Assisted Reproductive Technology Bill 2024

Explanatory Notes

Short title

The short title of the Bill is the Assisted Reproductive Technology Bill 2024.

Policy objectives and the reasons for them

The Assisted Reproductive Technology Bill (Bill) has two main policy objectives: establishing a state-based framework to regulate Assisted Reproductive Technology (ART) services in Queensland; and establishing a donor conception information register (Register) in Queensland.

State-based framework to regulate ART services

ART refers to treatments or procedures that address fertility. It can include artificial insemination (other than self-insemination), in-vitro fertilisation (IVF), gamete intrafallopian transfer and other related treatments or procedures. It helps 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.

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 health facilities (for example, day hospitals) under anaesthetic.

In Queensland, ART services are provided by a relatively small number of private providers. 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. Most providers operate across multiple Australian jurisdictions.

Queensland does not have legislation in place to regulate ART providers or services. In the absence of state-based legislation, ART providers operating in Queensland are 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* (Code of Practice).

The *Research Involving Human Embryos Act 2002* (Cwth) requires ART clinics to be accredited by RTAC. However, there is no Commonwealth legislation in place regulating ART services in Australia.

The NHMRC Guidelines provide an overarching framework for the conduct of ART in clinical practice and research. They are intended to be read in conjunction with federal and state or territory legislation to create a robust framework for the conduct of ART in Australia.

The RTAC Code of Practice provides a framework and sets criteria against which ART providers are audited in order to maintain their accreditation with RTAC.

Beyond the accreditation requirement in the Research Involving Human Embryos Act, the national framework is not legally binding, infringement of the NHMRC Guidelines or RTAC Code of Practice is not an offence, and states and territories cannot enforce compliance without their own legislation.

The only enforcement mechanism under the national framework is compliance auditing by an RTAC-appointed auditor. There is limited scope for RTAC to respond to emergent issues in a timely manner. Queensland cannot monitor ART 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.

Individual medical practitioners are registered by the Australian Health Practitioner Regulation Agency under the Health Practitioner Regulation National Law, however, this does not extend to clinics.

In 2023, there were several high-profile cases of failure involving the self-regulation of ART providers in Queensland. 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.

Failures of the current self-regulatory model can negatively impact patients and their children, with the potential for life-long impacts. For donor conception treatments, these failures also have the potential to push individuals toward other methods of donor conception, such as unregulated online groups. These alternatives carry significant health and social risks.

On 2 November 2023, the Minister for Health, Mental Health and Ambulance Services and Minister for Women (Minister) directed the Health Ombudsman under section 81 of the *Health Ombudsman Act 2013* to investigate the health services provided by ART providers in Queensland, including the examination of complaints relating to ART.

On 4 November 2023, the Minister publicly committed to introduce legislation to regulate the ART industry by 2024.

On 28 March 2024, the Health Ombudsman provided the Minister with interim findings of the investigation relating to identified issues, non-compliance or adverse events associated with the handling of gametes and embryos, including collection, labelling, storage and

transportation; screening techniques for gametes, embryos and donors; record keeping and information sharing; and maximum donation and distribution of gametes within Australia.

The interim findings highlight gaps and risks associated with relying on a self-regulatory regime, and that there is a compelling case for legislation to regulate ART providers in Queensland and strengthen the safeguards for consumers, donors and donor-conceived people. The interim findings contain preliminary recommendations, including that legislation be introduced to regulate ART services in Queensland to provide robust oversight of ART providers, including the licensing of ART providers, and the power to audit and investigate non-conformities and adverse events.

The Health Ombudsman's final report is expected to be provided to the Minister by 28 June 2024.

Donor Conception Information Register

In 2022, the then Legal Affairs and Safety Committee (the LAS Committee) conducted an inquiry into matters relating to donor conception information (the Inquiry). On 31 August 2022 the LAS Committee tabled its *Report No. 33, 57th Parliament – Inquiry into matters relating to donor conception information* (the Report).

In conducting the Inquiry, the LAS Committee considered the rights of donors and donor-conceived people and found that a donor-conceived person's right to know their genetic origin outweighs a donor's right to privacy. The LAS Committee was clear that a register of donor conception information should be established; and that all donor-conceived people should have access to identifying and medical information about their donor.

In the Report, the LAS Committee made six main recommendations and 20 sub-recommendations. The key recommendations were that:

- a central register of donor conception information should be established in the Registry of Births, Deaths and Marriages (RBDM) (recommendation 5);
- operation of the register should be retrospective and all donor-conceived people should be provided with the legislative right to access identifying and medical information about their donor when they turn 18, regardless of when they were born (recommendations 1 and 2);
- provision of information to the register should be mandatory for fertility clinics (recommendation 5)
- clinics involved now and historically with donor conception practices should be required to retrieve, check and submit all donor information to the register (recommendations 3);
- contact between donors and donor-conceived people, and contact between donor-conceived people and their siblings should be facilitated by consent (recommendations 2);
- donors should have access to non-identifying information about any person born as a result of their procedure (recommendation 2);
- the register be available voluntarily to those who have pursued donor conception in private procedures (recommendation 5)

- the Queensland Government considers funding counselling and support services for donor-conceived people, recipient parents and donors to facilitate positive outcomes from recommendations of the report (recommendation 4); and
- birth certificates of all donor-conceived people, including those already born, should be annotated to note the fact of donor conception (recommendation 3).

The Queensland Government response to the Report, tabled on 28 February 2023, supported all recommendations in principle noting that implementation would be subject to further consideration of resourcing and operational needs, as well as ongoing targeted consultation.

Achievement of policy objectives

State-based framework to regulate ART services

The Bill provides for the state-based regulation of ART providers and services in Queensland. The Bill will improve confidence in Queensland's ART industry by providing greater oversight, transparency and safeguards and ensuring that the interests of people receiving ART treatment and people born as a result of ART are central to the delivery of ART services. The Bill complements the existing national framework and balances an appropriate level of regulation of ART providers with robust protections for Queenslanders.

Key features of the regulatory framework are outlined below.

Main objects of the Act

The Bill provides that the main objects of the Act include protecting the welfare and interests of people who use ART and people who are born as a result of ART, as well as providing 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. This reflects the overarching policy objective of ART legislation, which is to ensure the best interests of people who are born as a result of ART.

Additional objects of the Act are to regulate the use of ART and to provide and regulate access to information relating to people born as a result of ART.

Licensing of ART providers

The Bill provides for a licensing framework to enable Queensland Health to regulate the provision of ART services in Queensland. This reflects a preliminary recommendation of the Health Ombudsman's interim findings. The establishment of a licensing framework will enable 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.

Requirement for ART providers to be licensed

The Bill requires an ART provider to apply for and be granted a licence from the chief executive of Queensland Health in order to provide ART services in Queensland. The

requirement to hold a licence enables the Queensland Government to oversee ART providers, ensure they are complying with legislative obligations and take regulatory action where necessary to minimise any risk of harm to people who use ART or who are born as a result of ART. The intent of the licensing framework is to regulate ART providers, rather than individual medical practitioners and other personnel working within ART clinics.

Where ART services are provided without a licence, or an unlicensed person represents themselves as a licensed ART provider, the Bill prescribes a maximum penalty of 200 penalty units or two years imprisonment. Additionally, an ART provider must ensure that any ART services provided are performed by or under the supervision of a medical practitioner, with the Bill prescribing a maximum penalty of 400 penalty units or two years imprisonment for non-compliance.

Licence applications

To apply for a licence, an ART provider needs to hold current RTAC accreditation, not be completely prohibited from providing ART services and satisfy any additional requirements prescribed in regulation.

Applications must be in the approved form and include information such as the address of the premises at which ART services will be provided, the name of each registered medical practitioner who will perform or supervise the ART services, other key personnel and other information prescribed by regulation. A provider's application must be accompanied by a fee. The Bill provides for licensing fees to be prescribed by regulation to assist with recovering costs of administering the scheme.

The chief executive may grant or refuse a licence application. In making this decision, the chief executive must refuse to grant the licence if the application is not properly made or the person is not eligible to make the application. The chief executive may also consider previous contravention by the applicant of their licence conditions or ART related legislation (including other jurisdictions' ART legislation), risks to people using ART or people born as a result, and any other relevant matter. If the chief executive refuses a licence application, they must provide the applicant an information notice about the decision as soon as practicable. The term of a licence is as stated in the licence and may be up to a maximum of three years. A licensed provider may apply for a further licence three months before the end of the term of their existing licence.

Licensing conditions

ART providers' licences will be subject to conditions. General licence conditions that apply to all providers will be prescribed in regulation and may include conditions such as complying with ART legislation, maintaining RTAC accreditation and providing information to the chief executive as required. As ethical and clinical standards in ART clinical practice are evolving rapidly, prescribing licence conditions in regulation provides the requisite flexibility to ensure they remain relevant and effective.

To supplement the general conditions, the Bill additionally enables the chief executive to impose specific conditions on a provider at the time a licence is granted or at any time during the term of the licence. Specific conditions may target a particular risk of harm that is time sensitive, requires a tailored mitigation strategy, or is limited in scope. The chief executive will

have the ability to vary or remove a specific condition at any time. If the chief executive imposes or varies a specific condition, they must provide an information notice to the licensed provider about the decision.

Improvement and prohibition notices

The Bill provides that the chief executive may issue an improvement notice to a licensed provider if they reasonably believe that it is necessary for the provider to rectify a particular matter to prevent or minimise a risk to the health, safety or welfare of people receiving ART services or people born as a result. Improvement notices must detail the relevant matter and timeframe for rectification, and may prescribe the action to be undertaken. Once a licensed ART provider is issued with an improvement notice, the requirements of the notice become a condition of their licence.

The chief executive may issue a prohibition notice to a licensed provider or other person if they reasonably believe that the person should be prohibited from providing some or all ART services because they have contravened a licence condition, breached relevant legislation or there is a risk to the health, safety or welfare of people receiving ART services or people born as a result. Prohibition notices may be limited to stated ART services, such as services of a stated kind, at a stated premises, or provided by stated individuals. A prohibition notice has effect until it is revoked. Where a prohibition notice limits particular ART services, this becomes a condition of the provider's licence.

Improvement and prohibition notices must be accompanied by (or combined with) an information notice about the decision. The chief executive has power under the Bill to revoke a notice at any time, either on their own initiative or after considering an application from the provider. This provision enables adaptability in the event of further evidence becoming available that indicates a notice is no longer needed or a different type of enforcement option is appropriate. If an application is refused, the chief executive must provide an information notice about the decision as soon as practicable.

Cancellation or suspension of a licence

The chief executive must cancel or suspend a licence if the person ceases to have RTAC accreditation or is completely prohibited from providing ART services by a prohibition notice. The chief executive may also cancel or suspend a licence if they find the licence was granted because of false or misleading information, the person notifies that they have ceased to provide ART services, or because of other circumstances prescribed in regulation. A licence may be suspended for a period of up to 12 months. A person may apply for a suspension to be lifted, which the chief executive may grant or refuse. For refusals, the chief executive must provide an information notice about the decision as soon as practicable.

Notification requirements

To ensure appropriate oversight and transparency of ART services and providers, the Bill requires licensed ART providers to provide notice to the chief executive of certain events. Providers must notify the chief executive of serious adverse events within seven calendar days of becoming aware the event has happened. Serious adverse events are intended to be prescribed by regulation or in licence conditions, and are expected to align with the prescribed list of serious adverse events in the RTAC Code of Practice. That list includes significant

medical or surgical conditions resulting from ART treatment, breach of legislation, gamete or embryo identification mix up and transmission of a communicable disease. The short notification period is commensurate with the risk and impact and will enable Queensland Health to assess these events and respond as necessary in a timely manner. Where a licensed ART provider does not comply with reporting requirements for serious adverse events, a maximum penalty of 100 penalty units will apply.

A notification period of within 14 calendar days of the event happening applies to a licensed ART provider ceasing to hold RTAC accreditation, changes to their RTAC accreditation, contravention of any condition of their licence and ceasing to provide ART services. This notification period is considered appropriate balancing the potential risks associated with these events and ensuring that notification requirements are not unduly burdensome.

A notification period of within 21 calendar days of the event happening applies where there is a change in a licensed ART provider's premises, the registered medical practitioner who performs or supervises ART services or a change in other key personnel prescribed by regulation. This notification period is considered appropriate, as these events relate to events of an administrative nature, rather than those which have the potential to directly impact the welfare and interests of people using ART and people born as a result.

Where a licensed ART provider does not comply with these reporting requirements, a maximum penalty of 50 penalty units will apply. Other notification requirements may be prescribed in regulation.

Register of licensed providers

The Bill enables the chief executive to keep a public register of ART providers. This will likely be made available on Queensland Health's website. The Queensland register will include information such as licensed ART providers' names, contact details, key personnel and RTAC accreditation number and expiry date. The register will provide transparency to the public about licensed ART providers operating in Queensland.

Investigation and enforcement powers

To support the licensing framework, the Bill provides the chief executive of Queensland Health with the ability to appoint inspectors to investigate, monitor and enforce compliance with the Act. Inspectors will have a range of general powers including to enter places; conduct a search; inspect, examine and seize things; require production of a document or information; and require reasonable help. This will ensure Queensland Health has robust oversight of ART providers, including the ability to audit providers and investigate non-conformities and adverse events, consistent with a preliminary recommendation of the Health Ombudsman's interim findings. The investigation and enforcement powers are consistent with the equivalent powers in other Queensland Health legislation.

Accessing ART Services

The Bill sets out requirements that must be met before a person accesses ART treatment or provides their gametes or embryos, including that ART providers must provide relevant information to patients, donors and gamete providers to ensure informed decision-making; make counselling available to people seeking ART treatment using their own gametes or

embryos and ensure mandatory counselling has been undertaken by people involved in donor conception programs; and obtain consent from patients, gamete providers and donors before any ART treatments are undertaken or gametes obtained.

Eligibility

The Bill does not stipulate any eligibility criteria for people to be able to access ART. Access to ART should be open, inclusive and respectful of individual choice, and be a matter for clinical assessment of whether ART is appropriate in the circumstances.

Provision of information

As outlined in the NHMRC Guidelines, individuals accessing ART services are entitled to participate in decision-making about their involvement and must give valid consent for each treatment or procedure. The provision of relevant information is important for ensuring valid consent. The Bill reflects this by requiring licensed ART providers to give particular people information and confirm that they understand the information before providing ART services.

For people seeking ART procedures that do not use donated gametes or embryos, or are proposing to provide their gametes for use in an ART procedure other than as donated gametes, ART providers must provide information about basic matters, which include the availability of counselling services, the effect of the person's consent, and other matters prescribed by regulation.

For people seeking an ART procedure that uses donated gametes or embryos or who are donating their gametes or embryos, ART providers must give them information about extended matters, including the requirement for counselling, ART providers' obligations to collect and keep information about donor conception arrangements, and the rights of the person and their donor-conceived offspring to obtain information from the Register.

The requirements for the provision of information by ART providers is intended to ensure people accessing ART services, including donor conception services, are given the necessary information to make informed decisions about the ART treatment they are seeking. This is intended to be high quality, easy to understand and evidence-based information. The additional information required for donor conception arrangements reflects the complexity inherent in such arrangements.

Counselling

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 Bill seeks to reflect the NHMRC Guidelines' position on counselling and what occurs in clinical practice and codify these requirements.

The Bill requires 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, any spouse of the person, 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.

A penalty of 50 penalty units will apply to an ART provider who fails to provide mandatory counselling for those involved in donor conception.

Where donor conception is not being contemplated, ART providers must make counselling services available to a person seeking an ART procedure and any spouse of that person, before the procedure is carried out. A penalty of 25 penalty units will apply to an ART provider who fails to make counselling services available in these circumstances.

The matters that should be covered in counselling, qualifications of counsellors, charging of fees and other requirements relating to counselling are intended to be set out in regulation. This is intended to ensure counsellors are sufficiently qualified for this type of work while also allowing gamete providers and people seeking to access ART services to choose their own counsellor. For example, a person may seek to use an independent counsellor, rather than one employed by the ART provider, particularly if they have an existing relationship with a counsellor.

Consent

Informed consent is a well-recognised part of medical treatment. For ART procedures it is particularly important, given the significance of a person's involvement in ART treatment, including donor conception programs, and the potential outcomes of treatment.

The NHMRC Guidelines recognise that the importance of obtaining valid consent from all parties for each specific ART treatment or procedure and that the process of obtaining consent for ART activities is ongoing and not a single event.

The Bill requires ART providers to obtain consent in writing from a person before a range of different activities associated with ART are performed, and requires providers to act in accordance with the person's consent. A maximum penalty of 200 penalty units applies for non-compliance with this requirement.

Specific consent requirements apply to gamete providers, depending on whether donated gametes or embryos are being provided, and to people undergoing an ART procedure. For gamete providers who are seeking to use their own gametes or embryos in an ART procedure, ART providers are required to confirm the person's consent every five years, to ensure it remains valid.

The Bill outlines additional consent requirements for donated gametes and embryos, including the need to seek the consent of the gamete provider regarding the maximum number of families that may use the donated gametes or embryos and the maximum period the donated gametes or embryos may be stored for. The Bill provides that the consent of a donor cannot limit the use of their donated gametes or embryos in an ART procedure on the basis of a protected attribute of a person in accordance with the protected attributes in the *Anti-Discrimination Act 1991*. For example, a donor cannot limit the use of their donated gametes or embryo to a married person or a person of a particular religion. To remove any doubt, this is not intended to limit a person's ability to donate gametes or embryos to a person they know for their use. This is in line with the NHMRC Guidelines.

The Bill also addresses withdrawal and variation of consent by gamete providers and a person who undergoes an ART procedure and the timeframes for doing so. Modification or withdrawal of consent by a gamete provider must be provided in writing to an ART provider who is, or has been, in possession of the gamete or embryo.

Use of gametes and embryos

The Bill reflects a number of prohibited or restricted uses of gametes and embryos that are addressed in the NHMRC Guidelines.

Prohibition on using gametes from close family members

The Bill makes it an offence for an ART provider to use a gamete to create an embryo knowing the gamete provider is a close family member of the other person whose gamete is being used to create the embryo. This provision reflects the position in the NHMRC Guidelines that state that clinics must not create embryos from gametes derived from close genetic relatives.

A *close family member* is defined to mean parent, child, sibling (including a half-sibling), grandparent or grandchild of the person from birth. This provision is not intended to prevent situations like a mother carrying her daughter's child using the daughter's gamete, or a woman's sister donating an egg to her to create an embryo with the woman's partner. It is about an embryo being created where both gamete providers are close family members.

Non-compliance with this requirement will be subject to a maximum penalty of 400 penalty units or two years imprisonment.

Prohibition on providing ART procedures or obtaining gametes from children

The Bill prohibits ART providers from providing an ART procedure to a child or obtaining a gamete from a child for use in an ART procedure. An exception applies where a medical practitioner has certified that there is a reasonable risk that the child will become infertile before they become an adult and the provider obtains the gamete for the purpose of storing it for the child's future benefit. This is consistent with the NHMRC Guidelines and most other Australian jurisdictions that have ART legislation in place. Non-compliance with this requirement will be subject to a maximum penalty of 400 penalty units or two years imprisonment.

Prohibition on sex selection

The Bill prohibits ART providers from using a particular gamete or embryo, or performing an ART procedure in a particular way, for the purpose of producing or attempting to produce a child of a particular sex. The exception to this is if it is necessary for the child to be of a particular sex to reduce the risk of transmission of a genetic abnormality or genetic disease.

This aligns with the NHMRC Guidelines, which state that sex selection is prohibited in Australia for non-medical reasons such as 'family balancing'. The NHMRC Guidelines list several reasons why sex selection for non-medical reasons is not ethical including, for example, the possibility that it may validate or reinforce gender stereotyping and discriminatory attitudes.

Non-compliance with this requirement will be subject to a maximum penalty of 240 penalty units or two years imprisonment.

Limit on number of donor-related families

Limits on the number of people or families who may use a particular gamete donor are an accepted part of ART regulation in Australia. Family limits seek to protect donor-conceived people, particularly from the risk of consanguineous relationships and the psychosocial impacts of having many genetic siblings. The NHMRC Guidelines provide that clinics must take all reasonable steps to minimise the number of families created through donated gamete treatment programs, but do not set a defined limit.

The Health Ombudsman's preliminary recommendations included a recommendation for a family limit on donor gametes to be clearly defined within legislation, with consideration of limits extending to both Queensland and Australia.

The Bill prohibits an ART provider from performing an ART procedure if it would result in more than 10 donor-related Australian families and the provider knew that it would have that result or did not exercise appropriate due diligence. Non-compliance with this requirement will be subject to a maximum penalty of 400 penalty units or two years imprisonment.

The Health Ombudsman's preliminary recommendations noted the need to include a definition of what constitutes a family. *Donor-related Australian families* is defined to include families that include a person born as a result of an ART procedure carried out in Australia using a gamete obtained from the same donor or an embryo created from a gamete obtained from the same donor; and the family of the donor, if the donor has a child who was born in Australia but was not donor-conceived. The 10-family limit is intended to include the donor's raised family, in addition to families who use donated gametes to have donor-conceived children.

The limit on families, rather than women or persons, is considered more inclusive. A same-sex couple who are both birth parents in a family unit using a sperm donor would constitute one family unit, but would count as two people if a person limit was applied. A family limit ensures that as both partners within the one family do not need to compete with others for access to their chosen donor's gametes, and reflects the fact that there is not the same risk of consanguineous relationships being formed between siblings who grow up in the same household and are known to each other.

Family is defined to mean a parent, their spouse (if any) and their children. The definition is intended to remove doubt that if a couple separates and one of the individuals re-partners and wishes to start a family with their new partner/s using the donor gametes, this would be counted as a separate family for the purposes of the family limit. This also applies to the donor's raised family.

The Bill provides that for the purposes of an ART provider performing due diligence to determine if the ART procedure would result in the 10-family limit being exceeded, due diligence by the ART provider includes:

- searching its records;
- making reasonable inquiries of the donor; and

- if the provider has reason to believe that another ART provider (including interstate ART providers) has obtained a gamete or embryo of the donor– requesting information from the other ART provider.

The Bill requires an ART provider who receives a request for information from another ART provider undertaking due diligence in relation to a donor to determine the number of donor-related families to give the other provider it has about ART procedures, and donated gametes and embryos, that would be relevant. Non-compliance with this requirement will be subject to a maximum penalty of 200 penalty units.

Use of gametes after death of gamete provider

The Bill prohibits ART providers from using a gamete in an ART procedure if they know, or ought reasonably to know that the gamete provider has died, unless:

- the gamete provider has provided consent to have their gametes used after the death and the person undergoing the ART procedure has consented to use of the gamete knowing the gamete provider has died; or
- if the gamete was retrieved under division 5 of the Bill relating to ante-mortem and posthumous retrieval and the use of the gamete is authorised by an independent review body under that division.

Non-compliance with this requirement will be subject to a maximum penalty of 200 penalty units.

ART providers must take reasonable steps to find out if a gamete provider is still alive if the gamete was obtained more than five years before the procedure. This includes making inquiries as to whether the death has been officially recorded in the Queensland register of deaths or other inquiries prescribed by regulation. Non-compliance with this requirement will be subject to a maximum penalty of 100 penalty units. The requirement does not apply if the ART provider has been in contact with the gamete provider in the previous five years or knows or reasonably believes that the gamete provider is dead.

Time limits on use of donated gametes and embryos and their disposal

Storage of gametes and embryos is an important part of ART clinical practice that requires gamete providers to make decisions about how their genetic material may be used, stored and transferred in the future, including after they die.

The Bill does not prescribe maximum storage or use time limits for people using their own gametes and embryos. A person's own gametes and embryos must be used in line with their consent. This includes gametes retrieved from people aged under 18 for medical reasons.

In relation to donated gametes and embryos, the Bill provides that an ART provider must not use a donated gamete in an ART procedure if the gamete was obtained more than 15 years before the procedure. In the case of a donated embryo, an ART provider must not use the embryo in an ART procedure if the gamete used to create the embryo was obtained from the gamete provider more than 15 years before the procedure.

The chief executive of Queensland Health 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. This is to serve as a quality assurance check that ART providers are operating ethically and appropriately when it comes to using older gametes and embryos. The intent of this condition is to ensure donated material is not being used across many decades which would result in donor-conceived people not being able to have the opportunity to form relationships with the gamete donor or siblings.

The effect of the provision is that an ART provider must not continue to store a donated gamete or embryo that was obtained more than 15 years before unless they have received an extension approval from the chief executive for continued use. Accordingly, an ART provider is required to dispose of any donated gamete or embryo in their possession if they are prohibited from using the donated material in an ART procedure.

Non-compliance with these requirements will be subject to a maximum penalty of 100 penalty units.

Posthumous retrieval and use of gametes

Posthumous retrieval of gametes from a person is currently permitted under Queensland's *Transplantation and Anatomy Act 1979* (the TAA Act). However, the requirements of the TAA Act are general in nature and relate to the donation of all tissue. Following retrieval, there is currently no regulatory regime in place for the posthumous 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).

For retrieval, noting time is of the essence in these matters, the Bill provides for a process that streamlines what is already permitted under the TAA Act. The Bill permits retrieval from deceased or unresponsive persons. 'Unresponsive' relates to circumstances where a person's respiration or blood circulation is being maintained in a hospital by artificial means, and a designated officer of a hospital (as defined under the TAA Act), who is also a medical practitioner, must certify in writing that the person would die if these means were withdrawn. Retrieval in these circumstances may result in better quality of gametes retrieved than waiting until the person is deceased, potentially improving the recipient's chances of conception and reducing the need for multiple treatment cycles.

Retrieval from a deceased or unresponsive person is authorised only where there is evidence the person had consented to the posthumous retrieval and use of their gametes, or had not expressly objected and is likely to have supported the use. Parties who may request retrieval are limited to the surviving spouse or, in exceptional circumstances, another family member of the deceased or unresponsive person or the spouse, acting on behalf of the spouse. Exceptional circumstances are when the spouse is incapacitated and cannot make a decision about the retrieval; or the spouse is uncontactable despite reasonable attempts to do so.

Generally, the provisions in the Bill will operate despite anything to the contrary in the TAA Act. However, it maintains requirements that a designated officer of a hospital must record details of the retrieval and the request for retrieval on the deceased or unresponsive person's hospital records; and that a coroner's consent is required before any retrieval takes place if a deceased person is in the coroner's jurisdiction.

The Bill provides a separate authorisation process for the subsequent use of gametes that have been retrieved and stored posthumously. This is because different considerations apply to protect the interests of the people involved. Time should be allowed for grieving, counselling and consideration of the health and psychosocial implications for the people that may be born.

To use stored gametes that were retrieved from a deceased or unresponsive person, the Bill requires that the proposed use has been reviewed by an independent review body and that body has certified in writing that it supports the proposed use. The qualifications of the body or individual will be prescribed in regulation, and are expected to include a clinic's ethics committee (if it has one) or an appropriately qualified fertility counsellor. The independent body will be required to consider several factors, including whether the spouse has capacity to consent to the ART procedure; whether the spouse has undertaken counselling; the best interests of any person born; and any other matter the body considers appropriate.

The provisions in the Bill for posthumous retrieval and use establish appropriate measures to facilitate decision-making in the best interests of the surviving spouse and the person who may be born as a result.

Information collection, record keeping and information sharing

ART providers are a crucial source of information about gametes and embryos used in ART procedures (including donated gametes and embryos), patients who have used ART services and outcomes of treatment. Good record keeping and data reporting are an integral part of ART clinical practice. Some of the significant issues identified with the ART industry in Queensland have related to record keeping and the availability of information to people accessing ART services and donor-conceived people.

Collection and keeping of records

The Bill requires ART providers to collect information about gametes, including donated gametes, before obtaining them for ART procedures or storage. The information required to be collected for all gametes includes the name of the gamete provider, address, contact details, date and place of birth and other information prescribed by regulation. For donated gametes, the ART provider must collect information about the donor's ethnicity, physical characteristics, relevant medical history, sex and year of birth of each offspring of the donor, and other information prescribed by regulation. The information collected about donated gametes is required for the Register. Failure to collect the information will be an offence, with a maximum penalty of 200 penalty units. Proper information and record keeping about non-donated gametes is required to ensure ART providers are storing and using all gametes appropriately.

The information must be collected whether a gamete is obtained directly from an individual, or indirectly through a sperm bank, clinic or another ART provider, whether in Australia or overseas.

It will be an offence for an ART provider to use a gamete or an embryo unless they have collected this information about the gamete or a gamete used to create the embryo, with a maximum penalty of 200 penalty units.

When an ART provider in Queensland obtains or supplies gametes or embryos, whether from within Queensland, interstate or overseas, they must obtain or supply information about the

gametes or embryos, including records about consent for use of the gametes or embryos. This helps to ensure proper record keeping where gametes or embryos are transferred between providers or clinics. It will be an offence to fail to do so, with a maximum penalty of 200 penalty units.

