

Impact Analysis Statement

Summary IAS

Details

Lead department	Queensland Health
Name of the proposal	Health Legislation Amendment Bill (No. 3) 2025
Submission type (Summary IAS / Consultation IAS / Decision IAS)	Summary IAS
Title of related legislative or regulatory instrument	<i>Assisted Reproductive Technology Act 2024</i> <i>Health and Wellbeing Queensland Act 2019</i> <i>Hospital and Health Boards Act 2011</i> <i>Hospital Foundations Act 2018</i> <i>Pharmacy Business Ownership Act 2024</i> <i>Private Health Facilities Act 1999</i> <i>Public Health Act 2005</i> <i>Transplantation and Anatomy Act 1979</i>
Date of issue	10 October 2025

Proposal type	Details
Minor and machinery in nature	The following amendments to the <i>Assisted Reproductive Technology Act 2024</i> (ART Act) are minor and have no regulatory costs: • clarification of information collection and record keeping requirements to streamline contact information requirements and put intent of provisions beyond doubt; • clarification of transitional provisions to refine and put scope beyond doubt; • updates to terminology; • correction of a cross-referencing error; • minor amendments to part 3 to clarify the relevant information to be included in the donor conception information register. Other amendments to the ART Act are detailed below. The amendment to the <i>Public Health Act 2005</i> makes a minor consequential amendment to require occupational respiratory diseases to be notified in accordance with proposed changes to Commonwealth legislation.

Regulatory proposals where no RIA is required	The following proposals relate to internal management of the public sector and do not require regulatory impact analysis under the Better Regulation Policy: • amendments to the <i>Hospital and Health Boards Act 2011</i>, <i>Health and Wellbeing Queensland Act 2019</i>, <i>Pharmacy Business Ownership Act 2024</i>, and <i>Hospital Foundations Act 2018</i> to allow the following statutory office holders to be removed by Governor in Council with or without grounds: ○ Hospital and Health Board members under the Hospital and Health Boards Act; ○ Health and Wellbeing Queensland Board members and chief executive officer under the Health and Wellbeing Queensland Act; ○ Queensland Pharmacy Business Ownership Council members and chief executive officer under the Pharmacy Business Ownership Act; and ○ Hospital Foundation Board members under the Hospital Foundations Act; and • amendment to the <i>Private Health Facilities Act 1999</i> to enable improved information sharing with Queensland Government entities.
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Assisted Reproductive Technology Act 2024

What is the nature, size and scope of the problem? What are the objectives of government action?
Amendments to the <i>Assisted Reproductive Technology Act 2024</i> (ART Act) clarify the policy intent of the Act, promote equitable outcomes and where appropriate, introduce a pathway for case-by-case decision making so the administration of the ART Act does not result in undue hardship. These amendments ensure the ART Act operates as intended and effectively supports the implementation of the regulatory framework. Several of these proposals are minor and machinery in nature and are noted above. <u>Chief executive approval – information collection requirements</u> Assisted reproductive technology (ART) providers are a critical source of information about gametes (eggs or sperm) and embryos used in ART procedures, patients and treatment outcomes. This information is particularly important for donor conception, where a donor-conceived person is born as a result of donor gametes. The ART Act requires providers to collect and keep relevant information. These provisions commenced on assent of the Act in September 2024. The information required to be collected by an ART provider includes the gamete provider's name, residential address, phone number and email address, with additional information required 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 or using a gamete or embryo in an ART procedure without first collecting the required information are offences attracting a maximum penalty of 200 penalty units. Operational issues with the information collection requirements have been raised during implementation of the ART Act. ART providers, patients, and advocacy groups have raised concerns about instances of particular information being unable to be collected, effectively prohibiting the use of the gamete in an ART procedure. This is creating unintended and harsh consequences for patients, particularly those who already have a donor-conceived child using a specific donor who wish to expand their family. 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 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, the Bill provides the chief executive (Director-General of Queensland Health) with the ability to approve use of gametes or embryos on a case-by-case basis despite the information collection requirements not being met in full. This provides flexibility where the chief executive is satisfied the ART provider has taken reasonable steps to collect the relevant information and there are reasonable grounds for the use.

The inclusion of this power is consistent with existing chief executive approvals in the ART Act, including in section 27 (Time limit on use of donated gametes or embryos and their disposal), section 37 (Destruction of records prohibited) and section 148 (Embryo not yet used for ART procedure).

Chief executive approval – family limit

The 10-family limit is a key restriction in the ART Act to protect donor-conceived people, particularly from the risk of consanguineous relationships and the psychosocial impacts of having many genetic siblings. 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 undertake appropriate checks to determine whether the limit would be breached. A maximum penalty of 400 penalty units applies for non-compliance.

A *family* is defined as a parent, their spouse (if any) and their children. Section 25(6) provides that to remove any doubt, if a person has a former spouse the person, their former spouse and children of both parties comprise a separate family. Under this restriction, if a couple with a donor-conceived child separates and one of the partners wishes to use the same donor again, this would be counted as a separate family. Where the 10-family limit has been exhausted, this would prohibit the person from using the donor, despite the potential psychosocial benefits to the existing child of having a genetic sibling.

