has prescribed accreditation during the initial licensing assessment period.

New subsection (3) provides that during the initial licensing assessment period, the ART provider is taken to be a licensed provider for the purposes of sections 12 (Requirement to be licensed), 61 (Chief executive to be notified of certain events), 77 (General power to enter places) and 145A (Licensed providers' notification of particular events that happened before commencement—new s 61) of the Act.

The effect of these changes is to ensure that important aspects of the Act related to a provider being licensed apply from commencement rather than having to wait until the licensing process is complete for the relevant provider. This will enable Queensland Health as regulator to be advised of and take action in relation to serious adverse events as necessary.

Insertion of new s 145A

Clause 39 inserts new section 145A (Licensed providers' notification of particular events that happened before commencement—new s 61) which clarifies that ART providers must notify the chief executive of serious adverse events that occurred prior to the commencement of section 61, if the ART provider becomes aware of the event after the commencement of section 61.

New section 145A(1) supports the application of section 61 (Chief executive to be notified of certain events) in relation to a licensed provider if:

- an event happened before the commencement of new section 61;
- the event would have been a serious adverse event for the licensed provider had new section 61 been in force when the event happened; and
- the licensed provider becomes aware of the event after the commencement of new section 61.

New section 145A(2) provides that new section 61 applies as if the event were a serious adverse event within the meaning of section 61. The effect of this change is to ensure that serious adverse events that happened before 19 September 2024 but become known after the commencement of new section 61 are treated to have always been notifiable serious adverse events under the Act.

Insertion of new pt 9, div 2, sdiv 3

Clause 40 inserts new part 9, division 2, subdivision 3 (Provisions for general operation of part 2). Subdivision 3 contains new transitional provisions to support the effective operation of the ART Act by specifying in greater detail how the Act applies to activities carried out, or to genetic material collected or created before commencement of the Act.

New section 145B (Donor-related Australian families—new s 25) confirms that for the purpose of calculating the number of donor-related Australian families for the family limit in new section 25 (clause 7), it does not matter whether a person or a child mentioned in new section 25 was born before or after the commencement of section 145B.

New section 145C (Time limits on use of existing donated gametes and embryos—new s 27) confirms the application of the time limit on the use under new section 27 to existing donated gametes and embryos (collected or created before 19 September 2024) used in an ART procedure carried out after the commencement of section 145C.

New section 145C(1) provides that subject to new sections 146 to 148, new section 27 applies in relation to the use of a donated gamete or donated embryo in an ART procedure carried out after the commencement of section 145C. This seeks to provide clarity about the interpretation of and interaction between new section 27 (clause 8) and new sections 146 to 148 (clause 42), which disapply section 27 requirements in specific circumstances.

New section 145C(2) provides that subsection (1) applies:

- whether or not the donated gamete was obtained, or the donated embryo was created, before the commencement of this section; and
- even if the period mentioned in new section 27(1) during which the donated gamete or donated embryo may be used in an ART procedure ended before the commencement of this section.

The effect of new section 145C(2) is to ensure that where gametes or embryos may have exceeded 15 years even before commencement of new section 27, new section 27 still applies to that material at the time a provider seeks to use it and would need to apply for a chief executive approval, unless a transitional provision (sections 146 – 148) applies.

New section 145D (Record-keeping—s 36) clarifies the application of the requirements in section 36 (Keeping of records) to information collected before 19 September 2024.

New section 145D(1) and (2) provide that if, before 19 September 2024, an ART provider collected information of a type mentioned in a provision of part 2, division 6 (Information collection and record keeping), a reference in section 36 to information an ART provider is required to collect under part 2, division 6 includes, and is taken to have always included, a reference to that information. The effect of this change is to ensure records already collected by ART providers of a type outlined in the ART Act are retained by providers and subject to the 99 year retention period and prohibition against destruction.

New section 145E (Disclosure of health information—s 38) clarifies the relevant parties may have health information disclosed to them by an ART provider for ART procedures that were carried out before the commencement of section 38 (Disclosure of health information by ART provider).

New section 145E(2) provides that references in section 38 to a donor-conceived person born as a result of an ART procedure or their donor-conceived sibling includes, and is taken to have always included, a reference to a donor-conceived person, or a donor-conceived sibling, born as a result of an ART procedure that was carried out before the commencement of section 38 (that is, before 19 September 2024).

Insertion of new part 9, division 2, sdiv 4, hdg

Clause 41 inserts new part 9, division 2, subdivision 4 (Provisions about use of particular gametes and embryos obtained before 19 September 2024).