The Bill requires ART providers to collect information about people who undergo an ART procedure, including their name, address, contact details, date and place of birth, and the name and date of birth of any spouse at the time of the procedure. If the ART procedure uses a donated gamete or embryo, the ART provider must take reasonable steps to collect information about whether the person became pregnant (within four months after the procedure), whether a child was born as a result of the procedure (within 15 months after the procedure) and if so, the child's name, sex and date and place of birth. Failure to collect this information will be an offence with a maximum penalty of 200 penalty units.

The Bill requires ART providers to keep a range of records about gametes and embryos that are or have been in the provider's possession and ART procedures, including the information required to be collected by the ART provider, consents given by the gamete provider, the uses to which gametes or embryos have been put, any period of storage, details of children born from ART procedures and other information prescribed by regulation. The records must be kept for a period of at least 99 years. This will ensure records relating to ART procedures and donor conception are available for donor-conceived persons to access during their lifetime. Failure to keep these records will be an offence with a maximum penalty of 200 penalty units.

Prohibition on destruction of records

The Bill makes it an offence for an ART provider to destroy records, including historical records about donor conception ART procedures carried out before commencement. The offence will have a maximum penalty of 400 penalty units. This implements recommendation 3.1 of the Report of the LAS Committee. The chief executive may approve the destruction of records on application by an ART provider if the chief executive is reasonably satisfied that destruction of the records would not adversely affect any person.

Disclosure of health information

The Bill includes provisions to facilitate disclosure of information about health conditions between persons who share DNA, including donors, family members of donors, donor-conceived persons and donor-conceived siblings. This is to ensure that information about health conditions that may arise after a donor has donated a gamete or embryo can be disclosed in an appropriate way. These health conditions may occur many years after the original donation or ART procedure or they could occur while a person is pregnant or gametes or embryos are in storage before they have been used. This is separate to a donor's 'relevant medical history' which is defined in the Bill and will be recorded on the Register. In order to activate these powers, a medical practitioner must certify that the disclosure of health information is necessary to prevent or reduce a serious risk to a person's life or health or to warn a person about the existence of a health condition that may be harmful to the person or their descendants. The provision allows an ART provider to disclose the health information to a variety of people who could be affected. As the health information is potentially sensitive and complex information, the disclosure is required to be done by a medical practitioner on behalf of an ART provider.

The medical practitioner will be required to take reasonable steps to ensure a donor-conceived person does not become aware they are donor-conceived as a result of the disclosure. The provisions do not oblige ART providers to disclose health information, but provide a facilitative regime to improve the proactive disclosure of information about health conditions for donors, donor-conceived persons and their families.

The Bill also includes a power for the chief executive to disclose health information if an ART provider has not disclosed the information. The chief executive must receive the same certification from a medical practitioner, but may disclose the information if the chief executive considers it is reasonably necessary. This will allow the chief executive to act in cases where there is a clear case for action, but information has not been disclosed by the ART provider.

Information sharing provisions

The Bill also includes a provision allowing information to be shared between Queensland Health and the Registrar of Births, Deaths and Marriages (Registrar). As the regulation of ART providers will be undertaken by Queensland Health, it is important that information can be shared between Queensland Health and the Registrar to ensure any identified issues with providers can be followed up through appropriate compliance and enforcement mechanisms, particularly as the focus of the Register is to collect information and provide access to the information and not monitor compliance with how ART providers are collecting and storing the information.

Donor Conception Information Register

The Bill achieves the policy objectives and implements the intent of the recommendations made by the LAS Committee by:

- establishing a Register in RBDM which is to be maintained and operated by the Registrar-General of RBDM (the Registrar);
- requiring ART providers to provide relevant information about donor conception ART procedures to the Registrar, including historical records;
- allowing persons who have undertaken private donor conception procedures to voluntarily provide information to the Registrar;
- establishing a framework to allow donor-conceived people, their parents, donors and others to access information held on the Register; and
- facilitating contact between persons by consent.

Information to be held on the Register

The Register will hold identifying and non-identifying information about donors, donor-conceived people and the parent/s of donor-conceived people. Clause 43 of the Bill provides that the Registrar must include in the Register:

- information provided by ART providers following the birth of a child (clause 45);
- historical information provided by ART providers within six months of commencement (clause 46); and
- information voluntarily provided to the Registrar by parties to a private donor conception procedure (clause 47).

The Registrar may also include other information prescribed by regulation or information the Registrar considers is appropriate for inclusion (clause 42).

The following table outlines the relevant information that will be held on the Register (clause 44).

Table 1: Relevant information that will be held on the Register

Relevant person	Type of information
Donors	• full name; • date and place of birth; • contact information; • ethnicity and physical characteristics; • relevant medical history; • donor's ID code; • donor's profile information that is collected and kept by the ART provider, includes information about the donor's hobbies and interests, information about the family history of the donor, information about the education of the donor, photos of the donor, correspondence of the donor, and information about the psychological history of the donor that is not relevant medical history; and • place where the donor's gamete was originally donated.
Donor-conceived person	• full name; • date and place of birth; • sex at the person; • name and place of the ART provider that carried out a donor conception ART procedure; and • number of any donor-conceived siblings (if the information is recorded and kept).
Parent/s of donor-conceived person	• full name; and • date of birth.

Obligations imposed on ART providers

The Bill will require ART providers to collect and maintain particular information about donor conception ART procedures carried out by the ART provider (clause 33). The Bill will also require ART providers to take reasonable steps to determine whether a child was born as a result of a donor conception ART procedure within 15 months after the procedure (clause 35).

If a birth has occurred, an ART provider must provide the Registrar with all relevant information about the donor conception ART procedure within three months of becoming aware of the birth of a donor-conceived person. The Bill outlines that it is an offence for an ART provider to fail to provide all relevant information to the Registrar within this timeframe (clause 45).

The information must be provided regardless of where the donor made the gamete donation and regardless of where the donor-conceived person was born. This is intended to ensure the Register holds information about international donors and about donor-conceived persons who are born outside of Queensland where the donor conception ART procedure has occurred in Queensland.

The Bill outlines that the Registrar may conduct an inquiry to ensure the Register holds all relevant information about donor conception ART procedures (clause 54). For the purpose of an inquiry, the Registrar may use information recorded in another register administered by RBDM (such as the birth register) or issue a notice to an ART provider to provide information to the Registrar or to answer specified questions held on the Register. The ART provider must comply with a notice unless they have a reasonable excuse.

Historical records

The LAS Committee recommended that all donor-conceived people should be legislatively provided with the right to know the identity of their donor when they reach the age of 18 years, regardless of when the person is born. To facilitate this, the LAS Committee recommended that fertility clinics involved now and historically with donor conception practices should be required to retrieve, check and submit all donor information to the Register.

The Bill implements the intent of the recommendations of the LAS Committee by compelling the provision of historical donor conception records and by allowing donor-conceived people to access this information.

Clause 46 of the Bill outlines that an ART provider must provide the Registrar with any relevant information in its possession or control within six months after the commencement of section 45, unless extended by the Registrar. The Bill clarifies that this obligation applies to a person who is no longer an ART provider as well as a medical practitioner who carried out donor conception ART procedures as part of their medical practice.

Clause 46 does not apply to information about private donor conception procedures, and donors, donor-conceived people or their parents are not obliged to provide information they may have in their possession or control about historical donor conception ART procedures to the Registrar.

The Bill outlines that if an ART provider previously had possession or control of relevant information about pre-commencement donor conception ART procedures and they no longer have possession or control of this information, they must notify the Registrar within six months (unless extended by the Registrar) of either:

- the name and contact details of the person to whom the ART provider gave possession or control of the information; or
- if the information was lost, destroyed or otherwise no longer available—when that occurred and the circumstances in which it occurred (for example, a flood or fire).

Clause 46 outlines the Registrar may issue a notice to a person named by an ART provider or to a person whom the Registrar reasonably believes has possession or control of the information, requiring the person to provide the relevant information that is in their possession or control. The ART provider must comply with this notice.

As the NHMRC Guidelines have been in place since 2004, it is anticipated that ART providers will be able to provide fulsome records for donor conception treatments since that time. Some information about donor conception ART procedures that occurred prior to 2004 may not be complete or may be lost or destroyed. The Bill does not oblige ART providers or the Registrar to take steps to verify the accuracy of information that is contained in historical donor conception records.

The Registrar will also be able to correct the Register on application by a person or on the Registrar's own initiative (clause 52). This power could be used, for example, to correct the spelling of a person's name or a person's date of birth if it was not correct in the historical information provided by an ART provider.

Clause 53 of Bill includes specific provisions which protect a person from civil or criminal liability in providing historical donor conception records to the Register. A person acting honestly and reasonably is not liable civilly, criminally, or under an administrative process, for providing historical relevant information that is required to be provided to the Register under clause 46. The person can not be held to have breached any code of professional etiquette or ethics, or departed from accepted standards of professional conduct merely because the person provides the information.

The Bill clarifies that the information is required to be provided even though the person to whom the information relates has not consented to the disclosure of the information; or the relevant donor conception ART procedure was carried out, at a time when an Act or law or any applicable clinical guidelines or codes of practice precluded the disclosure of the information.

Section 269 of the *Public Sector Act 2022* (PS Act) provides protection from civil liability for the Registrar and staff in administering the Register. This will include protection from liability for providing information to donor-conceived people in circumstances where the donor may not have consented to the disclosure of the information (particularly in relation to information about historical donor conception ART procedures) and where information provided through the Register may not be correct because it was not correctly provided to the Registrar in the first instance.

The Bill provides that the Registrar must make reasonable attempts to notify a donor that their identifying information has been provided to a donor-conceived person (clause 50). The Registrar must advise individuals about support and counselling services that are available to donors and donor-conceived people (clause 48). Additionally, the Registrar will only release a donor's contact information with their consent (clause 49).

Information about private donor conception procedures

Donor conception may occur through private procedures that are not carried out by ART providers or health practitioners.

The LAS Committee recommended that the Register should be available voluntarily for individuals who have pursued donor conception through private procedures. In making this recommendation, the LAS Committee noted that it is difficult to mandate reporting requirements for individuals involved in private donor procedures, and that verifying the accuracy of information can be challenging.

Clause 47 of the Bill allows parties to a private donor conception procedure, being the donor and the parents of the donor-conceived person, to provide information to the Registrar if a child was born as a result of the private procedure. In a surrogacy arrangement, the parties to the procedure will be the egg donor, being the person who carried the pregnancy, and the parents of the donor-conceived person.

Information may only be provided to be held on the Register if all parties to the private procedure have provided their written consent. If a party to a procedure has passed away, written consent must be provided by all other parties to the procedure and a statutory declaration by the remaining parties as evidence of the death of the party.

The information that may be provided is any of the relevant information held on the Register, which is outlined in clause 44. This includes the name, date and place of birth of the donor, the name and date of birth of the parent/s, and the name, date and place of birth of the donor-conceived person.

Accessing information held on the Register

The LAS Committee recommended that all donor-conceived persons be legislatively provided with the right to know the identity of their donor when they reach the age of 18, regardless of when they were born and whether the donor consented to the information being released.

The LAS Committee also recommended that information about the gender and year of birth of donor-conceived persons born from their donation be made available on request to all donors, and information about the gender and year of birth of donor-conceived siblings be made available on request to donor-conceived persons.

The Bill establishes a framework to allow access to information that is held on the Register. To provide an applicant with information, the Registrar must be reasonably satisfied of the identity of the applicant and of the relevant link between the applicant and the person whose information has been requested (clause 48).

The Bill will:

- allow a donor-conceived person 16 years or older to apply for and access identifying and non-identifying information held on the Register about the donor without consent;
- allow donor-conceived people, donors and parent/s of donor-conceived people to apply for non-identifying information held on the Register about another person who the applicant is linked to (i.e. donor-conceived siblings);
- allow a person with parental responsibility of a donor-conceived person under 16 years of age to apply for and access the same information that a parent can access;
- allow a descendant, who is 16 years or older, of a donor-conceived person (such as a child or grandchild of the donor-conceived person) to apply for and access the same information that the donor-conceived person can access;
- allow an interstate donor-conceived person or a child of a donor who is not donor-conceived to apply for non-identifying information held on the Register about a donor-conceived sibling and lodge their own contact information; and

- establish a consent-based framework to allow disclosure of an individual's identifying information and/or contact details (other than a donor's identifying information disclosed to a donor-conceived person).

Donor-conceived person: The Bill provides that all donor-conceived people aged 16 years or older may apply to the Registrar to access identifying and non-identifying information about their donor and non-identifying information about any donor-conceived siblings. If a donor consents to the release of their contact information, or if a donor-conceived sibling consents to the release of their identifying and/or contact information, a donor-conceived person may also access this information.

As recommended by the LAS Committee, any donor-conceived person may apply for and access identifying and non-identifying information about the donor that is held on the Register, regardless of whether the donor has consented to the release of the information. While the LAS Committee recommended donor-conceived people have the ability to access information from 18 years of age, the Bill allows people to apply to access information from 16 years old. This is intended to support donor-conceived people to access important information about their genetic origins from an age of relative maturity. This is consistent with a person 16 years or more being able to apply to RBDM for their own birth certificate or to change their sex.

Donor: The Bill will allow donors to apply for and access non-identifying information about any donor offspring that is held on the Register, which includes the year and sex at birth of the person. If a donor-conceived person consents, the donor may also access identifying and/or contact information about donor offspring.

Parents of, or other person with parental responsibility of, donor-conceived person: The Bill outlines that parents of a donor-conceived person of any age or another person with parental responsibility of a donor-conceived person who is under 16 years old may apply for and access non-identifying information about the donor and donor-conceived siblings of the donor-conceived person, and may access identifying or contact information of the donor or donor-conceived siblings if the person has consented to the information being released to the parent or person with parental responsibility.

Parents of a donor-conceived person are the parents at the time of the procedure. It is intended that a donor-conceived person's parent can make an application to access information held on the Register no matter the age of the child. If a donor-conceived person is under the care of a person (other than a parent) with parental responsibility, that person can access information on the Register while the child is under 16 years of age. This is intended to ensure a person with parental responsibility can support a donor-conceived person to know information about their donor from a young age, while recognising that such a person was not a party to the initial ART procedure and access to information about the donor should be limited from when the donor-conceived person is able to access the information themselves.

Interstate donor-conceived sibling: The Bill allows a donor-conceived person who was born outside of Queensland to apply for and access non-identifying information about any donor-conceived siblings that is held on the Register. A successful application will require the donor-conceived person to know some identifying information about the donor, such as the donor's name, date of birth and donor's ID code to be able to link the donor-conceived siblings. If a donor-conceived sibling has consented to the release of their identifying or contact information

to another donor-conceived sibling, it is intended that this information would also be released to an interstate donor-conceived sibling.

Donor-conceived people conceived interstate will not be able to access any information about the donor through the Register, as the person can access this information in the relevant register in their own jurisdiction.

Offspring of a donor who is not a donor-conceived person: The Bill also allows a non-donor-conceived child of a donor (that is, a donor's raised child) who is 16 years or older to apply for and access non-identifying information held on the Register about any donor-conceived siblings. A successful application will rely on the person knowing their parent was a donor and providing identifying information about the donor to the Register, such as the donor's name and date of birth. If a donor-conceived sibling has consented to the release of their identifying or contact information to the non-donor conceived person, it is intended that this information would also be released.

An overview of the type of information that can be accessed with or without consent is outlined below.

Table 2: Overview of information that can be accessed with or without consent

Application by:	**Information that can be provided *without consent***	**Information that can be provided *with consent only***
Donor-conceived person (16 years or older) and descendants	• About the donor - Identifying information (name, date of birth) - Non-identifying information (e.g. medical history, physical characteristics) • About donor-conceived siblings - Non-identifying information (year of birth, sex)	• About the donor - Contact information • About donor-conceived siblings - Identifying information (name, date of birth) - Contact information
Donor	• About donor-conceived offspring - Non-identifying information (year of birth, sex)	• About donor-conceived offspring - Identifying information (name, date of birth) - Contact information
Parent/s of donor-conceived person **Person with parental responsibility of a donor-conceived person who is younger than 16 years old**	• About donors - Non-identifying information (medical history, physical characteristics) • About donor-conceived siblings - Non-identifying information (year of birth, sex)	• About donors - Identifying information (name, date of birth) - Contact information • About donor-conceived siblings - Identifying information (name, date of birth) - Contact information

Application by:	**Information that can be provided *without consent***	**Information that can be provided *with consent only***
Interstate donor-conceived person who is 16 years or older **Offspring of a donor who is not a donor-concieved person and who is 16 years or older**	• About donor-conceived siblings - Non-identifying information (year of birth, sext)	• About donor-conceived siblings - Identifying information (name, date of birth) - Contact information

Consent framework

The LAS Committee recommended that requests for contact between donors and donor-conceived persons be facilitated subject to the consent of the persons.

The consent framework provided in the Bill is intended to facilitate contact between individuals and ensure people have autonomy as to if and how their name and/or contact details are shared.

Clause 49 of the Bill allows all applicant categories to voluntarily provide their contact details to the Register. Consent must be given by notice to the Registrar in the approved way, must state the kind of information that may be provided and the category of applicants to whom it may be provided, must be recorded in the Register and may be varied or revoked by notice to the Registrar in the approved way. A person may also provide notice to the Registrar that they do not consent to the provision of their contact or identifying information to particular applicant groups (except in the case of identifying information about a donor being provided to a donor-concieved person).

It is intended that the person may consent to their name and contact details being provided to a particular group or groups of individuals who apply for the information. A person can consent to the kind of contact they would like (for example, via email only). A person may contact the Register at any time to alter or revoke their consent to share their name and/or contact details.

A donor-conceived person will always be provided with the name and date of birth of the donor without the consent of the donor. The donor's contact details will only be provided if the donor has consented to release of the details. A donor-conceived person's name and/or contact details will only be provided to the donor or another person if they have consented to the information being released.

Support and counselling

When dealing with an application, the Registrar must advise applicants of available counselling services that are provided by counsellors with experience in donor conception (clause 48). It will not be mandatory for individuals to undergo counselling prior to accessing information that is held on the Register. This is intended to ensure a person's autonomy in how they access information that is relevant to them.

External review

The Bill (clause 56) allows a person to apply to the Queensland Civil and Administrative Tribunals (QCAT) for a review of the following decisions of the Registrar related to the Register:

- for information in the Register on a matter (but only if there is information in the Register on that matter) (a decision under clause 48(2)); and
- for the correction of information in the Register about the person (a decision under clause 52(1).

Birth certificates

The LAS Committee recommended that the birth certificates of donor-conceived people be annotated to note the fact of donor conception, including the birth certificates of donor-conceived people already born. The intention of the recommendation is to ensure donor-conceived people are able to ascertain the fact of their donor conception status even in circumstances where their parent/s might not inform them.

The Bill will require the Registrar to issue an addendum to a birth certificate if a donor-conceived person born in Queensland requests their birth certificate. The addendum will state that further information about the person's birth is available through the RBDM. Any person born in Queensland who over 16 years old and is recorded as being donor-conceived on the Register will receive this addendum when they apply for their birth certificate. This will apply prospectively to donor-conceived people born after the commencement of the Bill as well as donor-conceived people born before the commencement of the Bill if there is information about the person held on the Register. It will then be the choice of the person as to whether they contact RBDM for information.

The addendum procedure achieves the intent of the LAS Committee's recommendation by providing a donor-conceived person with an independent avenue to obtain information that they are donor-conceived, while providing donor-conceived people with choice as to when and how they disclose their donor-conceived status.

Miscellaneous provisions

Review of decisions and appeals

To ensure natural justice, licensed ART providers will be able to request decisions about a licence to be reviewed, initially through an internal review process to the chief executive of Queensland Health and then external review by the Queensland Civil and Administrative Tribunal (QCAT). Reviewable decisions include granting, refusing, cancelling or suspending a licence, imposing or varying a condition, issuing or refusing to revoke an improvement or prohibition notice, or refusing to lift a licence suspension.

Decisions dealing with property, namely decisions to refuse to return seized property or to forfeit seized property, are appealable to the Magistrate's Court.

Affected persons will be able to request a stay of the decision from either QCAT or the Magistrate's Court.

False or misleading information

It is an offence under the Bill for a person to give an official performing a function under the Act information that the person knows is false or misleading in a material particular. This offence attracts a maximum penalty of 100 penalty units. The Bill clarifies that this penalty will not apply to a person if the person, when giving the information, tells the inspector, to the best of the person's ability, how it is false or misleading; and if the person has, or can reasonably obtain, the correct information, and then gives the correct information.

Disclosure or use of confidential information

The *Human Rights Act 2019* provides that individuals have the right to protection of their privacy. Government agencies are required to comply with the privacy principles in the *Information Privacy Act 2009* when collecting and handling personal information. The privacy principles provide that agencies are not permitted to disclose personal information to another person unless an exception applies, for example, if an individual consents to the disclosure or the disclosure is authorised or required by law.

Accordingly, the Bill provides for and limits the disclosure or use of confidential information obtained by officers in administering or performing functions under the Act. The restrictions apply to the chief executive, Registrar, a member of either of their staff, a contractor engaged by them, a person who otherwise obtains confidential information in administering or performing a function under the Act, or people who formerly held such roles. These persons must not disclose or use that information, other than:

- in the performance of a function or exercise of a power under the Act; or
- with the consent of the person to whom the information relates; or
- to the extent the disclosure or use is otherwise required or permitted by law.

Disclosures may be made to:

- a coroner investigating the death of a person under the *Coroners Act 2003*; or
- a law enforcement agency, for the purposes of detecting, investigating, preventing or prosecuting an offence under any law; or
- a National Health Practitioner Board, or Australian Health Practitioner Regulation Agency, established under the Health Practitioner Regulation National Law; or
- an entity established under the *National Health Act 1953* (Cwlth); or
- an official under the *Health Ombudsman Act 2013*; or
- another entity (whether of the Commonwealth, of another State, of a Territory or of another country) that has functions relating to the regulation of ART services.

Before disclosing the confidential information, the person making the disclosure must be satisfied that the disclosure is reasonably necessary for the entity to exercise its functions.

Failure to comply with the provision is an offence with a maximum penalty of 50 penalty units.

Confidential information means information that could identify a person and is about the person or their affairs, and includes documents. It does not include information that is publicly available.

Transitional arrangements

The transitional arrangements are intended to ensure a smooth transition from the existing self-regulatory model in the ART sector to the regulatory framework provided in the Bill.

The Bill makes it clear that a person does not commit an offence under this Act for any act or omission that occurred before the commencement of this Act.

Requirement to apply for a licence within three months

When the licensing scheme provisions commence, ART providers with RTAC accreditation that are currently providing ART services in Queensland will be able to continue providing ART services in Queensland without a licence for three months or until their licence application is granted or refused, whichever is earlier. After this time, it will be an offence to provide ART services in Queensland without a licence.

Donated gametes and donated embryos allocated before commencement

The Bill provides that any person or couple who conceived a child using donated gametes as a result of an ART procedure before commencement may use any remaining donated gametes that have been allocated to them from that same donor in order to complete their intended family.

Where a donated embryo (that is, an excess embryo that has been donated for someone else's use) has been allocated to a person or couple for use in an ART procedure before commencement, the person or couple may use the donated embryo.

The transitional arrangements for donated gametes and donated embryos will apply despite the use of the donated gamete or embryo possibly breaching the family limit in clause 25 or the time limit for use in clause 27. In this situation, the donor's consent will be taken as though it has been given in accordance with the consent provisions in the Bill. However, nothing prevents the donor from varying or withdrawing their consent in line with clause 20.

Embryos created but not yet used before commencement

Where an embryo is created but not yet used before commencement, and use of the embryo would otherwise contravene the family limit in clause 25 or the time limit for use in clause 27, the chief executive may authorise the use of the embryo. In deciding whether to approve the use of the embryo, the chief executive is to be satisfied that use of the embryo is a reasonable use having regard to the period since the gametes that was used to create the embryo was obtained and the number of existing families related to a donor of the gamete.

In this situation, the donor's consent will be taken as though it has been given in accordance with the consent provisions in the Bill, however, nothing prevents the donor from varying or withdrawing their consent in line with clause 20.

Time limits for use of donated gametes and embryos

The Bill provides that the time limit for use in clause 27 applies to any donated gametes or donated embryos that have been retrieved but not yet used at the point of commencement. This

means that the chief executive must approve any donated gametes or donated embryos being used if the gametes were obtained more than 15 years before the Act commences.

The purpose of this provision is to ensure donated gametes and donated embryos are not stored for longer than 15 years, without due consideration by the chief executive about whether there are reasonable grounds for doing so.

Information about pregnancy, children conceived and born

ART providers will be required to take reasonable steps within six months after commencement to collect information about a person becoming pregnant as a result of an ART procedure that occurred within four months before commencement.

ART providers will also be required to take reasonable steps within 18 months of commencement to collect information about a child was born as a result of an ART procedure that occurred within 15 months before commencement.

The information that must be collected is outlined in clause 35.

The intention of this provision is to ensure that ART providers collect information about pregnancies or children born as a result of an ART procedure that occurs after commencement, despite the ART procedure occurring before commencement.

ART providers must keep records about pregnancies and children born after commencement.

Information given to the Donor Conception Information Register

The Bill allows ART providers to use gametes or embryos that were donated prior to the commencement of the Bill in ART procedures that are carried out after commencement in particular circumstances.

Where this occurs, clause 151 of the Bill outlines that the ART provider must provide all relevant information to the Registrar about the parent/s of the donor-conceived person and the donor-conceived person born as a result of the procedure, and any relevant information about the donor that the ART provider recorded and kept at the time the donated gamete was obtained or the embryo became a donated embryo.

This applies to a procedure that is allowed under clauses 146 to 148 and a procedure using an embryo that was created using a donated gamete before commencement other than under clause 148.

Alternative ways of achieving policy objectives

There are no other ways of achieving the policy objectives.

Continuation of the current self-regulation model would not achieve the policy objectives as it is clear from the instances of alleged failure that the industry is not self-regulating to an appropriate standard. An educative approach would also not achieve the policy objectives noting that there are already national guidelines and an industry Code of Practice in place to

set the expected standards of care in ART services, which have not prevented alleged poor outcomes within the industry as there is no mechanism for government to enforce compliance.

Legislation is the only way to achieve the policy objective to implement the LAS Committee's recommendations to establish a central register of donor conception information within the RBDM.

Estimated cost for government implementation

It is estimated that the cost to government to establish the ART regulatory function in Queensland Health and the Register in RBDM will be approximately $10.4 million. This figure includes existing funding of $2 million for the Register through the Queensland Women and Girls Health Strategy investment plan.

Ongoing operational costs of the ART regulatory function will be met from existing resources, offset to a modest degree by ART provider licensing fees. Operational funding arrangements for the donor conception register will be determined once it and the associated information access framework are completed.

Consistency with fundamental legislative principles

The Bill has been drafted with regard to the fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

The Bill seeks to protect the welfare and interests of people involved with the provision of ART services, including people born as a result of ART, people accessing ART treatment and people who provide or donate gametes and embryos, through the regulation of ART providers and services, and the creation of a Register. The Bill also seeks to complement existing industry self-regulation mechanisms. It is necessary to strike a balance between protecting the welfare and interests of people involved with ART while not unduly burdening ART providers.

For that reason, the Bill potentially departs from some fundamental legislative principles to ensure that the objects of the Bill are met. These potential departures are discussed in more detail below. In all cases, the Bill has been drafted to minimise and mitigate the impacts of these departures to the greatest extent possible.

Donor Conception Information Register

Part 3 of the Bill establishes the Register in RBDM which is to be maintained and operated by the Registrar and obliges ART providers to provide specific information to the Registrar to be held on the Register following the birth of a child as a result of a donor conception ART procedure carried out by the ART provider. Clause 46 of the Bill obliges any ART provider or other entity that holds information about donor conception ART procedures that were carried out prior to commencement of clause 45 of the Bill to provide this information to the Registrar to be held on the Register.

Division 4 of part 3 of the Bill establishes an access to information framework which allows all donor-conceived people to access identifying and non-identifying information about their

donor and provides for the release of identifying and contact information in other circumstances with consent of the relevant person.

The Bill will provide all donor-conceived people with the ability to access identifying information about their donor, and therefore their genetic origins, if this information is held on the Register, regardless of whether the donor has consented to the release of the information.

As part 3 of the Bill will require the provision of and allow for the disclosure of information, including identifying information, about individuals that were involved in donor conception ART procedures that occurred prior to commencement of the Bill, part 3 of the Bill departs from some fundamental legislative principles to ensure the Bill operates as intended.