The Bill enables the chief executive to approve the use of donated genetic material beyond the 10-family limit on a case-by-case basis, if satisfied there are reasonable grounds for use.

Alignment of chief executive approval powers

As outlined above, there are existing powers in the ART Act for the chief executive to provide case-by-case approvals in relation to the time limit on using donated gametes and embryos, and destruction of records. These approval powers provide flexibility for Queensland Health to exercise discretion and limit undue hardship while maintaining appropriate oversight. Implementation activities and stakeholder consultation have identified a need for regulatory discretion in relation to other aspects of the Act where the strict application of a requirement may lead to overly harsh outcomes in particular cases.

Noting the introduction of the new chief executive approval powers in relation to the information collection requirements and family limit, there is an opportunity for the Bill to align the existing and new approval processes across part 2 of the ART Act where possible. This supports clear and consistent chief executive decision-making processes across the ART Act.

Clarification of time limit on use of donated material

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. 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. An ART provider must dispose of any donated material in their possession if they are prohibited from using the material. Use of donated material across long periods of time may have an impact on any future donor-conceived people born as a result. The intent of the time limit on donated material is to ensure that providers are not using older gametes in ART procedures without oversight that the use is appropriate.

In aligning the chief executive approvals in the Act, a need has been identified to clarify the application of the disposal requirements with respect to the time limit on use of donated material requirements to ensure the requirements reflect the need for Queensland Health oversight of the use of older donated material, rather than on storage of the material. For example, a woman may be diagnosed with cancer at 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 the woman's ART provider to apply for an approval for ongoing storage of this material beyond 15 years or

be subject to a disposal requirement may cause undue stress and does not align with the policy intent that Queensland Health maintain oversight of the use of donated material.

Consent requirements

The ART Act provides that ART providers must obtain written consent before providing an ART service and must act in accordance with that consent. The consent requirements do not specifically require an ART provider to seek a gamete provider's consent for obtaining or attempting to obtain their gametes, despite this being an important step in the ART process for which clear consent processes should be in place. The Bill requires that consent must be obtained in writing before an ART provider obtains, or attempts to obtain, a person's gametes.

For donors, the ART Act provides that consent must be obtained before their genetic material may be used in an ART procedure. Donor consent must include the maximum number of families that may be created using their gametes within the family limit, and the maximum period for which donated genetic material may be stored, within the legislated limits (10 families; 15 years). Due to the Act setting maximum limits, there is no scope for a donor to consent to the use of their gametes beyond those limits.

However, the chief executive approval powers are intended to provide discretion for use beyond these limits where appropriate to prevent undue hardship. Given this, there is a need to clarify the interaction between the donor consent requirements and the chief executive approval powers by providing that donor consent is not required to the extent that donated material is used under a chief executive approval.

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 this use. Therefore, clarifying the interaction between sections 18, 25 and 27 ensures the Act operates as intended.

Disapplying information collection requirements for transitional provisions

Current section 146 and 147 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), 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 had not yet been used, the chief executive may approve use of the embryo if it would breach the above requirements, if satisfied the use is reasonable and other criteria are considered. This approval pathway is distinct from sections 146 and 147, which do not require approval, as the section only requires the embryo to have been created before the Act commenced. This is a low threshold, and Queensland Health needs to ensure the embryos created before the Act were created to be used and not to safeguard from the requirements of the Act applying in the future.

As outlined above, implementation activities to support the ART Act regulatory framework have identified that the information collection requirements may have a disproportionately harsh effect in particular cases where information is unable to be collected, and the Bill provides case-by-case to address this. The transitional provisions in sections 146 - 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 requirements.

During development of the Act, stakeholders were broadly supportive of the information collection requirements, noting they were already collecting relevant information. 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, there needs to be recognition under sections 146 to 148 that use can occur despite the information requirements not being met.

This approach seeks to reduce the emotional and regulatory burden of requiring a patient 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 requirements to now meet the requirements under the Act.

Disapplying these requirements for the cohorts of people who had started ART treatment prior to commencement of the Act 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.

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. The record keeping requirements also do not current reflect record keeping of the new consent requirement outlined above for ART providers to obtain consent from a gamete provider before obtaining, or attempting to obtain, their gametes.

To reflect the policy intent of the Act to ensure robust record keeping obligations are in place, the Bill provides for additional categories of records to be kept. These amendments ensure that appropriate records are maintained in relation to consents received from gamete providers and patients.

To support the record keeping requirements on ART providers in section 36, 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 remain.

The Bill also amends section 36 and section 37 (Destruction of records prohibited) 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. These amendments support 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.

Inspector powers

The ART Act introduced a state-based regulatory scheme to oversee the provision of ART services and providers in Queensland. The scheme is supported by the establishment of a licensing framework which enables the chief executive of Queensland Health to take a range of regulatory actions including to impose and vary licence conditions; issue an improvement notice; issue a prohibition notice; and cancel or suspend a licence. Taken together, these regulatory tools provide the ability for Queensland Health to take proportionate action when needed to reduce the risk of harm to ART patients and people born as a result of ART.

