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| Reforms to health regulation in Victoria |
| Consultation paper – 29 April 2024 |
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# Glossary

**Assisted reproductive treatment**

Assisted reproductive treatment (ART) is defined in the *Assisted Reproductive Treatment Act 2008* as a medical treatment or procedure that procures, or attempts to procure, pregnancy in a woman by means other than sexual intercourse or artificial insemination, and includes in-vitro fertilisation (IVF), gamete intrafallopian transfer, and any related treatment or procedure prescribed by the Assisted Reproductive Treatment Regulations 2019.

**Health portfolio legislation**

The suite of legislation that, under the [General Orders](https://www.vic.gov.au/general-orders) <https://www.vic.gov.au/general-orders> issued by the Premier of Victoria, is administered by the Minister for Health.

Health portfolio legislation creates powers, functions and duties that can be exercised by the Secretary to the Department of Health (the Secretary), delegates of the Secretary and (in many cases) authorised officers appointed by the Secretary. The staff supporting or exercising many of the department’s regulatory powers, functions and duties are in the Health Regulator.

**Health Regulator**

The Health Regulator is a branch of the Department of Health with a range of regulatory responsibilities across the health portfolio including in relation to child safety, medicines and poisons, legionella risk management, pest control, radiation safety, food safety, private hospitals and day procedure centres, non-emergency patient transport and first aid service providers, tobacco and e-cigarettes, and safe drinking water. It is proposed that the Health Regulator also have responsibility for regulating assisted reproductive treatment, subject to the proposed legislative reforms.

**Regulated entities**

The Department of Health regulates thousands of professionals, organisations and businesses across the state with the objective of preventing serious harm to the health and wellbeing of Victorians. This consultation paper uses the term ***regulated entities***to refer collectively to any person or other entity regulated by the department under the Acts proposed for amendment.

# Introduction

The Victorian Government is proposing legislative reforms to improve the regulatory tools available under health portfolio legislation, and to change the way that assisted reproductive treatment is regulated in Victoria.

The Department of Health is consulting on these reforms to seek stakeholder views, to build understanding of the reforms and to support their implementation.

The Department of Health (the department) regulates thousands of professionals, organisations and businesses across the state with the objective of preventing serious harm to the health and wellbeing of Victorians. Regulation plays a key role in contributing to the department’s vision that Victorians are the healthiest people in the world.

The department has a diverse range of regulatory responsibilities including in relation to child safety, communicable disease, medicines and poisons, legionella risk management, pest control, radiation safety, food safety, private hospitals and day procedure centres, non-emergency patient transport and first aid service providers, tobacco and e-cigarettes, and safe drinking water.

There are two external regulators in the health portfolio that are supported by the department: the Victorian Assisted Reproductive Treatment Authority (VARTA) and the Victorian Pharmacy Authority. The department also works closely with co-regulators such as the Health Complaints Commissioner, the Australian Health Practitioner Regulation Agency and local councils.

## Establishment of the Health Regulator

In December 2023, the Minister for Health announced the establishment of the Health Regulator – a new branch of the department that will have responsibility for most of the department’s existing areas of regulatory responsibility.[[1]](#footnote-2) The Health Regulator was formally established in February 2024 following a department restructure.

Consolidation of these regulatory functions will enable the department to adopt a more consistent, risk-based regulatory approach. The regulatory model will centralise regulatory resources and capability to maximise the department’s effectiveness as a regulator, enabling it to respond more rapidly and allocate appropriate resources to key priority areas.

## Reforms to health regulatory powers

The functions, powers and duties of the Health Regulator are set out in several health portfolio Acts.[[2]](#footnote-3) Many of these regulatory schemes have not kept pace with modern best practice regulatory design and do not include adequate mid-range compliance and enforcement tools.

It is proposed to make reforms to provide the Health Regulator with appropriate regulatory tools to enable graduated, risk-based and proportionate regulation. The proposed tools include consistent powers to issue infringement notices, issue improvement and prohibition notices, accept enforceable undertakings, and to require the provision of information or documents to support compliance monitoring.

Amendments are proposed to the Drugs, Poisons and Controlled Substances Act 1981 (DPCS Act), the Health Services Act 1988, the Non-Emergency Patient Transport and First Aid Services Act 2003 (NEPTFAS Act), the Public Health and Wellbeing Act 2008 (PHW Act), the Radiation Act 2005 and the Safe Drinking Water Act 2003 to ensure the Health Regulator has powers to effectively perform its role under these regulatory schemes.

Details of these reforms and questions for consultation are set out in Part 1: Improved compliance and enforcement tools.

## Reforms to assisted reproductive treatment regulation

As announced by the Minister in December 2023, the Victorian Government is also developing reforms to modernise the regulation of assisted reproductive treatment (ART) by transferring responsibility for the regulation of ART from VARTA to the Department of Health.

This will require reforms to the Assisted Reproductive Treatment Act 2008. As part of the proposed reforms, VARTA will cease to be established under the Assisted Reproductive Treatment Act, and its key powers and functions will be managed as follows:

* regulatory functions of registering ART providers and monitoring and enforcing compliance will transfer to the Secretary, Department of Health (with these functions to be performed by the Health Regulator)
* responsibility for maintaining and managing the Central Register and Voluntary Register (the registers) will transfer to a new Donor Conception Registrar, that will sit in the Department of Health
* requirements that counselling be offered or undertaken before the disclosure of information from the registers or lodgement of a contact preference, will be removed
* requirements for the regulator to pre-approve bringing donor gametes or embryos formed from them into or taking them out of Victoria will be removed and replaced with a certification requirement.

Reforms to improve regulatory tools are also proposed in line with reforms being made to other health regulatory schemes.