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

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

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

Given the scope and complexity of the scheme, the Bill prescribes a range of administrative powers for the chief executive to support its operation and administration. These powers are sufficiently defined and subject to appropriate review, as outlined below.

Imposition of suitability, eligibility or similar criteria

Several clauses impose criteria on licence holders. This is necessary to support the operation of the licensing scheme by providing for the minimum eligibility of persons or entities that may conduct ART procedures in Queensland, which is critical to protecting the welfare and interests of the people who use ART and who are born as a result. Unless licensed, a person may not offer or provide ART services (clause 12). Clauses that impose criteria are considered below.

Clause 57 (Application for licence) provides that a person may apply to the chief executive to be a licensed ART provider provided they meet the following minimum eligibility criteria:

- current RTAC accreditation;
- they are not completely prohibited from providing ART services by a prohibition notice; and
- the person satisfies any other requirement prescribed by regulation.

Clause 64 (Cancellation or suspension of a licence) provides that, if a licence is found to have been granted because of information that was materially false or misleading, the chief executive may cancel or suspend the licence.

Clause 58 (Deciding application for licence) gives the chief executive power to grant a licence if the applicant for the licence is a person who is eligible and if the application has been made

in accordance with clause 57 (Application for a licence). The chief executive also has power under clause 58 to refuse to grant a licence if they are satisfied that it should not be granted because of:

- contraventions of the conditions of any previous licence held by the applicant; or
- contraventions by the applicant of the Act or any ART related legislation (which may include that of another State or Territory); or
- the risk to the health, safety or welfare of persons provided with ART services by the applicant or to persons born as a result of the provision of those services; or
- any other relevant matter.

The Bill appropriately defines these administrative powers by expressly outlining minimum eligibility criteria and the factors the chief executive may take into account in making the decision to grant (or refuse to grant) a licence. These criteria are directly relevant to the person's professional conduct of ART and ability to comply with obligations in the Bill intended to safeguard the welfare and interests of people who use ART and who are born as a result. Prescribing clear criteria to exclude persons who are not qualified to provide safe ART services, or who have demonstrated they are unable to comply with legislative obligations, will promote public confidence in the ART services available in Queensland.

To balance the exercise of this power, the chief executive's decision is subject to internal review and external review by QCAT. The imposition of criteria in these provisions is therefore considered justified.

Imposition of conditions

Clause 59 (Conditions of licence) gives the chief executive power to impose conditions on licence holders at the time, or at any time after, the licence is granted. The chief executive may also, at any time, vary or remove the specific conditions to which a licence is subject.

Licence conditions may be general or specific in nature. The chief executive will have power to impose general conditions on all licence holders, and power to impose specific conditions on particular ART providers at any time to address issues particular to that provider.

General conditions are anticipated to include requirements such as the following:

- maintain RTAC accreditation;
- maintain compliance with ART legislation;
- maintain appropriate records and provide evidence of this on request;
- comply with identified best practice policies, standards and practices; and
- have appropriate governance, processes and systems in place to ensure compliance with applicable laws and RTAC accreditation.

The chief executive may impose specific conditions on the licence of any licensed ART provider at any time. While the Bill does not provide examples, specific conditions may respond to issues such as:

- particular risks or health and safety concerns that arise;

- any specific requirements that must be complied with in the provision of specific treatment;
- minimising specific risks, improving systems for legislative compliance and/or prioritising patient welfare;
- responding to specific incidents and/or conducting a risk assessment of current practices or new initiatives; and
- responding to developments in the sector that mean adjustments are necessary in the public interest.

The power to impose specific conditions on a licence is considered necessary as it allows the chief executive to adopt a responsive approach to any issues or risks of non-compliance particular to a provider. For example, if the chief executive considers an ART provider's policies or procedures may pose a risk to patient welfare, they could impose a specific condition that requires an ART provider to provide copies of their RTAC accreditation, audit or surveillance reports and conditions imposed by RTAC or any corrective action plans related to nonconformity under the RTAC Code of Practice for a period of time.

The Bill does not outline the factors that the chief executive must or may take into account in making the decision to impose conditions on a licence. This is because, given the rapidly evolving nature of the industry, it is not considered possible to fully prescribe the range of clinical or technical factors that may be relevant to making a decision to impose or vary a specific condition.

However, the Bill provides appropriate safeguards and review mechanisms. The chief executive must give the licensed provider an information notice about the decision to impose or vary a specific condition, which must include the reasons for the decision and rights of review.

Powers to direct others to take action

Clause 62 (Improvement notices) gives the chief executive power to issue an improvement notice. These powers are limited to where the chief executive has a reasonable belief that it is necessary to minimise a risk to health, safety or welfare of people who use ART or who are born as a result.

The Scrutiny of Legislation Committee has previously commented that a power authorising a chief executive to give a notice requiring works stated in the notice to be performed is sufficiently defined if it is a legislative requirement for the works required, and the period within which the works must be performed be reasonable. Accordingly, the Bill prescribes the information to be included in an improvement notice:

- the matter that is required to be rectified;
- the timeframe for rectification and, if the chief executive considers it appropriate, the action that the licensed provider must take to rectify the matter;
- the period within which the matter must be rectified; and
- that that the improvement notice has effect until it is revoked by the chief executive.

Given the range of clinical, technical and compliance matters where a compliance action by the chief executive may be warranted, reasonable timeframes will vary according to individual

circumstances. It is therefore not possible for the Bill to prescribe a period (for example, 30 days) that could be considered as a single benchmark for 'reasonable'.

However, the Bill provides appropriate safeguards and review mechanisms. The information notice about the decision must also include the reasons for the decision and rights of review. Further, a provider may apply for the decision to be revoked because the matter has been rectified or does not require rectification.

Should a licensed provider apply to the chief executive for the revocation of an improvement notice, the chief executive has power to revoke the improvement notice or refuse the application for the revocation of the improvement notice. Refusals must be accompanied by an information notice about the decision.

Powers relating to compliance action

The licensing scheme provides the chief executive with a range of administrative powers, which are essential to support the effective operation of the licensing framework, including to issue a prohibition notice to a licence holder (clause 63) and to suspend or cancel a licence (clause 64).

Clause 63 (Prohibition notices) gives the chief executive power to issue a prohibition notice if the chief executive reasonably believes that the person should be prohibited from providing ART services. The chief executive will only issue a prohibition notice in the most serious instances of non-compliance. This includes a person contravening a condition of their ART licence, contravention of the Act or any other ART related legislation, or because of the risk to the health, safety or welfare of persons to whom ART services are provided or to persons born as a result of those services. The chief executive may also issue a prohibition notice to an associated entity of a corporation because of a contravention or other conduct of the corporation, or another associated entity (clause 63(11)).

The chief executive may, by notice, limit the ART services provided by the person to which the prohibition notice applies, or revoke a prohibition notice issued to the person. A licensed provider may apply to the chief executive for the revocation of the prohibition notice, and the chief executive may revoke the prohibition notice or refuse the application.

Clause 64 (Cancellation or suspension of licence) provides the chief executive with power to cancel or suspend a person's licence if the person ceases to have RTAC accreditation or if the person is completely prohibited from providing ART services by a prohibition notice. The chief executive also has power to cancel or suspend a person's licence if:

- the licence was granted to the person because of information that was false or misleading in a material particular;
- if the person notifies the chief executive that they have ceased to provide ART services; or
- in any other circumstances prescribed by regulation.

The Bill provides appropriate safeguards and review mechanisms. The chief executive must provide an information notice about a decision to cancel or suspend a licence as soon as practicable following the decision, which must include information about the decision and review rights. Provide may apply for a suspension to be lifted. If the chief executive refuses to

lift a suspension, they must give the person an information notice, including rights of review, as soon as practicable.

Powers relating to forfeiture of property

To support the enforcement of licensed ART providers' obligations, part 5 (Investigation and enforcement) provides for the retention and forfeiture of property seized during inspections by inspectors appointed under the Act. Clause 101 (Return of seized thing) gives the chief executive powers to retain a seized thing if they are satisfied there are reasonable grounds for retaining it, after the owner has made application for its return.

Clause 102 (Forfeiture by chief executive decision) gives the chief executive powers to forfeit seized property to the State. Circumstances are limited to where an inspector is unable to identify the owner, cannot return the property or considers it necessary to keep it in order to prevent an offence. Clause 105 (How property must be dealt with) requires that the chief executive may deal with the item as they consider appropriate, however, they must not do so in a way that could prejudice the outcome of a review of the forfeiture decision. If the forfeited property is sold, they must also make reasonable efforts to return the proceeds to the immediately previous owner (if known).

Powers to keep a public register of licensed ART providers and key personnel

Clause 65 (Public register of licensed providers) provides the chief executive powers to keep a public register of licensed ART providers. The register may include such information as the name, contact details, address, key personnel and RTAC accreditation details of licensed ART providers, and any other information the chief executive considers appropriate. The public register is intended to provide assurance to the public that ART providers have been assessed as appropriately qualified and compliant with the consumer protections outlined in the Bill. Inclusion of key personnel will also reassure patients that the staff involved in their treatment are known to Queensland Health and can be held accountable for compliance with their legislative obligations, and therefore promote public confidence in the provision of ART services. The powers to keep a public register are appropriately limited in that, if a person requests that certain information be withheld from the public register and the chief executive is satisfied that publication may endanger a person's safety, the chief executive must not publish that information.

Powers relating to the use of gametes and embryos

The Bill provides several powers for the chief executive to make discretionary decisions on the use of gametes and embryos. These powers are intended to support the general provisions in the Bill for these matters, by allowing limited matters to be considered on a case-by-case basis, generally on application by the licensed ART provider. This will avoid any unintended consequences of the Bill's provisions for individuals, and support the achievement of its overall policy objectives.

Clause 27 (Time limit on use of donated gametes or embryos and their disposal) generally provides that ART providers must not use a donated gamete or embryo in an ART procedure if it was obtained or created more than 15 years prior to the procedure. However, the chief executive may approve use after this period, if they are satisfied there are reasonable grounds for doing so. An ART provider must have this approval in writing before use. This will enable

flexibility in the application of the time limit to ensure that individual cases can be considered where it is reasonable, and serve as a quality assurance check that ART providers are operating ethically and appropriately when it comes to using older gametes and embryos.

The Bill also provides powers for the chief executive that apply during the transitional period between the Act being made and various sections commencing. Clause 148 (Embryo not yet used for ART procedure) provides that the chief executive may authorise use of an embryo created, but not yet used, before commencement, if that use would result in limits on the number of donor-conceived Australian families being exceeded. This decision is appropriately limited, as the chief executive must be satisfied it is a reasonable use of the embryo having regard to the time since gamete donation and the number of existing families.

These powers for the use of gametes and embryos are appropriately defined and limited, but not subject to review. This is because reversal of the decision may not be practicable, and would limit other rights. If such a decision was reversed, this could necessitate a termination of pregnancy, impacting the pregnant person's autonomy and reproductive freedom, and their human rights relating to family and medical treatment.

Administrative powers relating to the disclosure of health information

Clause 39 (Disclosure of health information by chief executive) provides powers to the chief executive to disclose health information in limited circumstances. The Bill authorises ART providers to disclose health information about donors and donor-conceived people, to specified parties, if a medical practitioner certifies the disclosure is necessary to minimise a risk of harm (clause 38). This may include emergent information about a heritable medical condition. Clause 39 authorises the chief executive to disclose this information, in limited circumstances where they are satisfied that the ART provider who has the information has not disclosed it, and it is reasonably necessary to do so. This power is intended to facilitate sharing of important health information to minimise harm, and supplement rather than supplant the role of ART providers in doing so. Disclosure by the chief executive is subject to the same requirements as disclosure by an ART provider, including that a medical practitioner must disclose the information on their behalf.

This power is appropriately defined and limited, but not subject to review. This is because the decision is on health and safety matters where the chief executive is acting on expert advice (that is, the advice of the medical practitioner who certifies the disclosure is necessary).

Administrative powers related to appointment of inspectors

To support the efficient operation of the regulatory scheme, the Bill prescribes administrative powers to the chief executive related to the appointment of inspectors. These include powers to appoint inspectors, limited to those who are appropriately qualified (clause 70), and issue identity cards to inspectors (clause 74). These powers are appropriately defined and limited, but not subject to review. This is because they are relatively minor in nature and unlikely to affect the rights and liberties of individuals.

Administrative powers relating to the Donor Conception Information Register

Clause 42 of the Bill outlines that the Registrar is responsible for establishing and maintaining the Register for the purposes of part 3 of the Bill. The Registrar must ensure relevant

information is included in the Register and has responsibility for operating the access to information framework that allows individuals to apply for and access information on the Register.

The Registrar has administrative powers in relation to:

- determining whether a person is eligible to obtain information that is held on the Register and the information they may obtain (clause 48(2));
- correcting information on the Register on application by a person or on the Registrar's own initiative (clause 52(1));
- issuing a notice to an ART provider or other person in relation to the provision of historical information to the Registrar (clause 46(5));
- issuing a notice to an ART provider relating to an inquiry to determine whether the ART provider has given all relevant information that is required or if the information provided is correct (clause 54(2)).

Clause 48(1) of the Bill outlines that a person may apply for information on the Register about another person or about themself. Clause 48(2) outlines that the Registrar must provide the requested information to the applicant if the Registrar is:

- reasonably satisfied that the information is the kind that can be provided to the applicant as outlined in the Bill; and
- reasonably satisfied of the identity of the applicant and the relevant link between the applicant to the person whose information has been requested.

Clause 48 of the Bill does not explicitly outline the matters the Registrar must take into account when determining the applicant's link to the person whose information has been requested. The information an applicant provides to support a relevant link will differ depending on the applicant's circumstances and the information they have available to them.

For example, a parent of a donor-conceived person may be able to provide a donor's ID code, information about the ART provider that performed the procedure, and information about the donor-conceived person's name and date of birth in support of a relevant link to another person, while a donor-conceived person may only be able to provide information about themselves and their parents' names in support of a relevant link. This provision is intended to be broad to provide the Registrar with flexibility when determining a relevant link.

Clause 52 of the Bill allows the Registrar to correct the Register on application by a person whose information is on the Register. The clause outlines that a person cannot apply to remove identifying or other information that is required by the Bill to be included in the Register.

Clause 56 of the Bill outlines that a decision made by the Registrar on an application by a person in relation to clause 48(2)(b) or 52(1)(a) is subject to external review if:

- the decision is not the decision sought by the person; and
- the person is dissatisfied with the decision. The Bill outlines that a person may apply to QCAT for a review of the decision in these circumstances, which provides an appropriate avenue for review of these administrative decisions.

Clause 46(5) of the Bill outlines that the Registrar may issue a notice to an ART provider or other person that the Registrar reasonably believes has possession or control of historical information to require the provision of the information or details of the whereabouts of the information within a specific timeframe. An ART provider or other person must comply with the notice.

Clause 54 of the Bill outlines that the Registrar may conduct an inquiry to determine whether information provided to the Registrar is correct, or whether an ART provider or other person has provided all relevant information they are required to provide under the Part. Clause 54(2) outlines that the Registrar may issue a notice to an ART provider or other person for the purpose of an inquiry to require the ART provider or person to provide relevant information or to answer particular questions within a specified timeframe. An ART provider or person must comply with the notice unless they have a reasonable excuse.

The power of the Registrar to issue notices under clauses 46 or 54 are appropriately defined and limited, as each clause sets out the circumstances in which the Registrar can issue a notice and the persons to whom a notice may be issued. A decision of the Registrar to issue a notice is not reviewable, as an ART provider or other person may advise the Registrar that they do not have the relevant information to which the notice relates in response or, for a notice issued under clause 54, is not required to comply with the notice if they have a reasonable excuse.

Is the legislation consistent with principles of natural justice?

Section 4(3)(b) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation is consistent with the principles of natural justice. The three key principles of natural justice are that: a person should have a right to be heard if they are to be deprived of some right, interest, or legitimate expectation of a benefit; a decision-maker must be unbiased; and procedural fairness should be afforded to the person.

The licensing scheme may impact on a person's natural justice as it allows for licence holders to be deprived of the right to provide ART services in Queensland, whether in full or in part, in circumstances where a licence application is refused, a licence is suspended or cancelled, or a prohibition notice is issued. These provisions are considered necessary to support the operation of the licensing framework and to ensure the requirements relating who may provide ART services in Queensland can be effectively monitored and enforced.

Part 6 (Review of decisions and appeals) provides for review of decisions. These provisions ensure natural justice for persons affected by decisions made under the licensing framework and the Bill, setting out the processes for internal and external review of decisions. The decisions subject to review under the Bill are listed in the definition of reviewable decision (clause 119) and are the following decisions:

- a decision to refuse to grant a licence under clause 58;
- a decision to impose or vary a condition of a licence under clause 59(2) or (3);
- a decision to issue an improvement notice, or to refuse to revoke an improvement notice under clause 62;
- a decision to issue a prohibition notice or to refuse to revoke a prohibition notice, under clause 63;

- a decision to cancel or suspend a licence or to refuse to lift a licence suspension under clause 64.

Division 2 sets out the requirements for internal review of a reviewable decision. An affected person for a reviewable decision may apply to the chief executive for an internal review of the decision (clause 121). The application must be in the approved form and made within 20 business days after the person was given an information notice about the decision or becomes aware of the decision (clause 122). The chief executive must review the decision and either confirm the original decision, amend the decision, or substitute a new decision. The chief executive must also give the person a QCAT information notice for the internal review decision (clause 123). A QCAT information notice is defined in section 157(2) of the QCAT Act and must state the decision, the reasons for the decision, and information about the person's right to have the decision reviewed by QCAT. If the chief executive does not give the person a QCAT information notice, they are taken to confirm the original decision.

Division 3 allows an affected person for a reviewable decision to apply to QCAT for a stay of the decision (clause 124). A stay by QCAT may be given on conditions QCAT considers appropriate and for the period decided by QCAT. Division 4 provides an affected person for an internal review decision may apply to QCAT for a review of the decision (clause 125).

Separately to reviewable decisions, decisions to refuse to return seized property (clause 101) or to forfeit seized property (clauses 102 and 103) are appealable to the Magistrate's Court (clause 126).

Several provisions have features that are designed to support natural justice. For example, under clause 62, a licensed provider who is issued an improvement notice may apply to the chief executive for the revocation of that notice because the matter has been rectified or does not require rectification. Similarly, a person may apply for the revocation of a prohibition notice under clause 63. Where a licence is suspended, the provider may apply for the suspension to be lifted under clause 64. A suspension cannot be for longer than 12 months.

These provisions ensure natural justice for persons affected by decisions made under the Bill, with clear processes for external review of a decision.

Does the legislation provide for the reversal of the onus of proof in criminal proceedings without adequate justification?

Section 4(3)(d) of the Legislative Standards Act provides that whether legislation reverses the onus of proof in criminal proceedings without adequate justification is relevant to whether the legislation has sufficient regard to the rights and liberties of individuals.

Generally, for a reversal to be justified, the relevant fact must be something inherently impractical to test by alternative evidential means and the defendant would be particularly well positioned to disprove guilt. For example, if legislation prohibits a person from doing something 'without reasonable excuse', it is generally appropriate for a defendant to provide the necessary evidence of the reasonable excuse if evidence of the reasonable excuse does not appear in the case for the prosecution.

If legislation provides that something is conclusive evidence of a fact, without justification, this may also impinge on this principle.

Reasonable excuses

A number of offences within the Bill contain a reasonable excuse provision, which may be considered to reverse the onus of proof, including:

- clause 54 (Inquiries by Registrar relating to information in Register): an ART provider (or other person required to provide relevant information under the Bill) must comply with a notice from the Registrar relating to information in the Register, unless they have a reasonable excuse;
- clause 61 (Chief executive to be notified of certain events): a licensed ART provider must provide the chief executive of written notice of specified events within a specified timeframe, except where they have a reasonable excuse;
- clause 76 (Return of identity card): the person must return their identity card to the chief executive within 21 days after their office ends, unless they have a reasonable excuse;
- clauses 91 (Offence to contravene help requirement) and 97 (Offence to contravene seizure requirement): a person must help an inspector if asked to assist, including to secure property to be seized, unless the person has a reasonable excuse;
- clause 98 (Offence to interfere): a person must not interfere with a seized thing or enter a restricted place, unless they have a reasonable excuse;
- clauses 107, 109, 110 and 112: a person must provide their name and residential address, give information about suspected offences, produce a document and certify a copy if requested by an inspector, unless the person has a reasonable excuse; and
- clause 116 (Obstructing inspector): a person must not obstruct an inspector or a person helping an inspector, unless they have a reasonable excuse.

Reversing the onus of proof in these circumstances is appropriate because the person who is failing to comply with the offence provision is best placed to provide relevant information to support their reasonable excuse defence. This places the evidential and legal onus on the person, if they are charged with an offence of not complying, to prove the existence of a reasonable excuse for failing to comply. Without a 'reasonable excuse' provision, the relevant offences would be unnecessarily strict and penalise individuals for non-compliance with obligations that they may be unable to comply with. Any departure from fundamental legislative principles is therefore considered justified.

Evidentiary provisions

Clause 133 (Evidentiary provisions) provides that a certificate purporting to be signed by the chief executive and stating a range of matters is evidence of the matter. Those matters include a document being a licence, approval, notice or direction, form, identity card and so on. These provisions are considered appropriate to remove an unnecessary administrative burden for the prosecution to prove administrative and technical matters that are unlikely to be in dispute. This makes efficient use of a court's time and streamlines proceedings. Similar evidentiary provisions appear in other Acts.

Deemed executive liability

Clause 138 (Executive officer may be taken to have committed offence against deemed executive liability provision) provides that if a corporation commits an offence against a deemed executive liability provision, an executive officer of the corporation is taken to have also committed the offence if the officer authorised or permitted the corporation's conduct constituting the offence; or the officer was, directly or indirectly, knowingly concerned in the corporation's conduct constituting the offence. Deemed executive liability provisions include those relating to the regulation of ART (all clauses in part 2), information held in the Register (part 3, division 3), or providing false or misleading information (clause 139(2)).

This is not considered a reverse onus of proof, as the State would have the burden of proving that the officer authorised or permitted the conduct, or was knowingly concerned in it. This type of provision requires the prosecution to prove the individual knew the essential facts that constitute the corporate offence, and through their own act or omission, was a participant in the offence. Given the seriousness of the deemed executive liability offences, it is appropriate that an executive officer who is in a position to influence the conduct of a corporation be required to ensure the corporation complies with the legislation.

An executive officer who is responsible for a contravention of the legislation should be accountable for their actions and not be able to 'hide' behind the corporation. The executive liability provisions are therefore warranted to ensure there is effective accountability at a corporate level for individuals concerned. Similar provisions are contained in a range of other Acts, including section 214 of the *Medicines and Poisons Act 2019*, section 143 of the *Private Health Facilities Act 1999* and section 205A of the *Radiation Safety Act 1999*.

Does the legislation provide power to enter premises, and search for or seize documents or other property, only with a warrant issued by a judge or other judicial officer?

Section 4(3)(e) of the Legislative Standards Act refers to legislation which confers power to enter premises, and search for or seize documents or other property. It provides that legislation may have regard to rights and liberties of individuals if the powers are only conferred by a warrant issued by a judge or other judicial officer.

Part 5 of the Bill (Investigation and enforcement) provides for inspectors' functions and powers. The Office of the Queensland Parliamentary Counsel's Fundamental Legislative Principle Notebook provides that current Queensland drafting practice relating to legislation setting out inspector's powers includes the following requirements:

- an inspector must be issued with official identification documents and, when the inspector is exercising a power, the inspector must produce them to any person against whom the power is being exercised;
- entry of any premises without consent is strictly controlled through requirements for warrants and limitation of circumstance;
- entry without consent into anywhere a person lives requires the highest justification;
- the powers that may be exercised, particularly on entry of premises, must be specified as far as practical, and justifiable in proportion to the interference in rights and liberties involved;
- if it is an offence to obstruct or fail to obey, help, or provide information to an inspector, reasonable excuse must be provided as a defence;
- property must not be interfered with or seized without particular justification;

- if property may be seized, the circumstances of its return must be specified and the circumstances must be fair, and the owner must be permitted reasonable access to it while it is seized; and
- if property is damaged, provision must be made for notice to be given to the owner of property and for payment of compensation unless there is particular justification for not providing compensation.

Inspectors' powers in the Bill are consistent with these principles, contain appropriate safeguards and are considered necessary to support the effective and transparent exercise of inspectors' powers for monitoring, compliance and enforcement of the Act.

Part 5, division 3 (Entry of places by inspectors) empowers an inspector to enter a place with consent or under a warrant. They may also enter a premises used by a licensed ART provider that is open for entry. Following entry with consent or under a warrant, an inspector may seize anything they reasonably believe is evidence of an offence against the Bill or is otherwise covered by the terms of the consent or warrant.

The following safeguards included in the Bill ensure that inspectors' powers are justified and necessary to support the effective and transparent exercise of inspectors' powers for monitoring, compliance and enforcement of the Bill:

- entry of any premises without consent is strictly controlled through requirements for warrants and limitation of circumstance;
- an inspector must be issued with official identification documents;
- when the inspector is exercising a power, the inspector must produce their identification card to any person against whom the power is being exercised. If it is not practicable to comply with these requirements, the inspector must produce the identity card for the person's inspection at the first reasonable opportunity;
- an inspector must provide a person with receipt if a thing has been seized;
- an inspector must allow the owner of a seized thing to inspect it and copy it;
- the chief executive must return a seized thing to its owner, as soon as the chief executive stops being satisfied there are reasonable grounds for retaining the thing;
- if an inspector exercises a power, they must take all reasonable steps to cause as little inconvenience, and do as little damage, as possible;
- if an inspector damages something when exercising a power, they must give notice of the damage to the owner of the thing; and
- a person may claim compensation from the State if they incur loss because of the exercise of a power by an inspector.

The monitoring and enforcement functions and overall aim of the Bill would be undermined, and offences would not be able to be effectively investigated, prosecuted and enforced if these inspector powers were not available.

Does the legislation provide appropriate protection against self-incrimination?

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

Clause 58 (Deciding application for licence) of the Bill requires a person applying for a licence to comply with a request from the chief executive to provide additional information.

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

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

The information sought in the section is required to determine whether the applicant or licensee is eligible to hold a licence or is considered necessary by the chief executive for the administration of the Act. This may include information tending to incriminate the person, which is information peculiarly within the knowledge of the licensee.

The personal information sought by the chief executive is necessary for the effective implementation of the licensing scheme. In particular, the information may be relevant to a key aspect of the scheme, being whether someone is eligible to hold, or continue holding, a licence. This power is considered necessary and justified.

Several provisions in the Bill related to the production and certification of documents (clauses 109 and 110) provide that it is not a reasonable excuse for a person to fail to comply because it might tend to incriminate the person or expose them to a penalty.

The limitation on self-incrimination with respect to the production of documents is a necessary limitation as this material may be the only reliable evidence in an investigation. In its 2004 Report, *The abrogation of the privilege against self-incrimination*, the Queensland Law Reform Commission considered that, in the context of a legislative regulatory scheme where one of the requirements is to keep records and present them on request, a person's participation implies they have accepted the enforcement provisions and waived the privilege of self-incrimination. Other reasonable excuses are permissible.

The keeping of accurate records is essential to ensure the scheme operates effectively. To allow a claim of privilege for these documents or information may effectively facilitate a failure to keep the records, or their destruction or falsification. Further, without cooperation by the person who has been given or is required to keep or certify a document under the Bill, it would not be possible for an inspector to obtain documents by alternative means, or to ensure their authenticity. This limitation is therefore justified as the provisions enable inspectors to enforce the framework by ensuring their enforcement capability is not compromised. Clause 118 provides a limited immunity against the future use of the document given or certified in compliance with the requirements of clauses 109 and 110.

Clause 112 of the Bill expressly provides that self-incrimination is a reasonable excuse for an individual not to give information required by an inspector under clause 111. Clause 91 applies

a similar test to the offence of not providing reasonable help to an inspector (unless the help pertains to a document).

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

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

Clause 37 of the Bill provides that it is an offence for ART providers to destroy records of ART services or procedures, including historical records that are required to be provided to the Registrar under the Bill. The intention of this provision is to safeguard existing records to allow donor-conceived people born before commencement to exercise their rights under the Bill to obtain information about their donor through the Register. It is also intended to ensure the ongoing protection of records relevant to ART treatment.

The retrospective operation of this clause was recommended by the Report of the LAS Committee (recommendation 3.1). The LAS Committee noted the NHMRC Guidelines stipulate that ART providers must ensure all existing information about parties involved in donor conception programs before 2004 is maintained. However, the LAS Committee heard evidence that information was not always available from clinics. As a result, the LAS Committee recommended legislation to prohibit the deliberate destruction of historical donor records. The retrospective operation of this clause is intended to ensure that all donor-conceived persons, regardless of when they were born, are able to access information about their genetic heritage by ensuring historical records must not be destroyed. Although the offence applies to historical records, it will only be an offence from commencement, which minimises the impact of the retrospective operation.