Part 5 of the ART Act includes investigation and enforcement provisions to support the regulatory framework. Under section 69, 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 regulatory activities required to for effective regulation of the ART sector but are limited in scope. As section 108 only applies to documents required to be kept or issued under the ART Act, while this power may be utilised where there is an investigation into a falsified licence or to satisfy an inspector as to record keeping requirements being met, 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 conditions, improvement notices and prohibition notices, 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.

Similarly, there is no power to investigate a serious adverse event unless it is indicative of a breach of the Act. A power to investigate such events is critical for a proactive regulatory scheme that meets the objects 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 Australian Capital Territory, Victoria, South Australia and Western Australia all permit an authorised officer to request information from a person or registered ART provider where reasonably required to monitor compliance with the relevant Act. Similar powers are also available to the Office of the Health Ombudsman under section 228(2) of the *Health Ombudsman Act 2013* to support the provision of information about a matter being investigated.

The Bill amends section 111 to enable inspectors to seek information from persons where there is a reasonable belief the 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 under section 69(a) to investigate, monitor and enforce compliance with the Act. These new powers enable 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.

These amendments meet 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 scaleable compliance and enforcement powers.

What options were considered?

Option 1 (preferred) – Amendment to *Assisted Reproductive Technology Act 2024*

Amend the ART Act to:

- provide the ability for the chief executive to give a case-by-case approval for the use of gametes despite the information collection requirements if satisfied there are reasonable grounds for using the gamete;
- provide the ability for the chief executive to give a case-by-case approval for the use of gametes or embryos beyond the 10-family limit if satisfied there are reasonable grounds for using the gamete;
- align chief executive approval powers to ensure consistency of terminology, decision-making criteria and processes where possible;
- clarify the intent of the time limit on the use of donated material;

- require a gamete provider's consent for obtaining or proposing to obtain their gametes, and clarify the application of donor consent requirements where the chief executive has granted an approval to use donated gametes despite the 10-family limit or 15-year time limit;
- amend relevant transitional provisions to disapply the information collection requirements for patients who had started their ART treatment before the commencement of the ART Act and who are unable to comply;
- update record keeping requirements to provide for additional categories of records to be kept and to clarify that the record keeping requirements apply to current and former ART providers; and
- enable inspectors to seek information from persons where there is a reasonable belief the 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 under section 69(a) to investigate, monitor and enforce compliance with the Act.

Option 2 – Status quo

Maintain status quo. This option is not preferred, as without the amendments, the ART Act will not operate as intended, undermining the effectiveness of the regulatory framework.

What are the impacts?

Chief executive approval – information collection requirements

The inclusion of a chief executive approval in section 33 provides a degree of flexibility in the application of the requirements. For example, where an ART provider can demonstrate that they have taken reasonable steps to collect the required information, are unable to obtain it, and without it cannot use the gamete for a particular patient, which would result in unfairly harsh outcomes, they could make an application under section 33 rather than the status quo of the gamete never being able to be used.

To determine if there are reasonable grounds for use, the chief executive must have regard to:

- whether the ART provider has taken reasonable steps to collect the missing information;
- the information the ART provider has collected that complies with section 33; and
- whether, in the circumstances, the consequences of giving, or refusing to give, the approval would be unfairly harsh for any person.

It is anticipated that there would be some administrative burden on ART providers to make an application to the chief executive on behalf of the patient. It is likely any application process will result in the ART provider charging an administration fee to the patient; the cost is not able to be quantified at this stage. The impact of this administrative burden should be reduced through the operational approach which will include development of an application form, clear and published decision-making principles and guidance materials, and support from the relevant unit in Queensland Health to address queries about the process.

It is also anticipated the number of applications for use under section 33 should reduce over time as the new regulatory scheme becomes embedded and older materials, collected before commencement of the Act, cease being the majority of material in use by ART providers. Additionally, ART providers will only be making an application in exceptional cases where they have been unable to collect the information and are seeking to use the gamete or embryo in an ART procedure; this should represent a minority of total gametes or embryos used in a year.

On balance, any administrative burden of having to make an application is considered justified as the chief executive approval would ultimately benefit the ART provider and their patients by enabling them to use the gametes in an ART procedure and giving them assurance that they will not be considered to be in breach of the offence provision. This is contrast to the status quo where the gamete or embryo can never be used as there is no possibility of addressing the gap in information under the ART Act.

As outlined above, this proposal is intended to ensure that an appropriate balance is reached between regulating ART providers appropriately by requiring them to collect information about gamete providers, including about donors, which will benefit future donor-conceived individuals, and enabling ART patients to use chosen donor gametes where the chief executive considers it reasonable in the circumstances despite non-compliance with section 33.

Chief executive approval – family limit

The inclusion of a chief executive approval to use donated gametes beyond the 10-family limit provides a degree of flexibility in the application of the requirements, where application of the 10-family limit would result in undue hardship.

To determine what are reasonable grounds, the chief executive may have regard to:

- 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);
- whether, in the circumstances, the consequences of giving, or refusing to give, the approval 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 should give them an indication, at a point in time, of whether the donor would be supportive in the future. Any refusal by the donor or inability to contact them is a relevant consideration in the decision-making process.