Replacement of ss 146–149

Clause 42 replaces current sections 146 to 149 with new sections 146 to 149.

New section 146(1) provides that new section 146 (Donated gametes previously allocated to person for ART procedures) applies if:

- before 19 September 2024:
  - an ART provider allocated donated gametes for use by a person in ART procedures; and
  - the person, or a surrogate of the person, became pregnant as a result of the use of some of those donated gametes in an ART procedure; and
- after the commencement of this section, an ART provider proposes to use the remaining donated gametes in future ART procedures for the person.

New section 146(2) provides the ART provider may use the remaining donated gametes in future ART procedures for the person despite the donor's consent to the use of the remaining gametes in an ART procedure not complying with a requirement for consent mentioned in new section 18(2) (clause 6) or not being in writing.

This reflects the intent that before there is any use of a gamete there will be consent from the donor regardless of whether that consent explicitly complies with the ART Act. A provider should not be seeking to use a donor gamete, regardless of whether it has previously been allocated, where there is no evidence of the donor's consent; that consent may have been provided verbally or in writing.

New section 146(3) clarifies that subsection (2) does not apply in relation to the use of a gamete if:

- the donor had previously consented to the use of the gamete in an ART procedure; and
- since giving the consent, the donor has:
  - withdrawn the consent under section 20; or
  - otherwise clearly communicated the withdrawal of the consent to the ART provider, whether or not in writing.

The intent of new section 146(3) is to confirm that nothing in the transitional provisions overrides a donor's explicit wishes where consent has been withdrawn. This is because use should not occur under section 146 where the donor has expressly withdrawn consent for use of their gamete in an ART procedure. Given the withdrawal of consent may have occurred prior to new section 146 commencing, this withdrawal should apply with the same effect as one provided under section 20 of the ART Act.

New section 146(4) provides that the following limitations under part 2 do not apply to the use of the remaining donated gametes in future ART procedures for the person:

- any limit on the period within which the gametes may be used; and
- any limit on the number of donor-related Australian families who may use the gametes.

New section 146(5) provides that new section 33(4) does not apply in relation to the use of the remaining donated gametes in future ART procedures for the person. This seeks to disapply the new section 33(4) (clause 9) requirements from applying to a gamete that meets new section 146 requirements and is intended to be used.

New section 147(1) provides that new section 147 (Donated embryo previously allocated to a person for ART procedures) applies if:

- before 19 September 2024, an ART provider allocated a donated embryo for use by a person in an ART procedure; and
- after the commencement of this section, an ART provider proposes to use the donated embryo in a future ART procedure for the person.

New section 147(2) provides that the ART provider may use the donated embryo in the future ART procedure for the person despite the donor's consent to the use of the embryo in an ART procedure not complying with a requirement for consent mentioned in new section 18(2) (clause 6) or not being in writing.

This reflects the intent that before there is any use of an embryo there will be consent from the donor(s) regardless of whether that consent explicitly complies with the ART Act. A provider should not be seeking to use a donor embryo, regardless of whether it has previously been allocated, where there is no evidence of the donor's consent; that consent may have been provided verbally or in writing.

New section 147(3) clarifies that section 147(2) does not apply in relation to the use of the donated embryo if:

- the donor had previously consented to the use of the embryo in an ART procedure; and
- since giving the consent, the donor has:
  - withdrawn the consent under section 20; or
  - otherwise clearly communicated the withdrawal of the consent to the ART provider, whether or not in writing.

The intent of new section 147(3) is to confirm that nothing in the transitional provisions overrides a donor's explicit consent where that consent has been withdrawn. This is because use should not occur under section 147 where the donor has expressly withdrawn consent for use of their embryo in an ART procedure. Given the withdrawal of consent may have occurred prior to new section 147 commencing, this withdrawal should apply with the same effect as one provided under section 20 of the ART Act.

New section 147(4) provides that the following limitations under part 2 do not apply to the use of the donated embryo in the future ART procedure for the person:

- any limit on the period within which the embryo may be used; and
- any limit on the number of donor-related Australian families who may use the embryo.

New section 147(5) provides that the new section 33(4), which prevents ART providers from using embryos unless the information collection requirements have been met, does not apply

in relation to the use of the donated embryo in the future ART procedure for the person. The effect is to disapply the new section 33(4) requirements from applying to a gamete that meets new section 147 requirements and is intended to be used.