Clause 46 of the Bill outlines that an ART provider that has possession or control of relevant information that relates to a donor conception ART procedure that was carried out in Queensland before commencement of clause 45 and resulted in the birth of a child must provide the information to the Registrar within six months of commencement of the clause, unless extended by the Registrar.

An ART provider that previously had possession or control of relevant information must, if they no longer have possession or control of information, notify the Registrar of either the name and contact details of the person to whom they gave possession or control of the information to, or, if the information was lost, destroyed, or is otherwise no longer available, the ART provider must notify the Registrar of when and the circumstances in which this occurred.

Clause 53 of the Bill outlines that if an ART provider or person holds information that is captured by clause 46, they must provide the information to the Registrar even though the person to whom the information relates has not consented to the disclosure of the information, or the laws or guidelines at the time the procedure was carried out precluded the disclosure of the information.

Clause 48 of the Bill outlines the access to information framework, which provides that a donor-conceived person aged 16 years or older may apply for identifying and non-identifying information about the donor where this information is held on the Register. The donor's

identifying and non-identifying information will be provided to the donor-conceived person regardless of whether the donor consented to its disclosure.

The operation of these clauses will alter the nature of an agreement that a donor may have entered into with an ART provider or other person at the time of donating a gamete prior to commencement of the Bill (and particularly prior to commencement of the NHMRC Guidelines in 2004) that the donor's identity would not be disclosed to a person born as a result of the donor conception ART procedure. Under the Bill, the information must be provided to the Register and will be disclosed to a donor-conceived person if they apply for it.

Although historical donors may have been assured anonymity at the time they donated, these individuals made the decision to donate as competent adults, in full knowledge that the donation of their gametes may result in the conception and birth of a child. By comparison, donor-conceived people had no choice in the method of their conception and subsequently should not be denied the ability to have access to information about their genetic origins due to the timing and circumstances of their birth. In addition, submissions provided to the LAS Committee as part of its Inquiry outlined that ongoing donor anonymity is an increasingly redundant concept due to advances in at-home DNA testing kits and the use of social media, which are assisting donor-conceived people to identify the donor outside of regulated frameworks.

Retrospective operation of the legislation in this way is necessary to fulfil the purpose of the establishment of the Register, which is to ensure all donor-conceived people have the ability to access information about their genetic origins where this information is held by the Register, regardless of when the donor-conceived person was conceived or born.

To mitigate the risk of liability for an ART provider or person who provides information to the Register about historical donor conception ART procedures, clause 53 of the Bill outlines that a person acting honestly or reasonably in providing the information is not liable, civilly, criminally or under an administrative process, and cannot be held to have breached any code of professional etiquette or ethics, or departed from accepted standards of ethical conduct. This is intended to ensure all historical information is provided to the Register where it exists and is held by an ART provider or another person.

To provide support to donors who will be affected by the establishment of the Bill, the implementation of the Bill will be complemented by a public awareness campaign about the changes to the law, as well as the development of resources that will be accessible by donors.

Clause 50 of the Bill outlines that if a person's identifying information is provided to an applicant through the Register, the Registrar must make all reasonable attempts to contact the person to advise them that their information has been provided to an applicant. This is intended to provide an opportunity for the Registrar to advise donors of support and counselling services that are available to them, which would not happen for donors that are contacted by donor-conceived people outside of regulated frameworks.

The Bill will also provide donors with the ability to consent to their contact information being released to donor-conceived people and their parents. If the donor does not wish to be contacted, including by the Registrar when the donor's identifying information is provided to a donor-conceived person, the donor may also lodge this preference with the Register.

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

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

Does the legislation infringe on the right to privacy?

The Scrutiny of Legislation Committee has noted that the right to privacy is relevant to whether legislation has sufficient regard to the rights and liberties of individuals.

The Bill contains a range of provisions that may be seen to infringe the privacy of individuals, including provisions relating to collection and storage of confidential information and confidentiality requirements for officials who access information under the Bill. These provisions are considered justified as adequate safeguards are in place and the provisions enable the operation of the Act, protect the health of individuals accessing ART services and persons born from these procedures, as well as ensuring there are appropriate records to provide donor-conceived persons with information about their genetic heritage.

Clause 57 (Application for licence) requires ART providers to provide information to the chief executive in order to apply for a licence. This includes the applicant's name, ART clinic address(es), names of the medical personnel who will provide ART services along with the names of other key personnel prescribed by regulation, and any other information prescribed by regulation. This information allows the chief executive to make informed decisions about whether a person is eligible to be a licensed ART provider in Queensland and helps to ensure the health and safety of those who undergo ART procedures and individuals born as a result of ART. While the scheme will be new in Queensland, most Queensland ART providers operate nationally, including in states that have had similar legislation in place for many years. These provisions will enable the chief executive to assess whether contravention in those jurisdictions may be relevant to operations in Queensland, and take appropriate action in response to limit risks.

The licensing requirements ensure Queensland Health has oversight of the industry and can effectively enforce the scheme and achieve the Bill's objectives. The requirements for personal information to be provided to Queensland Health on application and during the licence term is to ensure that Queensland Health maintains up-to-date information about the personnel involved in the delivery of ART treatment and who are obliged to comply with the requirements in the Bill. This will ensure that only appropriate people can provide ART services in Queensland. It will also enable Queensland Health to undertake prompt and appropriate compliance action in response to risks of harm.

The Bill includes appropriate limitations on the collection, use and publication of personal information. The Bill requires the chief executive to refrain from publishing information on the public register if requested, and the chief executive is satisfied it may endanger the personal safety of a person (clause 65). Queensland Health will handle and use all personal information collected for these purposes securely and only for the purposes of its administration of the Act.

Collection and use of personal information will also remain subject to the requirements of the *Information Privacy Act 2009*, including the Information Privacy Principles that require Queensland Health to make the individual aware of the purpose of the collection of information and its potential disclosure.

Part 2, division 6 (Information collection and record keeping) requires ART providers to collect and retain a range of personal and confidential information about gamete providers, persons undergoing ART procedures, persons born as a result of ART procedures, including donor-conceived persons and the use and storage of gametes and embryos.

Information collection and record keeping are integral to the clinical practice of ART, as outlined in the NHMRC Guidelines. For all providers of gametes and embryos (donated and otherwise), the purpose of these provisions is to ensure a high standard of information collection and record keeping is maintained in order to promote the welfare and interests of people who use ART and the people born as a result of ART procedures.

For all gamete providers, it is essential that their personal information is accurately collected, stored and handled throughout ART treatment. This provides certainty for the intending parents about the origins of the gametes used in their treatment. It also provides certainty for donors that their donated gametes and embryos are being used in compliance with legislation and consistent with their consent.

For people who donate gametes and embryos, additional personal information needs to be collected and kept. The additional information is needed so that intending parents can make decisions about ART treatment in the best interests of themselves, their family and the person who may be born as a result of an ART procedure. Information about offspring of a donor is required in order to enforce the family limits (clause 25) which will protect donor-conceived people from the risks of consanguineous relationships. The information also needs to be collected for the operation of the Register, which will fulfil the rights of donor-conceived people to access information about their genetic heritage.

ART providers must have appropriate systems and processes in place to ensure proper information collection, record keeping and storage. This is required as part of good medical practice to ensure the privacy of patients, but is particularly important in the context of providing ART services, which involve fertility treatment and human reproduction. All medical practices are already required to comply with legislation, guidelines and maintain professional and ethical requirements about patient privacy and comply with privacy principles. Non-compliance by ART providers with requirements about information collection and record keeping may have long-term health and psychosocial impacts for people who use ART and the people born as result of ART procedures. As a result, the Bill includes specific offences for failing to collect or keep records in accordance with the requirements of the legislation which are commensurate with the possible impacts. There are also penalties for destroying records or providing false and misleading information or documents. The penalties for these offences are discussed below.

Part 2, division 7 (Disclosure of health information) permits ART providers and, in limited circumstances, the chief executive to disclose health information about a donor, donor-conceived person or a relative of either, if a registered medical practitioner has certified in writing that it is necessary to make the disclosure to prevent or reduce a serious risk to

someone's life or health or to warn about the existence of a health condition that may be harmful to a person or their descendants.

This circumstance would generally arise where a donor, donor-conceived person or a family member is diagnosed with a serious condition or disease and they want to notify or warn genetic relatives about a risk to their life or health. The person can request their medical practitioner to certify the details of their condition and the possible risks to others. This information can be provided to an ART provider to disclose to genetic relatives, including a donor, donor-conceived person, donor-conceived sibling, a descendant or a parent of a donor-conceived person. The information can also be shared with a person who is pregnant as a result of an ART procedure or a person who has a donated gamete from the same donor in storage with an ART provider.

Given the significant and sensitive nature of the information being shared, the Bill requires the information to be disclosed by a medical practitioner on behalf of the ART provider. This requirement helps to ensure that the person receiving the information is given the necessary support to consider the implications for their health. The Bill also permits the information to be provided to a medical practitioner who is treating the person to whom the disclosure may be made, for example, if they have a regular general practitioner. The Bill also requires a medical practitioner disclosing the information to take reasonable steps to ensure a donor-conceived person does not become aware that they are donor-conceived as a result of the disclosure. This helps to ensure the privacy of a donor-conceived person and their family and ensure that disclosure about their donor-conceived status is not made pre-emptively.

If the ART provider does not disclose the information, but there is a compelling reason to act, the chief executive may disclose the information. The chief executive must be satisfied disclosure is reasonably necessary in the particular circumstances. As this involves the disclosure of sensitive health information, it must be done by a medical practitioner.

The purpose of this provision is to share information in order to prevent or minimise harm and to allow a person to take proactive steps to deal with their health and wellbeing. The inclusion of the provision in the Bill removes ambiguity about how and with whom this information can be shared, providing a clear pathway for donors and donor-conceived persons to share important health information for mutual benefit.

Part 3 of the Bill contains provisions that will impact on a person's right to privacy.

Clause 46 of the Bill compels ART providers with possession or control of information about historical donor conception ART procedures to provide the information to the Register. This will include identifying information about donors, donor-conceived persons or their parent/s, including names, dates of birth, and other information that may be considered personal or confidential. The information must be provided to the Register by the ART provider regardless of whether the person to whom the information relates has consented to its provision to the Register. The operation of this clause will limit the right to privacy of these persons (being donors, parent/s of donor-conceived persons and donor-conceived persons) as their personal or confidential information will be provided to the Register.

Clause 48 of the Bill outlines when and how information on the Register can be accessed by another person. Clause 48 outlines that a donor-conceived person aged 16 years or older will be provided with identifying information (including the donor's name and date of birth) about

the donor upon application, and the consent of the donor is not required for this information to be released. Any donor-conceived person, regardless of when they were conceived and born, will be able to access identifying information about the donor under the framework, if the information is held by the Register. This will limit the right to privacy of donors who donated pre-commencement of the Bill and could not have provided consent to their information being provided to or disclosed by the Register.

The limitation on the right to privacy that will occur through the operation of clauses 46 and 48 of the Bill, particularly the right to privacy of donors who donated before commencement of the Bill, is necessary to achieve the purpose of the establishment and operation of the Register, which is to ensure all donor-conceived people are able to access identifying information about the donor, regardless of when the donor-conceived person was born. The Bill includes safeguards which will mitigate some impact on the right to privacy. A donor's identifying information will only be released without the donor's consent to donor-conceived offspring that apply for the information through the Register. A donor's identifying information will not be released to other applicant groups (for example, parent/s of donor-conceived people) unless the donor consents to release to these applicant groups. A donor's contact information will not be released to any applicant unless the donor has consented to the release.

Post-commencement, the Bill outlines that donors and parent/s of donor-conceived people will be made aware that their information will be collected and provided to the Register, and that donor information will be accessible to donor-conceived offspring once the person turns 16 years of age. The impact on the privacy of donors and parent/s of donor-conceived people post-commencement is therefore expected to be minimal, as donors and parent/s will have consented to this use and disclosure of their information by continuing with the donation (for donors) or the ART procedure using donated gametes (for parent/s).

Donor-conceived people do not have the ability to consent to their information being provided to the Register, and their privacy will be limited by clause 45 which requires ART providers to give relevant information to the Register within three months of becoming aware of the birth of a donor-conceived person. This will include information about the donor-conceived person's name, date of birth and place of birth. Provision of this information to the Register is necessary to assist the Registrar in verifying the identity of a donor-conceived person if they apply to the Register for information upon turning 16 years of age.

The impact on a donor-conceived person's right to privacy is limited, as identifying information about the donor-conceived person (being their name, date of birth, place of birth and the name and location of the ART provider that carried out a donor conception ART procedure) will never be released by the Register unless the donor-conceived person has provided their consent to the release.

The Bill also includes confidentiality provisions which prohibit the unlawful access, use or disclosure of information that is held on the Register (clauses 55 and 140). These clauses are intended to protect the privacy of persons with information held on the Register, as it will be an offence for a person to access, use or disclose confidential or private information that is held on the Register, unless it is permitted by law.

Clause 61 requires licensed ART providers to notify Queensland Health of serious adverse events (expected to be prescribed in regulation or licence conditions as events such as patient hospitalisation as a result of a complication of ART treatment or a mix-up of gametes) within

a specified time. These notifications may include disclosure of personal and medical information of patients or service providers. The purpose of this provision is to enable Queensland Health to proactively monitor current and emerging risks to the community from ART treatments and access to this data will enable targeted compliance action if needed to support the objectives of the Bill.

Clause 140 requires the chief executive, staff and contractors of Queensland Health as well as the Registrar of Births, Deaths and Marriages and their staff and contractors to maintain confidentiality of information obtained in administering or performing functions under the Bill. The Bill makes it an offence to disclose confidential information with a maximum penalty of 50 penalty units. The provision allows use or disclosure of confidential information in limited and appropriate circumstances, including to perform functions or exercise powers under the Bill, with the consent of the person to whom the information relates, or to the extent permitted by law. Confidential information can also be disclosed to a coroner investigating a person's death or a law enforcement agency. Information may also be disclosed to certain health bodies or entities, such as National Health Practitioner Boards, Australian Health Practitioner Regulation Agency, Queensland's Health Ombudsman and an entity established under the *National Health Act 1953* (Cth).

However, the Bill includes a limitation that confidential information may only be disclosed to these entities if the person disclosing the information is satisfied the disclosure is reasonably necessary for the entity to exercise its functions. This clause also enables the disclosure of confidential information to regulatory bodies for ART services in other Australian and overseas jurisdictions, which may include information about the compliance history of licensed ART providers. The ability to disclose relevant information to other regulatory bodies and law enforcement will enhance the overall safety and oversight of ART services. This is necessary in the Australian context where many ART providers offer services across state and territory borders, and some patients may travel interstate to access treatment.

The Bill provides safeguards to mitigate breaches of privacy including requirements that confidential information is kept confidential and ensure there are protections for people who use ART services or are born as a result of ART procedures. These provisions are considered justified, as appropriate protections are in place to minimise the disclosure of confidential information and deter unauthorised disclosure. The provisions are necessary to ensure the chief executive of Queensland Health can perform their functions under the Bill and ART providers can fulfill their ethical and clinical practice requirements.

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

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

The Bill regulates the business of providing ART services by mandating certain aspects of how the business may be carried on – for example, by requiring ART providers to provide persons undergoing ART procedures and donors with certain information (clause 14), provide counselling services to persons undergoing ART procedures using donated gametes (including the person's spouse) and to people who donate gametes or embryos (clause 15), and obtain a person's consent to certain ART procedures or services and use of gametes and embryos

(clauses 16 to 19). It prohibits ART providers using ART services for sex selection (clause 24) and limits the number of donor-related families from a single donor (clause 25).

These requirements recognise that decisions to undertake ART treatments, particularly those involving donor gametes and embryos, have the potential to have lifelong impacts on people's lives and relationships. The requirements about these issues in the Bill help to protect the welfare and interests of people accessing ART services and those born as a result, as well as donors to ensure the appropriate use of donor gametes and embryos.

The requirements for ART providers to give information to those undertaking ART procedures allows patients and their families to make informed decisions about ART treatment. The additional information that must be disclosed for services involving donor conception reflects the added complexity of those arrangements. These requirements are consistent with the NHMRC Guidelines, which ART providers must already comply with.

The requirement to undertake counselling before donor treatments is also consistent with the NHMRC Guidelines. It is critical that patients, families and donors are informed about the implications of their decisions and equipped with skills to manage the impacts. The counselling process is intended to complement discussions with their treating fertility specialist.

Obtaining a person's consent is a critical and significant part of undertaking good medical practice. However, it is particularly important in the case of fertility treatment, ART procedures and donor conception arrangements which have lifelong implications. It helps to ensure the safety and welfare of those undergoing ART treatment, as well as people born as a result, also ensuring donors are aware of the implications of donating gametes and embryos.

The Bill's prohibition on the use of ART services for sex selection is consistent with the NHMRC Guidelines, which were updated in 2017 through the Australian Health Ethics Committee after two rounds of public consultation. The Bill provides a limited exemption for sex selection on medical grounds. Sex selection of embryos is permitted when necessary to avoid transmission of a genetic abnormality or disease to a child (clause 24(2)).

The inclusion of a family limit in the Bill protects donor-conceived persons from the risk of consanguineous relationships and the psychosocial impacts of having many siblings. It reflects requirements of the NHMRC Guidelines, which provide that clinics must take reasonable steps to minimise the number of families created through donor conception.

The Bill generally aligns with the existing requirements of the NHMRC Guidelines so is not expected to have a significant impact on the operations of businesses. However, giving these requirements legislative status will ensure Queensland Health can monitor and enforce non-compliance, helping to ensure the protection of those accessing fertility treatments and a consistent standard for the industry.

Does the legislation include offence provisions?

Whether legislation has sufficient regard to the rights and liberties of individuals requires consequences such as new offences are appropriate and reasonable. This includes ensuring penalties for offences are proportionate and relevant to the offence. The Bill contains a range of offence provisions, including offences about consent and provision of information, licensing, prohibited uses of gametes and embryos and record keeping.

A considered approach was undertaken when determining the proposed penalty for each offence provision. Each proposed penalty was assessed to ensure it is commensurate with the nature of the offence and the harm that may be caused from breaches. Consideration was also given to penalties in other comparable health legislation and interstate ART legislation.

Consent and provision of information

The Bill includes the following offences and penalties that apply relating to the provision of information and consent before any ART service, or provision of gametes is undertaken:

- clause 14: ART provider does not give information before providing ART treatment (200 penalty units);
- clause 15: Not providing mandatory counselling to people in donor conception programs (50 penalty units), or making counselling services available to a person seeking ART services (25 penalty units); and
- clause 16: Not obtaining consent from a gamete donor or person seeking ART (200 penalty units).

These offences and penalties recognise the potential for ART treatment to have life-changing effects for all people involved. Informed consent, based on the provision of accurate information and counselling (where applicable) are foundational elements of ART treatment that are necessary to ensure people accessing ART services understand all the potential impacts, including financial, medical, emotional, psychological, and familial. The main objects of the Bill are to protect the welfare and interests of people who use ART and people born as a result of ART.

Licensing and enforcement

The Bill includes the following offences and penalties that apply as part of the licensing scheme:

- clause 12: offence to operate without a licence (200 penalty units or two years imprisonment or both);
- clause 13: ART services must be undertaken or supervised by a registered medical practitioner (400 penalty units or two years imprisonment or both);
- clause 61: offence to not notify the chief executive of certain events (for example, change of address, change to RTAC accreditation, and change to key personnel working at a clinic) (50 penalty units, or 100 penalty units for a serious adverse event);
- clause 91: offence to not give reasonable help to the inspector, if the person is asked to assist, unless the person has a reasonable excuse (50 penalty units);
- clauses 97 and 98: offence to contravene a seizure requirement or interfere with a seized thing (50 penalty units);
- clauses 107, 109, 110, and 112: offences to not answer questions or give information requested by the inspector, unless the person has a reasonable excuse (50 penalty units);
- clauses 116 and 117: offences to obstruct an inspector, or impersonate an inspector (50 penalty units); and
- clause 76: failure to return identity card (10 penalty units).

These offence provisions are necessary to ensure the effective operation of the licensing framework. The offence provisions compel compliance with the requirements to notify the chief executive of particular events occurring, to ensure Queensland Health's ability to oversee ART providers and services and address non-compliance or adverse events promptly. The offences relating to the inspector provisions ensures effective enforcement of the Bill.

Prohibited use of gametes and embryos

The Bill includes the following offence and penalties that prohibit certain uses of gametes and embryos, regulate the number of families that can be created from a single donor as well as storage, transfers and export of gametes and embryos:

- clause 22: prohibition on using gametes from family members (400 penalty units or two years imprisonment or both);
- clause 23: prohibition on obtaining a gamete from a child or young person or providing an ART procedure to a child (400 penalty units or two years imprisonment or both);
- clause 24: prohibition on sex-selective ART procedures (240 penalty units or two years imprisonment or both);
- clause 25: offence to breach family limit (400 penalty units or two years imprisonment or both) and for an ART provider to not provide another ART provider with information relevant to determining the number of families (200 penalty units);
- clause 26: unauthorised use of a gamete after the death of the gamete provider (200 penalty units), and not taking reasonable steps to determine if a gamete provider for a gamete obtained more than five years ago is still alive (100 penalty units); and
- clause 27: unauthorised use of a donated gamete or embryo after 15 years (100 penalty units).

In developing these offences and penalties, consideration has been given to the serious and long-lasting potential effects from these breaches. The offences and penalties relating to the use of gametes from family members, children, sex selection and family limit attract higher penalty units to acknowledge the seriousness of the potential impacts. This also reflects the main objects of the Bill, which are to protect people seeking ART and people born as a result of an ART procedure.

Record keeping and donor conception information register

The Bill includes the following offences and penalties about record keeping:

- clauses 33 and 35: offence to not collect information about gamete providers or people provided with ART procedures (200 penalty units);
- clause 34: offence to not provide or obtain relevant information about gamete providers when transferring gametes between ART providers (200 penalty units);
- clause 36: offence to not keep a record of information collected for 99 years (200 penalty units);
- clause 37: offence to destroy records, including historical records (400 penalty units);
- clauses 45 and 46: offences to not provide information to the Registrar (100 penalty units);
- clause 46: failure to comply with a notice of the Registrar (100 penalty units);
- clause 54: failure to comply with a notice in relation to an inquiry by the Registrar (50 penalty units); and

- clause 55: unauthorised access to or interference with the Register (100 penalty units).

These offences and penalties reflect the importance of maintaining ART records as part of good clinical practice and noting that these records can have direct impacts in particular on donor-conceived persons and their ability to know about their genetic history.

The offence to destroy records, including historical records, attracts a maximum penalty of 400 penalty units. This reflects the seriousness of this offence and that any such destruction would be deliberate and have permanent effects.

Information provisions

Within part 8, the Bill includes the following offence and penalty provisions about information requirements.

Clause 139 makes it an offence to provide false and misleading information with a penalty of 100 penalty units. Clause 140 makes it an offence to disclose or use confidential information with a penalty of 50 penalty units. Both clauses have a number of exceptions.

The above offence and penalty provisions are considered necessary to ensure the privacy of persons is safeguarded under the Bill. A considered approach was undertaken when determining the proposed penalty unit amount for each offence provision. Under this approach, each proposed penalty unit amount was assessed to ensure it is commensurate with the nature of the offence and the harm that may arise from a breach.

These offence provisions are necessary to compel compliance with the requirements to appropriately handle confidential health information, and to allow disclosure of confidential information as required.

Donor Conception Information Register

Part 3 of the Bill includes the following offences and penalties that apply to the provision of information to the Register by ART providers or other entities:

- Clause 45: ART provider failing to provide relevant information to the Registrar within three months of becoming aware of the birth of a child as result of a donor conception ART procedure carried out by the ART provider (100 penalty units);
- Clause 46: ART provider failing to provide relevant information or details on the location of relevant information about an ART procedure using a donated gamete carried out by the provider or entity that resulted in the birth of a child before commencement of the provision within six months of commencement of the provision (100 penalty units); and
- Clauses 46 and 54: ART providers failing to comply with a notice from the Registrar seeking relevant information within a specified timeframe (100 penalty units for clause 46 and 50 penalty units for clause 54).

These offences and penalties are intended to recognise the importance of ensuring the Register holds all relevant information about donor conception ART procedures that have been and are carried out by ART providers in Queensland. Thorough collection and timely provision of this information to the Registrar by ART providers is critical to ensure the Register holds all

relevant information. The provision also provides the Registrar with the ability to seek relevant information from ART providers, if required. The offences and associated penalties are intended to promote compliance with the relevant provisions to ensure the Register holds information that is accurate and complete, and that donor-conceived people are able to access this information about the donor.

Clause 55 (Unauthorised access to or interference with the Register) makes it an offence to unlawfully access, alter, delete, or interfere with information held on the Register, or to use or disclose any information that has been unlawfully obtained from the Register. The maximum penalty is 100 penalty units. The Register is intended to operate as a source of important information for donor-conceived people and others, including donors and parent/s of donor-conceived people. It is therefore important that the general public can trust the integrity of information that is held on the Register. In addition, protection of the privacy of individuals who are involved in donor conception ART procedures or born as a result of these procedures is integral to provide confidence in the establishment and operation of the Register. The offence and associated penalty are necessary to deter individuals from unlawfully accessing or interfering with information on the Register.

The provision makes it in an offence to unlawfully access, alter, delete, or interfere with information held on the Register, or to use or disclose any information that has been unlawfully obtained from the Register. The Register is intended to operate as a source of important information for donor-conceived people and others, including donors and parent/s of donor-conceived people. It is therefore important that the general public can trust the integrity of information that is held on the Register.

Whether the legislation has sufficient regard to the institution of Parliament (*Legislative Standards Act 1992*, s 4(2)(b))

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

Regulation-making power

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

Clause 143 of the Bill provides that regulations may be made under the Bill. A regulation may prescribe the fees payable under the Bill; the waiving of payment or refund of a fee payable; and provide for a maximum of 20 penalty units for a contravention of the regulation.

There are also several clauses throughout the Bill that enable a regulation to prescribe further requirements or definitions in addition to matters that are prescribed in the Bill, such as:

- the definition of ART procedure (clause 5), where in addition to the definition in the Bill a regulation may prescribe a related treatment or other procedure as an ART procedure;
- information to be provided to persons, in addition to the information listed in the Bill (clause 14);
- consent requirements, including the circumstances in which a gamete provider's consent is not required to be confirmed (clause 17) and what the consent of a gamete provider must

include (clause 18), what stages a person undergoing an ART procedure must consent to (clause 19);
- information to be collected about gametes and donated gametes in addition to that prescribed in the Bill (clause 33);
- records that must be kept by ART providers in addition to those prescribed in the Bill (clause 36);
- information or documents in addition to those prescribed in the Bill for licence applications (clause 58); and
- classes of person who can be appointed as inspectors, in addition to health service employees and public sector employees (clause 70).

Additionally, some provisions provide that detailed requirements may be prescribed in regulation, with the Bill not covering the requirements, such as:

- matters to be covered in counselling, the qualifications of counsellors, and the charging of fees and other requirements relating to counselling (clause 15);
- the qualification of any independent body deciding on posthumous use of a gamete (clause 31); and
- limitations on the powers of inspectors (clause 71).

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

- the matters to be prescribed are consistent with the policy objectives and purpose of the Bill;
- most matters to be prescribed are technical in nature and relate to the operational and clinical aspects of the Bill;
- this will allow the Government to respond promptly and flexibly if changes are needed to the framework in future, ensuring the scheme can be managed appropriately. Some flexibility for Queensland Health to be able to update requirements relating to technical, clinical matters, such as the specific additional information people should be provided with before undergoing ART, is considered appropriate; and
- the matters relating to fees are administrative in nature and subject to change.

Additionally, the ability to prescribe other classes of people as inspectors is consistent with the approach taken in other licensing schemes administered by Queensland Health.

ART is an evolving field, due to advances in underlying scientific knowledge, changes in service delivery models, societal and clinical expectations and the adoption of new technology. As new practices emerge and technology changes, there could be changes in the ART services provided by ART providers. Allowing a regulation to prescribe the operational detail ensures that there is flexibility to address these changes in a considered yet efficient way.

This is consistent with other regulatory practices for ART. The NHMRC specifically states that the ethical guidelines are subject to rolling review, meaning that parts of the NHMRC Guidelines are updated as required, rather than a whole-of-document review at any specific point in time. For example, the NHMRC Guidelines were most recently updated in 2023 to support the ethical introduction of mitochondrial donation into ART in Australia, along with minor administrative updates to the 2017 guidelines.