These reforms are intended to bring ART regulation more into line with how other health services are regulated by the department, and how a number of other jurisdictions regulate ART. It will also deliver on a number of recommendations of the *Independent Review of Assisted Reproductive Treatment* undertaken by Michael Gorton AM (the Gorton Review)[[3]](#footnote-4) including by providing the regulator with comprehensive, graduated compliance and enforcement powers.

Details of these reforms and consultation questions are set out in Part 2: Reforms to the regulation assisted reproductive treatment.

# Part 1: Improved compliance and enforcement tools

Health portfolio regulators play a key role in preventing serious harm to the health and wellbeing of Victorians and contributing to the department’s vision that Victorians are the healthiest people in the world. Reforms are proposed to the compliance and enforcement tools under health portfolio legislation to enable the Health Regulator to take graduated, risk-based, and proportionate regulatory action to achieve these objectives.

The department regulates a range of entities across several regulated sectors to ensure that minimum standards and other regulatory requirements are met. Effective regulation and compliance by regulated entities can also increase community confidence in regulated sectors by assuring the community that services are safe and well-regulated.

Examples of the department’s regulatory activities include:

* licensing almost 2,700 entities to authorise the possession, use, manufacture, sale, supply and/or administration of medicines and poisons
* licensing of 46 first aid service providers[[4]](#footnote-5) and 9 non-emergency patient transport providers[[5]](#footnote-6)
* registration of 78 private hospitals and 120 day procedure centres (including mobile services)[[6]](#footnote-7)
* in 2022-23, undertaking 24 inspections of the provision of first aid services, over 60 unannounced inspections of non-emergency patient transport vehicles, inspections of 1,270 cooling towers and 481 inspections of radiation safety management licences.

## The Health Regulator’s compliance and enforcement approach

In line with modern regulatory best practice the Health Regulator seeks to apply a graduated, risk-based and proportionate approach to regulation.

As set out in the compliance and enforcement pyramid in **Figure 1**, the Health Regulator will consider the level of risk and harm and the compliance posture of a regulated entity in determining the appropriate regulatory action to be taken. The Health Regulator will generally consider lower-level interventions (such as providing guidance and support to regulated entities about their compliance obligations) before considering more serious sanctions or applying the full force of the law (such as prosecuting offences).

The Health Regulator will publish a Compliance and Enforcement Policy in 2024 to provide regulated entities, co-regulators, stakeholders and the wider community with more information about its regulatory approach.

Regulatory tools

Refer to the diagram text at the end of this document in the section Diagram Text on page 25.

Figure 1 - compliance and enforcement pyramid (Better Regulatory Practice Framework (March 2018), Department of Health and Human Services, p 14)

## Purpose of the reforms to compliance and enforcement tools

In order for the Health Regulator to take a graduated, risk-based and proportionate approach, mid-range regulatory tools are required.

In the absence of mid-range options, the regulator may be forced to choose between taking inadequate regulatory action or taking potentially disproportionate action in response to less serious breaches (i.e. taking action at the bottom or top of the compliance and enforcement pyramid only). The proposed tools in this paper will enable the Health Regulator to better apply a best-practice compliance and enforcement approach.

While some regulatory schemes in the Health portfolio have compliance and enforcement tools that are closer to best practice, a number of the regulatory schemes the department is responsible for lack appropriate mid-range tools and limit the Health Regulator’s ability to take graduated compliance and enforcement action. There are instances where the need for improvements to the department’s compliance and enforcement activities has been identified (see e.g. Case study: SafeScript compliance). Improved regulatory tools will contribute to more effective regulation by the Health Regulator.

The proposed reforms aim to establish a consistent baseline of compliance and enforcement tools across health portfolio legislation to enable the Health Regulator to take graduated, risk-based and proportionate regulatory action across each of its regulatory areas. This will include:

* **Improvement and prohibition notices –** that may require a regulated entity to take action to remedy non-compliance, or to prohibit an activity from being undertaken.
* **Infringement notices –** that may enable certain contraventions to be discharged by payment of a fine in appropriate circumstances.
* **Enforceable undertakings –** that may enable regulated entities to offer to undertake certain actions as part of a binding agreement to remedy a contravention or prevent future contraventions.
* **Notice to provide information or documents –** that may require a regulated entity to provide information or documents to monitor compliance.

More information on each of these compliance and enforcement tools is set out in this Part.

The regulated entities that the proposed new compliance and enforcement tools will apply differ between regulatory schemes and are listed in **Appendix 1**. These are entities that are subject to regulatory requirements under health portfolio legislation that may include requirements to hold a licence, registration, permit, or some other kind of permission, before they are allowed to undertake a regulated activity.

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| **Case study: SafeScript compliance**  SafeScript is a clinical tool that provides medical practitioners, nurse practitioners and pharmacists with access to a patient’s prescription history for high risk medicines to enable safer clinical decisions. SafeScript is an ICT system that has over 36,000 registered users and records around 46,000 prescribing or supply events per day. SafeScript contributes to reducing and preventing serious harms from certain high risk prescription medicines, including deaths due to prescription medicine overdose.  It is mandatory for medical practitioners, nurse practitioners, and pharmacists to check SafeScript before prescribing or supplying a medicine monitored through the system (unless an exemption applies). There are offences in the DPCS Act that apply if these health practitioners fail to comply with requirements to check SafeScript. The Coroners Court of Victoria has made findings and recommendations to improve compliance with mandatory checking of SafeScript and the department has committed to developing additional enforcement tools to support compliance with SafeScript.  Currently, the regulator has limited options where non-compliance with SafeScript requirements is identified. The regulator undertakes activities to educate and remind health professionals of their obligations as a first step, and in some cases this may achieve the desired outcome. However, where there is continued non-compliance there are no alternative options under the DPCS Act other than prosecution. While prosecution is sometimes warranted, it is not always the most proportionate or timely means of addressing non-compliance.  Under the proposed reforms, additional compliance and enforcement options will be available, enabling the regulator to take graduated, timely and proportionate action to ensure compliance and minimise harm. For example:   * the regulator could issue an improvement notice to a practitioner requiring the practitioner to take action to ensure their compliance with SafeScript checking requirements * if the SafeScript offences were able to be prescribed as infringement offences, the regulator could issue an infringement notice requiring the practitioner to pay a financial penalty for not complying with the requirement (or elect to have the matter heard in court).   The regulator could still consider whether prosecution is a more appropriate response, but the availability of other compliance and enforcement options would enable a graduated approach having regard to its compliance and enforcement policy. |

## Power to issue an improvement notice

An **improvement notice** is a common regulatory tool that can be issued to a regulated entity to require the entity to take specified actions to remedy non-compliance with a regulatory requirement.