New section 148(1) provides that new section 148 (Embryo created with donated gamete not yet used for ART procedure) applies if:

- before 19 September 2024, an embryo was created with a donated gamete; and
- after the commencement of this section, an ART provider proposes to use the embryo in an ART procedure for a person.

New section 148(2) provides that the chief executive may, on application by the ART provider, approve the use of the embryo in the ART procedure for the person if satisfied there are reasonable grounds for using the embryo, having regard to when the embryo was created; whether, when the embryo was created, there was a reasonable expectation that it would be used in an ART procedure for a person; and any other relevant matter.

The addition of considerations for the decision-making process will promote natural justice by being transparent about the factors that are relevant in assessing a section 148 application. Additionally, the considerations are aimed at ensuring the decision-maker considers the most relevant factors, which are that the embryo was made in good faith and not in an attempt to circumvent the requirements of the ART Act. This is why the date the embryo was created and whether it was created with a clear intention for use, pending any unforeseen circumstances which may impact its use, are explicitly identified.

New section 148(3) provides that if an approval is given under subsection (2) to the ART provider, the ART provider may use the embryo in the ART procedure despite:

- new sections 25, 27 or 33 (clauses 7 to 9); or
- the consent of the donor to the use of the embryo in an ART procedure not complying with a requirement for consent mentioned in section 18(2) (clause 6) or not being in writing.

Consistent with new sections 146 and 147, where use is approved under new section 148 the intent is to disapply the requirements in sections 25, 27 and 33, as well as new section 18(2) and the requirement for consent to be in writing.

New section 148(4) clarifies that section 148(3)(b) does not apply in relation to the use of an embryo if:

- the donor had previously consented to the use of the embryo in an ART procedure; and
- since giving the consent, the donor has:
  - withdrawn the consent under section 20; or
  - otherwise clearly communicated the withdrawal of the consent to the ART provider, whether or not in writing.

The intent of new section 148(4) is to confirm that nothing in the transitional provisions overrides a donor's explicit wishes where their consent has been withdrawn. This is because use should not occur under section 148 where the donor has expressly withdrawn consent for use of the embryo in an ART procedure. Given the withdrawal of consent may have occurred

prior to new section 148 commencing, this withdrawal should apply with the same effect as one provided under section 20 of the ART Act.

New section 148(5) provides that if the chief executive decides to refuse to give an approval under subsection (2), the chief executive must, as soon as practicable after the decision is made, give the applicant an information notice for the decision. This supports natural justice by providing that chief executive decisions to refuse applications will be reviewable decisions that may be subject to internal review.

New section 148(6) provides that a decision of the chief executive mentioned in subsection (5) is taken to be a part 2 decision within the meaning of section 119.

New section 148(7) provides that new part 2, division 8 does not apply in relation to the use of the embryo in the ART procedure for the person.

This is to clarify that a provider who applies for chief executive approval to use an embryo under new section 148 cannot also apply under new sections 39B or 39C (clause 14) to use the embryo, should any of the exceptions in those sections apply. This is because the decision-making in section 148 is set at a lower threshold acknowledging that it applies to material created before the ART Act commenced. Conversely, the other sections have higher thresholds as they apply prospectively where the transitional provisions are not met. If a provider was refused approval under new section 148, they would not be able to meet the decision-making threshold for sections 39B or 39C. As an approval under section 148 disapplies these other provisions where there is a chief executive approval pathway, it is considered necessary to clarify the relationship between these application sections.

New section 149 (Use of particular gametes obtained before 19 September 2024—collection of information) confirms the application of the information collection requirements to gametes obtained before 19 September 2024.

New section 149(1) provides that the transitional provision applies if:

- an ART provider obtained a gamete before 19 September 2024 for use in an ART procedure or for storage for use in an ART procedure;
- immediately before the commencement of the section, the gamete had not been used in an ART procedure; and
- new sections 146 and 147 do not apply in relation to the use of the gamete in an ART procedure.

New section 149(2) clarifies that new section 33(4) does not prevent the use of the gamete, or an embryo created using the gamete, in an ART procedure if:

- the ART provider collected the information mentioned in new section 33(1) in relation to the gamete before the gamete was obtained; or
- the ART provider collects the information mentioned in new section 33(1) in relation to the gamete before the gamete or embryo is used in the ART procedure; or
- the chief executive approves the use of the gamete or embryo in the ART procedure under new section 39C.

The effect of this new section is to put beyond doubt that section 33(4) (clause 9), prohibiting use of gametes where not all the information has been collected as required by section 33(1), applies to all gametes including where they were obtained before commencement of the Act and where no exception applies.