If a regulation is made for any of these matters, it will be tabled in Parliament and subject to disallowance, ensuring Parliament has appropriate oversight of the matters dealt with by regulation.

Consultation

Queensland Health conducted two rounds of consultation on the regulation of ART providers, in February and April 2024.

In February 2024, written feedback on the proposed legislative framework was sought through a public consultation paper from stakeholders including ART providers, professional organisations, peak bodies, colleges, industry auditors, community groups, researchers, gamete and embryo donors, donor-conceived people, recipient parents and people who have accessed ART services. Some of the stakeholders that provided feedback included: Donor Conceived Australia; Australian Medical Association Queensland; Fertility Society of Australia and New Zealand; NHMRC; Queensland Nurses and Midwives' Union; Australia and New Zealand Infertility Counsellors Association; Royal Australian and New Zealand College of Obstetricians and Gynaecologists; Royal Australian College of General Practitioners; Queensland Law Society; and Rainbow Families Queensland.

Queensland Health also held two information sessions for industry and other stakeholders, focus group sessions with members of the donor-conceived community and people who have accessed ART services, and targeted stakeholder meetings.

Stakeholders broadly expressed support for the proposed Bill, with some stakeholders citing greater oversight and transparency of the industry, safeguards for consumers and prohibition of unacceptable ART practices as benefits. A number of stakeholders expressed the need for better protections for donor-conceived people, including support for the imposition of a family limit in the use of donor gametes to ensure a reduction in the risk of consanguineous relationships and psychosocial impacts of large numbers of genetic siblings.

Some ART providers expressed concerns that state-based regulation would result in duplication with existing national requirements and noted the impacts this would have on their resourcing – particularly to update internal systems and ensure compliance with licensing requirements. Some ART providers highlighted the need for a focus on affordability of ART services when designing legislation, stating that costs relating to regulatory changes would likely be passed on. Some providers also expressed the need to focus on patient autonomy to make decisions about their healthcare and not to unnecessarily impose additional barriers on access to ART services.

In April 2024, Queensland Health and the Department of Justice and Attorney-General hosted two targeted half day consultation sessions to brief stakeholders on the proposed Bill. The sessions were attended by ART providers and clinicians, peak bodies, representative groups, national bodies, community groups, fertility psychologists and counsellors, legal specialists and researchers. A number of targeted stakeholder meetings were also held.

Stakeholder groups provided additional feedback on particular aspects of the proposed framework, with feedback considered during drafting of the Bill, including:

- a number of stakeholders raised the need for the Bill to make clear that the welfare and interests of people who are born as a result of ART are of paramount importance. This has been reflected in the Bill;
- feedback on the current clinical approach to obtaining and managing patients' and gamete providers' consent;
- in relation to the proposed streamlined approach for posthumous retrieval and use of gametes, it had initially been proposed to provide for the Supreme Court to authorise the use of gametes retrieved posthumously, in line with similar provisions in the Australian Capital Territory. Stakeholders raised concerns about the considerable administrative burden this would place on the deceased person's spouse to seek approval to use the gametes. As a result, the Bill was updated to require this authority to be provided by an independent review body, consistent with the approach in the NHMRC Guidelines; and
- in relation to the requirement for ART providers to notify Queensland Health of key events, feedback was provided by industry that if notification timeframes were overly short, this would create an unnecessary administrative burden with little added benefit. As a result, the timeframes for reporting events were refined, and strike an appropriate balance between ensuring that Queensland Health has oversight of ART providers and is notified in a timely fashion of key events, and not placing an undue burden on clinics.

The LAS Committee undertook extensive consultation to prepare its Report. The LAS Committee received 71 written submissions and held a public hearing on 13 May 2022 attended by 17 individuals and organisations. All stakeholders who provided written submissions (except one) supported the establishment of a Register. Submissions from donor-conceived people and recipient parents were supportive of a retrospective Register, while the Office of the Information Commissioner and some ART stakeholders raised concerns about impacts on privacy.

Stakeholders including donor-conceived advocacy groups, ART providers, and relevant peak healthcare bodies were also consulted on a confidential basis during the development of the legislation. Stakeholder feedback from this consultation process was considered and incorporated into the Bill where appropriate.

Consistency with legislation of other jurisdictions

State-based framework to regulate ART services

Commonwealth legislation regulates human cloning and associated human reproductive technology research practices but does not regulate the practice of ART, beyond requiring clinics to be accredited. Regulating ART lies with the state and territory governments. ART legislation governing the regulatory requirements is relatively similar across all Australian jurisdictions that have introduced it.

In determining an appropriate ART licensing scheme and regulation framework for Queensland, regard was given to the legislation of other jurisdictions. Five Australian jurisdictions have ART legislation in place:

- **Australian Capital Territory** (ACT): *Assisted Reproductive Technology Act 2024*;
- **New South Wales** (NSW): *Assisted Reproductive Technology Act 2007*;
- **South Australia** (SA): *Assisted Reproductive Treatment Act 1988*;

- **Victoria**: *Assisted Reproductive Treatment Act 2008*; and
- **Western Australia** (WA): *Human Reproductive Technology Act 1991*.

These jurisdictions also regulate ART providers through registration or licensing schemes. The architecture of the schemes is broadly similar, regulating areas including access to ART services, use of gametes and embryos, posthumous retrieval and use of gametes, information sharing and record keeping.

The Bill brings Queensland into line with most other Australian jurisdictions by establishing a licensing scheme to regulate ART providers.

Donor Conception Information Register

Victoria, NSW, South Australia, WA and the ACT have legislation in place that provides for the establishment and operation of donor conception information Registers. There is some variation between models, primarily relating to access to historical information. The Queensland model is most similar to the Victorian and South Australian models, which are both wholly retrospective. The ACT Register will initially operate prospectively, with the establishment of a retrospective Register proposed following community and stakeholder consultation. The Registers in WA and NSW operate prospectively from 1 December 2004 and 1 January 2010 respectively.

The legislative approaches in other jurisdictions were considered in the drafting of this legislation. Lessons and insights from these jurisdictions were used to develop legislation that best supports the interests and wellbeing of all donor-conceived people and their families.

Birth certificate addendum

The legislation in Victora, NSW and SA were considered when developing the legislative approach in Queensland. The birth certificate addendum model is broadly consistent with the approaches in Victoria and NSW.

In Victoria, the Registrar-General of the Victorian Registry of Births, Deaths and Marriages may issue a birth certificate to a donor-conceived person which attaches an addendum stating that further information is available about the entry. The addendum must only be provided to the donor conceived person.

In NSW, a birth certificate issued to a donor-conceived person must attach an addendum noting a declaration that the person was conceived using a donated gamete and stating that further information may be available from the Central Register. The birth certificate itself must not include any reference to a person being donor conceived.

Notes on provisions

Part 1 Preliminary

Short title

Clause 1 states that the short title of the Act will be the *Assisted Reproductive Technology Act 2024*.

Commencement

Clause 2 provides that the following provisions will commence on a day to be fixed by proclamation:

- part 2, divisions 1 to 3;
- sections 25 to 31;
- part 3;
- part 4;
- part 6, divisions 1 to 4;
- sections 145 to 149 and 151;
- part 10, division 3.

Objects of Act

Clause 3 provides the main objects of the Act are to:

- protect the welfare and interests of people who use assisted reproductive technology (ART);
- protect the welfare and interests of people who are born as a result of ART;
- regulate the use of ART;
- provide and regulate access to information relating to people born as a result of ART.

Clause 3(2) states the welfare and interests of people who are born as a result of ART are, throughout their lives, of paramount importance in the administration and operation of the Act.

The objects of the Bill reflect the need to provide robust protections for people affected by the use of ART, and in particular people born as a result of ART, for whom the impacts may be life-long.

The object to regulate the use of ART reflects the need to ensure greater oversight and transparency of Queensland's ART industry, and to ensure safeguards are in place, including prohibitions on unacceptable ART services.

The object to regulate access to information about people born as a result of ART is primarily focussed on the establishment of the donor conception information register (register) and the requirement for the provision of information by ART providers. This aims to balance the need for privacy and transparency while prohibiting donor anonymity.

Definitions

Clause 4 provides that definitions for particular words used in this Act are in the dictionary in schedule 1.

Meaning of *ART procedure* and *undergoing ART procedure*

Clause 5 provides the meaning of an *ART procedure*. An ART procedure is:

- any medical treatment or other procedure that procures or attempts to procure, pregnancy in a person other than by sexual intercourse; or
- a related treatment or other procedure prescribed by regulation.

Examples of ART procedures include artificial insemination, in-vitro fertilisation and gamete intrafallopian transfer.

An ART procedure does not include self-insemination, which is separately defined in schedule 1 to mean artificial insemination not performed or supervised by a licensed ART provider. However, the provisions in part 3 of the Act relates to the register extend to self-insemination.

Clause 5(3) states the person who *undergoes* an ART procedure is the person who becomes or seeks to become pregnant as a result of the procedure.

Meaning of *ART service*

Clause 6 defines an *ART service* as any of the following provided for fee or reward, or in carrying on a business (whether or not for profit):

- an ART procedure;
- the storage of gametes or embryos for use in an ART procedure;
- obtaining a gamete from a gamete provider for use in an ART procedure.

Meaning of *ART provider*

Clause 7 defines an *ART provider* as a person who provides an ART service. An ART provider does not include a person who provides an ART service on behalf of a licensed ART provider under a contract of employment or a contract for services.

Meaning of *gamete* and *embryo*

Clause 8 defines a *gamete* as a human sperm or human egg, and includes any human cell that has resulted from a process of meiosis and any tissue containing the cell.

Clause 8(2) defines an *embryo* as a discrete entity that:

- has arisen from either:
  - the first mitotic division when fertilisation of a human egg by a human sperm is complete; or

  - any other process that initiates organised development of a biological entity with a human nuclear genome or an altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and
- has not yet reached 8 weeks of development since the first mitotic division.

Clause 8(3) clarifies that in working out the length of the period of development of an embryo for subsection (2)(b), any period when the development of the embryo is suspended is to be disregarded.

Meaning of *donated gamete* and *donated embryo*

Clause 9 defines a *donated gamete* as:

- a gamete donated by a gamete provider for use by someone other than the gamete provider or any spouse of the gamete provider; or
- a gamete used to create a donated embryo, whether or not the gamete was originally obtained from the gamete provider as a donated gamete or the embryo was originally created for use as a donated embryo.

Clause 9(2) defines a *donated embryo* as an embryo donated after its creation for use by someone other than the gamete provider from whom a gamete used to create the embryo was obtained or any spouse of the gamete provider.

Clause 9(3) states that a donated gamete *used* in an ART procedure includes a donated gamete that is used to create an embryo used in the procedure.

Clause 9 provides that under these definitions, a gamete that was not obtained as a donated gamete and is used to create an embryo becomes a donated gamete if the embryo is an excess embryo that later becomes a donated embryo.

Application of other legislation

Clause 10 states that the Act does not limit or otherwise affect the operation of any of the following:

- the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*;
- the *Surrogacy Act 2010*;
- the *Status of Children Act 1978*;
- the *Public Health Act 2005.*

Act binds all persons

Clause 11 provides that the Act binds all persons, including the State and, to the extent the legislative power of the Parliament permits, the Commonwealth and the other States. However, the State, the Commonwealth or another State cannot be prosecuted for an offence against this Act.

Part 2 Regulation of assisted reproductive technology

Division 1 ART providers to be licensed

Requirement to be licensed

Clause 12 states a person must not provide an ART service unless the person is a licensed ART provider. The maximum penalty for non-compliance with this provision is 200 penalty units or 2 years imprisonment.

Clause 12(2) states a person must not advertise or hold themselves out to be a licensed ART provider unless the person is a licensed ART provider. The maximum penalty for non-compliance with this provision is 200 penalty units or 2 years imprisonment.

Services to be performed or supervised by medical practitioners

Clause 13 states an ART provider must ensure that any ART services provided by the ART provider are performed by, or under the supervision of, a medical practitioner. The maximum penalty for non-compliance with this provision is 400 penalty units or 2 years imprisonment.

Division 2 Information and counselling

Information for persons provided with ART services

Clause 14 states that an ART provider must provide people intending to undergo an ART procedure and gamete providers, including gamete donors, with relevant information and confirm that the person has understood the information before providing an ART service. This requirement reflects the need to ensure people make informed decisions before accessing ART services.

For a person undergoing an ART procedure using their own gametes or embryos, or a person providing their gametes other than as donated gametes (that is, for their own use or use by their spouse), the ART provider is required to inform the person of basic matters.

Clause 14(2) defines *basic matters* as the availability of counselling services in accordance with section 15; the effect of a gamete provider's consent under division 3, including how and when consent may be modified or withdrawn; and any other matter prescribed by regulation. This will ensure that a person seeking to undergo ART using their own gametes or embryos, or a gamete provider seeking to provide their gametes for their own use, are advised of the availability of counselling services and have the requirements relating to consent explained to them.

For a person undergoing an ART procedure using donated gametes or embryos; a person providing their donated gametes or embryos; or a person who has already provided their gametes, other than as donated gametes (that is, a person who has previously provided their gametes for their own use and has since decided to donate the gametes for use by someone else), the ART provider is required to inform the person about extended matters.

Clause 14(2) defines *extended matters* as the provision of counselling services in accordance with section 15; the effect of a gamete provider's consent under division 3, including how and when consent may be modified or withdrawn; the ART provider's obligations to collect, keep and disclose information about the person and their donor-conceived offspring; the rights of the person, their donor-conceived offspring or other persons to obtain information from the register; and any other matter prescribed by regulation. This reflects the fact that entering into a donor conception arrangement carries with it significant and complex considerations that all parties involved should be aware of before proceeding, including the requirement for mandatory counselling and the effect of the register.

The maximum penalty for non-compliance with this provision is 200 penalty units.

The Bill is intended to set the minimum standard of information that should be provided to people. In practice, ART providers should be providing much more information so that people understand the impacts, risks and benefits of ART from a holistic perspective. This includes information about clinical matters such as the evidence base of procedures (including add-ons), cost, timeframes and success rates. This reflects that patient involvement in decision making is central to person-centred care to ensure treatment reflects a patient's values and preferences.

Counselling services for persons provided with ART services

Clause 15 provides that counselling must be provided or made available for people involved in ART, depending on the particular situation.

Clause 15(1) states that an ART provider must provide counselling services to a person and their spouse (if applicable) proposing to undergo an ART procedure using donated gametes or a donated embryo and to a person proposing to donate a gamete or donate an embryo. To remove any doubt, this also includes a person who previously provided their gametes for their own use but is now seeking to donate their gametes. The maximum penalty for non-compliance with this requirement is 50 penalty units.

Clause 15(2) states an ART provider must provide counselling services under this section:

- to a person proposing to undergo an ART procedure that uses donated gametes or a donated embryo and to any spouse of that person; and
- if a surrogate proposes to undergo an ART procedure that uses donated gametes or a donated embryo – to the intended parents.

The maximum penalty for non-compliance with this requirement is 50 penalty units.

Clause 15(3) states that an ART provider must make counselling services available to a person proposing to undergo an ART procedure using their own gametes or embryos, as well as the person's spouse (if applicable). The maximum penalty for non-compliance with this requirement is 25 penalty units. In this situation, there is nothing requiring the person and spouse (if applicable) to use the counselling services offered to them.

The counselling services must be provided or made available before the ART procedure is carried out or before the gamete or embryo is donated, depending on the circumstances.

Clause 15(5) provides that a regulation may prescribe the matters about which counselling is to be provided, the required qualifications for counsellors, the charging of fees for counselling services or any other requirements relating to counselling services.

Counselling is an important part of many people's ART experience, particularly those involved in donor conception programs. ART may involve significant and complex decisions and professional counsellors can help to support people in their decision making. The intent of the requirements is to assist people to make informed decisions and is not intended to hinder or prevent access to ART.

It is intended that counselling is provided by professionals with the appropriate training, skills, experience and competency while also allowing people to choose their own counsellor. For example, a person may seek to use an independent counsellor, particularly if they have an existing relationship with a counsellor.

Counselling should provide an opportunity to discuss and explore issues; explore personal and social implications for the individual, couple and person to be born as a result of ART; provide personal and emotional support and advice about additional supports to ensure people make informed decisions about ART services. It also provides opportunities to discuss the unique considerations for individuals and couples involved in donor conception programs.

Division 3 Consent

ART provider to obtain consent

Clause 16 provides that an ART provider must not do anything where the consent of a person is required under division 3 unless it is done with the prior written consent of the person and in a way that is consistent with that consent. The maximum penalty for non-compliance with this provision is 200 penalty units. This provision reflects the importance of ensuring a person's written consent is obtained prior to any ART services being provided.

Consent of gamete provider except in case of donated gametes or donated embryos

Clause 17 sets out requirements for obtaining the consent of gamete providers who are not donors, that is, people who are proposing to provide their gametes for their own (or their spouse's) use.

The following require the gamete provider's consent:

- use of a gamete obtained from the gamete provider in an ART procedure;
- the period of time an ART provider may store a gamete obtained from the gamete provider or an embryo created with the gamete provider's gamete;
- supply to another person (including to another ART provider) of a gamete obtained from the gamete provider or an embryo created with the gamete provider's gamete;
- export from Queensland of a gamete obtained from the gamete provider or an embryo created with the gamete provider's gamete.

Clause 17(2) clarifies that the consent of a gamete provider is not required for anything that is authorised under division 5, which relates to retrieval and use of gametes from deceased or unresponsive persons. Division 5 includes a separate authorisation process.

Clause 17(3) provides that the gamete provider's consent expires if it has been 5 years since the gamete provider's consent was given or was last confirmed under section 17; and an ART provider has not confirmed that consent. This is intended to ensure that a person's consent remains current.

However, clause 17(4) clarifies that a gamete provider's consent to use their gamete after their death does not expire after they die.

Clause 17(5) sets out how ART providers are expected to confirm a gamete provider's consent. A gamete provider's consent is taken to be confirmed if:

- the ART provider receives written confirmation by the gamete provider of their consent; or
- the ART provider has taken reasonable steps to confirm the consent. Reasonable steps are intended to include genuine steps to contact the person. At minimum, this should include attempting to contact the person by more than one method of communication such as via email and phone and following up with a phone call and email if the first attempt at communication is not successful.

Clause 17(6) states that an ART provider is not required to confirm a gamete provider's consent if the ART provider knows or reasonably believes that the gamete provider has died or in any other circumstances prescribed by regulation.

Clause 17(7) provides in relation to a child that a parent or person with parental responsibility for the child may consent, or confirm consent, on behalf of a child under their care.

Consent of gamete provider in case of donated gametes or donated embryos

Clause 18 sets out requirements for obtaining the consent of gamete providers who donate their gametes or embryos (that is, donors). It provides that the donor's consent is required to use their donated gamete, or a donated embryo created with the donor's gamete, in an ART procedure.

Clause 18(2) provides that the donor's consent must include:

- the maximum number of families that may use the donated gametes or donated embryos within the legislated limit imposed by section 25; and
- the maximum period within the legislated limit imposed by section 27 for which the donated gametes or donated embryos may be stored for use; and
- any other matter prescribed by regulation.

Clause 18(3) clarifies that a donor's consent cannot limit the use of the donated gamete or donated embryo in an ART procedure on the basis of a protected attribute of the persons who are provided with ART services. *Protected attribute* is defined to mean an attribute on the basis of which the *Anti-Discrimination Act 1991* prohibits discrimination. For example, a donor must not state that their gamete may be used only in the provision of an ART procedure to a married

person or to a person of a particular ethnicity. This provision is intended to prevent discrimination and inequity in access to ART services that use donated gametes. It is not intended to prevent known donations, in which the donor specifies a recipient that they know personally. This approach is consistent with the current NHMRC Guidelines, which states that clinics must not accept donations from donors who wish to limit their donation to specific ethnic or social groups.

Consent of person undergoing ART procedure

Clause 19 requires an ART provider to obtain the consent of a person undergoing an ART procedure.

Clause 19(2) states that a regulation may require consent for different cycles or other stages of an ART procedure.

Withdrawal or variation of consent

Clause 20 provides that a gamete provider may modify or withdraw their consent at any time until:

- for a donated gamete (other than a gamete that becomes a donated gamete only after being used to create an embryo) – the gamete is placed in a person's body or an embryo is created from the gamete; or
- for a gamete used to create a donated embryo – the embryo is implanted in a person's body; or
- in any other case (such as a person seeking an ART procedure using their own gametes or embryo) – the gamete, or an embryo created from the gamete, is placed or implanted in a person's body.

Clause 20(2) provides that a gamete provider may modify or withdraw their consent by written notice to an ART provider who is, or has been, in possession of the gamete or embryo to which the consent relates.

Clause 20(3) states if an ART provider receives notice of the modification or withdrawal of a gamete provider's consent relating to a gamete or an embryo that has been transferred to another provider, it must give the other provider written notice of the modification or withdrawal as soon as practicable. The maximum penalty for non-compliance with this provision is 200 penalty units.

Clause 20(4) states that the consent of a person to an ART procedure may be modified or withdrawn at any time before the procedure is carried out.

Verification of identity of gamete provider

Clause 21 provides that the relevant ART provider is required to take reasonable steps to verify the identity of the person purportedly giving, modifying or withdrawing consent as a gamete provider in accordance with division 3.

Division 4 Use of gametes and embryos

Use of gametes from close family members prohibited

Clause 22 states that an ART provider must not use a gamete to create an embryo if the provider knows that the gamete provider is a close family member of the other person whose gamete is used to create the embryo. The maximum penalty for non-compliance with this provision is 400 penalty units or 2 years imprisonment.

Clause 22(2) defines *close family member* as a parent, child, sibling (including half-sibling), grandparent or grandchild of the person from birth.

The intention of this provision is to avoid family members' gametes being used to create an embryo. It is not intended to limit other situations like a family member carrying another family's member child (such as a person carrying their sibling's child) or a family member donating gametes for use by another family member (such as a sibling donating egg or sperm to create an embryo with their sibling's partner).

ART services for children prohibited

Clause 23 provides that an ART provider must not carry out an ART procedure if the person undergoing the procedure is a child or obtain a gamete from a child for use in an ART procedure. The maximum penalty for non-compliance with this provision is 400 penalty units or 2 years imprisonment.

Clause 23(2) provides an exception to the general prohibition on obtaining a child's gamete if a medical practitioner has certified that there is a reasonable risk of the child becoming infertile before becoming an adult and the ART provider obtains the gamete for the purpose of storing it for the child's future use.

Sex selection prohibited

Clause 24 states that an ART provider must not use a particular gamete or embryo, or carry out an ART procedure in a particular way, for the purpose of producing or attempting to produce a child of a particular sex. The maximum penalty for non-compliance with this provision is 240 penalty units or 2 years imprisonment.

Clause 24(2) provides an exception to the general prohibition on sex selection if it is necessary for a child to be of a particular sex to reduce the risk of the transmission of a genetic abnormality or genetic disease to the child.

The prohibition reflects the existing position in the NHMRC Guidelines, which prohibits sex selection in Australia for non-medical reasons such as 'family balancing'.

Limit on number of donor-related Australian families

Clause 25 provides that an ART provider must not use a donated gamete or donated embryo in an ART procedure if:

- it would result in more than 10 donor-related Australian families; and

- the provider knew that it would result in more than 10 families being created from the same donor or did not exercise due diligence to determine whether it would have that result.

The 10-family limit is intended to include the donor's raised family (not born through donor conception).

The maximum penalty for non-compliance with this provision is 400 penalty units or 2 years imprisonment.

Clause 25(2) defines *donor-related Australian families* as:

- families that include a person born as a result of an ART procedure carried out in Australia using a gamete obtained from the same donor or using an embryo created from a gamete obtained from the same donor; and
- the family of the donor if the donor has a child who was born in Australia but was not donor-conceived.

Clause 25(3) clarifies *due diligence* by an ART provider includes searching its records, making reasonable inquiries of the donor and requesting information from another provider if the provider has reason to believe that another provider in Australia has obtained a gamete or an embryo from the donor.

Clause 25(4) provides for an ART provider to, at the request of another provider who is undertaking due diligence for subsection (1)(b) in relation to a stated donor, give the other provider information it has about ART procedures, and donated gametes or donated embryos, that would be relevant to determining the number of donor-related Australian families in relation to that stated donor. The maximum penalty for non-compliance with this provision is 200 penalty units.

Clause 25(5) defines a *family* as comprising a parent, their spouse (if any) and their children.

Clause 25(6) states to remove any doubt, it is declared that:

- if a person has a former spouse – the person, the former spouse and the children of both the person and the former spouse comprise a separate family; and
- if a person has more than 1 spouse – the person, any other spouse and the children of the person and the other spouse comprise a separate family.

Use of gametes or embryos after death of gamete provider

Clause 26 provides that an ART provider must not use a gamete or an embryo in an ART procedure if the ART provider knows, or ought reasonably to know, that the gamete provider has died unless:

- the gamete provider has consented to the use of the gamete or embryo after their death; and
- the person who undergoes the procedure has consented to the use of the gamete or embryo after being notified that the gamete provider has died.

The maximum penalty for non-compliance with this provision is 200 penalty units.

Clause 26(2) states if a surrogate undergoes the ART procedure, the consent of the intended parents and not the surrogate is required under subsection (1)(b).

Clause 26(3) states that an ART provider who uses a gamete or an embryo in an ART procedure must take reasonable steps to find out whether the relevant gamete provider is still alive if the gamete, or gamete used to create the embryo, was obtained from the gamete provider more than 5 years before the ART procedure. The maximum penalty for non-compliance with this provision is 100 penalty units.

Clause 26(4) provides that the ART provider does not have to take reasonable steps to find out whether the gamete provider is alive if:

- the ART provider (or another ART provider who supplied the gamete or embryo) had been contacted by the gamete provider less than 5 years before the procedure; or
- the ART provider knows or reasonably believes that the gamete provider is dead.

Clause 26(5) provides that *reasonable steps* to find out whether a gamete provider is still alive includes making an inquiry as to whether the death of the gamete provider has been recorded in the Queensland register of deaths. Other methods of making inquiries may be prescribed by regulation. Clause 26(6) clarifies that an ART provider is authorised to make the inquiries referred to in subsection (5).

Clause 26(7) provides that this section does not apply to a gamete that was retrieved under division 5 and that is authorised under that division to be used in an ART procedure.

Time limit on use of donated gametes or embryos and their disposal

Clause 27 provides that an ART provider must not use a donated gamete in an ART procedure obtained from the gamete provider more than 15 years before the ART procedure, unless the chief executive provides written approval. ART providers must also not use a donated embryo in an ART procedure if the gamete used to create the embryo was obtained from the gamete provider more than 15 years before the procedure, without written approval from the chief executive. The maximum penalty for non-compliance with this provision is 100 penalty units.

To remove any doubt, ‘obtained’ refers to the gamete being retrieved from the gamete provider’s body.

Clause 27(2) states that the chief executive may give approval to the use of donated gametes or donated embryos beyond the 15-year time limit if satisfied there are reasonable grounds for doing so.

Clause 27(3) provides that an ART provider must dispose of any donated gametes or donated embryos in the provider’s possession if the provider is prohibited from using the donated gamete or donated embryo in an ART procedure. This is to ensure that once a donated gamete or embryo is no longer permitted to be stored or used under the Act, that it is appropriately disposed of. The maximum penalty for non-compliance with this provision is 100 penalty units.

Division 5 Retrieval and use of gametes from deceased or unresponsive persons

Interpretation for division

Clause 28 states a person is *unresponsive* if:

- the person's respiration or circulation of blood is being maintained in a hospital by artificial means; and
- a medical practitioner who is a designated officer for the hospital under section 6 of the *Transplantation and Anatomy Act 1979* has certified in writing that they have carried out a clinical examination of the person and that they are of the opinion that the person would die if the artificial means of respiration or circulation of blood was withdrawn.

Clause 28(2) states a gamete is used for a person's spouse if the gamete is used in an ART procedure for the spouse or for a surrogate of the spouse.

Retrieval of gametes from deceased or unresponsive persons

Clause 29 sets out the circumstances in which gametes can be retrieved from a deceased or an unresponsive person. It provides that a gamete may be retrieved from a deceased or an unresponsive person by, or under the supervision of, a medical practitioner for use in an ART procedure involving the person's spouse.

Clause 29(2) provides that the retrieval of a gamete from the deceased or unresponsive person is authorised only if there is evidence that:

- the person had consented to the retrieval of their gametes for use in an ART procedure for their spouse; or
- the person:
    - had not expressly objected to the posthumous use of their gametes for use in an ART procedure for their spouse; and
    - the person is likely to have supported the posthumous use of their gametes for that purpose.

Clause 29(3) clarifies that the gamete retrieved from the deceased or an unresponsive person under this division is not a donated gamete at the time of its retrieval. The posthumous use of donated gametes is considered by clause 26.