The purpose of an improvement notice is to bring a regulated entity back into compliance, and to help to prevent risks to health and safety from arising.

There are already powers to issue improvement notices in some health portfolio legislation (for example, the PHW Act and the Radiation Act). It is proposed to also include a power to issue an improvement notice in the DPCS Act, the Health Services Act and the NEPTFAS Act.

It is proposed that an improvement notice:

* may be issued to a regulated entity by the Secretary (or their delegate) or an authorised officer based on a reasonable belief that the regulated entity is contravening, has contravened or is likely to contravene a relevant regulatory requirement
* may require the regulated entity to take actions the regulator considers reasonably necessary to remedy the contravention or likely contravention
* must include specified details including the grounds for the notice, the actions required under the notice, the date of effect and period for compliance, and the penalties for not complying
* can be reviewed in the Victorian Civil and Administrative Tribunal (VCAT) on application by the regulated entity.

Failure to comply with an improvement notice without reasonable excuse is proposed to be an offence. The proposed maximum penalty is 240 penalty units ($46,154)[[7]](#footnote-8) for an individual, or 1,200 penalty units ($230,772) for a corporation.

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| **Example**  Schedule 4 and Schedule 8 poisons are subject to storage requirements under the DPCS Act and regulations. For example, certain poisons must be stored in a locked facility meeting the requirements in the regulations. These requirements aim to manage serious risks to health that may arise if these poisons are accessed and used inappropriately.  Compliance monitoring may identify that a regulated entity (for example a health practitioner or wholesaler) is not complying with these requirements (for example, by not having or not using a storage facility that meets the requirements). Currently, the regulator is limited to relying on the cooperation of the regulated entity to comply or resorting to prosecution, that may not be timely or proportionate in some instances.  Under the proposed reforms, the regulator could issue an improvement notice requiring the regulated entity to take actions to ensure they are complying with storage requirements (for example, by installing an appropriate storage facility by a specified date). This may be a more timely and proportionate remedy than the tools currently available to the regulator.  See also: Case Study: SafeScript compliance. |

## Power to issue a prohibition notice

A **prohibition notice** is another type of notice that can be issued in response to non-compliance, but unlike an improvement notice can prohibit a regulated entity from engaging in an activity that poses a risk of harm to health or safety.

The purpose of a prohibition notice is to prevent harm by stopping the activity posing the risk while the non-compliance is being remedied.

There are already powers to issue prohibition notices in some health portfolio legislation (for example, the PHW Act and the Radiation Act). It is proposed to also include a power to issue an improvement notice in the DPCS Act, the Health Services Act and the NEPTFAS Act.

It is proposed that a prohibition notice:

* may be issued by the Secretary (or their delegate) or an authorised officer to a regulated entity, based on a reasonable belief, has failed to, is failing to or is likely to fail to comply with their legal obligations, **and** that, having regard to the immediacy of the risk of harm, prohibiting activity is necessary to minimise the risk
* may prohibit the person from engaging in the activity, and take any other actions the regulator considers reasonably necessary to minimise the risk
* must include specified details including the grounds for the notice, the activity prohibited and any other actions required under the notice, the date of effect and period for compliance, and the penalties for not complying
* can be reviewed in the Victorian Civil and Administrative Tribunal (VCAT) on application by the regulated entity.

Failure to comply with a prohibition notice without reasonable excuse is proposed to be an offence. The proposed maximum penalty is 240 penalty units ($46,154)[[8]](#footnote-9) for an individual, or 1,200 penalty units ($230,772) for a corporation.

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| **Example**  Non-emergency patient transport (NEPT) is for patients who require clinical monitoring or supervision during transport, but do not require a time critical ambulance response. NEPT vehicles must meet certain requirements in the regulations to ensure they are fit for purpose. These requirements include vehicle mechanical quality, mileage limits, cleanliness and minimum clinical equipment standards.  Compliance monitoring may identify that a NEPT vehicle is not compliant with the regulations or is not provided with sufficient equipment to safely care for patients, and that continued use of the vehicle would pose an immediate risk to the health or safety of patients or NEPT staff.  In these circumstances the regulator could issue a prohibition notice, prohibiting use of the vehicle until specified actions have been taken to ensure the vehicle is compliant with the requirements. |

## Power to accept an enforceable undertaking

An **enforceable undertaking** is a binding, formal and legally enforceable agreement in which the regulated entity promises to take specific actions within an agreed timeframe. Unlike most other regulatory tools, an enforceable undertaking is offered by the regulated entity (rather than issued by the regulator).

The regulator has discretion to accept the enforceable undertaking and may negotiate with the regulated entity on the terms of the undertaking. Once an enforceable undertaking has been entered into, the regulated entity can only withdraw or vary the undertaking with the consent of the regulator.

If an enforceable undertaking has been entered into, the regulated entity cannot be prosecuted for the non-compliance that the undertaking relates to while the undertaking is in force and being complied with, or once it has been fulfilled.

It will not be an offence to fail to comply with an undertaking. However, the regulator will be able to enforce the undertaking in a court. The court may order the regulated entity to take actions to comply with the undertaking.