Renumbering and relocation of s 150 (Time within which information about pregnancies and births to be collected by ART providers)

Clause 43 renumbers section 150 as section 144A and relocates it to part 9, division 1.

Insertion of new pt 9, div 2, sdiv 5, hdg

Clause 44 inserts new part 9, division 2, subdivision 5 (Miscellaneous).

Insertion of new ss 152 and 153

Clause 45 inserts new sections 152 (Relationship of division with s 144) and 153 (Transitional regulation-making power).

New section 152 provides that to the extent of any inconsistency between a provision of part 9, division 2 and section 144(1)(a), (c) or (d), the provision of part 9, division 2 prevails.

New section 153 provides for a transitional regulation-making power to enable a transitional regulation to make provision about a matter for which the ART Act does not provide or sufficiently provide. A transitional regulation may have retrospective operation to a day not earlier than the day section 153 commences and must declare that it is a transitional regulation. New section 153(4) provides that this section and any transitional regulation expires on the day 2 years after the day new section 153 commences.

Amendment of sch 1 (Dictionary)

Clause 46 amends schedule 1 (Dictionary) of the ART Act.

Clause 46(1) omits the definition of *RTAC accreditation*.

Clause 46(2) inserts definitions or references to definitions for *accreditation standard*, *donor-related Australian families, part 2 decision* and *prescribed accreditation*.

The definition of *accreditation standard* for part 4 is provided in section 56A (clause 21).

The definition for *donor-related Australian families* is provided in section 25(3) (clause 7).

The definition of *part 2 decision* for part 6 is provided in section 119 (clause 28) in relation to review of decisions and appeals.

Prescribed accreditation, in relation to a person, means accreditation of the person, or of facilities operated by the person, by an entity prescribed by regulation.

Clause 46(7) omits the previous reference to the definition of *contact information* for part 3 and inserts a new definition for *contact information*. *Contact information*, for a person, means

the person's residential address, phone number or email address or any other way the person may be contacted.

Part 3 Amendment of Health and Wellbeing Queensland Act 2019

Act amended

Clause 47 states that this part amends the *Health and Wellbeing Queensland Act 2019.*

Amendment of s 23 (Vacancy in office)

Clause 48 inserts new subsection 23(2) to provide that the Governor in Council may, at any time, remove a Board member from office for any reason or none. This means the Governor in Council can remove a board member with or without grounds.

This clause also amends section 23(d) to state there is a vacancy in the office of a Board member if the member is removed by the Governor in Council under new subsection 23(2). This is equivalent to existing section 23(d).

Amendment of s 24 (Acting board member)

Clause 49 amends section 24(5) to amend a cross-reference to the *Acts Interpretation Act 1954*, for clarity and for consistency with the other amendments in the Bill.

Section 24 of the HWQ Act provides that the Minister may temporarily appoint a Board member if the office is vacant. Section 24(5) currently provides that the Minister's power to temporarily appoint a Board member does not limit the Governor in Council's power under section 25(1)(b)(iv) of the Acts Interpretation Act. The Bill updates the cross-reference to refer to section 25(1)(b) of the Acts Interpretation Act to ensure that the Minister's power to temporarily appoint a member does not limit the Governor in Council's power for any of the circumstances set out in section 25(1)(b).

Amendment of s 37 (Vacancy in office)

Clause 50 inserts new subsection 37(3) to provide that the Governor in Council may, at any time, remove the Chief Executive Officer (CEO) from office for any reason or none. This means the Governor in Council can remove the CEO with or without grounds.

This clause also amends section 37(1)(d) to state there is a vacancy in the office of the CEO if the person removed by the Governor in Council under the new subsection 37(3). This is equivalent to existing section 37(1)(d).

Amendment of s 38 (Acting chief executive officer)

Clause 51 amends section 38(5) to amend a cross-reference to the Acts Interpretation Act, for clarity and for consistency with the other amendments in the Bill.

Section 38 of the HWQ Act provides that the Minister may temporarily appoint a CEO if the office is vacant, or if the CEO is absent or unable to perform their functions. Section 38(5) currently provides that the Minister's power to temporarily appoint a CEO does not limit the Governor in Council's power undersection 25(1)(b)(iv) and (v) of the Acts Interpretation Act. The Bill updates the cross-reference to refer to section 25(1)(b) of the Acts Interpretation Act to ensure that the Minister's power to temporarily appoint a member does not limit the Governor in Council's power for any of the circumstances set out in section 25(1)(b).

