Impact Analysis Statement

Summary IAS

Details

Lead department	Queensland Health
Name of the proposal	Assisted Reproductive Technology Regulation 2026
Submission type	Summary IAS
Title of related legislative or regulatory instrument	Assisted Reproductive Technology Regulation 2026
Date of issue	February 2026

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

The Assisted Reproductive Technology Regulation 2026 (Regulation) is proposed to prescribe matters that support the effective operation of the *Assisted Reproductive Technology Act 2024* (Act). The matters contained in the Regulation are essential for regulating Queensland's assisted reproductive technology (ART) industry.

Background

ART refers to the treatment or procedures that address fertility. It can include artificial insemination, in-vitro fertilisation, gamete intrafallopian transfer and other related treatments or procedures. ART can help those with fertility issues, genetic risks and diverse genders and sexualities who may not be able to conceive naturally. Donor conception is a growing area of ART that supports LGBTIQ+ people, single women and couples experiencing infertility who would not be able to conceive without the use of donated gametes (sperm or eggs) or embryos.

Many aspects of ART are now part of standard medical practice, with many turning to ART treatment options to be able to have children. ART is typically performed in dedicated clinics that specialise in fertility treatment. Some of the more invasive procedures, such as egg retrieval, are also performed in private health facilities (for example, day hospitals) under anaesthetic.

The Australian fertility industry has revenue of approximately $810 million annually and employs over 3,300 people, according to IBIS world. The 2023 annual report from the Australian and New Zealand Assisted Reproduction Database (the most recent available report) indicates there were 103,556 ART cycles performed in Australia in 2023. Based on Queensland comprising approximately 21 per cent of the national population, this equates to approximately 21,750 ART cycles initiated in Queensland in 2023.

According to the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia and New Zealand, there are 24 accredited ART units across Queensland, with eight different providers running these clinics. Some ART providers operate large networks of clinics while other clinics are independent. Six of the eight providers operate across multiple Australian jurisdictions. Queensland has clinics located in metropolitan areas of Brisbane and the Gold Coast, as well as regional centres including Cairns, Townsville, Mackay and Rockhampton.

Identification of the problem

Queensland's ART industry was previously self-regulated and in the absence of state-based legislation, ART providers operating in Queensland were only required to adhere to professional accreditation and guidelines, namely the:

- National Health and Medical Research Council (NHMRC) *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC Guidelines); and
- RTAC *Code of Practice for Assisted Reproductive Technology Units* (RTAC Code of Practice).

While the RTAC Code of Practice mandates the reporting of adverse events, and RTAC certification requires annual audits by independent auditors who report results to RTAC, the monitoring of compliance in self-regulated sectors rests with the industry and is not subject to external verification, reporting or oversight. Compliance with these documents is an accreditation requirement, not a legal requirement, and there are no robust enforcement mechanisms in place. Accordingly, infringement of the NHMRC Guidelines or the RTAC Code of Practice is not an offence, and states and territories cannot enforce compliance without their own legislation. Further, there is limited scope for RTAC to respond to emergent issues in a timely manner, and government cannot monitor providers or enforce compliance with the accreditation scheme. Typically, where non-compliance is identified in an RTAC audit, clinics are required to rectify the non-compliance and report back to RTAC, with these changes confirmed at the next audit.

The self-regulatory model lacked avenues for recourse for patients who have had negative experiences with ART providers. Without a state-based regulator, civil action, or complaints to Queensland's Health Ombudsman, or the Australian Health Practitioner Regulation Agency were the main avenues of complaint for ART users.

There have been several high-profile cases of failure of ART providers in Queensland and in other jurisdictions. This included the alleged use of the wrong donor sperm resulting in children in the same family

not being biological siblings and the alleged use of donated sperm many more times than contemplated by the NHMRC Guidelines, resulting in some donor-conceived people having many genetic siblings. Following this, Queensland introduced legislation to regulate the ART industry (see overview of the *Assisted Reproductive Technology Act 2024* below). More recently, there have been further high-profile failures including embryo mix-ups by a provider in Queensland and Victoria.

Such failures have the potential for significant negative impacts on patients and their children, with the potential for life-long impacts. Receiving adequate and tailored treatment is essential as repeated ART services can be extremely expensive for consumers. With regard to donor procedures, these failures had the potential to push individuals towards other methods of donor conception, such as unregulated online groups. These alternatives carry significant health and social risks.

On 1 July 2024, the Office of the Health Ombudsman released the *Investigation of ART providers in QLD Final Report* (OHO Report). The report detailed the findings of the investigation into health services delivered by ART providers in Queensland. The investigation identified systemic issues relating to the provision of ART services and its effect on ART consumers in Queensland. This included the gaps and risks in the self-regulatory system with respect to ensuring the safety and quality of ART services. The findings and observations of the investigation also found there was a compelling case for the need for legislation to regulate ART providers in Queensland and strengthen the safeguards for consumers, donors and donor-conceived people.

On 13 June 2025, the regulation of the ART sector was considered at the Health Ministers' Meeting (HMM), following growing public concern over high-profile failures by the sector. 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 (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.

Assisted Reproductive Technology Act 2024

The Act established a state-based framework to regulate ART services in Queensland. The Act was passed by the Queensland Parliament on 10 September 2024 and is being commenced in tranches, with the first tranche having commenced on assent on 19 September 2024 and the remainder of the regulatory framework scheduled to commence on 1 March 2026. The Registry of Births, Deaths and Marriages within the Department of Justice is responsible for the establishment of the donor conception information register (Register), which is expected to commence in two stages during 2026.

The Act aims to improve public confidence in Queensland's ART industry by providing greater oversight, transparency, and safeguards. The main objects of the Act, as set out in section 3, are to protect the welfare and interests of the people who use ART and people born as a result of ART. It also regulates the use of ART and aims to provide and regulate access to information relating to people born as a result of ART.

The key elements of the Act include:

- establishing a state-based licensing scheme to oversee and regulate ART providers – the Act makes it an offence to provide ART services in Queensland without a licence issued by Queensland Health. ART providers will be subject to licence conditions, including general conditions for all licensees that are prescribed in regulation and specific conditions to respond to particular issues if necessary. Queensland Health will be able to issue improvement notices and prohibition notices, and to suspend or cancel licences. Providers will be obliged to inform Queensland Health of the occurrence of particular events, such as adverse events affecting patient safety;
- imposing requirements providers must meet before a patient can access ART services, including requirements to provide information to patients to ensure informed decision-making, and particular consent requirements;
- regulating the use of gametes and embryos, including by providing for prohibited and restricted uses of gametes and embryos (such as prohibiting the creation of embryos from close family members and prohibiting ART procedures on children), limiting the number of families that can use a donor's gametes and embryos to 10, and time limits on the use of older donated gametes and embryos;

- prescribing information requirements, including requirements to collect, retain and not destroy certain records about ART treatments, patients, and gamete providers, and the ability to disclose health information about a donor or donor-conceived person to warn a person about a health condition;
- providing a streamlined process for posthumous and ante-mortem retrieval of gametes and their subsequent use in an ART procedure; and
- establishing a donor conception information register in the Registry of Births, Deaths and Marriages that will hold identifying information and non-identifying information about donors, donor-conceived people and the parents of donor-conceived people. As mentioned, part 3 of the Act, which establishes the Register, is expected to commence during 2026.