For a regulated entity, the benefits of an enforceable undertaking include that:

* it enables the regulated entity to demonstrate proactive responsibility for addressing compliance issues, particularly where systemic change is required
* there is scope to negotiate with the regulator on the actions and timeframes to bring the regulated entity back into compliance
* there is certainty that they cannot be prosecuted for the non-compliance provided they meet the terms of the undertaking.

There are already powers to accept enforceable undertakings in some health portfolio legislation (for example, the Safe Drinking Water Act). It is proposed to also include a power to accept enforceable undertakings in the DPCS Act, the Health Services Act, NEPTFAS Act, the PHW Act and the Radiation Act.

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| **Example**  A holder of a radiation management licence under the Radiation Act is required to develop and implement a radiation management plan (RMP). An RMP sets out procedures that must be followed to ensure that radiation sources are used in a safe and secure way that minimises harm to people and the environment.  A licence holder may identify non-compliance within their organisation with aspects of their RMP, for example in relation to staff training, use of safety equipment or safe storage of radiation sources.  The licence holder may offer an enforceable undertaking to the regulator setting out the actions that the licence holder proposes to take to bring the holder back into compliance with their obligations. If the undertaking is accepted by the regulator, the regulator cannot bring proceedings against the licence holder provided the undertaking is complied with. |

## Power to issue infringement notices

An **infringement notice** is a common regulatory tool that enables non-compliance to be dealt with by payment of an infringement penalty in appropriate circumstances. It can be a more proportionate means of dealing with less serious breaches, instead of pursuing prosecution. The power to issue infringement notices can be a timely and effective tool for deterring future non-compliances and over time contributing to improved regulatory outcomes.

An infringement notice will be able to be issued by the Secretary (or their delegate) or an authorised officer to any person that they reasonably believe has committed an offence against the Act or the regulations that is prescribed as an infringement offence.

The making of regulations prescribing infringement offences, including the penalty amounts, are subject to the requirements of the *Subordinate Legislation Act 1994* and the *Attorney-General’s Guidelines to the Infringements Act 2006* (the Guidelines). The issuing of infringement notices will be consistent with existing Victorian Government legislation and policies that govern infringements including the *Infringements Act 2006*.

The Guidelines specify that generally, the infringement penalty will be set at a level that is not more than 25% of the maximum penalty for the offence, and in any case should not be more than 12 penalty units for an individual or 60 penalty units for a body corporate. For example, if the maximum penalty for an offence is 10 penalty units for an individual or 50 penalty units for a body corporate, the infringement penalty should be not more than 2.5 penalty units for an individual or 15 penalty units for a body corporate. If the maximum penalty for an offence is 100 penalty units for an individual or 500 units for a body corporate, the infringement penalty should be not more than 12 penalty units for an individual or 60 penalty units for a body corporate.

If an infringement penalty is paid, no further action is taken against the person for the offence that the notice relates to. A person may choose not to pay an infringement penalty and instead have the matter heard in court.

There are already powers to issue infringement notices in some health portfolio legislation (for example the Radiation Act). It is proposed to include a power to issue infringement notices in the DPCS Act, the NEPTFAS Act and the Safe Drinking Water Act. It is also proposed to amend the infringement notice power in the Health Services Act to modernise the existing power, including to enable offences in the Act to be specified as infringement offences (not only offences in the regulations).

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| **Example:** see Case Study: SafeScript compliance. |

## Power to require the provision of information or production of documents

Powers to require the provision of information or production of documents (**information gathering notice**) are commonly available to regulators, in particular to support regulators to perform their functions in monitoring compliance with regulatory requirements in order to minimise risks of harm.

Generally, the Health Regulator will work collaboratively with entities to seek voluntary provision of information or documents. Compulsory information gathering powers support the regulator to obtain necessarily information or documents where information is not provided voluntarily.

It is proposed that an information gathering notice:

* may be issued by the Secretary (or their delegate) or an authorised officer based on a reasonable belief that the information or documents are necessary to monitor a regulated entity’s compliance with the relevant Act or regulations
* the notice may be issued to a regulated entity, a person carrying out an activity that can only be undertaken by a regulated entity, or a person the Secretary or authorised officer reasonably believes has the information or documents
* must include specified details including the purpose of the notice, the information or documents required, and the period for compliance, which is proposed to be a minimum of 10 business days
* can be reviewed in VCAT on application by the person required to comply with the notice.

Powers to issue information gathering notices are proposed to be included in the DPCS Act, the Health Services Act, the NEPTFAS Act, the PHW Act and the Radiation Act.

Failure to comply with the notice without a reasonable excuse, or providing false or misleading information or documents, is proposed to be an offence with a maximum penalty of 60 penalty units for an individual or 300 penalty units for a body corporate.

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| **Example**  Under the NEPTFAS (FAS) Regulations, if a licensed first aid provider proposes to provide first aid services at an event, they are required to ensure that the first aid service can meet the first aid needs for the event before providing the services.  For example, licensed first aid providers generally conduct and document a risk assessment based on engagement with the event organiser and local health services, event information, characteristics and history to inform a decision about whether to provide services and what form the service offering will take to ensure the first aid needs for the event can be met.  To assess and monitor compliance with this requirement, the regulator could issue an information gathering notice to a licence holder to require the provision of information or documents, such as the first aid provider’s risks assessment, to demonstrate compliance with this requirement and ensure the safe and quality provision of first aid services. |

## Other related reforms

The department is separately consulting on a number of other regulatory reforms that may be relevant to the reforms outlined in Part 1. These include the review of the ‘sunsetting’ (expiring) Health Services (Health Service Establishments) Regulations 2013 and the review of the sunsetting Safe Drinking Water Regulations 2015.