Insertion of new pt 7

Clause 52 inserts transitional provisions which provide that the Governor in Council's powers to remove a Board member or CEO under the Bill apply whether the person was appointed before or after the commencement.

Part 4 Amendment of Health Legislation Amendment Act 2025

Act amended

Clause 53 states that this part amends the *Health Legislation Amendment Act 2025.*

Replacement of s 7 (Amendment of s 28 (Removal from office of board members))

Clause 54 is a technical drafting amendment to ensure section 7 of the *Health Legislation Amendment Act 2025* takes effect under the amended provisions of the Bill and operates as intended. This clause replaces section 7 with a provision that amends section 25A to provide that a HHB member is disqualified from continuing as a Board member if they were appointed because they were a HHS clinician and they have stopped being a HHS clinician.

Section 7 of the *Health Legislation Amendment Act 2025* as originally drafted amends section 28(e) of the Hospital and Health Boards Act. However, the Bill omits section 28 of the Act and moves the external grounds for removal of Board members to new section 25A.

This clause is consistent with the original intent of section 7 of the *Health Legislation Amendment Act 2025*.

Part 5 Amendment of Hospital and Health Boards Act 2011

Act amended

Clause 55 states that this part amends the *Hospital and Health Boards Act 2011.*

Insertion of new s 25A

Clause 56 inserts a new section 25A, which provides the criteria for when a HHB member is disqualified from becoming or continuing as a HHB member.

The disqualification criteria are based on the grounds for removal that were previously included in section 28, which is omitted by the Bill. The disqualification criteria are if the person:

- is an insolvent under administration;
- is disqualified from managing corporations because of the Corporations Act, part 2D.6;
- has a conviction for an indictable offence; or
- has a conviction for an offence against this Act.

The inclusion of criteria for disqualification more closely aligns the approach in the Hospital and Health Boards Act with the Health and Wellbeing Queensland Act, Hospital Foundations Act and Pharmacy Business Ownership Act, which all have disqualification criteria.

In addition, from 1 April 2026, section 25A is amended to provide that a person is disqualified from continuing as a HHB member if the member was appointed because they were a HHS clinician and they have stopped being a HHS clinician (in accordance with the amendment to section 7 of the *Health Legislation Amendment Act 2025* outlined above).

Amendment of s 27 (Vacation of office of board member)

Clause 57 inserts new subsection 27(2) to provide that the Governor in Council may, at any time, remove a Board member from office for any reason or none. This means the Governor in Council can remove the Board member with or without grounds.

For consistency with the approach taken in the Health and Wellbeing Queensland Act and Pharmacy Business Ownership Act, this clause also amends section 27 to state that the office of a Board member becomes vacant if the person completes a term of office and is not reappointed or if they are disqualified from continuing as a member under new section 25A. This clause also amends section 27 to state there is a vacancy in the office of a Board member if the member is removed by the Governor in Council under the new subsection 27(2). This is equivalent to existing section 27(b).

Amendment of s 27A (Suspension from office of Hospital and Health Board members)

Clause 58 makes consequential amendments to section 27A. It omits section 27A(1)(b), which is no longer required, as a Board member can be removed for any reason or none. As a result of the amendment, section 27A provides that the Minister can suspend a Board member if a matter has arisen in relation to the member and the Minister considers it necessary in the public interest for the member to be suspended from office pending further consideration of the matter.

This clause also renumbers section 27A(1)(c) as section 27A(1)(b).

Omission of s 28 (Removal from office of board members)

Clause 59 omits section 28. This reflects that the Bill allows the Governor in Council to remove a Board member for any reason or none.

The external matters currently included in section 28 have been moved to new section 25A as criteria for when a person is disqualified from becoming or continuing as a HHB member.

These include being insolvent, disqualified from managing corporations or being convicted of an indictable offence or an offence against the Hospital and Health Boards Act.

Insertion of new pt 13, div 9

Clause 60 inserts a transitional provision which provides that the Governor in Council's power to remove a Board member under the Bill applies whether the member was appointed before or after the commencement.

Amendment of sch 2 (Dictionary)

Clause 61 inserts a definition of 'conviction' in the dictionary for consistency with the definition in the Health and Wellbeing Queensland Act and Pharmacy Business Ownership Act. The definition puts beyond doubt that a conviction includes a finding of guilt, or the acceptance of a guilty plea, whether or not a conviction is recorded.