A summary Impact Analysis Statement was prepared for the Assisted Reproductive Technology Bill 2024 and published in June 2024: Assisted Reproductive Technology Bill 2024 - (health.qld.gov.au).

Scope

A range of matters in the Act are designed to be supported by regulation to prescribe technical, detailed and operational matters. Section 143 of the Act provides broad regulation-making power. The Act also contains specific regulation-making powers throughout different sections in the Act. It is proposed the Regulation will support the Act to achieve its objectives by prescribing a range of matters, outlined below. A number of provisions in the Regulation provide for requirements that are broadly consistent with the current practice of ART providers or provide detailed matters relating to requirements already enshrined in the Act and are therefore unlikely to impose significant additional burden.

Australian Jurisdictions

The majority of Australian states and territories have state-based legislation in place to regulate ART services. The only remaining jurisdictions without an ART legislation have significantly smaller ART industries than Queensland, namely Tasmania, which has two clinics and Northern Territory, which has one. All the states with an Act also have a regulation supporting it. The Australian Capital Territory, which introduced ART legislation in 2024 does not currently have a regulation, but its relevant Act has a regulation-making power.

Objectives of Government Action

The objects of the Act are to protect the welfare and interests of people who use ART and people who are born as a result of ART; regulating the use of ART; and regulating access to information relating to people born from ART. The Act provides that the welfare and interests of people born as a result of ART are of paramount importance throughout their lives, in the administration and operation of the Act.

The Regulation will support the Act's objects by prescribing detailed and technical matters to support the regulatory framework established by the Act. This will support the intent of the legislative framework to enable greater oversight, transparency and safeguards, improve public confidence in Queensland's ART industry and provide robust protections for consumers. The provisions in the Regulation will support Queensland Health to take prompt and appropriate action in response to non-compliance, adverse events and incidents, and will also allow for responsiveness to issues within the ART industry.

What options were considered?

Option 1 – Status quo / no regulation

Option 1 is to not make a regulation to support the Act. This option is not preferred as a number of provisions and requirements in the Act would be ineffective or incomplete without a supporting regulation to provide for detailed matters. Not having a regulation supporting the Act would hinder Queensland Health's ability to effectively provide oversight to the delivery of ART services in Queensland through the regulatory framework. This would negatively impact people accessing ART services and people born as a result of ART, and also on the confidence of the broader community in the industry and in Queensland Health as the regulator. It would also impact ART providers, as they would lack clarity about the details of the requirements they are expected to meet under the Act. This would also have the potential effect of leaving some elements of the scheme to self-regulation or self-compliance by ART providers, which is contrary to the problem seeking to be resolved by the Act and regulatory scheme.

Option 2 – Assisted Reproductive Technology Regulation 2026

Option 2 is to make the Regulation. This is the preferred option as the Regulation is necessary to prescribe matters to support key aspects of the Act. The Regulation will enable Queensland Health to effectively implement the regulatory framework provided for in the Act, which will in turn support Queensland Health to ensure robust oversight of the delivery of ART services in Queensland and provide certainty to ART providers.

It is intended to prescribe the following matters in the Regulation:

- further information an ART provider must give to people before providing them with an ART service;
- matters that must be considered as part of counselling provided;
- additional consent requirements for gamete providers and for separate ART procedures;
- reasonable steps an ART provider must take when inquiring as to whether a gamete provider is still alive, where the gamete was obtained more than five years before the ART procedure;
- requirements for an independent review body for the purposes of authorising the use of gametes retrieved from a deceased or an unresponsive person;
- additional categories of people an ART provider may disclose health information to;
- matters to support the licensing framework, namely:
    - documents that must be provided with a licence application;
    - licence fees;
    - licence conditions;
    - events that ART providers need to notify Queensland Health of;
    - circumstances in which Queensland Health may cancel or suspend a licence; and
    - information that may be published on the public register of licensed providers;
- the relevant accrediting body and accreditation document to align the Act with the current accreditation framework;
- requirements to support the compensation provisions provided in the Act;
- additional information to be included in the Register; and
- voluntary information that can be provided by parties of private donor conception procedures for inclusion in the Register.

Details for the matters in the Regulation are provided below.

What are the impacts?

Information provision before ART treatment

The Act outlines information a person needs to be given before an ART service is provided, to ensure they make an informed and considered decision. Section 14 of the Act prescribes information people must be provided with, depending on whether they are undertaking donor conception or doing ART treatment using their own gametes. Section 14(2) of the Act provides that further information may be prescribed by regulation.

The Regulation will require further information a person must be provided with before undertaking an ART service. This includes information such as the risks, benefits and limitations of undergoing an ART procedure, the cost of an ART service and the options available for managing gametes or embryos that were not used for the ART procedure (that is, surplus gametes). For donated material, additional information is prescribed, noting the complex considerations involved in donor conception. For example, a person undergoing an ART procedure using donated material must be provided with the donor's relevant medical history and the maximum period during which the donated material may be used in an ART procedure. This aligns with other requirements in the Act which limit the time during which donor gametes may be used and

ensures a patient is able to consider a range of relevant factors before proceeding with the donor material or undergoing an ART procedure.

The additional information proposed is considered appropriate to prescribe as it is key information a person needs to be aware of to ensure they are able to provide fully informed consent before an ART service is undertaken. The proposed information in the Regulation will ensure people are provided with accessible, clinically relevant, and evidence-based information when accessing ART services. Together, the matters in the Act and Regulation provide a strong baseline of information to be provided from the ART provider to the ART user. This provision will be effective as it removes ambiguity for ART users as to the minimum types of information they can expect to receive and provides clarity to ART providers about their obligations to provide information. This requirement is expected to have minimal administrative burden on ART providers as they are already required to provide information to ART users as part of standard clinical practice in line with the NHMRC Guidelines (see chapter 4). ART providers also already undertake a comprehensive consenting process with patients so where the information prescribed may be additional to current practice, it can easily be added to existing processes and documents rather than requiring entirely new processes to be established.

Counselling matters

Section 15 of the Act sets out requirements relating to counselling services. Section 15(1) and (2) require an ART provider to provide counselling to people involved in donor conception programs, including the person seeking an ART procedure using donated gametes or a donated embryo, and a person proposing to donate a gamete or embryo. Mandatory counselling must be provided before the ART procedure is carried out or before the gamete or embryo is donated, due to the unique considerations associated with these procedures. The intent of counselling is to assist people to make informed decisions about their choices. It is not intended to add an additional barrier to access to ART services.

Section 15(5) of the Act provides for further counselling matters to be prescribed by regulation. The Regulation provides for matters about which counselling is to be provided.