The department is conscious of the impacts on regulated entities required to comply with any new regulatory requirements and will seek to coordinate implementation of related reforms where possible. This could include, for example, aligning implementation of new infringement offences under the Health Service Establishments Regulations with new compliance and enforcement powers proposed to be included in the Health Services Act.

As it is proposed to include new powers in the Safe Drinking Water Act to issue infringement notices, the department will also consult on potential infringement offences as part of the review of the Safe Drinking Water Regulations.

Forthcoming reforms to the *Food Act 1984* may also be required in line with the department’s response to the Victorian Auditor-General’s report on *Regulating Food Safety*.[[9]](#footnote-10) Separate consultation will take place on these reforms, including requirements for food businesses to display the owners name, registration number and registering council prominently on any online profile.

## Consultation questions: Part 1

Consultation questions for Part 1 are set out below. Please provide rationale and any relevant details to support your response.

1. Do you support the Health Regulator having access to the proposed compliance and enforcement tools across the regulatory schemes it is responsible for?
2. Do you agree that these compliance and enforcement powers will enable the Health Regulator to adopt a more graduated, risk-based and proportionate approach to compliance and enforcement?
3. Can you provide examples of a regulator that has used similar compliance and enforcement tools in a manner that you consider to be effective, or ineffective?
4. Are there any other matters that should be considered in implementing the proposed compliance and enforcement tools (including any specific impacts or benefits for you, your sector or the regulated services you use)?
5. Do you have any feedback on the penalties that are proposed to apply in relation to the new compliance and enforcement tools?
6. Do you have any other feedback or suggestions in relation to the Health Regulator’s compliance and enforcement approach or other related matters?

# Part 2: Reforms to the regulation of assisted reproductive treatment

Victoria has long been a leader in the provision and regulation of ART. The first Australian IVF baby was born in Victoria in 1980, and Victoria was the first jurisdiction in the country to provide legislative safeguards for individuals undertaking ART through the *Infertility (Medical Procedures) Act 1984*. Victoria was also the first Australian jurisdiction to recognise the needs of people conceived through donor treatment procedures to have access to information about their genetic heritage.[[10]](#footnote-11)

Although ART has become an increasingly normalised way for Victorians to start or grow their family, the specific regulation of ART remains an important way to provide safeguards for the children who may be born as a result of treatment (such as ensuring access to information about genetic heritage), donors, surrogates, and those undertaking treatment (such as mandating pre-treatment counselling to help individuals understand possible risks and implications).

## Background

ART in Victoria is currently regulated by the Victorian Assisted Reproductive Treatment Authority (VARTA). VARTA is established under the *Assisted Reproductive Treatment Act 2008* (ART Act) and its functions include:

* registering ART providers and monitoring compliance with the ART Act, the *Assisted Reproductive Treatment Regulations 2019* (ART Regulations) and conditions of ART providers’ registration
* managing the registers that hold information about donor conception in Victoria (the Central and Voluntary registers) including processing applications from people who want to seek and store information on the registers and providing them with counselling and support
* considering applications to bring donated gametes or embryos formed from them into, or take them out of, Victoria
* promoting education and research about fertility, infertility and ART.

The reforms announced by the Minister for Health in December 2023 include transferring responsibility for ART regulation from VARTA to the Health Regulator, a new branch of the department that will bring together most of the department’s regulators.

## Purpose of the ART reforms

The proposed reforms will make changes to the functions currently performed by VARTA under the ART Act – transferring some functions to the department and removing other functions from the legislation. They will also introduce new compliance and enforcement powers to the legislation. The changes are set out in more detail below. As a result of the changes to these functions, subject to passage of the reforms VARTA will no longer be established under the ART Act. The department will work closely with VARTA during the transition period on transitional matters including the safe and secure transfer of ICT systems and records.

The reforms are intended to improve and streamline regulation of ART providers and other matters under the ART Act so that the protections in the legislation can operate most effectively as safeguards for Victorians – including those seeking and receiving ART treatment, people conceived through donor treatment procedures, donors, and surrogates.

The reforms are also intended to reflect changes since VARTA was established, that include significant clinical and social advances in relation to fertility treatment. The specialised aspects of ART as a health service will continue to be recognised. It is also acknowledged that ART raises issues that are not common to other health services – for those accessing ART, for people conceived through donor treatment procedures, and for donors and surrogates – and that these issues may require specific legal protections. However, ART is an increasingly common and normalised means of family formation. The most effective avenue of support for those who are involved or impacted may not require legislated functions that are delivered by a regulatory agency.

### Registration of ART providers

Responsibility for registering ART providers in Victoria is proposed to transfer from VARTA to the Health Regulator. All registrations in place at the date of transfer will continue in effect, including any conditions of registration.

It is proposed that general conditions that apply to all ART providers will be able to be prescribed in the ART regulations, and specific conditions on individual registrations can be imposed by the Health Regulator. There will be consultation requirements before new conditions can be imposed.

The Gorton Review recommended penalties for providers who breach a condition of their registration. The reforms will introduce an offence for providers who breach of a condition of registration without reasonable excuse. A maximum penalty of 240 penalty units for an individual or 1,200 penalty units for a body corporate is proposed.

VARTA has recently undertaken a review of the conditions of registration and intends to publish revised conditions. Consideration is being given to delayed commencement of the new offence provision to enable a further review to ensure the conditions of registration are suitable to be subject to an offence provision.

Like VARTA currently, it is proposed the Health Regulator will also be able to suspend a provider’s registration if they reasonably believe the provider has contravened a provision of the ART Act, ART Regulations or the conditions of registration.

### Monitoring and enforcing compliance with the ART Act and Regulations

Responsibility for monitoring and enforcing compliance with the ART Act, the ART Regulations, and registered ART providers’ conditions of registration will transfer from VARTA to the Health Regulator as part of the reforms. Regulated entities include registered ART providers and other entities listed in **Appendix 1**.