Part 6 Amendment of Hospital Foundations Act 2018

Act amended

Clause 62 states that this part amends the *Hospital Foundations Act 2018.*

Amendment of s 33 (Disqualification from becoming member)

Clause 63 amends section 33 to provide that a person is disqualified from becoming or continuing as a member of a Hospital Foundation Board, if they have consented to the borrowing of an amount that the foundation is not lawfully authorised to borrow under the *Statutory Bodies Financial Arrangements Act 1982*. This basis for disqualification was a ground for removal of a Board member in section 34(b), which is removed by the Bill.

Omission of s 34 (Removal from office)

Clause 64 omits section 34. This reflects that the Bill allows the Governor in Council to remove a Board member for any reason or none.

Amendment of s 35 (Vacancy in office)

Clause 65 inserts new subsection 35(2) to provide that the Governor in Council may, at any time, remove a Board member from office for any reason or none. This means the Governor in Council can remove a Board member with or without grounds.

For consistency with the approach taken in the Health and Wellbeing Queensland Act and Pharmacy Business Ownership Act, this clause also amends section 35 to state that the office of a Board member becomes vacant if the person is disqualified from continuing as a member under section 33. This clause also amends section 35 to state there is a vacancy in the office of a Board member if the member is removed by the Governor in Council under the new subsection 35(2). This is equivalent to existing section 35(b).

Insertion of new s 35A

Clause 66 inserts a new section 35A to provide that the Minister may appoint a person to act in the office of a Board member if the office is vacant. New section 35A is consistent with the approach in the Health and Wellbeing Act and the Hospital and Health Boards Act, which allow the Minister to appoint acting or temporary board members.

Under new section 35A, the Minister may appoint a person to act in the office of a Board member for up to six months. However, the Minister can extend the appointment for a further period of up to six months. The Minister can only appoint an acting Board member if they could recommend the person for appointment under section 30. The Minister's power does not limit the Governor in Council's power under section 25(1)(b) of the Acts Interpretation Act.

Amendment of s 36 (Criminal history report)

Clause 67 makes a consequential amendment to section 36 to reflect that the Bill is removing section 34 of the Hospital Foundations Act, so the cross-reference to section 34 is no longer required.

Insertion of new pt 9, div 3

Clause 68 inserts a transitional provision which provides that the Governor in Council's power to remove a Board member under the Bill applies whether the Board member was appointed before or after the commencement.

Part 7 Amendment of Pharmacy Business Ownership Act 2024

Act amended

Clause 69 states that this part amends the *Pharmacy Business Ownership Act 2024.*

Replacement of s 156 (Vacancy in office)

Clause 70 replaces section 156, which includes new subsection 156(2) to provide that the Governor in Council may, at any time, remove a Board member from office for any reason or none. This means the Governor in Council can remove a board member with or without grounds. The grounds in section 156(1)(a) to (d) are consistent with the grounds in existing section 156.

This clause also inserts new section 156A, which provides that the Minister may appoint a person to act in the office of a Council member if the office is vacant. New section 156A is consistent with the approach of appointing an acting CEO under section 172 of the Pharmacy Business Ownership Act, an acting HWQ Board member under section 24 of the Health and Wellbeing Queensland Act, and an acting HFB member under new section 35A of the Hospital Foundations Act.

The Minister can only appoint an acting Council member if they could recommend the person for appointment under section 150(3). In addition, the Minister may only appoint a person to

act in the office for a period of up to six months. However, the Minister can extend the appointment for a further period of up to six months. The Minister's power does not limit the Governor in Council's power under section 25(1)(b) of the Acts Interpretation Act.

Amendment of s 171 (Vacancy in office)

Clause 71 inserts new subsection 171(2) to provide that the Governor in Council may, at any time, remove the CEO from office for any reason or none. This means the Governor in Council can remove the CEO with or without grounds.

This clause also amends section 171 to provide that there is a vacancy in the office of the CEO, if the CEO is removed by the Governor in Council under new subsection 171(2).

Amendment of s 172 (Acting chief executive officer)

Clause 72 amends section 172 to amend a cross-reference to the Acts Interpretation Act, for clarity and for consistency with the other amendments in this Bill.

Replacement of pt 14, hdg (Transitional provisions)

Clause 73 replaces the title of part 14, to make it clear that part 14 relates to the transitional provisions for Act No. 9 of 2024, and the repeal provision which is being moved to part 14.

Relocation and renumbering of pt 15, div 1 (Repeal)

Clause 74 moves the repeal provision contained in part 15 division 1, to part 14, division 5.