For a person proposing to donate a gamete or embryo, this will include:

- the social and psychological implications of donating a gamete or embryo for use in an ART procedure;
- the effect of their consent, including how they may modify or withdraw their consent in accordance with the Act and the effect of chief executive approval for someone to use their donated material beyond the family limit and time limit; and
- what information an ART provider must collect about the donor and the donor-conceived person born as a result of the ART procedure, and how the information may be disclosed, including in the Register.

For a person or surrogate proposing to undergo an ART procedure using donated material, the matters about which counselling is to be provided will include:

- the social and psychological implications of a decision to use a donated gamete or donated embryo in an ART procedure for the person proposing to undergo the procedure if they are an intended parent and a spouse of that person (excluding a spouse from whom the person undergoing the procedure is separated from);
- the possible effects of a decision to use donated material for a donor-conceived person born as a result of the procedure;
- the cultural, philosophical, religious or other beliefs of the person that may influence their decision about storing or otherwise dealing with gametes or embryos not used in an ART procedure;
- the effect of the donor's consent, including how they may modify or withdraw their consent in accordance with the Act and the effect of chief executive approval for someone to use their donated material beyond the family limit and time limit; and
- the collection and disclosure of information by the ART provider about a child born as a result of an ART procedure, including in the Register.

Counselling is an important part of many people's ART experience, particularly those involved in donor conception programs. ART involves significant and complex decisions, and professional counsellors can help to support people in their decision-making process. The proposed inclusion in the Regulation of matters

about which counselling is to be provided will ensure a baseline of matters that must be considered as part of the counselling provided. This will ensure that mandatory counselling for people involved in donor conception includes discussion of considerations specific to donor conception, and not just counselling related to general infertility.

This provision is effective as it will support the requirements in the Act to provide mandatory counselling for people involved in donor conception, by setting a baseline of key matters that must be discussed as part of the counselling process. This support's the paramount object of the Act to protect the welfare and interests of people who are born as a result of ART through the administration and operation of the Act.

There should be minimal administrative burden to ART providers from this provision as providing counselling and discussing matters relating to donor conception for both the prospective donor and recipient parent is already part of current clinical practice. While many counsellors will cover the topics being prescribed, there is no set requirement for what counselling must include so there is variability in the extent and quality of counselling. The prescribing of the requirements will ensure minimum information is canvassed during counselling session/s and provides a structure for counselling. It is expected that counsellors have the capability of discussing these topics so should not require additional training or expertise to meet the requirements. It is also understood that there are sufficient counsellors to support the ART sector so these requirements should not create a workforce or other issue, making compliance with the requirements administratively straightforward.

Consent requirements

Part 2, division 3 of the Act sets out consent requirements ART providers must comply with. This includes that ART providers must get prior written consent from ART users and only act in a way that is consistent with that consent. The Regulation proposes further consent requirements.

Additional consent requirement for donated gametes or embryos

Section 18 of the Act outlines the consent requirements for a gamete donor. This consent must include the maximum number of families that can use the donated gametes or embryos, the maximum period the gametes or embryos can be stored for (within the limits imposed by the Act), and any other matter prescribed by regulation.

Section 20 of the Act outlines the point at which a gamete provider may no longer withdraw or modify their consent, depending on the circumstances. To ensure donors are aware of their right to modify or withdraw consent and the point at which they may no longer do so, the Regulation will require that the consent of a gamete provider includes an acknowledgement that the ART provider has informed them of how and when their consent may be modified or withdrawn.

This provision is effective as it supports the Act by ensuring donors are aware of their rights provided in the Act. There should be minimal administrative burden to ART providers from this provision as collecting and managing consents from donors is already part of their current practice. The requirement will support ART providers in the delivery of their donor conception programs by ensuring donor consent is managed appropriately and parties to the procedure are fully informed. It is expected that this information can be included in existing consent forms/processes to satisfy the requirement in the Regulation; this includes in overseas donor bank consent processes as providers require overseas banks to meet Australian legislative requirements. Any minor administrative impact is outweighed by the importance of ensuring donors are made aware of their rights in relation to their consent.

Additional consent requirement for each cycle of ART

Section 19 of the Act requires that a person undergoing an ART procedure must provide consent. Section 19(2) states that a regulation may require consent for different cycles or other stages of an ART procedure. To ensure ART users are providing informed consent for each cycle of their fertility process, which may involve several rounds of treatment, the Regulation will require a person undergoing an ART procedure to provide their consent for each cycle.

This provision ensures consent is collected for every cycle of an ART procedure instead of an ART user having consented once at the beginning, with an overarching consent covering the duration of all ART procedures. This is effective as a cycle-by-cycle consent ensures informed consent each time and enables the consenting information to be revisited. This supports ART users in applying their knowledge and experience from previous cycles to ask additional questions or seek updated information relevant to their consent for the next cycle. This provision is expected to have some administrative impact for ART providers

that are not currently obtaining procedure-specific consent. This will not be all providers as consenting processes differ, which is part of why prescribing the minimum consent requirements in the Regulation is important to ensure users of ART can have consistent expectations and consent experiences across the ART sector; noting users often switch between providers. For some providers this will have no or very minimal administrative burden as it is understood that they already seek consent for each cycle as part of their clinical practice. Chapter 4 of the NHMRC Guidelines notes that in order to obtain valid consent, clinics should ensure consent for each specific procedure. This requirement will support existing practice and ensure ART users are providing informed consent throughout their ART journey.

Use of gametes after death of gamete provider

Section 26 of the Act prohibits an ART provider from using a gamete or an embryo in an ART procedure if they know, or ought reasonably to know, the gamete provider has died. The exception to this is if the gamete provider has consented to the use of their gamete or embryo after their death, and if the person who is seeking to use the gamete or embryo has also consented after being notified of the death. Under section 26(3) of the Act, the ART provider must take 'reasonable steps' to find out whether the gamete provider is still alive if the gamete was obtained more than five years before the ART procedure. Section 26(5) of the Act provides that 'reasonable steps' include:

- making an inquiry as to whether the death of the gamete provider has been officially recorded in the Queensland register of deaths; and
- making other inquiries prescribed by regulation.

The Regulation will support the requirements of the Act by prescribing other inquiries for the purposes of ascertaining whether the gamete provider has died. The additional reasonable steps are:

- attempting to contact the donor using any contact information the provider has in their possession;
- if the most recent residential address of the gamete provider is in another Australian jurisdiction or if the gamete or embryo was supplied by an interstate ART provider, asking the equivalent registering authority whether the death of the gamete provider has been officially registered. This could be done using the Australian Death Check website; or
- if a gamete or embryo was supplied by an overseas ART provider, asking the provider whether the gamete provider is still alive. If the gamete provider has died, the ART provider should ask for the date of death.