Persons authorised to request retrieval of gamete

Clause 30 provides that only the spouse of the deceased or an unresponsive person is able to request that a gamete be retrieved from the deceased or unresponsive person. In exceptional circumstances, any member of the deceased or unresponsive person's family or the spouse's family acting on behalf of the spouse may request that a gamete be retrieved from the deceased or unresponsive person.

Clause 30(2) provides that the 'exceptional circumstances' described in subsection (2) are where an urgent decision must be made for the gamete to be successfully used in any future ART procedure and the spouse is incapacitated and cannot reasonably make an informed

decision about the retrieval of the gamete or cannot be contacted despite reasonable attempts to do so.

This exceptional circumstances provision recognises that time is of the essence in retrieving viable gametes from a deceased person, and there may be times where waiting for the spouse to make the request could affect the viability of the gametes. This could include, *inter alia*, a situation where both partners are involved in an accident in which one dies but the other survives but is not able to make the request immediately after the accident due to being unconscious; or instances where the partner is overseas and uncontactable.

Use of retrieved gametes

Clause 31 states an ART provider may use a gamete retrieved from a deceased or an unresponsive person under this division in an ART procedure for the person's spouse if its use has been authorised by an independent review body.

Clause 31(2) states the 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.

Clause 31(3) provides that the independent review body must consider the following matters when deciding whether to authorise the use of the retrieved gamete in an ART procedure:

- whether the spouse has the capacity to consent to the procedure;
- whether the spouse has undertaken appropriate counselling;
- the best interests of any child born as a result of the procedure, including:
    - whether the spouse has the capacity to provide for the child's emotional, intellectual and other needs;
    - whether the child is likely to have safe and stable living arrangements;
- any other matter the independent review body considers appropriate.

Clause 31(4) states a gamete that is retrieved from a deceased or an unresponsive person may be stored by the ART provider until the independent review body decides whether to authorise the use of the retrieved gamete.

Application of *Transplantation and Anatomy Act 1979* and related provisions

Clause 32 states that this division has effect despite anything to the contrary in the *Transplantation and Anatomy Act 1979.* Part 3 of the *Transplantation and Anatomy Act 1979* does not apply to the retrieval of a gamete under this division.

The *Transplantation and Anatomy Act 1979* currently allows for the posthumous retrieval of gametes, as part of provisions relating to the general removal of tissue from a person after death (for example, for organ donation purposes).

Clause 32(3) provides that a gamete must not be retrieved from a deceased person under this division if the death is required by law to be reported to a coroner, or a coroner is investigating the death, unless:

- a coroner has given consent for the retrieval of the gamete; or

- a coroner has advised that a coroner's consent is not required.

This mirrors existing requirements in the *Transplantation and Anatomy Act 1979* regarding deceased persons who are in the coroner's jurisdiction.

Clause 32(4) states that a designated officer for a hospital under section 6 of the *Transplantation and Anatomy Act 1979* must ensure that, as soon as practicable after a gamete is retrieved at the hospital from a dead or an unresponsive person under this division, the following is recorded in the person's hospital records:

- the retrieval of the gamete;
- the name of the person who requested the retrieval of the gamete and, if the person was not the spouse, the exceptional circumstances under which the person acted on behalf of the spouse in requesting the retrieval of the gamete.

This is also intended to mirror existing requirements and ensure that hospital records are kept up to date regarding any retrieval, or request for retrieval, of gametes from a deceased or unresponsive person.

Division 6 Information collection and record keeping

Information to be collected about gamete providers

Clause 33 states that an ART provider must collect certain information before obtaining gametes for an ART procedure or for storage for future ART procedures. The information required to be collected is:

- for all gametes:
  - the gamete provider's full name;
  - the gamete provider's residential address, phone number and email address;
  - the gamete provider's date and place of birth; and
  - any other information prescribed by regulation;
- for donated gametes:
  - the donor's ethnicity and physical characteristics; and
  - the donor's relevant medical history; and
  - the sex and year of birth of each offspring of the donor (whether or not donor-conceived); and
  - any other information prescribed by regulation.

The maximum penalty for non-compliance with this provision is 200 penalty units.

Clause 33(2) states that subsection (1) applies to gametes whether or not they were obtained directly from the gamete provider. For example, the information must be collected if the gametes were obtained from a sperm bank, clinic or another ART provider, whether in Australia or overseas.

Clause 33(3) provides that information obtained by an ART provider from another ART provider under section 34 is taken to have been collected under subsection (1).

Clause 33(4) states that for information about the offspring of a donor who were not donor-conceived, subsection (1) only requires an ART provider to take reasonable steps to collect that information. Information about children raised by the donor may not have always been obtained from the donor, so an ART provider is only required to take reasonable steps to obtain this information.

Clause 33(5) states that an ART provider must not use a gamete or an embryo unless the provider has collected the information under subsection (1) in relation to the gamete or to any gamete used to create the embryo. The maximum penalty for non-compliance with this provision is 200 penalty units.

This provision is intended to set the minimum standard of information that ART providers must collect. ART providers are able to collect other information about gamete providers.

The significant maximum penalty for this offence reflects the serious consequences of failing to collect information about gamete providers, which could prevent a donor-conceived person from knowing their genetic history.

Transfer between ART providers of information about gametes or embryos

Clause 34 states that this section applies when an ART provider supplies gametes or embryos to another ART provider or receives gametes or embryos from another ART provider. This includes ART providers in and outside of Queensland.

Clause 34(2) states that the ART provider must:

- transfer a copy of the consents and other information they have collected in relation to gametes or embryos when supplying those gametes or embryos to another ART provider; and
- obtain a copy of the consents and other information when receiving gametes or embryos from another provider.

The maximum penalty for non-compliance with this provision is 200 penalty units.

Information to be collected about persons who undergo ART procedures

Clause 35 provides that an ART provider must collect the following information about a person who undergoes an ART procedure:

- the person's full name;
- the person's residential address, phone number and email address;
- the person's date and place of birth;
- the full name and date of birth of any spouse of the person at the time of the procedure.

The maximum penalty for non-compliance with this provision is 200 penalty units.

Clause 35(2) states if an ART provider uses a donated gamete or donated embryo in an ART procedure, the provider must take reasonable steps to collect the following information:

- whether a person became pregnant as a result of the procedure within 4 months after the procedure;
- whether a child was born as a result of the procedure within 15 months after the procedure and, if so, the child's full name, sex and date and place of birth.

The maximum penalty for non-compliance with this provision is 200 penalty units.

Keeping of records

Clause 36 states an ART provider must keep the records required by this section for at least 99 years. The maximum penalty for non-compliance with this provision is 200 penalty units.

Clause 36(2) states that an ART provider must keep a record of the following information about each gamete or embryo that is, or has been, in the provider's possession:

- the information the ART provider is required to collect under this division about the gamete or embryo before it was obtained, including a copy of any information the provider receives from another ART provider under section 34 when the provider receives a gamete or an embryo from another provider;
- the name of any other ART provider who has previously been in possession of the gamete or embryo, whether in or outside Queensland;
- each consent of the gamete provider under division 3 in relation to the gamete or embryo, including a copy of any consent the ART provider receives from another ART provider under section 34 when the provider receives a gamete or an embryo from the other provider;
- the uses to which the gamete or embryo has been put by the ART provider, including any supply of the gamete or embryo to another ART provider or other person, whether in or outside Queensland;
- the period during which the gamete or embryo has been in storage by the ART provider.

Clause 36(3) states an ART provider must also keep a record of the following information about its ART procedures:

- the information the ART provider is required to collect under this division about the persons who undergo those procedures;
- for procedures using a donated gamete or donated embryo – the place where the procedure was carried out.

Clause 36(4) provides that ART providers must keep a record of the following information about each child the provider knows was born as a result of its ART procedures:

- the child's full name, sex and date and place of birth;
- the full name, residential address, phone number and email address of the person who gave birth to the child;
- if a donated gamete or donated embryo was used in the procedure – the donor's full name and date and place of birth.

Clause 36(5) states an ART provider must keep a record of any other information prescribed by regulation.

Clause 36(6) provides that the section does not prevent the destruction of records under section 37(3).

Destruction of records prohibited

Clause 37 provides that an ART provider or other person must not destroy any record that the provider is required to keep under the division or any record of information that is required to be provided to the Registrar under section 46. This makes it an offence to destroy current or historical records. The maximum penalty for non-compliance with this provision is 400 penalty units.

Clause 37(2) provides that subsection (1) does not apply to any records the chief executive authorises to be destroyed under subsection (3).

Clause 37(3) provides the chief executive may, on application by an ART provider, authorise the provider to destroy any stated record of a kind referred to in the section if the chief executive is reasonably satisfied that the destruction of the record would not adversely affect any person.

Division 7 Disclosure of health information

Disclosure of health information by ART provider

Clause 38 provides an ART provider may disclose health information in accordance with this section if a medical practitioner certifies that the disclosure of the information is necessary to prevent or reduce a serious risk to someone's life or health or to warn a person about the existence of a health condition that may be harmful to the person or to the person's descendants, including future descendants.

Clause 38(2) provides the ART provider may disclose health information about a donor or a relative of a donor, to any of the following:

- a donor-conceived person born as a result of an ART procedure using a gamete donated by the donor;
- a descendant of a donor-conceived person born as a result of an ART procedure using a gamete donated by the donor;
- a parent of, or other person with parental responsibility for, a donor-conceived person born as a result of an ART procedure using a gamete donated by the donor;
- a person who is pregnant as a result of an ART procedure using a gamete donated by the donor or who is a spouse of the pregnant person;
- a person who has a gamete donated by the donor in storage with an ART provider;
- any other person prescribed by regulation.

Clause 38(3) provides the ART provider may disclose health information about a donor-conceived person, or a relative of a donor-conceived person, to any of the following:

- the donor;
- a donor-conceived sibling of the donor-conceived person who was born as a result of an ART procedure using a gamete from the same donor;
- a parent of, or other person with parental responsibility for, the donor-conceived sibling;

- a person who is pregnant as a result of an ART procedure using a gamete donated by the same donor or who is the spouse of the pregnant person;
- a person who has a gamete donated by the same donor in storage with an ART provider;
- any other person prescribed by regulation.

Clause 38(4) states a disclosure of health information under this section may also be made to a medical practitioner treating the person to whom the disclosure may be made.

Clause 38(5) states a disclosure of health information by an ART provider is to be made by a medical practitioner on behalf of the provider.

Clause 38(6) states this section does not require an ART provider to disclose health information.

Clause 38(7) states a medical practitioner who discloses health information under this section is to take reasonable steps to ensure that a person does not become aware they are donor-conceived as a result of the disclosure of the health information.

Disclosure of health information by chief executive

Clause 39(1) provides that the chief executive may disclose health information to a person that an ART provider is authorised to disclose to the person under section 38 if:

- the ART provider who has the information has not disclosed the information; and
- a medical practitioner certifies that the disclosure of the information is necessary:
  - to prevent or reduce a serious risk to someone's life or health; or
  - to warn a person about the existence of a health condition that may be harmful to the person or to the person's descendants, including future descendants; and
- the chief executive is satisfied that the disclosure of the information is reasonably necessary for a purpose referred to in paragraph (b).

Clause 39(2) provides a disclosure of health information by the chief executive is to be made by a medical practitioner on behalf of the chief executive.

Clause 39(3) states the section does not require the chief executive to disclose health information.

Part 3 Donor Conception Information Register

Division 1 Preliminary

Definitions for part

Clause 40 provides the following definitions for this part: *approved way, contact information, donor-conceived, donor-conceived offspring, donor-conceived siblings, donor conception ART procedure, donor's ID code, donor's profile information, identifying information, non-identifying information, private donor conception procedure, register, relevant information.*

Information relating to donor-conceived persons to which part applies

Clause 41 outlines this part applies to information relating to a donor-conceived person who was born as a result of a donor conception ART procedure or a private donor conception procedure.

Division 2 Establishment and maintenance of register

Registrar to establish and maintain register

Clause 42 provides that the Registrar must establish and maintain a register for the purposes of this Part.

Clause 42(2) requires that the register must contain the information required by division 3 to be included in the register and may contain other information that is prescribed by regulation or that the register considers appropriate for inclusion in the register. This will ensure mandatory information is contained on the register and allow the Registrar some discretion to include information voluntarily provided to be included on the register.

Clause 42(3) provides that the register may be wholly or partly in the form of a computer database, in documentary form or in another form the register considers appropriate. This is consistent with the other registers maintained by the Registrar.

Clause 42(4) requires the Registrar to maintain the information in the register in a way that makes the information reasonably accessible.

Clause 42(5) clarifies that despite the *Public Records Act 2002*, the Registrar is to retain control over access to any information or records maintained under this part.

Clause 42(6) provides that the register is not a register under the *Births, Deaths and Marriages Act 2023* and that Act does not authorise or require information that a person is donor-conceived to be recorded as a registrable event under that Act.

Division 3 Information held in register

Sources of information included in register

Clause 43 outlines that the Registrar must include the following information in the register:

- information provided to the Registrar by an ART provider under section 45;
- historical information provided to the Registrar by ART providers or others under section 46; and
- information voluntarily provided to the Registrar by parties to a private donor conception arrangement under section 47.

Relevant information to be included in register

Clause 44 outlines the relevant information to be included in the register relating to the birth of a donor-conceived person as a result of a donor conception ART procedure or private donor conception procedure.

Clause 44(2) defines relevant information as:

- the donor's full name;
- the donor's contact information;
- the donor's date and place of birth;
- the donor's ethnicity and physical characteristics;
- the donor's relevant medical history;
- the donor's ID code;
- the place where the donor's gamete was originally obtained from the donor if the information has been collected and kept;
- any donor's profile information;
- the full name and date of birth of the person who gave birth to the donor-conceived person as a result of the procedure, and the full name and date of birth of any spouse of that person at the time of the procedure;
- in the case of a procedure to which a surrogate was a party, the full name and date of birth of the intended parents;
- the full name, the date and place of birth and sex of the donor-conceived person born as a result of the procedure;
- the number of any donor-conceived siblings of the donor-conceived person if the information has been recorded and kept;
- if the ART procedure was carried out by an ART provider – the name of the provider and the place where the procedure was carried out;
- any other information prescribed by regulation.

This subclause also includes a note that section 42(2)(b) enables the Registrar to include additional information in the register.

Mandatory provision of information by ART providers

Clause 45 requires ART providers to provide the Registrar with all relevant information relating to the birth of a donor-conceived person after the commencement of this section as a result of a donor conception ART procedure carried out by the provider. The maximum penalty for non-compliance with this provision is 100 penalty units.

Clause 45(2) provides that the information required in subsection (1) is to be provided within 3 months after the ART provider becomes aware of the birth of the donor-conceived person.

Mandatory provision of historical information

Clause 46 applies to information that relates to the birth of a donor-conceived person before the commencement of section 45 as a result of a donor conception ART procedure carried out

by an ART provider as part of an ART service; and that is relevant information. Relevant information is outlined in clause 44(2).

Clause 46(2) requires an ART provider who has possession or control of information to which the section applies on commencement of this section to provide all the information to the Registrar within the period specified in subsection (4). The maximum penalty for non-compliance with this provision is 100 penalty units.

Clause 46(3) provides that if an ART provider had possession or control of information to which this section applies before the commencement of this section, but is not in possession or control of the information on commencement of this section, the provider must notify the Registrar within the period specified in subsection (4) of:

- the name and contact details of the person to whom the ART provider gave possession or control of the information;
- if the information was lost, destroyed or otherwise not available – when, and the circumstances in which the information was lost, destroyed or otherwise not available.

The maximum penalty for non-compliance with this provision is 100 penalty units.

Clause 46(4) outlines that the period within which information must be provided to the Registrar under subsection (2) or (3) is 6 months after commencement of this section or, if the Registrar is satisfied that there is sufficient reason to extend the period, a longer period determined by the Registrar on application or on the Registrar's own initiative.

Clause 46(5) outlines that the Registrar may issue a notice to a person named by an ART provider in subsection (3)(a) or a person the Registrar reasonably believes has possession or control of information to require the person to provide the Registrar, within a period specified in the notice, with any information to which this section applies in their possession or control.

Clause 46(6) outlines that a person must comply with such a notice. The maximum penalty for non-compliance with the provision is 100 penalty units.

Clause 46(7) clarifies that for this section an ART provides includes:

- a person who is no longer an ART provider but who had been an ART provider before the commencement of this section; and
- a medical practitioner who carried out donor conception ART procedures before the commencement of this section as part of their medical practice.

Requiring ART providers and other people that has carried out a donor conception treatment in the past to provide historical records ensures all donor-conceived people will be able to apply to the register for identifying information about their donor, regardless of when they were born. It is acknowledged that this will impact on some donors' right to privacy however this right is not absolute, and the right a of donor-conceived person to know their genetic origins outweighs a donor's competing right to information privacy. Making the register retrospective ensures all donor-conceived people are treated equally before the law, instead of making different classes of donor-conceived people with different entitlements depending on when they were conceived.

Voluntary provision of information by parties to private donor conception procedures

Clause 47(1) allows parties to a private donor conception procedure to provide all or any relevant information to the register that relates to the birth of a donor-conceived person as a result of the procedure.

Clause 47(2) clarifies that the parties to a private donor conception procedure are the donor of any gamete used in the procedure and the parents of the donor-conceived person. In a surrogacy arrangement, the parties to the procedure will be the egg donor, being the person who carried the pregnancy, and the parents of the donor-conceived person.

Clause 47(3) requires written consent of all parties to the procedure to provide information to the Registrar. If any party to the procedure has died, the written consent of all the remaining parties to the procedure and evidence of the death of that party is required to provide information to the Registrar.

Clause 47(4) clarifies that evidence that a party to the procedure has since died is a relevant statutory declaration by the remaining parties or any other evidence authorised by regulation.

Division 4 Disclosure of information in register

Persons who may access information in register

Clause 48 outlines a table that sets out persons that may apply the Registrar for information in column 1 and the information the person may access and circumstances in which the access will be provided in column 2.

Clause 48(1) allows a person in column 1 to apply to the Registrar in the approved way for any or all information outlined opposite the person in column 2. A person in column 1 may also apply for all or any of the information that is held on the register about themself.

Clause 48(2) provides that the Registrar must provide the information requested by the applicant if the Registrar is reasonably satisfied of the identity of the applicant and their relevant link to the person whose information has been requested; and the Registrar is reasonably satisfied that the information is of a kind that can be provided to the applicant under the table.

Clause 48(3) clarifies that if column 2 of the table provides that information can only provide with the consent of a person, the Registrar must ensure the person has given consent in accordance with section 49.

Clause 48(4) requires the Registrar to advise applicants of available counselling services that are provided by counsellors with relevant experience in dealing with donor conception.

An example of a counsellor with relevant experience is a counsellor who is a member of the Australian and New Zealand Infertility Counsellors Association.

The table outlines that a donor-conceived person who is 16 years or older may apply for and have access to:

- identifying and non-identifying information about the donor;
- contact information of the donor, but only with the donor's consent;
- non-identifying information about a donor-conceived sibling of the applicant;
- identifying and contact information about a donor-conceived sibling of the applicant, but only with the consent of the sibling;
- information about the number of donor-conceived siblings of the applicant.

A donor may apply for and have access to:

- non-identifying information about donor-conceived person who was born using a donated gamete obtained from the donor;
- identifying and contact information about donor-conceived person who was born using a donated gamete obtained from the donor, but only with consent of the person.

A parent of a donor-conceived person of any age or another person with parental responsibility for a donor-conceived person who is under 16 years old may apply for and have access to:

- non-identifying information about the donor of the donor-conceived person;
- identifying information or contact information about the donor, but only with the donor's consent;
- non-identifying information about a donor-conceived sibling of the donor-conceived person;
- identifying information or contact information about a donor-conceived sibling of the donor-conceived person, but only with consent of the sibling;
- information about the number of donor-conceived siblings of the donor-conceived person.

A person with parental responsibility of a donor-conceived person includes a guardian of the donor-conceived person.

A descendant, who is 16 years or older, of a donor-conceived person may apply for and have access to:

- identifying and non-identifying information about the donor of the donor-conceived person;
- contact information of the donor, but only with the donor's consent;
- non-identifying information about a donor-conceived sibling of the donor-conceived person;
- identifying and contact information about a donor-conceived sibling, but only with the consent of the sibling;
- information about the number of donor-conceived siblings of the donor-conceived person.

A descendant refers to a child or grandchild of a donor-conceived person.

A donor-conceived person 16 years or older who was born as a result of a donor conception ART procedure or a private donor conception procedure carried out in Australia but outside Queensland may apply for and have access to:

- non-identifying information about a donor-conceived sibling of the person;

- identifying information or contact information about a donor-conceived sibling of the person, but only with the consent of the sibling;
- information about the number of donor-conceived siblings of the person.

A child of a donor who is not a donor-conceived person and who is 16 years or older may apply for and have access to:

- non-identifying information about a donor-conceived sibling of the person;
- identifying information or contact information about a donor-conceived sibling of the person, but only with the consent of the sibling;
- information about the number of donor-conceived siblings of the person.

Consent to provision of information

Clause 49 provides criteria for how a person's consent to share their information is to be given to the Registrar and recorded on the register.

Clause 49(1) provides that consent of a person to the provision of information:

- may be given in advance of applications;
- must be given by notice to the Registrar in the approved way;
- must state the kind of information they consent to providing, and to whom it may be provided;
- where consent to share contact information is given, may specify how contact is to be made;
- must be recorded in the register; and
- may be varied or revoked by the person by notice to the Registrar in the approved way.

Clause 49(2) provides that a person whose consent is required for the provision of information may give the Registrar notice that they do not consent to the provision of information to any applicant.

Clause 49(3) provides that if an application is made for information that requires the consent of a person, but that person has not given their consent, the Registrar must not attempt to contact the person to give them an opportunity to consent. This is intended to ensure the Registrar does not inadvertently disclose to a person that they are donor-conceived by attempting to contact them in relation to consent and to avoid circumstances where a donor-conceived person may feel pressured to provide their consent to release identifying or contact information if donor siblings or the donor have made an application for the information. This clause is not intended to apply to applications by donor-conceived people for contact information about the donor, as these applications are dealt with under clause 49(4).

Clause 49(4) outlines that if a donor-conceived person applies for contact information about a donor, and the donor has not given consent, the Registrar may take reasonable steps to contact the donor to provide them with the opportunity to consent to the release of their contact information. This clause outlines that if a donor has already given notice that they do not consent to the provision of their contact information to a donor-conceived person, the Registrar will not contact the donor for subsequent applications from donor-conceived people for that donor's contact information.

Notification of provision of information

Clause 50 outlines when the Registrar must take reasonable steps to notify a person that information about them has been provided to another person.

Clause 50(1) outlines that if the Registrar has provided information that requires a person's consent to another person, the Registrar must take reasonable steps to notify the person to whom the information relates of this. This will ensure the person is aware of that their identifying or contact information has been released which may be many years after providing consent.

Clause 50(2) outlines that if the Registrar has provided a donor's identifying information to a person where the donor's consent is not required to do so, the Registrar must take reasonable steps to notify the donor that their information has been disclosed. This will apply where the Registrar has provided a donor's identifying information to a donor-conceived person or a descendant of a donor-conceived person.

Clause 50(3) outlines that when notifying a person under this section that their contact information or identifying information has been provided to another person, the Registrar must not identify the person to whom the information has been provided unless the other person has consented to their identity being disclosed.

Clause 50(4) outlines that this section does not apply if the person concerned has notified the registrar, in the approved way, that they do not wish to be notified. For example, a donor may notify the Registrar that they do not want to be notified when their identifying information is released to donor-conceived persons. In that circumstance, the Registrar would not be required to take reasonable steps to notify the donor under subclause 50(2).

Provision of statistical and other non-identifying information to authorised entities

Clause 51 provides that the Registrar may provide an authorised entity with statistical or other non-identifying information in the register, upon application by that entity.

Clause 51(2) states that the Registrar must maintain a written statement of the policies relating to the provision of information to entities under this section.

Clause 51(3) clarifies that *authorised entity* means an entity that is authorised by regulation or by the policies maintained by the Registrar under subsection (2).

Division 5 Miscellaneous provisions relating to register

Accuracy of register

Clause 52 states that the Registrar may correct the register on application by a person whose information is in the register, or on the register's own initiative.

Clause 52(2) provides that a person can not make an application to remove information that is required to be included in the register. For example, a donor cannot apply to have their

identifying information removed from the register if the information was required to be provided to the register under clauses 45 or 46.

Clause 52(3) provides that the Registrar must correct the register on the order of a Queensland court or QCAT.

Clause 52(4) clarifies that the Registrar is not required to ensure the accuracy and completeness of information in the register, despite the *Information Privacy Act 2009* or any other law.

Protection from liability for persons providing historical information

Clause 53 outlines protections from liability in relation to historical information.

Clause 53(1) outlines that a person who, acting honestly and reasonably, provides information under section 46 is not liable civilly, criminally, or under an administrative process, for providing the information. This clause further clarifies that a person who provides the information to the Registrar can not be held to have breached any code of professional etiquette or ethics or departed from expected standards of professional conduct.

Clause 53(2) outlines that in a proceeding for defamation the person has a defence of absolute privilege and that a person does not contravene a requirement under another Act, oath, rule of law or practice to maintain confidentiality and is not liable for disciplinary action for providing the information.

Clause 53(3) states that subsections (1) and (2) do not affect any liability for an offence against this Act or any obligation to provide information under this part. This means that the operation of clause 53 does not protect a person from liability if they, for example, fail to comply with a notice issued by the Registrar under clause 46(5).

Clause 53(4) outlines that a person must provide information as required under this part even though the person to whom the information relates has not consented to the disclosure of the information or the ART service to which the information relates was provided at a time when an Act or law or any applicable clinical guidelines or codes of practice precluded the disclosure of the information.

This clause expressly negates a duty of confidentiality that arises in connection with medical practice, particularly where a donor has not consented to the release of their information at the time of donation. This clause protects a person who provides confidential or personal information to the Registrar, from civil and criminal liability and disciplinary proceedings for breaching any code of professional ethics.

Inquiries by Registrar relating to information in register

Clause 54(1) provides the Registrar with the power to conduct an inquiry relating to information held in the register to find out:

- whether information provided to the Registrar is correct; or
- whether an ART provider or other person has provided all relevant information that they are required to provide.

Clause 54(2) provides that for the purpose of an inquiry the Registrar may, by notice, require an ART provider or other person to answer specified questions or provide other information in a stated way and within a certain time.

Clause 54(3) requires an ART provider or person to comply with the notice unless they have a reasonable excuse. The maximum penalty for failing to comply with this provision is 50 penalty units.

Clause 54(4) clarifies that for the purpose of an inquiry, the Registrar may use information recorded in register under the *Births, Deaths and Marriages Act 2023*. For example, the Registrar may use information contained on the birth register to correct or confirm information held on the register.

Clause 54(5) provides that if an application is made for information on the register that is not there, or is incomplete, the Registrar may share confidential or other information with an ART provider in order to obtain relevant information to include on the register. For example, if a donor-conceived person makes an application for information but the register does not contain information that relates to the person, the Registrar may provide details about the person's application, such as the name of the person's parents, to an ART provider to confirm whether the ART provider holds records that relate to the donor-conceived person.

Unauthorised access to or interference with register

Clause 55(1) states that a person must not, without lawful authority, access or interfere with the register, including making, altering or deleting any information in the register. The maximum penalty for failing to comply with this provision is 100 penalty units.

Clause 55(2) provides that a person has lawful authority to do something mentioned in subsection (1) if:

- they are carrying out a function under this Act or another Act; or
- the Registrar has authorised the person to do so.

Clause 55(3) provides that a person must not use or disclose information that they know has been obtained from the register in contravention of subsection (1). The maximum penalty for failing to comply with this provision is 100 penalty units.

The penalties in this clause are consistent with the offence for unauthorised access to or interference with a register section 126 of the *Births, Deaths and Marriages Act 2023*.

External review of Registrar's decisions

Clause 56 outlines when a person may apply to QCAT for a review of a decision by the Registrar.

Clause 56(1) outlines that the section applies to a decision of the Registrar on an application made by a person:

- for information in the register about a matter, but only if there is information in register on the matter (this is an application under clause 48(2)); or

- for the correction of information in the register about the person (this is an application under clause 52(1)(a)).

Clause 56(2) outlines that the person may apply to QCAT for a review of the decision if it was not the decision sought by the person and the person is dissatisfied with the decision.

For the purpose of section 157 of the QCAT Act, a decision outlined in subclause (1) becomes a reviewable decision when criteria in subclause (2) are met.