Replacement of pt 15 (Repeal and amendments of legislation)

Clause 75 replaces part 15 to insert two transitional provisions which provide that the Governor in Council's powers to remove Council members and the CEO apply whether the person was appointed before or after commencement.

Part 8 Amendment of Private Health Facilities Act 1999

Act amended

Clause 76 states that this part amends the *Private Health Facilities Act 1999.*

Amendment of s 48 (Conditions of licence)

Clause 77 replaces section 48(1)(b) to provide that a licence for a private health facility must be issued on the condition that the licensee must comply with a standard of accreditation prescribed for a type of health service, or all health services, provided at the facility.

This ensures that a regulation can prescribe the standard of accreditation that the facility must comply with for health services provided at the facility. For example, the Private Health Facilities Regulation will continue to provide that all facilities must comply with the NSQHS Standards. It also allows the Private Health Facilities Regulation to prescribe that facilities that

provide cosmetic surgery must comply with the National Safety and Quality Cosmetic Surgery Standards.

This clause also makes a minor amendment to section 48(1)(c) to insert the words 'made under part 3' to make it clear the reference to standards in section 48(1)(c) is referring to the standards made under part 3 of the Act. This is a minor drafting change and there is no change in the effect of the provision. The change clarifies that a licence for a private health facility must be issued on the condition that the licensee must comply with the standards made under part 3 relevant to the facility. These standards are different to those referred to in section 48(1)(b), and are made by the chief health officer under part 3 and are currently notified by the *Private Health Facilities (Standards) Notice 2016*.

Amendment of s 50 (Term of licences)

Clause 78 replaces section 50(2) of the Private Health Facilities Act to make a minor drafting clarification. New section 50(2) makes it clear that if a licence under the Act is being renewed, it can be renewed for a term of up to three years. However, the first licence for a private health facility can only be for a term of up to one year.

Amendment of s 144 (Submission of reports)

Clause 79 amends section 144(2)(b) to refer to information given to Queensland Government entities under a prescribed agreement. This amendment is a consequential amendment from the change to section 147. It ensures that the reports that the licensee of a private health facility must give to the chief health officer can be used to give information to a government entity under a prescribed agreement.

Amendment of s 147 (Confidentiality of information)

Clause 80 amends section 147(4)(c)(i) of the Private Health Facilities Act to allow a regulation to prescribe information sharing agreements with Queensland Government entities about information collected under the Act. The new provision states the chief executive can give information to a government entity under an agreement with the entity that is prescribed under a regulation. The term 'government entity' is defined to mean the Commonwealth or another State, an entity of the Commonwealth or another State, or an entity of the State.

This clause also defines 'agreement' to include arrangement, which puts beyond doubt that a Memorandum of Understanding between two Queensland Government departments can be prescribed as an agreement in a regulation.

Part 9 Amendment of Transplantation and Anatomy Act 1979

Act amended

Clause 81 states that this part amends the *Transplantation and Anatomy Act 1979.*

Amendment of s 4 (Interpretation)

Clause 82 inserts definitions of *ante-mortem intervention* and *tissue donation viability*.

Ante-mortem intervention is defined in new section 25A for the purposes of new part 3A.

Tissue donation viability means the viability of tissue for transplanting from a person after death to the body of another living person.

Replacement of pt 2, div 4, hdg (Blood transfusions)

Clause 83 replaces the heading 'Blood transfusions' in part 2, division 4 with 'Removal of blood for particular purposes'.

This amendment clarifies that division 4 relates to the removal of blood from a person only for the purposes as set out in division 4 which are for a blood transfusion, using the blood or any of its constituents for other therapeutic purposes or for other medical or scientific purposes, or for determining tissue donation viability.

Amendment of s 17 (Consents by adults to removal of blood)

Clause 84 amends section 17 to include a new subsection (c) which provides that an adult may consent to the removal of blood from their body for the purpose of determining tissue donation viability.

Amendment of s 18 (Consents to removal of blood from children)

Clause 85 amends the heading of section 18 to insert refence to 'for particular purposes'. This is to make it clear that the section deals with consent to removal of blood from children for the particular purposes set out in section 18.

Clause 85(2) also amends section 18 to clarify that a parent of a child may consent, in writing, to the removal of blood from the body of a child for any of the purposes in section 17, other than for the purpose of determining tissue donation viability.