While Queensland Health understands that providers may already reach out to donors from time to time as part of their clinical practice, there is likely to be some administrative burden on ART providers associated with completing these additional steps. However, this requirement is effective as it directly supports the Act by prescribing the additional reasonable steps to ensure gametes are not used after the gamete provider's death unless all relevant parties have consented. The Regulation also supports objects of the Act in protecting the welfare and interests of people born as a result of ART. This is because it enables ART users to make an informed decision about the gametes they may potentially use and what it could mean for a person born as a result. Making these inquiries will prevent gametes being used posthumously without consent in the instance where a gamete provider has died, and will reduce the likelihood of a donor-conceived person being born without the possibility of forming a relationship with their donor. The Regulation is also a more effective way to achieve the outcomes of the Act as it sets clear parameters for what steps are required to validate death rather than leaving these requirements ambiguous and open to interpretation, which can create inconsistent administrative burden and outcomes as some ART providers may take more steps than others. This approach creates a fairness and ensures consistent information is being obtained/steps are being taken across the sector.

Independent review body for authorising posthumous use of gametes

Part 2, Division 5 of the Act streamlines an existing process previously permitted under the *Transplantation and Anatomy Act 1979* to enable the posthumous retrieval and use of a person's gametes (for example, to be stored and used at a later date by the surviving spouse in an ART procedure). The Act establishes appropriate measures to facilitate decision-making in the best interests of the surviving spouse and a person who may be born as a result of the ART procedure. Section 31 of the Act allows an ART provider to use a gamete retrieved from a deceased or unresponsive person in an ART procedure for the person's spouse if its use has been authorised by an independent review body.

Section 31(2) of the Act states that an *independent review body* is a body that is constituted by one or more persons who are not engaged by the ART provider in providing ART services and complies with any requirement prescribed by regulation.

The Regulation prescribes further requirements for an independent review body, namely that the independent review body must be:

- established by a licensed ART provider or established by another person and engaged by a licensed ART provider;
- constituted of members independent of the deceased person and their spouse; and
- constituted by at least a person or persons with five or more years' experience in all of the following fields: medical ethics, mental health, law, and child protection or child welfare.

Posthumous use of gametes is a complex matter and enshrining an independent review body in the Act ensures consistent and fair decisions are made. To further support the intent of the body provided in the Act, the requirements in the Regulation are effective as they will ensure the body is:

- independent of the deceased person and their spouse for whom the treatment is sought (for example, not a family member, legal representative or fertility specialist of the person or their spouse), enabling an objective consideration of the situation;
- qualified to make the assessment outlined in section 31(3) of the Act, noting the considerations span clinical, social, and legal ethics as experience in relevant fields is critical to enable the body to make impartial and rational decisions while balancing the various interests (for example, user of the ART service versus the person to be born as a result);
- capable of, and resourced to, make consistent decisions, supported by proper governance arrangements, including terms of reference, governance escalation pathways should the body need further advice or be unable to agree, and appropriate record keeping mechanisms for decisions;
- clearly defined for the person seeking authority to use the retrieved gamete so they can have confidence in the decision-making; and
- feasible to be implemented by ART providers as it does not rely on a specific governance structure already in place but rather provides industry with the requirements they need to meet.

Where an ART provider is seeking to use a posthumously retrieved gamete in an ART procedure, the provision allows the provider to either establish the independent review body or to engage the independent review body that has been established by another person. This is a flexible approach that aims to reduce the administrative burden on ART providers. Situations of posthumous gamete retrieval and use of gametes where an independent review body will be needed is expected to be rare and establishment of such a body can occur on an ad hoc basis or utilise an existing permanently established body. If the body is established by an ART provider, it is expected to have terms of reference and sit within the ART provider's governance framework. It could be an addition to an existing body's scope or the creation of a new body. It is expected that a body established by another person would still have a terms of reference.

The requirement for members of the body to be independent of both the deceased person and the spouse seeking to use the gametes may cause some administrative burden to the provider seeking to establish the body but will ensure an impartial decision is made. If the spouse's fertility specialist would normally sit on the ART provider's ethics committee, they would need to excuse themselves from consideration of the matter.

Should there be an individual who possesses five or more years' experience in each of the above fields, the review body could consist of that single individual. It is however expected that in most cases, the body would be constituted by multiple people. This may result in some administrative burden to the provider to constitute the body with relevant individuals.

This provision is effective as the requirements for the independent review body will ensure decisions regarding posthumous use of gametes are in the best interests of the surviving spouse and the person who may be born as a result of the ART procedure, further supporting the objects of the Act, in particular the paramount object of the Act to ensure the welfare and interests of people born as a result of ART. Any administrative burden caused by these requirements is necessary as posthumous use is significant, which is demonstrated by other jurisdictions like the ACT where an application is required to be made to the

Supreme Court to authorise use. Further, this burden only applies at the time use is being considered. Processes for retrieval of gametes from a deceased or unresponsive person under part 2, division 5 of the Act remain unchanged and represent no additional administrative burden.

Disclosure of health information

ART providers have an important role in ensuring the appropriate disclosure of health information to people involved in donor conception. This includes health information that may become known many years after the original gamete donation or ART procedure occurred, while a person is pregnant, or while gametes or embryos are in storage. Section 38 of the Act enables ART providers to disclose health information about a donor or donor-conceived person to a range of relevant people where a medical practitioner certifies that the disclosure is necessary in order to prevent or reduce a serious risk to someone's life or health, or to warn them about a health condition that may be harmful.

The purpose of this provision is to enable ART providers to disclose important health information to donor-conceived people and other people who share DNA, supporting the paramount object of the Act to protect the welfare and interests of people who are born as a result of ART. Section 38(2)(f) of the Act allows an ART provider to disclose health information about a donor, or about a relative of a donor, to any other person prescribed by regulation. Section 38(3)(f) allows an ART provider to disclose health information about a donor-conceived person or a relative of a donor-conceived person to any other person prescribed by regulation. Accordingly, the Regulation proposes to support the Act by prescribing further people who may receive health information. This is intended to capture people that were not captured by the Act who share a genetic link with the donor or donor-conceived person, such as the 'raised' children of the donor (that is, biological children of the donor who are not donor-conceived), so they can receive potentially life-saving information.

This provision is anticipated to result in minimal administrative burden on ART providers as the Regulation supplements the existing list of people in the Act who an ART provider may disclose health information to in relation to donors, donor-conceived persons and their families and noting that ART providers already receive requests to share information from donor-conceived people and donors. It does not oblige ART providers to disclose health information but provides a facilitative regime to improve the proactive disclosure of information and gives certainty to providers about their ability to share information. Prescribing these additional categories of people in the Regulation is effective as it will ensure that biological relatives who share DNA have an equal ability to have relevant health information disclosed to them. This will support the intent of the Act to ensure providers can warn relevant people of potentially life-threatening health conditions.

Licensing requirements

Part 4 of the Act provides for a licensing framework to enable Queensland Health to regulate the provision of ART services in Queensland. This enables Queensland Health to oversee ART providers, ensure they are complying with legislative obligations and can take regulatory action where necessary to minimise any risk of harm to people who use or are born as a result of ART services. A range of licensing requirements in the Act provide for detailed matters to be prescribed by regulation.

<u>Documents for licence application</u>

The Act requires an ART provider to apply for and be granted a Queensland Health ART licence to provide ART services in Queensland, and sets out the documents that need to be included in a licence application.