All decisions may 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/s, 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.

Providing a case-by-case approval allows Queensland Health 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 approvals would be by exception and only for cases of significant hardship where on balance, the use is considered reasonable.

As with the section 33 chief executive approval process, it is anticipated there will be some administrative burden on ART providers to make an application on behalf of a patient and this will likely involve a cost. Similarly to section 33, operational supports will be implemented to lessen this burden and streamline the application process, where possible. The number of applications should be small in proportion to overall ART procedures in a year as ART providers should only apply where it can demonstrate there are reasonable grounds for using donor gametes above the 10-family limit. On balance, any administrative burden of having to make such an application is also considered justified as the chief executive approval will ultimately benefit the ART provider and their patients by enabling them to use the gametes in an ART procedure and giving them assurance that they will not be considered to be in breach of the offence provision. This is in comparison to the status quo where there is no pathway for an exception to the 10-family limit regardless of the circumstances; this is not tenable for diverse family dynamics and the changing nature of 'family' over time.

The inclusion of the approval power is intended to ensure an appropriate balance between regulating the use of donated material to support the welfare and interests of donor-conceived people and enabling ART patients to use their chosen donor and avoiding unfairly harsh outcomes.

Alignment of chief executive approval powers

The Bill aligns terminology, decision-making criteria and processes where possible across the existing and new chief executive approval powers. These amendments include improving transparency in relation to the existing section 27 approval process for the time limit on use by including additional and more specific decision-making criteria to be considered by the chief executive.

Current section 27 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 satisfied there are reasonable grounds for the use. The amended chief executive approval process requires the chief executive to have regard to:

- the time period consented to by the donor (for example, whether the donor only wanted their genetic material used for a five-year period);
- whether, in the circumstances, the consequences of giving, or refusing to give, the approval 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. Any refusal by the donor or inability to contact them is a relevant consideration in the decision-making process.

Setting out the relevant factors that must be considered when determining whether an approval should be granted for the use of donated gametes or embryos beyond the 15-year time limit to align with the criteria for a family limit decision ensures consistent decision-making processes and provides clarity to ART providers as applicants, ART patients and other interested stakeholders. Similar to sections 33 and 25, operational support will be provided for all chief executive approval provisions to reduce the regulatory burden of complying with the application requirement, which should reduce the burden on ART providers and provide greater certainty to patients, donor-conceived people, donors, and other key stakeholders so they can have confidence in the decision-making.

The Bill supports natural justice across existing and new chief executive approval powers by providing that chief executive decisions to refuse applications under part relating to the family limit, time limit on use, information collection requirements or destruction of records are reviewable decisions and may be subject to internal review. To support this, 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 that applicants may seek an internal review within 20 business days of receiving the information notice. This ensures procedural fairness, including by providing an opportunity for substantial new information to be supplied in support of the application and for the decision to be revisited with that new information.

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 is required if an application to use the donated genetic material is not approved by the chief executive, rather than the material proactively requiring either disposal or approval for ongoing storage at the 15-year mark. These amendments ensure the time limit and disposal requirements, and related chief executive approval process, are clear for ART providers and patients. Queensland Health will retain oversight of any proposed use of donated gametes and embryos beyond the 15-year time limit to ensure the use is appropriate. This is considered to reduce regulatory burden for ART providers, and the emotional burden on patients, because an application will not need to be made until use is being considered. This is opposed to the status quo of a proactive disposal requirement set at 15-years, which may necessitate an application being made in advance of use ever being considered simply so that they material can continue to be stored. For example, a person may have embryos created when they are 20 years old due to fertility preservation and then not actually seek to use those embryos until they are 39 (if at all), but under the current requirements they would need to apply at the 15-year mark to continue to store the embryos for future use when no such decision may have been made.

Consent requirements

The change to the consent requirements requires an ART provider to specifically obtain written consent for obtaining or attempting to obtain a gamete provider's gametes, in addition to the activities for which consent is currently specified in the ART Act. It is not anticipated this will result in any additional administrative burden on ART providers, as they, or the overseas donor banks from which they source material, should already be obtaining consent for obtaining gametes as part of standard medical practice and in line with the National Health and Medical Research Council (NHMRC) *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (section 4.5).

The inclusion of this additional consent requirement enables Queensland Health to monitor compliance with consent requirements and ensure that appropriate consent has been received for the full range of activities undertaken by ART providers. These amendments reflect the existing intent of the ART Act by reinforcing the importance of patients and gamete providers giving informed consent as part of ART treatment.

As outlined above, where an existing patient is unable to meet the new consent requirement, the transitional arrangements in sections 146 - 148 address this by providing them with an ability to use their chosen donated material despite the new requirement, or in the case of embryos created but not yet used, to apply to the chief executive for approval to use the embryo.