The Health Regulator regulates a range of other health services, entities and professionals, and is well placed to take on these functions. In addition, the reforms will provide the Health Regulator with improved tools with which to monitor and enforce compliance.

Consistent with the reforms being made to other areas regulated by the Health Regulator, and with the recommendations of the Gorton Review, graduated compliance and enforcement tools will be included in the ART Act. In addition to powers to impose conditions on registration or suspend an ART provider’s registration, the Health Regulator will have powers to:

* issue improvement and prohibition notices
* issue infringement notices
* issue notices requiring the provision of information or documents, and
* accept enforceable undertakings.

Further information about these compliance and enforcement tools is provided in Part 1 of this paper (Improved compliance and enforcement tools).

### Oversight of donated gametes/embryos being brought into, or taken out of, Victoria

Currently it is an offence under the ART Act to move donor gametes, or embryos formed from them, into or out of Victoria without VARTA’s written approval. The current process imposes barriers for those who may need to access donated gametes/embryos to conceive a child, including people in a same-sex relationship and single-parents-by-choice.

Consistent with recommendation 56 of the Gorton Review, this offence will remain in the Act but the requirement for the regulator’s pre-approval is proposed to be replaced with a certification requirement. It is proposed that a person seeking to move donated gametes or embryos formed from them into or out of Victoria must certify to the Health Regulator that specified criteria have been satisfied in relation to the donated gametes or embryos. A separate certification would be required for each individual or class of donor gametes, or embryos formed from them, that is proposed to be moved into or out of Victoria.

The matters that must be certified will be set out in the Act, with any further details to be prescribed in the regulations. These matters are based on requirements currently in the Act that apply to the use of all donated gametes/embryos in ART, regardless of where they are donated. These include informed consent and provision of information for the donor conception registers.

A proposed list of matters to be dealt with in the certification is provided in **Appendix 2**.

Where a certification has been made under the ART Act, but the donated material does not meet specified criteria in the ART Act for use in an ART procedure (such as consent being given to a designated officer of a Victorian registered ART provider) the Health Regulator will be able to grant an exemption in particular circumstances (similar to VARTA’s current exemption power under section 37 of the ART Act).

The new compliance and enforcement tools will enable the Health Regulator to monitor and enforce compliance with the certification requirements. For example, the Health Regulator will be able to issue an information gathering notice to assess compliance with the certification requirements and it will be an offence to provide false or misleading information in a certification.

To provide for measures to be taken, where necessary, to place greater restrictions on donor gametes and embryos coming into Victoria, it is proposed regulations may be made to:

* prohibit donor gametes and embryos (or a class of them) being brought into or taken from Victoria in specified circumstances
* specify conditions to which the movement of donor gametes and embryos (or a class of them) into or from Victoria is subject
* prescribe additional requirements in respect of moving donor gametes or embryos (or a class of them) into or from Victoria.

### Donor conception registry functions

VARTA manages the donor conception registers – the Central Register and the Voluntary Register. It receives information from registered ART providers and medical practitioners and responds to applications for information on the registers.

The reforms will transfer responsibility for maintaining and managing the Central and Voluntary registers to a new Donor Conception Registrar, that will sit in the Department of Health. The registry functions will be administratively separate from the regulatory functions of the Health Regulator.

No substantial changes are proposed to requirements and processes for access to information on the registers or the registry functions in the Act, except as set out below in relation to counselling and donor-linking services.

### Counselling and donor-linking functions

VARTA provides counselling to people applying to the donor conception registers for information and to those about whom information is sought. Under the ART Act it is mandatory for VARTA to provide or offer counselling in some circumstances.

It is proposed to remove mandatory requirements relating to counselling before information on the registers can be accessed or a contact preference lodged. Donor treatment procedures have become an increasingly normalised form of family formation, and this change recognises the ability of individuals to make an informed choice about their needs in relation to discovering their genetic heritage. Consideration will be given to providing funding to an appropriate organisation to deliver counselling and other services for those who wish to access them. All other counselling requirements in the ART Act, including requirements for donors to receive counselling prior to consenting to the use of their gametes in a treatment procedure, will remain in place.

Establishing contact between persons linked by donor conception may present challenges and difficult decisions for those involved and for their families. Before information can be disclosed or a contact preference lodged, the ART Act will require the Donor Conception Registrar to provide information to the person seeking information from the registers, or about whom information is sought. The prescribed information will cover matters that are currently required to be covered during mandated counselling, such as information about the duties and rights of parties in relation to the registers, the potential implications of disclosure for the parties involved, and information about a person’s options if they wish to seek counselling, including any available counselling provided by a state-funded entity.

Current requirements for a counsellor to confirm the maturity of a child involved in accessing information on the registers are proposed to be retained.

To further support individuals about whom information is sought, it is intended the ART Act will require that the applicant for that information provide a ‘statement of reasons’ and this will be given to the individual to assist their decision-making.

VARTA also undertakes a donor-linking function to facilitate communication and support people conceived through donor treatment procedures and others if they seek support in managing contact with each other. It is proposed that these services will no longer be provided by VARTA, the Registrar or the department under the ART Act. While the importance of these services is recognised, it is considered that, like counselling, these services can be appropriately provided as needed – and as sought by individuals – outside the legislative scheme in the ART Act.

### Education, research promotion and community consultation functions

VARTA’s functions under the ART Act include undertaking public education and community consultation and promoting research into infertility. It is intended that these functions will be removed from the ART Act. While the importance of these functions is recognised, it is considered that they can be performed by the department or other bodies with relevant expertise as required without needing to be legislated. It is therefore not proposed that these be retained as a specific function of the Health Regulator under the ART Act.

### Other reforms

The proposed reforms to the ART Act are focused on the reforms necessary to transition VARTA’s functions to the department and changes to other functions as outlined in this Part. The department acknowledges stakeholders may have other reforms they would like to be considered and welcomes input on these matters to inform any future reforms to the ART Act.