To apply for a licence, section 57(2) of the Act sets out the necessary information to be included in an application. This includes the applicant's name, the address of each premises and the name of each medical practitioner who will perform or supervise ART services provided by the applicant.

Section 57(2)(b)(v) of the Act provides that the application must include any other information or document prescribed by regulation. To support this provision, the Regulation proposes to prescribe that applicants must include the following documents in their licence application:

- a copy of the applicant's most recent audit report; and
- a declaration that the applicant is solvent and able to pay the costs associated with operating and maintaining record-keeping systems and systems for storing human biological products.

The Regulation prescribes a copy of the audit report for the most recent audit of the ART services being provided by the applicant. This is effective because being accredited by RTAC is a prerequisite to being

eligible to apply for a Queensland Health ART licence. On that basis, it is reasonable to require a copy of the most recent audit report be provided with the application prior to the licencing period, particularly as the audit report is the basis on which an ART provider is granted an RTAC licence. The audit report may also contain important information relevant to an assessment of a licence application. For example, there may be concerns raised in an audit that warrant specific licence conditions to be applied to protect patient safety and without this information the main object of the Act would not be adequately met. This is likely to have minimal administrative burden on an ART provider as they will already possess this document.

The Regulation also prescribes a declaration of the applicant being solvent. This is effective because appropriately storing human biological material and maintaining records are two significant obligations on an ART provider, which if not met, can cause serious harm to ART users and those born as a result. Given this, an ART provider must be able to declare that for the period of the licence term (one or three years) they are financially solvent to meet these obligations. This declaration will provide Queensland Health with the assurance that an ART provider is suitable to be licensed as they can meet their obligations in the Act. This is unlikely to cause significant administrative burden as ART providers are commercial businesses and should have information about their current financial status readily available. Accordingly, the applicant should be in a position to make this declaration and should not be operating if they are not certain they are solvent enough to store gametes, and operate and maintain record keeping systems, at any given time.

Providing for these further documents that must be included in a licence application will assist Queensland Health in effectively undertaking its regulatory role.

Licence fees

Section 57(2)(c) of the Act provides that an application for a licence must be accompanied by any fees prescribed by regulation.

The Regulation prescribes the following licensing fees:

- an application for an initial licence: 3,324 fee units ($3,643 as at February 2026 based on the 2025-26 prescribed fee unit amount of $1.096);
- a one-year further licence: 995.5 fee units ($1,091); and
- a three-year further licence: 2,991 fee units ($3,278).

The fees proposed in the Regulation were developed to align with licensing fees for private health facilities under the *Private Health Facilities Act 1999.* The fees are also comparable to those in other jurisdictions that charge provider licensing/registration fees as part of their ART regulatory schemes. Namely, New South Wales has a $3,207 fee for an application and a $2,270 annual renewal fee. Western Australian has a $1,699 practice licence fee and a $1,062 storage licence fee. The other jurisdictions with an ART legislation do not prescribe fees.

For the purposes of this IAS, the compliance cost of the licensing fees have been costed using the assumption that ART providers will apply for an initial licence and subsequently apply for a one-year further licence. Based on there currently being 24 clinics in Queensland, the estimated compliance cost associated with the licensing fees is anticipated to be 79,776 fee units ($87,432) in the first year and approximately 23,892 fee units per year over the subsequent nine years. The compliance cost over the first ten years of the Regulation is therefore estimated to be approximately 294,804 fee units ($323,105). These costs reflect the prescribed fee unit value for 2025-26 of $1.096.

As noted in the Bill IAS, during consultation on the Bill, ART providers advised that any additional costs incurred through changes in regulation would likely be passed on to consumers. This was considered when developing the legislation, noting that ART is already an expensive service for many consumers. As such, the proposed fees are modest noting that the Australian fertility industry is estimated to have $810 in annual revenue. It is not anticipated to have a significant impact on ART providers, and any impact on the cost to consumers of receiving ART treatment is expected to be minimal. Further, there should be no/limited administrative burden on providers in paying the fees as appropriate mechanisms are being established to make payment of the fee with the licence application streamlined.

Licence conditions

Section 59(1) of the Act provides that a licence is subject to the conditions prescribed by regulation. These conditions are intended to apply to all licensed ART providers to support Queensland Health in regulating ART providers and protecting the welfare and interest of people using ART.

The Regulation prescribes the following licence conditions:

- *Display of licence number* - the licensed provider's licence number must be stated on the website of the licensed provider. This condition aims to support transparency and confidence in the licensing framework and ensures that members of the public can easily identify licensed ART providers. This requirement also assists with the usefulness of the public register of licenced providers that can be kept by the Chief Executive. By ensuring users of ART, those born from ART, donors, and members of the public can access both the licence number and register confirming the provider is licensed is an important alignment of publicly available information. This requirement is not expected to have any administrative burden to ART providers.
- *Audit documentation* - the licensed provider must give Queensland Health a copy of an audit report for each audit of the ART services of the licensed provider as soon as practicable after receiving the audit report. This requirement is effective as it ensures Queensland Health has appropriate oversight of any issues identified during an audit, assisting in its regulatory role of the ART industry. In line with the requirement to provide audit documentation as part of the initial licence application, there is expected to be minimal administrative burden associated with the ongoing requirement to provide reports from each annual audit as the ART provider will already have possession of the audit report.

Notifiable events

Under section 61 of the Act, a licenced ART provider must provide notification to Queensland Health within 7 days of a serious adverse event occurring, or in the case of any other notifiable events, within a specific timeframe. This is to ensure Queensland Health has appropriate oversight of ART providers enabling response to any issues as necessary. It also supports an ongoing drive for transparency across the ART sector, ensuring events are reported and managed.

Serious adverse event is defined in section 61 of the Act. The Health Legislation Amendment Bill (No. 3) 2025 amended the definition to provide that a serious adverse event is an event that is identified in the accreditation standard (that is, the RTAC Code of Practice). Serious adverse events are an existing concept under the RTAC Code of Practice and include events that cause a significant medical or surgical condition as a result of ART treatment or events that result in hospitalisation of a patient due to a complication of ART treatment. ART providers are required to report serious adverse events to RTAC under the Code of Practice, however the OHO Report noted delays in adverse events being notified to RTAC, with one notable case (Case Study 15 in the OHO Report) involving a significant delay of nearly one year in reporting a gamete mix-up incident, highlighting the importance of timely reporting. The OHO Report recommended that legislation be designed to provide robust oversight of ART providers, including through investigation of non-conformities and adverse events (Recommendation 29).

There have recently been further incidents in the provision of ART services, namely embryo mix-ups and a cyber incident resulting in the breach of the personal data of patients. Although the Queensland embryo mix-up was voluntarily notified to Queensland Health due to the Act and Regulation not having commenced, without prescribing notifiable events by regulation, Queensland Health would have to rely on voluntary notification of incidents by ART providers as specific serious adverse events are not listed in the Act. This would undermine a significant pillar of the regulatory scheme to ensure events are notified to Queensland Health, triaged and assessed, and action take where necessary. Prescribing the events also means they are subject to reporting timeframes, ensuring contemporaneous reporting of events, mitigating potential risks to users of ART and those born from ART. Event reporting is critical in all health sectors and is essential for successful regulation. In time, event reporting will also support transparency and continuous improvement through the publication of aggregate event data.