The amendment to clarify that donor consent is not required if the chief executive has given an approval relating to the family limit or time limit supports these case-by-case chief executive approval processes and ensure that in individual cases where there are reasonable grounds to go beyond the legislated limits, the chief executive can exercise discretion. This clarification ensures these chief executive approvals operate as intended and can be granted if required to prevent undue hardship, benefiting ART patients. It also provides clarity to donors and ART providers about the interaction of the consent requirements and the chief executive approval processes.

Noting that, as outlined above, the chief executive must be satisfied that the gamete provider has consented to the making of the application by the ART provider in considering such an application, or that alternatively, the ART provider has taken reasonable steps to contact the gamete provider, it is considered that the implications of such an application for the ART patient, gamete provider and potential donor-conceived individuals born as a result of ART treatment are appropriately balanced. As noted above, where a donor has only given consent to a lower family limit (for example, they have only consented to their gametes being used to create five families) this must be a relevant consideration in the decision-making as to whether there are reasonable grounds for using the donated material. It would also be expected, operationally, that they ART provider would go back to the donor to ascertain if they would increase the limit within their consent. This should further limit any regulatory burden as the ART provider may not need to make an application if there is an alternative pathway already provided for within the ART Act that they can explore directly with the donor. Any refusal by the donor or inability to contact them is a relevant consideration in the decision-making, ensuring that while a donor cannot formally give consent over the legislated limits, the implications of the application for all parties are appropriately balanced.

Disapplying information collection requirements for transitional provisions

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 this cohort 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, noting that it may not be possible to comply with requirements that were not in place at the time the Act commenced.

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. In certain circumstances, 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. The amendment to section 148 ensures consistency with sections 146 and 147, ensuring patient cohorts are treated equitably. It also aligns with the policy intent of the transitional provisions of disapplying other requirements in the Act.

These amendments will have a positive impact for patients who had already started ART treatment before the Act commenced by enabling them to continue treatment despite non-compliance with the information collection requirements. It also ensures an ART provider, and by extension patient, are not put through the regulatory burden of having to apply for a chief executive approval to use material under section 33.

In the case of embryos created but not yet used (section 148), the Bill removes the need for the ART provider to apply for multiple approvals from Queensland Health. For example, a person may be permitted to use an embryo under section 148 but because they are missing 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 the section 148 decision. It is also inconsistent with how the exclusion of the other limits applies. For example, a person is not required to make an application under section 25 to exceed the family limit if use is approved under section 148. There is no rationale for treating section 33 requirements differently to sections 25, 27, and consent, which are all taken to not apply to an embryo approved for use under section 148.

The amendments reflect the fact that these cohorts had already commenced treatment at the time the Act commenced and the policy intent not to unfairly disadvantage this cohort. While the Act includes strict information collection requirements, this amendment reaches a fair balance between the ability of patients to continue treatment using their chosen donor, and protecting the welfare and interests of donor-conceived people.

Without the amendment, ART patients would be required to seek a case-by-case approval from the chief executive for use of the donated material despite non-compliance with the information collection requirements. This would not align with the original policy intent of the transitional provisions to enable patients who had already started their ART treatment prior to commencement of the Act to continue their treatment despite non-compliance with particular requirements.

Record keeping and destruction of records

The amendment to the record keeping requirements to include additional categories of consent-related information protects patients, gamete providers and ART providers by ensuring comprehensive records are kept and requirements are clear. It is not anticipated that this will have a material impact on ART providers, who already collect records as part of consenting processes.

The amendments 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 support the policy intent to ensure records are appropriately maintained for the period prescribed under the Act (99 years). The amendment ensures 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. It is not anticipated that this will have a significant impact on ART providers – to date, no ART clinic in Queensland has ever ceased operating. This amendment future-proofs the legislation to put beyond doubt that the record keeping requirement continues to apply if a provider ceases to operate.

Inspector powers

The amendment to the power to require information aligns the inspector powers to support the functions of inspectors under the Act.

The amendment will have minimal regulatory burden on ART providers, as the expanded power applies only in circumstances where there is a reasonable belief the 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 under section 69(a) to investigate, monitor and enforce compliance with the Act. This will support inspectors taking action in circumstances such as a suspected breach of licensing requirements or where a notifiable event requires investigation. Inspectors are required to exercise their powers appropriately, in accordance with the limitations or other parameters outlined in the ART Act so an exercise of this power must be based on a reasonable belief. It cannot be a hypothetical and intangible belief, and all inspectors appointed under the ART Act will have access to an extensive suite of standard operating procedures to guide the appropriate and proportionate exercise of their powers. Additionally, the inspector is required, in accordance with the existing power, to give a notice to the person to provide the information by a stated reasonable time, so an ART provider would have notice of the requirement and accordingly be able to allocate resources towards providing the required information. What is a reasonable time is also governed by case law so, where the circumstances permit, the maximum time possible to enable collation

of the information with minimal disruption would be provided to the party from whom the information is requested.

Section 112 (Offence to contravene information requirement) 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.

The amendment to the power to require information is anticipated to provide benefits to ART patients and members of the public by ensuring the regulatory framework encourages transparency and safeguards against non-compliance, and positions Queensland Health to investigate emerging matters, including where early intervention may prevent further harm. This in turn may support consumer confidence in ART services delivered in Queensland.