## Consultation questions: Part 2

Consultation questions for Part 2 are set out below. Please provide rationale and any relevant details to support your response.

1. Do you have any feedback on the proposals for the management of regulatory and other functions under the ART Act (including the transfer of regulatory functions to the Department of Health and donor registry functions to the new Donor Conception Registrar)?
2. Do you support the proposed compliance and enforcement powers for the Health Regulator under the ART Act?
3. Are the proposed matters included in the information provision requirements in relation to accessing information on the donor conception registers appropriate? Is there anything that should be added?
4. Do you have any feedback on the proposed criteria that must be addressed in the certification for bringing donor gametes/embryos into/taking them out of Victoria (see **Appendix 2**)? Are there any that should be added, amended, or removed?
5. Do you have any comments on the operation of the certification process for bringing donor gametes/embryos into/taking them out of Victoria?
6. Are there any transitional matters that you think should be considered as part of the transition of VARTA’s functions under the proposed reforms?
7. Are there any other matters you think should be considered in implementation of the reforms?
8. Are there other reforms relating to ART that you would like the department to consider as part of any future reforms?

# Providing feedback

The department is seeking feedback from interested parties that will inform drafting of the legislative amendments needed to achieve the reforms discussed above and support their implementation.

## How to make a submission

A feedback template is available on the department’s website at [Reforms to health regulation in Victoria](http://www.health.vic.gov.au/legislation/reforms-to-health-regulation-in-victoria) <www.health.vic.gov.au/legislation/reforms-to-health-regulation-in-victoria>. You may use this template to submit your response or provide your feedback in another written format.

Stakeholders are invited to submit responses to the consultation paper by [email to the Department of Health’s Legislative and Regulatory Reform Team](mailto:legandregreform@health.vic.gov.au) at <legandregreform@health.vic.gov.au>.

**Submissions will be accepted until midnight 31 May 2024.**

## Publication of submissions

Submissions will not be made public, however an anonymised summary of submissions may be published. Please clearly indicate if you do not wish any part of your submission to be made public by marking your submission as ‘private and confidential’.

Please read the following privacy collection notice before completing your submission.

## Privacy collection notice

Participation in this consultation is voluntary and by providing your submission you will be taken to have provided consent for collection and use of the information provided.

The Department of Health (department) is committed to protecting your privacy, and any personal information you provide is collected and handled in accordance with the *Privacy and Data Protection Act 2014* (Vic).

The information you provide in your submission will be used by the department to administer the consultation process associated with the *Reforms to health regulation in Victoria – consultation paper*. This information will be used to prepare for any further required consultation, design the proposed reforms and support their implementation. Your email address may also be used to send you updates as the consultation and reforms progress.

When you email your submission, the department will collect your email address. Your contact email address will not be shared with any third party. You are not required to provide any further personal or contact information in order to contribute to this consultation.

You are asked not to provide any identifying information about yourself or any third party in your submission. If personally identifying information is inadvertently provided/collected, we will take reasonable steps to delete it.

Material in submissions may be published unless you have clearly indicated that you do not wish it to be made public by marking your submission as ‘private and confidential’.

For more information on the department’s privacy collection practices, please refer to the department’s [Privacy policy](https://www.health.vic.gov.au/department-of-health-privacy-policy) <https://www.health.vic.gov.au/department-of-health-privacy-policy>.

You may contact the Legislative and Regulatory Reform team supervising the consultation by emailing [Legislation and Regulation Reform](mailto:Legislation%20and%20Regulation%20Reform%20(HEALTH)%20%3clegandregreform@health.vic.gov.au%3e) <legandregreform@health.vic.gov.au>.

You may contact the department’s Privacy team by emailing [Privacy team](mailto:privacy@health.vic.gov.au) <privacy@health.vic.gov.au>.

# Next steps

Feedback from consultation will be used by the department to design the proposed reforms and plan for their implementation. The department may have further targeted discussions with stakeholders in relation to any feedback received.

Further detail on the reforms and a timeframe for implementation will be available later in 2024.

# Appendix 1

## Regulated entities

For the purposes of the proposed reforms, the entities considered to be regulated entities under each of the Acts to be amended are listed below.

### Assisted Reproductive Treatment Act 2008

* A registered ART provider
* A designated officer for a registered ART provider
* A doctor carrying out artificial insemination
* A doctor carrying out ART
* A person who has given a certification under section 36 of the Act in relation to bringing donor gametes or embryos formed from them into or out of Victoria (only for the issue of a notice requiring the provision of information or production of documents).

### Drugs, Poisons and Controlled Substances Act 1981

* A person who is licensed or otherwise authorised by or under sections 13 or 19 or Regulation 7 of the Drugs, Poisons and Controlled Substances Regulations 2017 to obtain, possess, supply, use, sell, manufacture, purchase or administer a poison or controlled substance, and is required to comply with other requirements in Part II of the Act or relevant Regulations
* A person who obtains, possesses, supplies, uses, sells, manufactures, purchases or administers a poison or controlled substance without the required licence, permit, warrant or authorisation
* A person who is subject to the requirements of section 27A of the Act.

### Health Services Act 1988

* The proprietor of a health service establishment
* The legal personal representative carrying on the establishment after the death of the proprietor (pursuant to section 97 of the Act).

### Non-Emergency Patient Transport and First Aid Services Act 2003

* The operator of a non-emergency patient transport service
* The operator of a first aid service

### Public Health and Wellbeing Act 2008 (Part 7)

* A person who owns any land where a cooling tower system operates
* A person who owns, manages or controls a cooling tower system
* A person in charge of a cooling tower system
* A person who owns, manages or controls a water delivery system located at premises where residential aged care, health or inpatient forensic mental health services are provided, at prisons or at premises where commercial vehicle washes are operated
* A pest control operator

### Radiation Act 2005

* A person conducting a radiation practice
* A person using a radiation source
* The owner or occupier of land used for or intended to be used for a radiation facility
* An approved tester
* An approved assessor.