Insertion of new s 18A

Clause 86 inserts new section 18A (Consents to removal of blood from children or adults with impaired capacity for determining tissue donation viability) to provide that in relation to a child, or an adult who does not have capacity to consent to the removal of blood from their body, the senior available next of kin can consent, in writing, to the removal of blood from the person's body for the purpose of determining tissue donation viability.

Senior available next of kin is a defined term in section 4 of the Act.

Replacement of s 19 (Consent to be sufficient authority for removal of blood)

Clause 87 replaces section 19 to provide that a consent provided, by or for a person, under the division is sufficient authority to remove blood from the person.

Insertion of new pt 3A

Clause 88 inserts new part 3A (Ante-mortem interventions) to provide the consent framework for ante-mortem interventions.

New section 25A (What is an *ante-mortem intervention*) defines *ante-mortem intervention*.

An *ante-mortem intervention* is a medical procedure that is carried out on a living person to determine, maintain or improve the viability of tissue for transplanting, after the person's death, to the body of another living person.

For the purposes of the definition, removing blood from the body of a living person for the purposes of determining tissue donation viability is not an ante-mortem intervention. New section 18A (Consents to removal of blood from children or adults with impaired capacity for determining tissue donation viability) separately provides for the removal of blood for determining tissue donation viability.

New section 25B (Authority for ante-mortem intervention—adult with capacity) provides the authority for an adult with capacity to consent to an ante-mortem intervention being carried out on them.

New section 25C (Authority for ante-mortem intervention—child or adult with impaired capacity) provides the authority for an ante-mortem intervention to be carried out on a child or adult with impaired capacity.

Subsection (1) provides that new section 25C applies if the following criteria are met:

- the person is in a hospital; and
- the person is a child, or an adult who does not have capacity to consent to the carrying out of an ante-mortem intervention on them; and
- a decision or direction has been lawfully made to withhold or withdraw life-sustaining measures for the person; and
- before the withholding or withdrawal of life-sustaining measures, the decision or direction has not been revoked.

In relation to withholding or withdrawing life-sustaining measures for an adult who has impaired capacity, the *Guardianship and Administration Act 2000* and *Powers of Attorney Act 1998* apply.

If the relevant criteria are met, subsection (2) provides that the designated officer may authorise the carrying out of an ante-mortem intervention on the person, in writing, if the senior available next of kin of the person consents in writing to the carrying out of the ante-mortem intervention and that consent is not revoked.

Subsection (3) provides that if it is not practicable for the consent to the carrying out of an ante-mortem intervention to be given in writing by the senior available next of kin, it may be given orally. Subsection (4) provides that if consent to the carrying out of an ante-mortem intervention is given orally, the designated officer must ensure, as soon as practicable, the fact the consent was given orally, and the details of the oral consent are put in writing and placed

on the person's hospital record. Reasonable attempts must also be made to have the consent confirmed in writing by the senior available next of kin.

Subsection (5) provides that the designated officer must ensure the written consent to the carrying out of an ante-mortem intervention is placed on the person's hospital records as soon as practicable.

Subsection (6) provides that an authority by the designated officer under subsection (2) is sufficient authority for the carrying out of an ante-mortem intervention on the person.

Part 10 Other Amendments

Clause 89 inserts new Schedule 1 (Legislation amended).

Schedule 1 Other amendments

Public Health Act 2005

Clause 1 removes the definition of Commonwealth chief medical officer from section 279AA.

Clause 2 inserts a definition for *relevant Commonwealth officer* in section 279AA.

Clause 3 changes a reference to Commonwealth chief medical officer to relevant Commonwealth officer in the heading for section 279AB.

Clause 4 changes a reference to Commonwealth chief medical officer to relevant Commonwealth officer in section 279AB(2).

Clause 5 changes a reference to Commonwealth chief medical officer to relevant Commonwealth officer in section 279AC(1)(a)(i).

Clause 6 removes the definition of *Commonwealth chief medical officer* in schedule 2.

Clause 7 inserts a definition of *relevant Commonwealth officer* into schedule 2, by referring to the definition inserted in chapter 6, part 3A, division 1, section 279AA.

Transplantation and Anatomy Act 1979

Clause 1 amends the heading in section 9 (Blood transfusions not subject to this division) following amendment to the heading of division 4. It removes the reference to 'Blood transfusions' and replaces it with 'Particular blood removal'.

Clause 2 amends the heading in section 12A (Blood transfusions and donations for approved research are not subject to this division) following amendment to the heading of division 4. It removes the reference to 'Blood transfusions and donations for approved research' and replaces it with 'Particular blood removal and donations'.