Section 61(1) of the Act provides that licensed providers must notify Queensland Health of other events, including events prescribed by regulation. The timeframe for notifying of these events may also be specified in regulation.

The Regulation prescribes the following events an ART provider must notify Queensland Health of, supplementing the notifiable events in section 61 of the Act:

- *Acting without consent or departure from consent* – if an ART provider does something for which consent of the person is required without the prior written consent of that person or acts in a way that is inconsistent with the prior written consent of the person, Queensland Health must be notified within seven days. In relation to departure from consent, this includes consent for an ART service provided to the person or the use of a gamete obtained from the person, or embryo being used or donated by the person. Given the findings in the OHO Report identifying consent as a major theme, notification of consent events is necessary to ensure the regulatory scheme is fulfilling its obligation to ensure ART services are safe for users of ART, persons born from ART, and donors. The embryo mix-up in Queensland demonstrates the need for this event category.
- *Laboratory practices that are substandard or result in harm* – if a licensed provider reasonably believes their laboratory practices are inconsistent with acceptable industry standards or have resulted (or could result) in physical or psychological harm to a person provided with ART services or a person born as a result of an ART procedure, Queensland Health must be notified within seven days.

  There are core activities undertaken in ART laboratories, which are not provider specific, and for which there is a reasonable understanding of the expected standard. For example, witnessing in a laboratory (whether manual, manual and digital, or digital) has key components and an ART provider should be able to identify when witnessing practices are below standard for the individual laboratory and when considering the practice against a comparable laboratory of another ART provider across Australia. If the witnessing practices were below the standard reasonably expected, then an ART provider would be required to notify Queensland Health. A laboratory is a critical component of the ART process. Many of the activities associated with ART services occur within the laboratory. While accreditation looks at the clinical and scientific operations of the laboratory it does not consider whether laboratory practices meet expected standards. Further, the RTAC Code of Practice does not provide for these types of laboratory issues in its categories of serious adverse events so there is a potential gap that could have real consequences for the safety of ART services if laboratory events are not notified, triaged and assessed, and action taken if necessary.
- *Disruption of business operations* – if a licensed provider's business operations have been disrupted to the extent that ART services cannot be provided, patient care is or is likely to be compromised, or the disruption has resulted in (or could result in) physical or psychological harm, Queensland Health must be notified within seven days.

  Business disruption could include a natural disaster, an equipment fault or cyber attack. This event is intended to cover circumstances, often outside of an ART provider's control, which can still have, or have the potential to have, a serious impact on a person provided with ART services or a person born as a result of an ART procedure. It is expected that Queensland Health would also be notified of the steps taken to manage the situation. While these events are usually expected to be outside of the ART provider's control, it is still important that the regulator is aware of any disruptions to patient care. This is important intelligence for a range of regulatory functions, including if complaints are received about a period where care is disrupted, or care continues despite being unsafe, is all relevant to ensure Queensland Health can monitor the regulatory response in case action needs to be taken.
- *Cancellation or suspension of licence of associated entity or prohibition of associated entity in another state* – if the licensed provider is a corporation and an associated entity has had its licence (or equivalent authorisation) to provide ART services cancelled or suspended, or the associated entity is prohibited from providing ART services in another Australian jurisdiction, Queensland Health must be notified within seven days. This includes if the licensed provider is a corporation and a subsidiary has had its licence cancelled or suspended.

  Given many ART providers operate across jurisdictions and have national policies and procedures, these requirements are reasonable to ensure any issues identified in another jurisdiction that could have implications for a Queensland provider are managed under Queensland's regulatory scheme.

  For example, the suspension or cancellation of an authorisation to provide ART services in another jurisdiction could be relevant to services provided in Queensland. This notification requirement will therefore provide Queensland Health with relevant information.

  In relation to prohibition in another jurisdiction, this is relevant information for Queensland Health as for an assessment to be made, Queensland Health needs to know about the change in circumstances elsewhere and the ART provider is best placed to notify that a prohibition has occurred.

The above aspects are particularly important as there are disparate information sharing provisions in jurisdictions with ART legislation, with some jurisdictions having no information sharing arrangements. This would mean Queensland Health can only obtain this information directly from the provider so making this an event notification requirement addresses any privacy or other considerations to support lawful disclosure.

- *Change of ownership or business structure* – if the licensed provider is a corporation or a subsidiary of another corporation, Queensland Health must be notified within 21 days of:
    - any assets or liabilities of the licensed provider (or parent entity) being merged with another corporation;
    - another change in relation to assets or liabilities if the change affects (or is likely to affect) the ownership, governance or operations of the provider; or
    - another change to operations if the change materially affects (or will materially affect) the provision of ART services.

  This will provide Queensland Health with information relevant to consideration of the Queensland Health ART licence, for example, if one ART provider purchases the business of another then this could have implications for the licence and needs to be assessed. As most ART providers are private companies, information about these types of corporate changes are not readily available in the public domain so the information needs to be provided by the ART provider.

These requirements may have a moderate administrative impact on ART providers as it will require them to notify Queensland Health of the prescribed events, within a certain period of time. However, the administrative impact is intended to be streamlined by the ability for providers to report these events through a Queensland Health ICT platform. is outweighed by the importance of these notification requirements as Queensland Health must have appropriate oversight of key events that occur in clinics, enabling Queensland Health to carry out its regulatory role effectively. This event reporting is also expected by the community as the event reporting through RTAC is considered to be insufficient and not appropriately actioned. The event categories represent information that is only available from an ART provider. There are no other methods by which Queensland Health could obtain this vital information so there will necessarily be an administrative impact. Some of this impact will also be mitigated through support provided by Queensland Health to ART providers about the boundaries of the categories and an online system for notifying about the events to make the process less administratively time consuming. The notification period is commensurate with the risk and impact of the event and will enable Queensland Health to assess the event and respond in a timely manner, with a view to ensuring users of ART, those born from ART, and donors are safe. The requirements will provide ART users and the broader community with assurance that there is appropriate oversight of providers and events that occur in the provision of ART services.

Cancellation or suspension of licence

Section 64(1) of the Act provides that a licence must be cancelled or suspended if a person ceases to have RTAC accreditation or if they are completely prohibited from providing ART services by a prohibition notice under section 63 of the Act. A licence may be suspended for up to 12 months.

Section 64(2) of the Act provides that Queensland Health may cancel or suspend a licence where the licence was granted based on false or misleading information, the person notifies Queensland Health that they have ceased to provide ART services, or in any other circumstances prescribed by regulation. Accordingly, the Regulation proposes an ART provider's licence may be cancelled or suspended in the following additional circumstances:

- their licence or other authorisation to provide ART services in another Australian jurisdiction is cancelled or suspended;
- they are prohibited from providing some or all ART services in another Australian jurisdiction;
- they are or have been under voluntary administration;
- they are or have been insolvent under administration; or
- personnel engaged in the provision of ART services cease to perform their role and replacement personnel have not been appointed within 30 days.