### Safe Drinking Water Act 2003

New powers to issue infringement notices may apply to entities subject to offence provisions under the Act.

# Appendix 2

## Proposed certification criteria for moving donor gametes/ embryos into/out of Victoria

Prior to bringing donor gametes or embryos formed from them into Victoria, a person must certify that:

* any payments made in relation to the donation are permitted by Victorian and Commonwealth legislation (*Human Tissue Act 1982* and *Prohibition of Human Cloning for Reproduction Act 2008*);
* best efforts have been made to ensure compliance with the requirements in section 29 of the ART Act in relation to the limitation that a treatment procedure using gametes or embryos obtained from a single donor does not lead to more than 10 families having children from the same donor (including children not born as a result of a treatment procedure);
* the donor has consented in writing to the storage and later use of their donated materials;
* the donor has consented in writing to their gametes/embryo formed from their gametes being moved into Victoria;
* the donor has been given written advice about the matters in section 19(b)(i) – (iv) of the ART Act;
* the donor has provided the prescribed information required for the registers;
* the donor has received counselling on the prescribed matters from a counsellor with expertise in fertility counselling;
* the transferring clinic (where relevant) has undertaken to provide any change or withdrawal of consent relating to the donated material to the receiving clinic (section 23 of the ART Act provides this for transfers within Victoria);
* the transferring clinic (where relevant) has undertaken to make reasonable efforts to give the donor written notice of the name of the receiving clinic (section 24 of the ART Act provides this for transfers within Victoria);
* where relevant, the person has complied with any additional requirements relating to bringing donor gametes or embryos formed from them into Victoria, specified in regulations;
* any other prescribed criteria have been satisfied.

Prior to taking donor gametes or embryos formed from them out of Victoria, a person must certify that:

* The purpose and way in which the gametes/embryos will be used is consistent with the purpose/way they could be used in Victoria. (This is currently a relevant factor to be considered by VARTA in accordance with section 36(3)(a));
* Where relevant, the person has complied with any additional requirements relating to taking donor gametes or embryos formed from them out of Victoria, specified in regulations;
* Any other prescribed criteria have been satisfied.

# Diagram text

**Figure 1 - Regulator tools**

This figure is an enforcement pyramid. The figure seeks to demonstrate that the department will use the full range of tools available to it in line with the risks that it is seeking to manage. The enforcement pyramid illustrates a graduated and proportionate enforcement approach. The bottom of the pyramid outlines the lighter touch interventions such as guidance material and advice services to regulated parties, through to criminal prosecution at the top of the pyramid, where regulated parties deliberately work against intended outcomes and intend to evade compliance obligations.

1. All of the 10 Department of Health regulators listed on p 13 of the [*Statement of Expectations Framework for Regulators*](https://www.dtf.vic.gov.au/sites/default/files/document/Statement%20of%20Expectations%20Framework%20for%20Regulators%20-%20March%202023%20%28updated%20August%202023%29.pdf)<https://www.dtf.vic.gov.au/reducing-regulatory-burden/statement-expectations-regulators> (Department of Treasury and Finance, 2023) are now within the Health Regulator branch, other than the Communicable Disease Section. [↑](#footnote-ref-2)
2. Relevant powers, functions and duties are conferred on the Secretary to the Department of Health (the Secretary) and authorised officers appointed by the Secretary. Many of the Secretary’s powers, functions and duties are delegated to Department of Health staff including in the Health Regulator branch. [↑](#footnote-ref-3)
3. Available on the [Department of Health’s website](https://www.dtf.vic.gov.au/reducing-regulatory-burden/statement-expectations-regulators) <https://www.health.vic.gov.au/patient-care/review-of-assisted-reproductive-treatment> [↑](#footnote-ref-4)
4. As at 4 April 2024. A current list of providers is available on the [Department of Health website](https://www.health.vic.gov.au/patient-care/first-aid-services) at https://www.health.vic.gov.au/patient-care/first-aid-services [↑](#footnote-ref-5)
5. As at 4 April 2024. A current list of providers is available on the [Department of Health website](https://www.health.vic.gov.au/patient-care/non-emergency-patient-transport) at https://www.health.vic.gov.au/patient-care/non-emergency-patient-transport [↑](#footnote-ref-6)
6. As at 4 April 2024. A current list of private hospitals, day procedure centres (including mobile services) is available on the [Department of Health website](https://www.health.vic.gov.au/hospitals-and-health-services/private-health-service-establishments) at https://www.health.vic.gov.au/hospitals-and-health-services/private-health-service-establishments [↑](#footnote-ref-7)
7. Based on the current value of a penalty unit of $192.31 from 1 July 2023 to 30 June 2024. Further information about the current value of a penalty unit is available on the [Department of Treasury and Finance’s website](https://www.dtf.vic.gov.au/financial-management-government/indexation-fees-and-penalties) <https://www.dtf.vic.gov.au/financial-management-government/indexation-fees-and-penalties>. [↑](#footnote-ref-8)
8. Based on the current value of a penalty unit of $192.31 from 1 July 2023 to 30 June 2024: <<https://www.dtf.vic.gov.au/financial-management-government/indexation-fees-and-penalties>>. [↑](#footnote-ref-9)
9. See Appendix A-2: Response provided by the Secretary, Department of Health, available at the [Victorian Auditor-General’s Office website](https://www.audit.vic.gov.au/report/regulating-food-safety?section=) <https://www.audit.vic.gov.au/report/regulating-food-safety?section=> [↑](#footnote-ref-10)
10. Assisted Reproductive Treatment Bill, Second reading speech, 10 October 2008 [↑](#footnote-ref-11)