Who was consulted?

The amendments to the ART Act have been developed following ongoing stakeholder consultation with ART providers on the operation of the regulatory framework throughout implementation. A consultation paper as well as a working draft of the ART Act amendments was published on the Queensland Health website between August and September 2025, for a two-week period. It was also sent directly to a wide range of stakeholders including ART providers, donor-conceived advocates, recipient parent advocates, and general health care stakeholders.

Most stakeholders who responded broadly supported the amendments. Some stakeholders provided further recommendations for changes to the Act or sought clarification on specific amendments. These were taken into consideration during the final drafting of the amendments.

What is the recommended option and why?

Option 1 is recommended. The amendments to the ART Act ensure the regulatory framework operates effectively, ensuring ART patients and the broader community can have confidence in the ART industry, and providing certainty to ART providers about their obligations under the framework.

Impact assessment

	First full year	First 10 years
Direct costs – Compliance costs	Unable to be quantified but expected to be minimal	Unable to be quantified but expected to be minimal
Direct costs – Government costs	Unable to be quantified but expected to be minimal	Unable to be quantified but expected to be minimal

Private Health Facilities Act 1999

What is the nature, size and scope of the problem? What are the objectives of government action?

The Private Health Facilities Act provides the statutory framework for protecting the health and wellbeing of patients receiving health services at private health facilities. Section 48(1)(b) of the 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 Australian Commission on Safety and Quality in Health Care (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. In September 2022, in response to concerning reports of patient harm, Australian Health Ministers 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, the Health Ministers' Meeting 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, developed by the Commission, are intended to only apply to private health facilities that provide cosmetic surgery procedures. 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 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.

What options were considered?

Option 1 (preferred) – Amendment to the Private Health Facilities Act

An amendment to the Private Health Facilities Act to clarify the current head of power to provide that a private health facility must comply with a standard of accreditation prescribed for a type of health service provided at the facility. For example:

- to continue to provide that all private health facilities must comply with the NSQHS Standards; and
- to require a private health facility that provides cosmetic surgery procedures to comply with the Cosmetic Surgery Standards.

Option 1 ensures licensed private health facilities understand and comply with appropriate safety and quality requirements with regard to the provision of services they provide.

Option 2 - Status quo

Maintain status quo. This option is not preferred, as it would result in Queensland not giving effect to nationally agreed cosmetic surgery reforms and patients undergoing cosmetic surgery remaining at greater risk of harm.

What are the impacts?

The preferred approach (option 1) is to clarify that the current head of power, in section 48(1)(b) of the Private Health Facilities Act, provides that a private health facility must comply with a standard of accreditation prescribed for a type of health service provided at the facility. This amendment provides a mechanism to require relevant facilities to comply with the Cosmetic Surgery Standards. It is anticipated there will be minimal adverse impacts on persons, businesses and the community arising from the proposed amendments and any impacts are proportional to the issue the amendment seeks to address.

The proposed amendment will not impact directly on private health facilities until the *Private Health Facilities Regulation 2016* is amended to prescribe a requirement to comply with the Cosmetic Surgery Standards.

The purpose of the amendment is to ensure the Private Health Facilities Act has the power to reduce the risk of harm associated with patients undergoing cosmetic surgery by requiring relevant facilities to meet safety and quality standards specific to cosmetic surgery. Requiring private health facilities to comply with the Cosmetic Surgery Standards provides the community with confidence that facilities where cosmetic surgery is performed have the safety and quality systems and processes in place to meet patient safety and quality standards of care.

The Cosmetic Surgery Standards are aligned in structure and intent to the NSQHS Standards, which are implemented in all Australian hospitals and day hospitals. Mapping of the actions in the Cosmetic Surgery Standards against the actions required under the NSQHS Standards identified that of the 101 actions in the Cosmetic Surgery Standards:

- 81 were a full match with actions in the NSQHS Standards;
- 9 were a partial match, with further implementation activities required; and
- 11 actions had no direct match.

Each of the actions specified in the Cosmetic Surgery Standards that have no direct match to the NSQHS Standards are specific to the cosmetic surgery sector. Accordingly, licensed facilities are only be required to implement 11 additional actions and 9 partial actions to achieve compliance with both sets of standards.

In consideration of this, and to reduce the burden on services, the Commission developed the Cosmetic Surgery Module, which outlines the limited set of actions that health services are required to implement in addition to the NSQHS Standards, allowing them to comply with both the NSQHS Standards and the Cosmetic Surgery Standards. Therefore, a private health facility providing cosmetic surgery procedures, which is already required to meet the NSQHS Standards, is required to only comply with a small number of additional actions from the Cosmetic Surgery Standards. This allows facilities to be accredited to both the NSQHS Standards and Cosmetic Surgery Standards in a single assessment, thereby reducing compliance burden, ensuring efficiency, and providing a least-cost approach.

While there will be a small burden on businesses in complying with additional compliance standards, this is outweighed by the benefits to the community. It is expected that compliance with the Cosmetic Surgery Standards will provide improved safety and confidence to the community that a service where cosmetic surgery is performed is able to meet expected standards of care.