The Regulation permits Queensland Health to cancel or suspend a Queensland Health ART licence where a provider, or an associated entity's licence or authorisation, is cancelled, suspended or their practice prohibited in another jurisdiction. This is an effective provision to ensure actions are not siloed between jurisdictions where an issue is of a sufficient magnitude as to suggest concurrent action should be taken in Queensland. It is expected this would be rare and Queensland Health would follow all usual pathways under the Act before action was taken, noting that Part 6 of the Act provides that such a decision would be a reviewable decision, ensuring natural justice by providing for both internal review and external review by the Queensland Civil and Administrative Tribunal.

The Regulation requires ART providers to be financially solvent. The obligations provided for under the Act are significant, as is the provision of ART services. As such, if an ART provider was to be under voluntary administration or insolvent under administration, then Queensland Health would need to consider whether they should be permitted to continue trading, having regard to the welfare and safety of ART users and those born as a result.

The Regulation also requires personnel to be replaced within 30 days. Personnel are referenced in the Act as part of licensing and the RTAC Code of Practice, which highlights their importance to the appropriate operation of an ART service. As personnel, within the meaning of the RTAC Code of Practice, hold a significant role, it would be inappropriate for an ART provider to operate for a sustained period without filling the role. Filling the role can include backfill arrangements and a role is only taken to be vacant where there is no temporary or substantive occupant in the role. The personnel is a key consideration for granting a licence and as a corollary is relevant to any consideration of suspending or cancelling a licence where this requirement is no longer met.

An ART provider having their licence cancelled or suspended would likely have significant impacts on the provider however, would occur only in the circumstances prescribed in the Act or Regulation, which are considered to be sufficiently serious to warrant such action being taken to support the objects of the Act, to protect the welfare and interests of the people who use ART and people who are born as a result. Further, the Act does not mandate that a licence is to be cancelled or suspended but only that it can be if these categories are satisfied. Given this, Queensland Health would undertake all usual administrative decision-making processes before any cancellation or suspension was enacted.

Register of licensed providers

Section 65 of the Act provides that Queensland Health may keep a public register of licensed providers. Section 65(2) of the Act states that the public register may include information about licensed ART providers such as the name and contact of the licensed ART provider, the names of medical practitioners who perform or supervise ART services and their RTAC accreditation identifier number.

Section 65(2)(f) of the Act provides that the public register may contain other information prescribed by regulation. The Regulation proposes that in the event an ART provider has been issued with one of the following, this information may be published on the public register:

- a specific licensing condition under section 59(2) of the Act, including the date it was imposed and, if the condition has been removed, the date of removal;
- a prohibition notice under section 63 of the Act, including the date it took effect, particulars of the matters stated in the prohibition notice and, if the prohibition notice has been revoked, the date of revocation; and
- a licence suspension under section 64 of the Act, including the date the suspension took effect, the reason for the suspension and, if the suspension has been lifted, the date it was lifted.

This has the potential to have some impact on an ART provider where one of the above licensing actions has been taken, as ART users may choose not to use a provider based on what is published in this register. However, the intent of the register is to provide transparency to the public about licensed ART providers operating in Queensland. Publishing the information outlined in the provision is effective as it will provide assurance to the public that ART providers have been assessed as appropriately qualified and compliant with the consumer protections outlined in the Act. It is standard practice to include present and past actions taken against a licence (for example, register of practitioners operated by the Australian Health Practitioner Regulation Agency) as providing this history provides a transparent view of the ART provider. The public register is important for ART users as this will be an independent source of information they can access to make an informed choice about an ART provider. The register is also discretionary so if there is a clear

rationale for not publishing information then this will be evaluated on a case-by-case basis rather than a one-size-fits-all approach to publication. This approach ensures sound administrative decision-making is applied in choosing when and if to publish information.

Accreditation requirements

It is a requirement of Commonwealth legislation that all ART providers be accredited. In September 2025, Australian Health Ministers agreed that the Commission should replace RTAC as the accrediting authority from January 2027.

In December 2025, the Health Legislation Amendment Bill (No. 3) 2025, which included amendments to the Act, was passed by Queensland Parliament. The Bill amends the Act to reflect the decision of Australian Health Ministers and enable requirements in the Act to be responsive to changes in the accreditation landscape as follows:

- amended section 57 of the Act provides that a person may apply for an ART licence if they have the prescribed accreditation. The Act also requires an ART provider to notify Queensland Health of changes to the provider's prescribed accreditation and enables Queensland Health to cancel or suspend a licence if a provider ceases to have prescribed accreditation. *Prescribed accreditation*, in relation to a person, is defined for the Act to mean accreditation of the person, or of facilities operated by the person, by an entity prescribed by regulation; and
- amended section 56A of the Act provides the meaning of *accreditation standard* for the purposes of key concepts in the Act (serious adverse events and personnel). *Accreditation standard* means a document approved by regulation that provides for matters in relation to prescribed accreditation.

The Regulation proposes to prescribe RTAC as the entity for the definition of *prescribed accreditation* in the Act. This will ensure that the current accreditation framework is reflected in the Act to support the Queensland licensing framework.

The Regulation proposes to approve the RTAC Code of Practice as the document for the meaning of *accreditation standard* in the Act. This will be updated as and when the Commission's accreditation scheme commences. Prescribing the RTAC Code of Practice as the accreditation standard for the purposes of the Act will align requirements in the Act relating to serious adverse events (see discussion of serious adverse events in Notifiable events above) and personnel with the accreditation framework.

These provisions are effective as they will align the Act with the current accreditation model and give providers certainty about the accreditation requirements that apply to support the Queensland licensing framework.

Requirements to support the compensation provision

Section 115 of the Act provides that a person may claim compensation from the State if they incur a loss because of the exercise of a power by an inspector under the Act. Under section 115(3), a court may only order the payment of compensation if the court is satisfied it is just to do so in the circumstances of the particular case. Section 115(5) of the Act provides that a regulation may prescribe other matters that may or must be taken into account by a court when considering whether it is just to order compensation. To ensure that the court has regard to relevant matters and supports the provision provided in the Act, the Regulation provides that whether the exercise, or purported exercise, of a power by or for an inspector was lawful is a matter the court must take into account.

This provision may potentially impact an ART provider as if an inspector has damaged the ART provider's property while acting in accordance with the Act, the court will have to take this into account, which may affect the damages the ART provider could be awarded. However, it is appropriate for the court to consider whether damage resulted from the exercise of power under the Act in determining a claim for compensation.

Donor conception information register

Part 3 of the Act establishes the Register and provides the information to be held within it, how that information may be accessed and other relevant matters. The primary purpose of the Register is to provide donor-conceived people (16 years and older) with access to information about the donor and their donor-conceived siblings. This allows donor-conceived people to understand their full genetic history, health risks, and may also enable donor-conceived people to connect with the donor and their donor-conceived siblings

with mutual consent. Other persons connected with a donor-conceived birth may also apply for information in the Register.