Part 4 Licensing of ART providers

Application for licence

Clause 57 provides that a person may apply to the chief executive for a licence if:

- the person has RTAC accreditation; and
- the person is not completely prohibited from providing ART services by a prohibition notice under section 63; and
- the person satisfies any other requirement prescribed by regulation.

Clause 57(2) provides that the application for a licence must be in the approved form, accompanied by any fee prescribed by regulation and include the following:

- the applicant's name and how the applicant may be contacted;
- the address of each of the premises at or from which the applicant will provide ART services;
- the name of each medical practitioner who will perform, or supervise the performance of, ART services provided by the applicant;
- any other key personnel prescribed by regulation who will be engaged in the provision of ART services by the applicant; and
- any other information or document prescribed by regulation.

Clause 57(3) states the applicant must provide any further information or document that the chief executive asks the applicant to provide by written notice to enable the chief executive to deal with the application. For example, this may include a copy of a person's RTAC accreditation or other document relevant to the chief executive's consideration of the application.

Clause 57(4) states that a licensed provider may apply for a further licence not earlier than 3 months before the end of term of their existing licence.

Deciding application for licence

Clause 58 states that the chief executive may grant a licence to a person if:

- an application for the licence is made under section 57; and
- the person is eligible to make the application under that section.

Clause 58(2) states that the chief executive must refuse to grant a licence if the chief executive is not authorised under subsection (1) to grant the licence to the applicant or if the chief executive is satisfied that the licence should not be granted because of:

- contraventions of the conditions of any previous licence held by the applicant; or
- contraventions by the applicant of the Act or any ART related legislation; or
- the risk to the health, safety or welfare of persons provided with ART services by the applicant or of persons born as a result of those ART services; or
- any other relevant matter.

ART related legislation is defined in schedule 1 and includes the ART legislation of other states and territories. This will enable the chief executive to consider, among other things, any contraventions by an applicant of the corresponding ART legislation in other jurisdictions where they may operate.

Clause 58(3) provides that the chief executive must, as soon as practicable after deciding to refuse to grant a licence, give the applicant an information notice about the decision.

Conditions of licence

Clause 59 provides that licences are subject to conditions prescribed by regulation. These general conditions are intended to apply to all licensed ART providers.

Additionally, a licence may also be subject to specific conditions imposed by the chief executive at the time, or at any time after, the licence is granted. The chief executive may vary or remove the specific licence conditions at any time. If the chief executive decides to impose or vary a specific condition, they must give the licensed ART provider an information notice about the decision. *Information notice* is defined in the dictionary.

Term of licence

Clause 60 provides for the term of the licence, including that a licence comes into effect on the day stated in the licence and, subject to section 60, has effect for the period stated in the licence (not exceeding 3 years). A licence ceases to have effect if it is cancelled under section 64. If a licensed provider applies for a further licence before their current licence expires, their current licence is still valid until the chief executive gives the applicant notice of the chief executive's decision on the application.

Chief executive to be notified of certain events

Clause 61 states that a licensed ART provider must give the chief executive written notice of certain events within a specified timeframe. This is intended to ensure the chief executive has appropriate oversight of ART services and providers and can respond to any issues as necessary.

For serious adverse events related to the ART services provided by a licensed provider, a licensed provider must give the chief executive written notice within 7 days of the provider becoming aware that the event has happened. Serious adverse events may be prescribed by regulation, or in the conditions of the provider's licence, and are intended to align with the list of serious adverse events in the RTAC Code of Practice, which includes: significant medical

or surgical conditions resulting from ART treatment, breach or potential breach of legislation, gamete or embryo identification mix up and transmission of a communicable disease.

A licensed provider must also give written notice within 14 days of the following events happening:

- the licensed provider ceases to have RTAC accreditation;
- a change in the licensed provider's RTAC accreditation;
- a contravention of any condition of the provider's licence;
- the licensed provider ceases to provide ART services.

Additionally, a licensed provider must give written notice within 21 days of the following events happening:

- a change in the premises at or from which the licensed provider provides ART services;
- a change in the medical practitioner who performs, or supervises the performance of, ART services by the licensed provider;
- a change in any other key personnel prescribed by regulation who are engaged in the provision of ART services by the licensed provider.

These timeframes are intended to refer to calendar days.

Licensed providers are also required to provide written notice of any other event prescribed by regulation within the time specified in the regulation for the event.

The maximum penalty for not notifying the chief executive of a serious adverse event in the prescribed timeframe is 100 penalty units, with a maximum penalty of 50 penalty units for all other events.

The licensed provider is not required to give the chief executive notice of the event if the licensed provider has a reasonable excuse.

Improvement notices

Clause 62 provides that the chief executive may issue a licensed ART provider with an improvement notice, if the chief executive reasonably believes it is necessary for the licensed provider to rectify a particular matter to prevent or minimise a risk to the health, safety or welfare of persons who access ART services or of persons born as a result of ART. An improvement notice must be in writing.

An improvement notice must state the following:

- that it is an improvement notice under the Act;
- the name of the licensed provider to whom it is issued;
- the matter that is required to be rectified and, if the chief executive considers it appropriate, the action that the licensed provider must take to rectify the matter;
- the period within which the matter must be rectified;
- that the improvement notice has effect until it is revoked by the chief executive.

Clause 62 sets out the required process for dealing with an improvement notice, including that:

- the chief executive is required to give the licensed provider an information notice about the decision when issuing an improvement notice, whether it is in the same or a separate document;
- the chief executive may extend the period within which the matter stated in the improvement notice must be rectified, or revoke an improvement notice issued to the licensed provider, by written notice to the licensed provider;
- a licensed provider may apply to the chief executive for the revocation of an improvement notice issued to them because the relevant matter has been rectified or does not require to be rectified;
- the chief executive may revoke the improvement notice or refuse the application for the revocation of the improvement notice;
- the chief executive must give the licensed provider an information notice about the decision to refuse an application to have an improvement notice revoked as soon as practicable after the refusal;
- if a licensed provider is issued with an improvement notice, the requirements of the notice become a condition of the provider's licence.

For the purposes of section 62, *licensed provider* includes, in the case of a corporation, an associated entity of the corporation.

Prohibition notices

Clause 63 provides the chief executive may issue a prohibition notice to a person if the chief executive reasonably believes that the person should be prohibited from providing ART services (or stated ART services) because:

- the person has contravened a condition of the person's licence; or
- the person has contravened the Act or any ART related legislation; or
- the provision of ART services (or those stated services) by the person is a risk to the health, safety or welfare of persons to whom they are provided of the persons born as a result of the provision of those ART services.

A prohibition notice must be in writing and may be issued to any person, including a licensed ART provider.

A prohibition notice may be issued in relation to all ART services, or stated ART services. A prohibition notice that is limited to stated ART services may be limited to ART services of a stated kind, provided at or from stated premises or premises in a stated area, or provided to or by stated persons.

A prohibition notice must state the following:

- that it is a prohibition notice under this Act;
- the name of the person to whom it is issued;
- that it applies to ART services of any kind or only stated services; and
- that the prohibition notice has effect until it is revoked by the chief executive.

Clause 63 sets out the required process for dealing with a prohibition notice, including that:

- the chief executive must give the person an information notice about the decision to issue a prohibition notice, whether in the same or in a separate document;
- the chief executive may by written notice to the person limit the ART services provided by the person to which a prohibition notice applies, or revoke a prohibition notice issued to the person;
- a person may apply to the chief executive for the revocation of a prohibition notice issued to them because the reasons for the issue of the notice do not or no longer justify the prohibition;
- the chief executive may revoke the prohibition notice or refuse the application for the revocation of the prohibition notice;
- the chief executive must give the person an information notice about the decision to refuse an application to have the prohibition notice revoked as soon as practicable after the refusal;
- if a licensed provider is prohibited by a prohibition notice from providing stated ART services, the prohibition becomes a condition of the provider's licence.

The chief executive may issue a prohibition notice to an associated entity of a corporation because of a contravention by, or other conduct of, the corporation or another associated entity of the corporation.

For the purposes of section 63, *licensed provider* includes, in the case of a corporation, an associated entity of the corporation.

Cancellation or suspension of licence

Clause 64 provides that the chief executive must cancel or suspend a person's licence if:

- the person ceases to have RTAC accreditation; or
- the person is completely prohibited from providing ART services by a prohibition notice under section 63.

Additionally, the chief executive may cancel or suspend a person's licence under the following circumstances:

- if the licence was granted to the person because of information that was false or misleading in a material particular;
- if the person notifies the chief executive under section 61 that they have ceased to provide ART services; or
- in any other circumstances prescribed by regulation.

The chief executive may suspend a licence for any period not exceeding 12 months.

If a licence is suspended, the licensed ART provider may apply to the chief executive for the suspension to be lifted, and the chief executive may lift the suspension by written notice to the licensed provider.

The chief executive must give the licensed provider an information notice about the decision to cancel or suspend a licence or to refuse an application to lift a suspension as soon as practicable after making the decision.

Public register of licensed providers

Clause 65 states that the chief executive may keep a public register of licensed ART providers.

The public register may contain any of the following information for a licensed provider:

- the name of the licensed provider and how the licensed provider may be contacted;
- the address of each premises at or from which the licensed provider provides ART services;
- the name of the medical practitioner who performs, or supervises the performance of, ART services provided by the licensed provider;
- the names of any other key personnel prescribed by regulation who are engaged in the provision of ART services by the licensed provider;
- the identification number for the RTAC accreditation of the licensed provider and the date of expiry of the RTAC accreditation;
- other information prescribed by regulation.

The public register may contain any other information the chief executive considers appropriate.

The chief executive must not make particular information about a person that is on the public register available to the public if the person asks the chief executive not to make that information available to the public, and the chief executive is satisfied that the publication of that information might endanger the personal safety of that person or any other person.

Part 5 Investigation and enforcement

Division 1 Interpretation

Definitions for part

Clause 66 provides definitions for terms used in part 5.

References to exercise of powers

Clause 67 provides that a reference in part 5 to the exercise of a power by an inspector, other than a reference to the exercise of a specific power, is a reference to the exercise of all or any of an inspector's powers under part 5 or a warrant, to the extent the powers are relevant.

Division 2 General provisions about inspectors

Inspectors under part

Clause 68 states that part 5 includes provision for the appointment of inspectors and gives inspectors particular powers.

Functions of inspectors

Clause 69 provides that an inspector has the following functions:

- to investigate, monitor and enforce compliance with the Act;
- to investigate or monitor whether an occasion has arisen for the exercise of powers under the Act;
- to facilitate the exercise of powers under the Act.

These inspector functions will ensure that Queensland Health has robust oversight of ART providers, including the ability to audit providers and investigate non-conformities and adverse events.

Appointment

Clause 70 provides that the chief executive may appoint, by instrument in writing, any of the following persons who are appropriately qualified as inspectors:

- a person appointed as a health service employee under the *Hospitals and Health Boards Act 2011*, section 67;
- a public sector employee under the *Public Sector Act 2022,* section 12;
- any other person prescribed by regulation.

Appointment conditions and limit on powers

Clause 71 states that an inspector holds office on any conditions stated in the inspector's instrument of appointment, a signed notice given to the inspector or a regulation.

The instrument of appointment, a signed notice given to the inspector or a regulation may limit the inspector's powers.

For the purposes of section 71, *signed notice* means a notice signed by the chief executive.

When office ends

Clause 72 states that the office of a person as an inspector ends if any of the following happens:

- the term of office stated in a condition of office ends;
- under another condition of office, the office ends;
- the inspector's resignation under division 2 takes effect.

This does not limit the ways the office of a person as an inspector ends.

For the purposes of this section, *condition of office* means a condition under which the inspector holds office.

Resignation

Clause 73 provides for that an inspector may resign by providing a signed notice to the chief executive.

Issue of identity card

Clause 74 states the chief executive must issue an identity card to each inspector.

The identity card must:

- contain a recent photo of the inspector; and
- contain a copy of the inspector's signature; and
- identify the person as an inspector under the Act; and
- state an expiry date for the card.

These requirements do not prevent the issue of a single identity card to a person for this Act and other purposes.

Production or display of identity card

Clause 75 states that in exercising a power in relation to a person in the person's presence, an inspector must:

- produce the inspector's identity card for the person's inspection before exercising the power; or
- have the identity card displayed so it is clearly visible to the person when exercising the power.

If it is not practicable to comply with these requirements, the inspector must produce the identity card for the person's inspection at the first reasonable opportunity.

An inspector is not taken to have exercised a power in relation to a person only because the inspector has entered a place as mentioned in section 77(1)(b) or (d).

Return of identity card

Clause 76 states that if the office of a person as an inspector ends, they must return their identity card to the chief executive within 21 calendar days after the office ends, unless they have a reasonable excuse. The maximum penalty for non-compliance with this provision is 10 penalty units.

Division 3 Entry of places by inspectors

Subdivision 1 Power to enter

General power to enter places

Clause 77 provides that an inspector may enter a place if:

- an occupier at the place consents under subdivision 2 to the entry and section 80 (which sets out matters the inspector must tell the occupier before asking for consent to enter) has been complied with for the occupier; or
- the place is a public place and the entry is made when the place is open to the public; or

- the entry is authorised under a warrant and, if there is an occupier of the place, section 87 (which sets out entry procedure for an inspector intending to enter a place under a warrant) has been complied with for the occupier; or
- the place is the premises used by a licensed ART provider and is open for entry. This does not include a part of the premises where a person resides.

If the power to enter arose only because an occupier of the place consented to the entry, the power is subject to any conditions of the consent and ceases if the consent is withdrawn.

If the power to enter is under a warrant, the power is subject to the terms of the warrant.

Subdivision 2 Entry by consent

Application of subdivision

Clause 78 states that subdivision 2 applies if an inspector intends to ask an occupier of a place to consent to the inspector or another inspector entering the place under section 77(1)(a).

Incidental entry to ask for access

Clause 79 states that for the purpose of asking the occupier for the consent, an inspector may, without the occupier's consent or a warrant:

- enter land around premises at the place to an extent that is reasonable to contact the occupier; or
- enter part of the place the inspector considers members of the public ordinarily are allowed to enter when they wish to contact an occupier of the place.

Matters inspector must tell occupier

Clause 80 states that before asking for the consent, the inspector must:

- explain to the occupier the purpose of the entry, including the powers intended to be exercised; and
- tell the occupier that the occupier is not required to consent, and the consent may be given subject to conditions and may be withdrawn at any time.

Consent acknowledgement

Clause 81 states if the consent is given, the inspector may ask the occupier to sign an acknowledgement of the consent.

The acknowledgement must state:

- the purpose of the entry, including the powers to be exercised; and
- that the occupier has been given an explanation about the purpose of the entry, including the powers intended to be exercised; and
- that the occupier has been told that the occupier is not required to consent and that the consent may be given subject to conditions and may be withdrawn at any time; and

- that the occupier gives the inspector or another inspector consent to enter the place and exercise the powers; and
- the day and time the consent was given; and
- any conditions of the consent.

If the occupier signs the acknowledgement, the inspector must immediately give a copy to the occupier.

If an issue arises in a proceeding about whether the occupier consented to the entry and a signed acknowledgement for the entry is not produced in evidence, the onus of proof is on the person relying on the lawfulness of the entry to prove the occupier consented.

Subdivision 3 Entry under warrant

Application for warrant

Clause 82 provides that an inspector may apply to a magistrate for a warrant for a place.

The inspector must prepare a written application that states the grounds on which the warrant is sought. The written application must be sworn.

The magistrate may refuse to consider the application until the inspector gives the magistrate all the information the magistrate requires about the application in the way the magistrate requires. For example, the magistrate may require additional information supporting the written application to be given by statutory declaration.

Issue of warrant

Clause 83 provides that the magistrate may issue a warrant for a place only if they are satisfied there are reasonable grounds for suspecting there is at the place, or will be at the place within the next 7 days, a particular thing or activity that may provide evidence of an offence against the Act.

The warrant must state:

- the place to which the warrant applies;
- that a stated inspector or any inspector may with necessary and reasonable help and force:
  - enter the place and any other place necessary for entry to the place;
  - exercise the inspector's powers;
- particulars of the offence that the magistrate considers appropriate;
- the name of the person suspected of having committed the offence, unless the name is unknown or the magistrate considers it inappropriate to state the name;
- the evidence that may be seized under the warrant;
- the hours of the day or night when the place may be entered;
- the magistrate's name;
- the day and time of the warrant's issue; and
- the day, within 14 days after the warrant's issue, the warrant ends.

Electronic application

Clause 84 provides that an application for a warrant under section 80 may be made by phone, fax, email, radio, videoconferencing or another form of electronic communication if the inspector considers it necessary because of urgent circumstances or other special circumstances, including, for example, the inspector's remote location.

The application may not be made before the inspector prepares the written application under section 82(2) but may be made before the written application is sworn.

Additional procedure if electronic application

Clause 85 states that for an application made under section 84, the magistrate may issue the warrant (the *original warrant*) only if the magistrate is satisfied:

- it was necessary to make the application under section 84; and
- the way the application was made under section 84 was appropriate.

After the magistrate issues the original warrant:

- if there is a reasonably practicable way of immediately giving a copy of the warrant to the inspector, including, for example, by sending a copy by fax or email, the magistrate must immediately give a copy of the warrant to the inspector; or
- otherwise:
    - the magistrate must tell the inspector the information required to be stated in the warrant under section 83(2); and
    - the inspector must complete a form of warrant, including by writing on it the information mentioned in subparagraph (i).

The copy of the warrant mentioned in subsection (2)(a), or the form of warrant completed under subsection (2)(b) (in either case the *duplicate warrant*), is a duplicate of, and as effectual as, the original warrant.

The inspector must, at the first reasonable opportunity, send to the magistrate:

- the written application complying with section 82(2) and (3); and
- if the inspector completed a form of warrant under subsection (2)(b), the completed form of warrant.

Despite subsection (3), if an issue arises in a proceeding about whether an exercise of a power was authorised by a warrant issued under this section and the original warrant is not produced in evidence, the onus of proof is on the person relying on the lawfulness of the exercise of the power to prove a warrant authorised the exercise of the power.

Section 85 does not limit section 82.

Defect in relation to a warrant

Clause 86 states that a warrant is not invalidated by a defect in the warrant or compliance with subdivision 3, unless the defect affects the substance of the warrant in a material particular.

For the purposes of section 86, *warrant* includes a duplicate warrant mentioned in section 85(3).

Entry procedure

Clause 87 outlines the entry procedure if an inspector is intending to enter a place under a warrant issued under subdivision 3.

Before entering the place, the inspector must do or make a reasonable attempt to do the following things:

- identify themself to a person who is an occupier of the place and is present by producing the inspector's identity card or another document evidencing the inspector's appointment;
- give the person a copy of the warrant;
- tell the person the inspector is permitted by the warrant to enter the place;
- give the person an opportunity to allow the inspector immediate entry to the place without using force.

The inspector need not comply with subsection (2) if the inspector reasonably believes that entry to the place without compliance is required to ensure the execution of the warrant is not hindered.

For the purposes of section 87, *warrant* includes a duplicate warrant mentioned in section 85(3).

Subdivision 4 General powers of inspectors after entering places

Application of subdivision

Clause 88 provides that the powers under subdivision 4 may be exercised if an inspector enters a place under section 77(1)(a), (c) or (d). If the inspector enters a place under section 77(1)(a) or (c), the powers under subdivision 4 are subject to any conditions of the consent or terms of the warrant.

General powers

Clause 89 states that the inspector may do any of the following:

- search any part of the place;
- inspect, examine or film any part of the place or anything at the place;
- take for examination a thing, or a sample of or from a thing, at the place;
- place an identifying mark in or on anything at the place;
- take an extract from, or copy, a document at the place, or take the document to another place to copy;
- produce an image or writing from an electronic document at the place or, to the extent that is not practicable, take either or both of the following to another place to produce an image or writing from an electronic document:
    - a thing containing an electronic document;
    - a thing that can be used to produce an image or writing from an electronic document;

- take to, into or onto the place and use any person, equipment and materials the inspector requires for exercising the inspector's powers under part 5;
- remain at the place for the time necessary to achieve the purpose of the entry.

The inspector may do anything necessary to exercise a power under subsection (1).

If the inspector takes a document from the place to copy it, the inspector must copy the document and return it to the place as soon as practicable.

If the inspector takes a thing from the place to produce an image or writing from an electronic document, the inspector must produce the image or writing from the document and return the thing to the place as soon as practicable.

The inspector may not examine, or take for examination, a gamete or an embryo in the exercise of a power under this section.

The terms *examine*, *film* and *inspect* are defined for the purposes of the section.

Power to require reasonable help

Clause 90 provides that the inspector may require an occupier of the place or a person at the place to give the inspector reasonable help to exercise a power under section 89(1), including, for example, to produce a document or to give information.

When making such a requirement, the inspector must give the person an offence warning for the requirement.

Offence to contravene help requirement

Clause 91 states that a person of whom a requirement is made under section 90(1) must comply with the requirement unless the person has a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

It is a reasonable excuse for an individual not to comply with a requirement under section 90(1) if complying might tend to incriminate the individual or expose the individual to a penalty. This does not apply if a document or information that is the subject of the requirement under section 90(1) is required to be held or kept by the individual under this Act. However, section 118 relating to evidential immunity should also be considered.

Division 4 Seizure by inspectors and forfeiture

Subdivision 1 Power to seize

Seizing evidence at place that may be entered without consent or warrant

Clause 92 states that an inspector who enters a place the inspector may enter under part 5 without the consent of an occupier of the place and without a warrant may seize a thing at the place if the inspector reasonably believes the thing is evidence of an offence against the Act.

Seizing evidence at place that may be entered only with consent or warrant

Clause 93 states that this section applies if an inspector is authorised to enter a place only with the consent of an occupier of the place or a warrant, and the inspector enters the place after obtaining the consent or under a warrant.

If the inspector enters the place with the occupier's consent, the inspector may seize a thing at the place only if:

- the inspector reasonably believes the thing is evidence of an offence against the Act; and
- seizure of the thing is consistent with the purpose of entry as explained to the occupier when asking for the occupier's consent.

If the inspector enters the place under a warrant, the inspector may seize the evidence for which the warrant was issued.

The inspector may also seize anything else at the place if the inspector reasonably believes:

- the thing is evidence of an offence against the Act; and
- the seizure is necessary to prevent the thing being hidden, lost or destroyed.

The inspector may also seize a thing at the place if the inspector reasonably believes the thing has just been used in committing an offence against the Act.

Gametes and embryos not subject to seizure

Clause 94 states that division 4 does not confer a power on an inspector to seize a gamete or an embryo.

Seizure of property subject to security

Clause 95 provides that an inspector may seize a thing, and exercise powers relating to the thing, despite a lien or other security over the thing claimed by another person. The seizure does not affect the other person's claim to the lien or other security against a person other than the inspector or a person acting under the direction or authority of the inspector.

Subdivision 2 Powers to support seizure

Power to secure seized thing

Clause 96 states that having seized a thing under division 4, an inspector may:

- leave the thing at the place where it was seized (the *place of seizure*) and take reasonable action to restrict access to it; or
- move the thing from the place of seizure.

For the purposes of taking reasonable action to restrict access to the thing, the inspector may, for example:

- seal the thing, or the entrance to the place of seizure, and mark the thing or place to show access to the thing or place is restricted; or
- for equipment – make it inoperable, for example, by dismantling it or removing a component without which the equipment cannot be used; or
- require a person the inspector reasonably believes is in control of the place or thing to do an act mentioned in paragraph (a) or (b) or anything else an inspector could do under subsection (1)(a).

Offence to contravene seizure requirement

Clause 97 states that a person must comply with a requirement made of the person under section 96(2)(c) unless the person has a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

Offence to interfere

Clause 98 states that if access to a seized thing is restricted under section 96, a person must not tamper with the thing or with anything used to restrict access to the thing without an inspector's approval or a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

If access to a place is restricted under section 96, a person must not enter the place in contravention of the restriction or tamper with anything used to restrict access to the place without an inspector's approval or a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

Subdivision 3 Safeguards for seized things

Receipt for seized thing

Clause 99 provides for this section to apply if an inspector seizes anything under division 4 unless:

- the inspector reasonably believes there is no-one apparently in possession of the thing or the thing has been abandoned; or
- because of the condition, nature and value of the thing it would be unreasonable to require the inspector to comply with this section.

The inspector must, as soon as practicable after seizing the thing, give an owner or person in control of the thing before it was seized a receipt for the thing that generally describes the thing and its condition.

If an owner or person from whom the thing is seized is not present when it is seized, the receipt may be given by leaving it in a conspicuous position and in a reasonably secure way at the place where the thing is seized.

The receipt may relate to more than one seized thing.

The inspector may delay giving the receipt if the inspector reasonably suspects giving it may frustrate or otherwise hinder an investigation by the inspector under part 5. The delay may be

only for so long as the inspector continues to have the reasonable suspicion and remains in the vicinity of the place where the thing was seized to keep the thing under observation.

Access to seized thing

Clause 100 provides the ability to access a seized thing. Until a seized thing is forfeited or returned, the inspector who seized the thing must allow an owner of the thing to inspect it at any reasonable time and from time to time, and if it is a document – to copy it. However, this requirement does not apply if it is impracticable or unreasonable to allow the inspection or copying. The inspection or copying must be allowed free of charge.

Return of seized thing

Clause 101 relates to the return of seized things and applies if a seized thing is not forfeited or transferred under subdivision 4 or 5.

As soon as the chief executive stops being satisfied there are reasonable grounds for retaining the thing, the chief executive must return the thing to its owner.

If the thing is not returned to its owner within 3 months after it was seized, the owner may apply to the chief executive for its return.

Within 30 days after receiving the application, the chief executive must:

- if the chief executive is satisfied there are reasonable grounds for retaining the thing and decides to retain the thing – give the owner an information notice about the decision; or
- otherwise – return the thing to the owner.

There are reasonable grounds for retaining a seized thing if:

- the thing is being, or is likely to be, examined; or
- the thing is needed, or may be needed, for the purposes of:
  - a proceeding for an offence against this Act that is likely to be started or that has been started but not completed; or
  - an appeal from a decision in a proceeding for an offence against the Act; or
- it is not lawful for the owner to possess the thing.

This does not limit the grounds that may be reasonable grounds for retaining the seized thing.

Nothing in this section affects a lien or other security over the seized thing.

For the purposes of section 101, *examine* includes analyse, test, account for, measure, weigh, grade, gauge and identify.

Subdivision 4 Forfeiture

Forfeiture by chief executive decision

Clause 102 provides for the forfeiture of a seized thing by the chief executive. The chief executive may decide a seized thing is forfeited to the State if an inspector:

- after making reasonable inquiries, cannot find an owner; or
- after making reasonable efforts, cannot return the thing to an owner; or
- reasonably believes it is necessary to keep the thing to prevent it being used to commit the offence for which it was seized.

The inspector is not required to:

- make inquiries if it would be unreasonable to make inquiries to find an owner; or
- make efforts if it would be unreasonable to make efforts to return the thing to an owner, for example, the owner of the thing has migrated to another country.

Regard must be had to the thing's condition, nature and value in deciding:

- whether it is reasonable to make inquiries or efforts; and
- if inquiries or efforts are made – what inquiries or efforts, including the period over which they are made, are reasonable.

Information notice about forfeiture decision

Clause 103 states if the chief executive decides under section 102(1) that a thing is forfeited, the chief executive must as soon as practicable give a person who owned the thing immediately before the forfeiture an information notice about the decision.

If the decision was made under section 102(1)(a) or (b), the information notice may be given by leaving the notice at the place where the thing was seized, in a conspicuous position and in a reasonably secure way.

These requirements do not apply if:

- the decision was made under section 102(1)(a) or (b); and
- the place where the thing was seized is a public place or a place where the notice is unlikely to be read by the person.

Subdivision 5 Dealing with property forfeited or transferred to State

When thing becomes property of the State

Clause 104 states that a thing becomes the property of the State if the thing is forfeited to the State under section 102(1) or the owner of the thing and the State agree, in writing, to the transfer of the ownership of the thing to the State.

How property may be dealt with

Clause 105 states this section applies if, under section 104, a thing becomes the property of the State.

The chief executive may deal with the thing as the chief executive considers appropriate, including, for example, by destroying the thing or giving it away.

The chief executive must not deal with the thing in a way that could prejudice the outcome of a review of the forfeiture under the Act.

If the chief executive sells the thing, the chief executive must, after deducting the costs of the sale, make reasonable efforts to return the proceeds of the sale to the person who owned the thing immediately before the thing became the property of the State.

Division 5 Other information-obtaining powers of inspectors

Power to require personal details

Clause 106 states this section applies if an inspector:

- finds a person committing an offence against the Act; or
- finds a person in circumstances that lead the inspector to reasonably suspect the person has just committed an offence against the Act; or
- has information that leads the inspector to reasonably suspect a person has just committed an offence against the Act.