If the status quo was maintained and the proposed amendments were not made to the Private Health Facilities Act, it would result in Queensland not giving effect to nationally agreed cosmetic surgery reforms and patients who undergo cosmetic surgery remaining at greater risk.

Who was consulted?

The proposal was nationally agreed by Health Ministers in September 2022 as part of a range of urgent actions to strengthen national regulation of cosmetic surgery. The Commission sought feedback on the draft Cosmetic Surgery Standards in May 2023 as part of a public consultation process, with feedback informing the finalisation of the Standards. The Health Ministers' Meeting approved the Cosmetic Surgery Standards to apply to all facilities that provide cosmetic surgery in September 2023. Licensed private health facilities have been advised of the proposed changes and tentative timelines for implementation

A two-week public consultation was undertaken on the draft amendments from 29 August to 11 September 2025. The consultation paper was sent to all licensees of private health facilities, industry bodies, peak bodies representing health practitioners who provide cosmetic surgery, professional indemnity insurers, approved accrediting agencies, representatives of health consumers and legal stakeholders.

Stakeholders were generally supportive of the proposed amendments to the *Private Health Facilities Act 1999* 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, Health Consumers Queensland and Queensland Nurses and Midwives' Union.

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, Australian Health Ministers 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. This feedback was passed on to the Australian Commission on Safety and Quality in Health Care for development of additional guidance material for implementation of the standards and consideration of future improvements to the standards.

What is the recommended option and why?

Option 1 is recommended. An amendment to the Private Health Facilities Act is needed to clarify that a private health facility must comply with accreditation standards that relate to the type of health service provided at the facility. This amendment provides a mechanism to require private health facilities that provide cosmetic surgery procedures to comply with the Cosmetic Surgery Standards, in addition to the NSQHS Standards, and assist licensed private health facilities to understand and comply with appropriate safety and quality requirements with regard to the provision of cosmetic surgery.

This amendment enhances protections for consumers and support greater national consistency of regulated cosmetic surgical procedures, giving effect to the Health Ministers' cosmetic surgery reforms.

Impact assessment

	First full year	First 10 years
Direct costs – <i>Compliance costs</i>	Unable to be quantified but expected to be minimal	Unable to be quantified but expected to be minimal
Direct costs – <i>Government costs</i>	Unable to be quantified but expected to be minimal	Unable to be quantified but expected to be minimal

Transplantation and Anatomy Act 1979

What is the nature, size and scope of the problem? What are the objectives of government action?

Organ and tissue donation saves and improves lives, but it is only possible in about two percent of cases where a person dies in hospital, because specific criteria must be met for organ donation for transplantation to occur. In 2024, 96 people in Queensland met these criteria and donated their organs with family consent. As a result of this, 273 Australians received a transplant. There are currently about 1,800 people on the organ transplant waitlist in Australia, as well as a further 14,000 people undergoing kidney dialysis who may require a transplant in the future. These statistics highlight that it is critical to maximise every opportunity for organ donation.

The *Transplantation and Anatomy Act 1979* 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 in the Act as the senior available next of kin) can consent to removal of tissue from a deceased donor. For the purposes of organ donation, a person is considered deceased if:

- their brain has irreversibly stopped functioning (known as brain death); or
- their heart has stopped beating and the blood has irreversibly stopped pumping around the body (known as circulatory death).

Circulatory death usually occurs when a person is in an intensive care unit following a severe illness or injury that they are unable to recover from, and the doctors and family agree it is in the person's best interests to remove artificial ventilation and any other life supports. Examples include:

- a person who has suffered a severe spinal injury where they cannot move or breathe unassisted;
- a person with terminal heart and lung failure;
- a person who suffers a severe brain injury resulting in a serious, permanent disability, but the person does not meet the definition of brain death.

Once there is medical consensus about end of life for a person through circulatory death, consent to withdraw life-sustaining measures is obtained from a lawful substitute decision-maker. Following this, the possibility of organ donation is raised and further consent to organ donation can be obtained.

To facilitate organ donation, certain treatments and investigations (known as 'interventions') may need to be carried out on a potential donor to determine suitability for donation, enable organ matching with suitable recipients and maintain or improve organ function and viability.

Examples of interventions to support organ donation include:

- taking blood tests for organ function, matching tissue and screening for infectious diseases;
- conducting x-rays, ultrasounds or CT imaging;
- administering medications to maintain blood pressure or to prevent blood clots;
- conducting specialised tests to examine the lungs.

For organ donation following brain death, because the potential donor is legally deceased but remains on artificial ventilation, these interventions can be carried out after the certification of death.

For organ donation after circulatory death, the person remains legally alive until life-sustaining measures are withdrawn and their heart stops beating. Because organ donation is time sensitive, and the quality and viability of organs can rapidly deteriorate once life-sustaining measures are withdrawn, it is important that testing and supporting interventions are carried out before the withdrawal of artificial ventilation and prior to the certification of death, to ensure the organs are as viable for transplantation as possible.