Relevant information

Section 44 of the Act prescribes the relevant information to be included in the Register in relation to a donor-conceived person. This includes a range of information about the donor, the donor-conceived person, their parents and the donor conception procedure. Section 44(2)(n) enables additional information to be prescribed by regulation.

The Regulation proposes the following matters for inclusion in the Register:

- whether the donor donated sperm or an egg; and
- if the donor has died, information stating the donor has died, and the date and cause of death, if known.

This provision is effective as it contributes to the Register containing relevant information about donors for the benefit of donor-conceived people, supporting the Register's primary purpose.

Private donor conception procedure

A private donor conception procedure is a self-insemination procedure (not through an ART provider) using a donated gamete. Section 47 of the Act allows parties to a private donor conception procedure to voluntarily provide all or any relevant information relating to a donor-conceived person born as a result of a private donor conception procedure to the Register.

To provide information, the written consent of all the parties to the procedure is required. If one or more of the parties have died since the procedure, the written consent of all remaining parties and evidence of the death(s) is required before information may be provided to the Register. Section 47(4) of the Act states that evidence of a death may be a statutory declaration by the remaining parties or any other evidence authorised by regulation.

The Regulation proposes that evidence that a party to a private donor conception procedure has died can be a copy of the person's death certificate.

This provision is effective as it will enable parties to a private donor conception procedure to provide evidence that one of the parties to the procedure has died, supporting the remaining parties to provide information to the Register about the procedure.

Efficiency

There are likely to be some administrative costs for ART providers associated with the requirements in the Regulation however, these requirements are proposed to be prescribed to support the Act, which is necessary to support the effective regulation of ART services in Queensland. The requirements have also been developed to be the least-cost option, with the same requirements applying across all providers and clinics.

These administrative costs cannot be readily quantified noting the variation in size, location and business model of ART clinics, and the varying levels of current compliance with the RTAC Code of Practice. Additionally, because elements of the Regulation, such as notifiable event reporting, are dependent on the operations of an ART provider, it is not possible to determine the costs of compliance. For example, some ART providers may have limited interaction with aspects of the Regulation (because they have no notifiable events to report) while others could be heavy users because of a high level of notifiable events. It is for this reason that all aspects of implementation of the regulatory framework have focused on supporting external stakeholders to comply with the requirements in a streamlined and least administratively burdensome manner as is possible.

Section 15 of the Regulation prescribes licensing fees however, this is attributable to the operation of section 57(2)(c) of the Act. As outlined above, based on there currently being 24 clinics in Queensland, the estimated compliance cost associated with the licensing fees is anticipated to be 79,776 fee units ($87,432) in the first year and approximately 23,892 fee units per year over the subsequent nine years. The compliance cost over the first ten years of the Regulation is therefore estimated to be approximately 294,804 fee units ($323,105). These costs reflect the prescribed fee unit value for 2025-26 of $1.096.

Competition impacts

ART providers have stated in consultation on the Bill that they may pass on any additional costs resulting from the legislative framework to ART users. However, noting the low cost of licensing fees and that many of the requirements in the Regulation broadly align with requirements set out in the NHMRC Guidelines and should already be being met by providers as part of their RTAC accreditation, it is unlikely to have a significant impact on the cost of ART services. The legislative framework is not expected to reduce the range or availability of ART services in Queensland but instead, will improve the quality and reliability of ART services. For these reasons, there are no competition impacts relevant to making the Regulation.

Adverse impacts

The Regulation supports the Act and prescribes technical and detailed matters. The requirements are also largely consistent with current industry practice. The Regulation is not anticipated to have significant adverse impact on current practices. As outlined above, ART providers will be subject to modest licensing fees ($3,643 for an initial licence and $1,091 for a further one-year licence based on the prescribed fee unit value for 2025-26 of $1.096).

Implementation

Certain provisions of the Act have already commenced and the remainder of the regulatory provisions of the Act are expected to commence at the same time as the Regulation. Consultation was undertaken with industry and other stakeholders during development of the Act, and Queensland Health is working closely with providers during implementation of the framework.

Who was consulted?

Public consultation with stakeholders including ART providers, members of the public, members of the donor-conceived community and peak bodies was undertaken in November-December 2025. A consultation paper was released by Queensland Health for a three-week period. The paper was published on 20 November 2025 on the Queensland Health website and was sent directly to a wide range of industry and consumer groups.

Feedback was received from 10 stakeholders, including ART providers, Queensland Donor Conceived People (QDCP), Assisted Reproductive Treatment Families Australia (ARTFam), Egg Donation Australia, the Australian and New Zealand Infertility Counsellors Association (ANZICA) and the Queensland Nurses and Midwives' Union. Stakeholders were generally supportive of the proposed Regulation and feedback received was considered as part of finalising the Regulation.

Some stakeholders provided feedback in relation to counselling. One stakeholder expressed that to safeguard the interests of donor-conceived individuals and their families, it is vital that the Regulation prescribe matters about which counselling is to be provided. This feedback was incorporated into the Regulation.

A number of stakeholders expressed concern about the proposed requirements for establishing an independent review body to support the use of gametes retrieved from a deceased person being authorised. Some ART providers raised concerns about the difficulty of establishing a body that would meet the requirements, while other stakeholders were concerned that separate bodies established by ART providers would apply inconsistent decision-making or not be sufficiently impartial Based on feedback, the Regulation was amended to allow for an independent review body to be either established by the ART provider or established by another person and engaged by the ART provider. This provides sufficient flexibility for ART providers to engage a third party to establish an independent review body with the requisite experience.

ART providers sought clarity and raised operational issues in relation to other aspects of the Regulation including consent requirements, grounds for suspension or cancellation of a licence, and notifiable event reporting. Queensland Health has addressed these issues in consultation sessions and correspondence with providers, and will continue to provide guidance to providers as part of implementation of the regulatory framework.

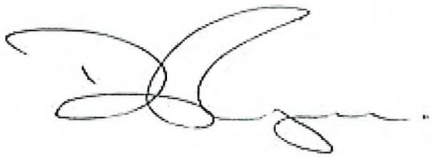
What is the recommended option and why?
The recommended option is to make the Regulation to prescribe detailed and technical matters needed to support and meet the objectives of the Act. The Regulation will provide details that are necessary to support the regulatory framework and without which, Queensland Health would be unable to effectively regulate the provision of ART services in Queensland.

Impact assessment

	First full year	First 10 years**
Direct costs – *Compliance costs (ART providers)**	$87,432*	$323,105*
Direct costs – *Government costs*	As per comments above	As per comments above

*This figure reflects the estimated compliance costs for ART provider licensing fees only based on the 2025-26 fee unit amount, as other potential compliance costs to ART providers associated with the Regulation cannot be readily estimated.

Signed



Dr David Rosengren
Director-General, Queensland Health
Date: 23 January 2026

The Honourable Tim Nicholls MP
Minister for Health and Ambulance Services
Date: 31/1/26