The inspector may require the person to state the person's name and residential address.

The inspector may also require the person to give evidence of the correctness of the stated name or address if, in the circumstances, it would be reasonable to expect the person to be in possession of evidence of the correctness of the stated name or address or otherwise be able to give the evidence.

When making a requirement under this section, the inspector must give the person an offence warning for the requirement.

Offence to contravene personal details requirement

Clause 107 states a person of whom a requirement is made under section 106 must comply with the requirement unless the person has a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

A person may not be convicted of this offence unless the person is found guilty of the offence in relation to which the requirement under section 106 was made.

Power to require production of document or certification of copy

Clause 108 provides for the ability for an inspector to require a person to make available for inspection by an inspector, or to produce the inspector for inspection, at a reasonable time and place nominated by the inspector:

- a document issued or granted to the person under the Act; or
- a document required to be kept by the person under the Act; or
- if a document mentioned in paragraph (a) or (b), or information required to be kept by the person under the Act, is kept, stored or recorded electronically – a document that is a clear written reproduction of the document or information that is kept, stored or recorded electronically.

The inspector may copy the document or an entry in the document.

If the inspector copies the document, or an entry in the document, the inspector may require the person responsible for keeping the document to certify the copy as a true copy of the document or entry.

The inspector must not keep the document after copying the document or an entry in the document.

However, if a requirement is made of a person under subsection (3), the inspector may keep the document until the person complies with the requirement.

Offence to contravene production requirement

Clause 109 states that a person of whom a production requirement is made must comply with the requirement unless the person has a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

It is not considered a reasonable excuse for a person to fail to comply with a production requirement on the basis that complying with the requirement might tend to incriminate the person or expose the person to a penalty. However, section 118 relating to evidential immunity is also relevant.

The inspector must inform the person, in a way that is reasonable in the circumstances, that:

- the person must comply with the production requirement even though complying might tend to incriminate the person or expose the person to a penalty; and
- if the person is an individual – there is a limited immunity under section 118 against the future use of the information or document given in compliance with the production requirement.

If the person fails to comply with the production requirement when the inspector has failed to comply with subsection (3), the person may not be convicted of the offence against subsection (1).

If a court convicts a person of an offence against subsection (1), the court may, as well as imposing a penalty for the offence, order the person to comply with the production requirement.

For the purposes of section 109, *production requirement* means a requirement under section 108(1).

Offence to contravene certification requirement

Clause 110 states that a person of whom a certification requirement is made must comply with the requirement unless the person has a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

It is not considered a reasonable excuse for a person to fail to comply with a certification requirement on the basis that complying with the requirement might tend to incriminate the

person or expose the person to a penalty. However, section 118 relating to evidential immunity is also relevant.

The inspector must inform the person, in a way that is reasonable in the circumstances, that:

- the person must comply with the certification requirement even though complying might tend to incriminate the person or expose the person to a penalty; and
- if the person is an individual – there is a limited immunity under section 118 against the future use of the information or document given in compliance with the certification requirement.

If the person fails to comply with the certification requirement when the inspector has failed to comply with subsection (3), the person may not be convicted of the offence against subsection (1).

For the purposes of section 110, *certification requirement* means a requirement under section 108(3).

Power to require information

Clause 111 states that this section applies if an inspector reasonably believes:

- an offence against the Act has been committed; and
- a person may be able to give information about the offence.

The inspector may, by notice given to the person, require the person to give the inspector by a stated reasonable time, information related to the offence, or if the information is kept, stored or recorded electronically – a clear written reproduction of the information.

For the purposes of section 111, *information* includes a document.

Offence to contravene information requirement

Clause 112 states that a person who has had been given an information requirement under section 111(2) must comply with the requirement unless the person has a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

It is a reasonable excuse for an individual not to give the information if giving the information might tend to incriminate the individual or expose the individual to a penalty.

Division 6 Damage, compensation and other provisions

Duty to avoid inconvenience and minimise damage

Clause 113 states that when an inspector is exercising a power, the inspector must take all reasonable steps to cause as little inconvenience, and do as little damage, as possible.

Notice of damage

Clause 114 states that this section applies if:

- an inspector damages something when exercising, or purporting to exercise, a power; or
- a person (the *assistant*) acting under the direction or authority of an inspector damages something.

This section does not apply to damage the inspector considers is trivial or if the inspector reasonably believes there is no-one apparently in possession of the thing or the thing has been abandoned.

The inspector must give notice of the damage to a person who appears to the inspector to be an owner, or person in control, of the thing. However, if for any reason it is not practicable to comply with this requirement, the inspector must leave the notice at the place where the damage happened and ensure the notice is left in a conspicuous position and in a reasonably secure way. The inspector may delay complying with these requirements if the inspector reasonably suspects complying may frustrate or otherwise hinder the performance of the inspector's functions. The delay may be only for so long as the inspector continues to have the reasonable suspicion and remains in the vicinity of the place.

If the inspector believes the damage was caused by a latent defect in the thing or other circumstances beyond the control of the inspector or the assistant, the inspector may state the belief in the notice.

The notice must state particulars of the damage and that the person who suffered the damage may claim compensation under section 115.

Compensation

Clause 115 provides that a person may claim compensation from the State if the person incurs loss because of the exercise, or purported exercise, of a power by or for an inspector including a loss arising from compliance with a requirement made of the person under division 4 or 5.

The compensation may be claimed and ordered in a proceeding:

- brought in a court with jurisdiction for the recovery of the amount of compensation claimed; or
- for an alleged offence against the Act the investigation of which gave rise to the claim for compensation.

A court may order the payment of compensation only if it is satisfied it is just to make the order in the circumstances of the particular case. In considering whether it is just to order compensation, the court must have regard to any relevant offence committed by the claimant and whether the loss arose from a lawful seizure or lawful forfeiture.

A regulation may prescribe other matters that may, or must, be taken into account by the court when considering whether it is just to order compensation.

Section 113 does not provide for a statutory right of compensation other than as provided by this section.

For the purposes of section 115, *loss* includes costs and damage.

Obstructing inspector

Clause 116 states that a person must not obstruct an inspector exercising a power, or someone helping an inspector exercising a power, unless the person has a reasonable excuse. The maximum penalty for non-compliance with this provision is 50 penalty units.

If a person has obstructed an inspector or someone helping an inspector, and the inspector decides to proceed with the exercise of the power, the inspector must warn the person that:

- it is an offence to cause an obstruction unless the person has a reasonable excuse; and
- the inspector considers the person's conduct an obstruction.

For the purposes of section 116, *obstruct* includes hinder, resist, attempt to obstruct and threaten to obstruct.

Impersonating inspector

Clause 117 states that a person must not impersonate an inspector. The maximum penalty for non-compliance with this provision is 50 penalty units.

Evidential immunity for individuals complying with particular requirements

Clause 118 states that subsection (2) applies if an individual gives or produces information or a document to an inspector under section 90 or 108.

Clause 118(2) states that evidence of the information or document, and other evidence directly or indirectly derived from the information or document, is not admissible against the individual in any proceeding to the extent the evidence tends to incriminate the individual, or expose the individual to a penalty, in the proceeding.

Subsection (2) does not apply to:

- a proceeding about the false or misleading nature of the information or anything in the document or in which the false or misleading nature of the information or document is relevant evidence; or
- a proceeding in relation to an administrative action taken against an individual.

For the purposes of section 118, *administrative action*, taken against an individual, means imposing or varying a condition of a licence under the Act, issuing an improvement notice or a prohibition notice under the Act, or suspending or cancelling a licence under the Act.

Part 6 Review of decisions and appeals

Division 1 Preliminary

Definitions for part

Clause 119 provides definitions for part 6, including a definition of *reviewable decision*, which provides that any of the following are reviewable decisions:

- a decision to refuse to grant a licence under section 58;
- a decision to impose or vary a condition of a licence under section 59(2) or (3);
- a decision to issue an improvement notice, or to refuse to revoke an improvement notice, under section 62;
- a decision to issue a prohibition notice, or to refuse to revoke a prohibition notice, under section 63;
- a decision to cancel or suspend a licence, or to refuse to lift a licence suspension, under section 64;

Review process must start with internal review

Clause 120 states that an application to QCAT for the review of a reviewable decision may only be made if a decision on an application for internal review of the decision has been made, or taken to have been made, under division 2.

Division 2 Internal review

Who may apply for internal review

Clause 121 outlines who may apply for an internal review. It provides that an affected person for a reviewable decision may apply to the chief executive for a review of the decision under division 1 (an *internal review*).

An application cannot be made for a further internal review of an internal review decision.

If the affected person has not been given an information notice about the reviewable decision, the affected person may ask the chief executive for an information notice about the decision.

A failure by the chief executive to give the affected person an information notice about the reviewable decision does not limit or otherwise affect the person's right to apply for an internal review of the decision.

Requirements for application for internal review

Clause 122 states that an application for internal review of a reviewable decision must:

- be in the approved form; and
- for a person who has been given an information notice about the decision – include enough information to enable the chief executive to decide the application; and
- be made to the chief executive within:
  - for a person who has been given an information notice about the decision – 20 business days after the day the person is given the notice; or
  - for a person who has not been given an information notice about the decision – 20 business days after the day the person becomes aware of the decision.

The chief executive may, at any time, extend the period within which the application may be made.

The application does not affect the operation of the reviewable decision or prevent the decision being implemented.

Internal review

Clause 123 provides for the process for an internal review. It states that the chief executive must, within 20 business days after receiving an application for internal review of a reviewable decision:

- review the original decision; and
- decide to:
  - confirm the original decision; or
  - amend the original decision; or
  - substitute another decision for the original decision; and
- give the affected person a QCAT information notice about the internal review decision.

The chief executive and the affected person may, before the period stated in subsection (1) ends, agree to a longer period for the chief executive to comply with that subsection.

The application may be dealt with only by a person who did not make the original reviewable decision, and holds a more senior office than the person who made the original reviewable decision. This does not apply to if the original reviewable decision was made by the chief executive personally.

If the chief executive does not give the affected person a QCAT information notice within the period required under subsection (1) or a longer period agreed under subsection (2), the chief executive is taken to confirm the original reviewable decision.

Division 3 Stays of reviewable decisions

QCAT may stay operation of reviewable decision

Clause 124 states that an affected person for a reviewable decision may apply to QCAT, as provided under the QCAT Act, for a stay of the operation of the decision.

The application may be made at any time within which an application for an internal review of the original decision may be made under division 2.

QCAT may make an order staying the operation of the reviewable decision to secure the effectiveness of the internal review or any later review by QCAT of the decision.

A stay by QCAT under this section:

- may be given on conditions QCAT considers appropriate; and
- operates for the period fixed by QCAT; and
- may be amended or revoked by QCAT.

The period of a stay by QCAT under this section must not extend past the end of the period within which an application for a review of the internal review decision may be made under

the QCAT Act. The QCAT Act, section 22(3) enables QCAT to stay the operation of the internal review decision, either on application by a person or on its own initiative.

Division 4 External review

Applying for QCAT external review

Clause 125 states an affected person for an internal review decision may apply to QCAT, as provided under the QCAT Act, for a review of the internal review decision.

Division 5 Appeals against property decisions

Appealing seizure or forfeiture decisions

Clause 126 states this section applies to a person who must be given an information notice about a decision of the chief executive (a *property decision*):

- to refuse to return seized property under section 101; or
- to forfeit seized property under section 103.

Clause 126(2) states that the person may appeal to a Magistrates Court (the *court*) against the property decision by filing a notice of appeal with the Registrar of the court. The notice of appeal must state fully the grounds of the appeal. The person must file the notice of appeal within 28 days after an information notice about the decision is given to the person or the person otherwise becomes aware of the decision.

Clause 126(5) states the court may, on application and at any time, extend the time for filing the notice of appeal.

Clause 126(6) states the person must serve a copy of the notice of appeal, and any application to extend the time for filing the notice of appeal, on the chief executive. The appeal does not affect the operation of the property decision or prevent the property decision being implemented.

Staying operation of property decision

Clause 127 states a person who may appeal to the court against a property decision may apply to the court for a stay of the operation of the property decision.

Clause 127(2) states the court may, by order, stay the operation of the property decision to secure the effectiveness of the appeal. The court may stay the operation of the property decision on conditions the court considers appropriate. The stay operates for the period decided by the court. The period of the stay must not extend past the time when the court decides the appeal.

Powers of court on appeal

Clause 128 states when deciding the appeal against a property decision, the court has the same powers as the chief executive in making the property decision, is not bound by the rules of evidence and must comply with natural justice.

Clause 128(2) states an appeal is by way of rehearing.

Clause 128(3) states the court may:

- confirm the property decision; or
- substitute another decision for the property decision; or
- set aside the property decision and return the matter to the chief executive with directions the court considers appropriate.

Effect of court's decision on appeal

Clause 129 states if the court substitutes another decision for the property decision:

- the substituted decision is taken to be a decision of the chief executive; and
- the chief executive may give effect to the substituted decision as if:
  - the substituted decision were the original decision of the chief executive; and
  - no application for an appeal against the original decision had been made.

Clause 129(2) states if the court sets aside the property decision and returns the matter to the chief executive with directions, any decision made by the chief executive in accordance with directions may not be appealed against under this division.

Part 7 Legal proceedings

Application of part

Clause 130 states that part 7 applies in relation to a proceeding under the Act.

Appointments and authority

Clause 131 states that the following must be presumed unless a party to the proceeding, by reasonable notice, requires proof of it:

- the appointment of the chief executive, an inspector or the Registrar;
- the authority of the chief executive, an inspector or the Registrar to do anything under the Act.

Signatures

Clause 132 states that a signature purporting to be the signature of the chief executive, an inspector or the Registrar is evidence of the signature it purports to be.

Evidentiary provisions

Clause 133 states that a certificate purporting to be signed by the chief executive and stating any of the following matters is evidence of the matter:

- a stated document is any of the following:
  - a licence to provide ART services;
  - an approval given under the Act;
  - a notice or direction given under the Act;

  - an approved form;
  - an identity card;
  - an acknowledgement of consent signed under section 81;
  - a stated record kept under the Act;
- a stated document is a copy of, or an extract from or part of, a document mentioned in paragraph (a);
- on a stated day, or during a stated period, a person's appointment as the chief executive, an inspector or the Registrar was, or was not, in effect;
- on a stated day, or during a stated period, a licence:
  - was or was not in effect; or
  - was or was not subject to a stated condition;
- on a stated day, a stated person was given a stated notice or direction under the Act;
- on a stated day, a stated requirement was made of a stated person;
- a stated amount is payable under the Act by a stated person and has not been paid.

The Registrar may also sign a certificate under subsection (1) in relation to a matter to which part 3 applies.

Summary offence proceedings

Clause 134 states that a proceeding for an offence against the Act must be heard and decided summarily on complaint of the chief executive or the Registrar.

Limitation on time for starting offence proceeding

Clause 135 states that a proceeding for an offence against the Act must start:

- within 1 year after the commission of the offence; or
- within 6 months after the offence comes to the complainant's knowledge, but within 2 years after the commission of the offence.

Allegations of false or misleading information

Clause 136 states that in a proceeding for an offence against section 139, it is enough for a charge to state that the information to which the offence relates was, without specifying which, 'false or misleading'.

Conduct of representatives

Clause 137 states that if it is relevant to prove a person's state of mind about particular conduct, it is enough to show:

- the conduct was engaged in by a representative of the person within the scope of the representative's actual or apparent authority; and
- the representative had the state of mind.

Conduct engaged in for a person by a representative of the person within the scope of the representative's actual or apparent authority is taken to have also been engaged in by the person unless the person proves:

- the person was not in a position to influence the representative in relation to the conduct; or
- if the person was in a position to influence the representative in relation to the conduct – the person took reasonable steps to prevent the conduct.

A number of defined terms are included for the provision.

Executive officer may be taken to have committed offence against deemed executive liability provision

Clause 138 states that if a corporation commits an offence against a deemed executive liability provision, an executive officer of the corporation is taken to have also committed the offence if:

- the officer is authorised or permitted the corporation's conduct constituting the offence; or
- the officer was, directly or indirectly, knowingly concerned in the corporation's conduct constituting the offence.

The executive officer may be proceeded against for, and convicted of, the offence against the deemed executive liability provision whether or not the corporation has been proceeded against for, or convicted of, the offence.

This section does not affect:

- the liability of the corporation for the offence against the deemed executive liability provision; or
- the liability, under the Criminal Code, chapter 2, of any person, whether or not the person is an executive officer of the corporation, for the offence against the deemed executive liability provision.

For the purposes of section 138, *deemed executive liability provision* means any of the following provisions:

- a provision of part 2;
- a provision of part 3, division 3;
- section 139(2).

Part 8 Miscellaneous

False or misleading information

Clause 139 provides that a person must not give an official performing a function under the Act information the person knows is false or misleading in a material particular. The maximum penalty for non-compliance with this provision is 100 penalty units.

Official is defined for section 139 to mean the chief executive, a member of the staff of the chief executive or a contractor engaged by the chief executive, an inspector, the Registrar, or a member of the staff of the Registrar or a contractor engaged by the Registrar.

The provision does not apply to a person if the person, when giving the information in a document:

- tells the official, to the best of the person's ability, how the document is false or misleading; and
- if the person has, or can reasonably obtain, the correct information – gives the correct information.

Disclosure or use of confidential information

Clause 140 applies to a person:

- who is, or has been, any of the following persons:
  - the chief executive;
  - a member of the staff of the chief executive or a contractor engaged by the chief executive;
  - the Registrar;
  - a member of the staff of the Registrar or a contractor engaged by the Registrar; and
- who obtains confidential information in administering, or performing functions under, this Act.

Clause 140(2) provides the persons the section applies to must not disclose the confidential information to anyone, or use the confidential information, other than under this section. The maximum penalty for non-compliance with this provision is 50 penalty units.

Clause 140(3) provides the person may disclose or use the confidential information:

- in the performance of a function or exercise of a power under the Act; or
- with the consent of the person to whom the information relates; or
- to the extent the disclosure or use is otherwise required or permitted by law.

Clause 140(4) provides the person may disclose the confidential information to:

- a coroner investigating the death of a person under the *Coroners Act 2003*; or
- a law enforcement agency, for the purposes of detecting, investigating, preventing or prosecuting an offence under the Act or any other law.

Clause 140(5) provides the person may disclose the confidential information, to any of the following:

- a National Health Practitioner Board, or the Australian Health Practitioner Regulation Agency, established under the Health Practitioner Regulation National Law;
- an entity established under the *National Health Act 1953* (Cwlth);
- an official under the *Health Ombudsman Act 2013*;
- another entity (whether of the Commonwealth, of another State or of another country) that has functions relating to the regulation of ART services.

Clause 140(6) provides the person may disclose confidential information to an entity under subsection (4) or (5) only if the person is satisfied the disclosure is reasonably necessary for the entity to exercise its functions.

Clause 140(7) defines terms for section 140, including for *confidential information*, to mean information that could identify a person and is about the person or the person's affairs, but does not include information that is publicly available.

Chief executive and Registrar may share confidential or other information

Clause 141 provides that the chief executive and the Registrar may share confidential or other information for the purposes of the administration of the Act, including information obtained by an inspector under part 5 or by the Registrar under section 54.

Clause 141(2) provides that without limiting subsection (1), the information may be shared for the purposes of the exercise of a function of the chief executive or of the Registrar under the Act; or for the purposes of an investigation by an inspector under part 5 or an enquiry by the Registrar under section 54.

Approved forms

Clause 142 provides for the chief executive to approve forms for use under the Act (except for part 3).

The Registrar may approve forms for use under part 3.

Regulation-making power

Clause 143 provides for the Governor in Council to make regulations under the Act.

A regulation may:
- prescribe fees payable under the Act; and
- provide for a maximum penalty of 20 penalty units for a contravention of the regulation.

Part 9 Transitional provisions

Application of Act to existing matters

Clause 144 provides that this Act extends, subject to this part, to the following:

- ART services or ART procedures even when they were provided or carried out before the commencement of this Act;
- gametes or embryos even though they were obtained or created before the commencement of this Act;
- consents given to ART providers by gamete providers or other persons even though they were given before the commencement of this Act;
- information provided or recorded in connection with ART services even though the information was provided or recorded before the commencement of this Act.

Clause 144(2) provides that a person does not commit an offence under this Act for any act or omission that occurred before the commencement of this Act.

Licensing of existing ART providers

Clause 145 provides for an initial licensing assessment period that commences immediately after section 12 commences and applies for 3 months. During the initial licensing assessment period, section 12 (requirement to be licensed) does not apply to an ART provider if the ART provider provided ART services before commencement of the Act and the ART provider has RTAC accreditation. The 3-month period ends if the person applies for a licence during the limital licensing assessment period and the chief executive gives the ART provider notice of the chief executive's decision on the application.

This means that that when the licensing provisions commence, ART providers with RTAC accreditation will be able to continue providing ART services in Queensland without a licence for 3 months or until the chief executive grants or refuses their licence application, whichever event is earlier. After this time, it will be an offence to provide ART services without a licence.

Donated gametes previously allocated to person for ART procedures

Clause 146 provides a transitional arrangement for donated gametes allocated to a person for use in ART procedure before commencement of the Act. This section applies if:

- before commencement, a person has been allocated donated gametes for use in an ART procedure and has previously become pregnant using some of those allocated donated gametes as a result of an ART procedure; and
- an ART provider proposes to use the remaining donated gametes in further ART procedures for the person.

Clause 146(2) provides that a person may use the remaining gametes in an ART procedure, even though the donor has not consented under part 2, division 3. The donor's consent is taken as given unless the donor has since withdrawn their consent under part 2, division 3.

Clause 146(3) provides that the following limitations do not apply to use of the remaining donated gametes:

- any time limit on the period the gametes may be used (section 27);
- any limit on the number of donor-related Australian families who may use the gametes (section 25).

Donated embryo previously allocated to a person for ART procedures

Clause 147 provides a transitional arrangement for donated embryos allocated to a person for use in ART procedure before commencement. If a person is allocated a donated embryo for use in an ART procedure before commencement of this Act, an ART provider may use the donated embryo in an ART procedure.

Clause 147(2) provides that a person may use the donated embryo even though the donor had not consented under part 2 division 3 to the use of the donated embryo in the procedure. The

donor's consent is taken as given unless the donor has since withdrawn their consent under part 2, division 3.

Clause 147(3) provides that the following limitations do not apply to the use of the donated embryo in the ART procedure:

- any time limit on the period the embryo may be used (section 27);
- any limit on the number of donor-related Australian families who may use the donated embryos (section 25).

Embryo not yet used for ART procedure

Clause 148 provides a transitional arrangement for embryos not yet used in an ART procedure. This section applies where:

- a person has created an embryo before the commencement of the Act; and
- an ART provider proposes to use the embryo in an ART procedure for a person; and
- the embryo cannot be used because it would breach the time limit for use in clause 27 or breach the limit on the number of donor-related Australian families in clause 26.

Clause 148(2) provides that the chief executive may authorise the use of the embryo if satisfied it is a reasonable use of the embryo. In making the decision, the chief executive is to have regard to the period since the gamete was obtained and the number of existing donor-related families related to the donor of the gamete.

Clause 148(3) provides that the ART provider may use the embryo in an ART procedure even though the donor has not consented under part 2, division 3. The donor's consent is taken as given unless the donor has since withdrawn their consent under part 2, division 3.

Clause 148(4) provides the following limitations do not apply:

- any time limit on the period the embryo may be used (section 27);
- any limit on the number of donor-related Australian families who may use the embryo (section 25).

Time limits on use of existing donated gametes and embryos

Clause 149 provides that section 27 (time limit on use of donated gametes or embryos and their disposal) applies to donates gamete and donated embryo obtained or created before the commencement of this Act. This means that an ART provider must not use a donated gamete, donated embryo or embryo created from a donated gamete in an ART procedure if the gamete was obtained from the gamete provider more than 15 years before the procedure, unless the chief executive provides written approval.

The purpose of this provision is to ensure donated gametes, donated embryos and embryos created using donated gametes are not used after being stored for longer than 15 years, without due consideration by the chief executive about whether there are reasonable grounds for doing so.

Time within which information about pregnancies and births to be collected by ART providers

Clause 150 provides the time within which information about pregnancies and births must be collected that relate to ART procedures that occurred before commencement of the Act. The clause provides that section 35 applies to a person that becomes pregnant or gives birth as a result of an ART procedure carried out before the commencement of this Act, but only if:

- in the case of pregnancy – the procedure was carried out within 4 months before commencement (in which case the ART provider may collect this information about the pregnancy within 6 months after the procedure was carried out); or
- in the case of the birth of a child – the procedure was carried out within 15 months before that commencement (in which case the ART provider may collect the information about the birth within 18 months after the procedure was carried out).

This provision ensures that an ART provider collects information about a pregnancy or child born as a result of an ART procedure that occurs after commencement, despite the ART procedure occurring before commencement.

Information to be provided for donor conception information register for births using existing gametes or embryos

Clause 151 outlines the transitional provision for information to be provided to the register.

Clause 151(1) outlines that if a donor-conceived person is born after commencement of section 45 as a result of a procedure using a gamete that was donated before commencement of the section or a donated embryo that was created before commencement of the section, the obligations on ART providers outlined in section 45 apply to the birth of that person.

Clause 151(2) clarifies that in relation to a birth outlined in subclause (1), an ART provider is only required to provide the relevant information about the donor that the ART provider has recorded and kept at the time the donated gamete was obtained or the embryo became a donated embryo. That is, the ART provider is not required to provide all relevant information about the donor and will not be liable to penalty under 45(1) if the ART provider does not provide all relevant information about the donor.

To be clear, clauses 151(1) and (2) apply to the birth of a donor-conceived person after commencement of section 45 as a result of:

- a procedure that is allowed under clause 146;
- a procedure that is allowed under clause 147;
- a procedure that is allowed under 148; and
- a procedure using an embryo that was created using a donated gamete before commencement of section 45.

Part 10 Amendment of legislation

Division 1 Amendment of this Act

Act amended

Clause 152 provides that this division amends this Act.

Amendment of long title

Clause 153 provides that the words ‘and to’ are omitted from the long title.

Division 2 Amendment of *Anti-Discrimination Act 1991*

Act amended

Clause 154 provides that this division amends the *Anti-Discrimination Act 1991*.

Omission of s 45A (Non-application of s 46 to provision of assisted reproductive technology)

Clause 155 provides that section 45A of the Anti-Discrimination Act is omitted. By omitting this provision, ART providers can no longer discriminate on the basis of sexuality or relationship status in the provision of ART. The Bill omits this provision given it is redundant and no longer meets the clinical, ethical and community standards.

The Bill, and the omission of section 45A, reflects that ART services should be available to anyone who needs them regardless of their relationship status or sexual orientation. For example, clause 18 of the Bill provides that a donor cannot limit their consent to only allow the use of their donated gametes or donated embryos to a person based on particular attributes.

Division 3 Amendment of *Births, Deaths and Marriages Registration Act 2023*

Clause 156 outlines the division amends the *Births, Deaths and Marriages Act 2023*.

Amendment of s 23 (Addendum to birth certificate)

Clause 157 amends section 23 of the *Births, Deaths and Marriages Act 2023* to insert a reference to parentage orders in the heading of that section.

Insertion of new s 23A

Clause 158 inserts new section 23A into the *Births, Deaths and Marriages Act* 2023 which provides for an addendum to birth certificates in relation to donor conception.

New section 23A(1) outlines that the section applies if a person applies to the Registrar for requested information or their birth certificate, the person is at least 16 years at the time of making the application, and the person is recorded in the register as a donor-conceived person.

New section 23A(2) outlines that in these circumstances, the Registrar must attach an addendum to the information or birth certificate of the person which states that further information about the person is available in a register kept by the Registrar.

New section 23A(3) states that to remove any doubt, the Registrar must not issue the addendum with a birth certificate of the person expect to a birth certificate issued to the person themselves.

Amendment of s 99 (The registrar)

Clause 159 amends section 99(3) of the *Births, Deaths and Marriages Act 2023* to insert a note which states that the ART Act, part 3 gives the Registrar functions in connection with the register and that the register is not a register for the purposes of the *Births, Deaths and Marriages Act 2023*.

Amendment of s 100 (Staff)

Clause 160 amends section 100 of the *Births, Deaths and Marriages Act 2023* to outline that the Registrar's staff consist of the staff that are necessary for the proper administration of the BDMR Act and the ART Act.

Amendment of s 105 (Registrar may collect and maintain other information)

Clause 161 amends section 105 of the *Births, Deaths and Marriages Act 2023* to insert new subsection (4) which outlines that the powers of the Registrar to collect and maintain other information relating to registrable events outlined in the section do not apply to information in the register under Part 3 of this Act.

Schedule 1 Dictionary

Schedule 1 provides a dictionary of terms used in the Act.