The Transplantation and Anatomy Act does not provide clear authority for the senior available next of kin to provide consent for ante-mortem interventions. Without clear legislative authority for clinical staff to undertake the ante-mortem interventions that would support successful organ donation, there is a risk of

missed opportunities for lifesaving and life-improving transplants. It also means that a patient's wishes for organ donation may not be honoured.

What options were considered?

Option 1 (preferred) – Amendment to Transplantation and Anatomy Act

An amendment to the Transplantation and Anatomy Act to enable consent to be given for ante-mortem interventions necessary to support organ donation in cases of circulatory death of a donor.

Option 2 – Status quo

Maintain status quo. This option is not preferred, as there would continue to be no clear authority to enable consent to ante-mortem interventions to determine suitability for donation, enhance organ matching, and enhance organ viability for donation after circulatory death. This would result in ongoing missed opportunities for organ donation.

What are the impacts?

The amendment to the Transplantation and Anatomy Act is intended to allow a person's next of kin to consent to ante-mortem interventions in cases of circulatory death. The amendments streamline and improve clinical processes by providing clear legislative authority for ante-mortem interventions, which will enable more lifesaving and life-improving organ donations to occur.

Under the Act, the *designated officer* (medical superintendent of a hospital or their nominee) can authorise the removal of tissue for donation after death. The amendments will include an additional safeguard by providing that the designated officer of a hospital can authorise ante-mortem interventions be conducted on a potential donor if:

- consent has been given by the appropriate decision-maker to withdraw life-sustaining measures; and
- consent to conduct ante-mortem interventions has been given either by the potential donor, if they have capacity, or the senior available next of kin.

The amendments are anticipated to have no adverse impacts on businesses or the community.

The potential additional length of time the person remains on life-sustaining measures in order to carry out the ante-mortem interventions is considered to be a minor adverse impact on the person. In circumstances of circulatory death, where organ donation has not been consented to, the person's life-sustaining measures are withdrawn shortly after consent is received from the lawful decision-maker, which results in the person dying shortly after. Under the proposal, when a person is considered to be on the pathway to circulatory death and consent to withdraw life-sustaining measures has been given, the person is kept on life-sustaining measures for a period of time to undertake the ante-mortem interventions. While this may prolong the time the person is in hospital and ultimately, their death, the benefit of undertaking ante-mortem interventions to facilitate successful organ donation outweighs this impact.

Ante-mortem interventions are crucial to ensure successful organ donation. By creating a consent structure for ante-mortem interventions to occur, the proposal will have a positive impact on the families of those who have previously expressed a wish to donate their organs, knowing that their loved one's wish was able to be realised.

The impact on the potential donor's human rights has also been considered as a minimal adverse impact. As ante-mortem interventions are administered while the potential donor remains on life-sustaining measures and prior to the declaration of death, consent is required by the next of kin.

The type of ante-mortem interventions that are commonly undertaken include blood tests, imaging, bronchoscopy and administering of heparin (an anticoagulant to prevent blood clots). These are all listed as accepted interventions in the *Best Practice Guideline for Donation after Circulatory Determination of Death* (Guideline). The Guideline was developed by the Australian Organ and Tissue Authority and endorsed by all Australian Governments to promote a nationally consistent, medically appropriate, and highly ethical practice of donation after circulatory determination of death in Australia.

If the status quo is maintained and the amendments are not made, the authority to enable a person's next of kin to consent to ante-mortem interventions remains unclear, which will result in ongoing missed opportunities for organ donation. Amending the legislation to provide an authority under the Transplantation and Anatomy Act enables more donations to proceed and will also result in improved health outcomes for

patients in Queensland and Australia suffering serious chronic disease, and who require a life-saving transplant.

Who was consulted?

A two-week public consultation was undertaken from 29 August to 11 September 2025. A consultation paper and draft version of the Transplantation and Anatomy Act amendments was published and key stakeholders were notified and invited to provide feedback. All stakeholders, including key stakeholders such as DonateLife Queensland (DLQ) and the Australian Organ and Tissue Authority (OTA) generally supported the amendments.

DLQ and OTA provided feedback in relation to the definition of *ante-mortem interventions* and highlighted that routine blood tests were time critical and should not require separate designated officer authority. This feedback was incorporated in the Bill.

What is the recommended option and why?

Option 1 is recommended.

With the number of potential organ donors in Australia so small, it is critical to maximise opportunities for donation. To achieve this, an amendment to the Transplantation and Anatomy Act is needed to provide clear authority for ante-mortem interventions necessary to support organ donation in the case of circulatory death. The amendments provide the person's next of kin with appropriate authority to consent to ante-mortem interventions. There will be no adverse impacts on businesses and the community and the impacts on the person are minimal and are outweighed by the benefit to the community that increased organ donation brings.

Impact assessment

	First full year	First 10 years
Direct costs – Compliance costs	Unable to be quantified but expected to be minimal	Unable to be quantified but expected to be minimal
Direct costs – Government costs	Unable to be quantified but expected to be minimal	Unable to be quantified but expected to be minimal



Dr David Rosengren
Director-General, Queensland Health
Date: 9 October 2025



The Honourable Dale Last MP
Acting Minister for Health and Ambulance Services
Date: 10 October 2025