

# Rapid Review of Assisted Reproductive Technology and *In Vitro* Fertilisation Regulation and Accreditation in Australia

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**OFFICIAL**



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# Executive summary

Australia's Assisted Reproductive Technology (ART) sector has changed significantly since *in vitro* fertilisation (IVF) was first pioneered in the early 1980s. From the beginning, ART providers sought to establish a self-regulatory framework that would ensure high quality, safe, and ethical care.

However, whether industry-based self-regulation remains sufficient to govern the increased size and complexity of Australia's ART sector has been recently questioned. Further, significant errors by some ART providers have raised broader concerns about the adequacy of current governance and oversight of the ART sector in Australia.

It is within this context that, at the joint Health and Mental Health Ministers Meeting on 13 June 2025, Health Ministers agreed to request the Health Chief Executives Forum to commission a rapid review of the regulatory and accreditation environment for the ART and IVF sectors and identify opportunities for improvement.

## Chapter 1: Background and context

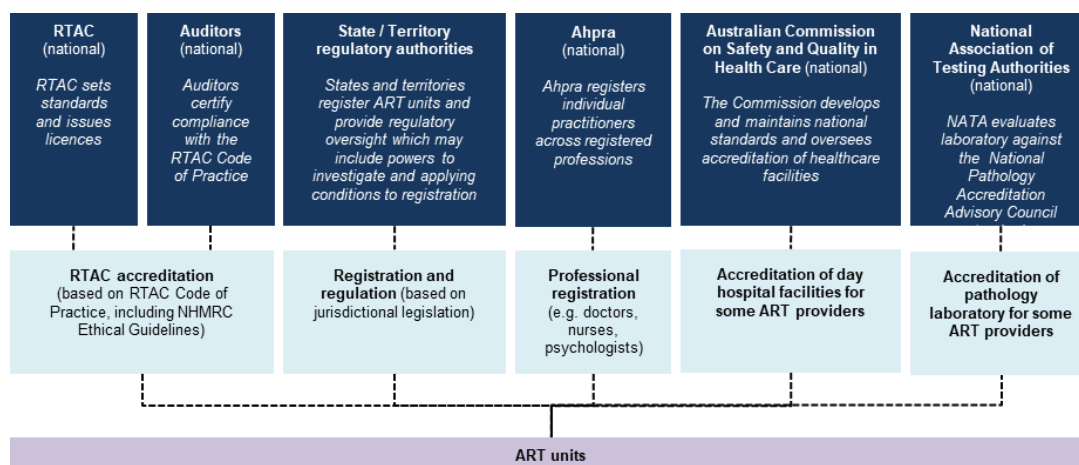
This chapter seeks to set the scene for this rapid review. This review follows 12 other reviews and inquiries into various aspects of ART legislation and care provision that have been undertaken over the past 11 years. Those reviews have found a growing need for national reform of various aspects of ART provision, including its regulation.

ART services in Australia are shaped by a complex and evolving landscape, marked by concentrated private sector delivery, rising demand, and expanding service offerings. While Medicare provides funding support, significant out-of-pocket costs and limited access to public services continue to compromise equitable access.

## Chapter 2: Current state of ART sector accreditation and regulation

In this chapter we outline the current state of ART accreditation and regulation in Australia. Governance of ART accreditation and regulation is fragmented with six different entities involved in the accreditation and regulation of ART units in Australia. Figure 1.1 summarises the six entities.

**Figure 1.1: Snapshot of the ART regulatory landscape in Australia.**



## Chapter 3: Strengths and weaknesses of current ART accreditation and regulation

In this chapter we describe the strengths and weaknesses of the current ART accreditation and regulatory landscape. In summary, the Reproductive Technology Accreditation Committee (RTAC) accreditation scheme no longer meets current needs, and the standards underpinning accreditation lack sufficient rigour. State and Territory regulatory oversight varies across jurisdictions in terms of role and posture. Current compliance monitoring is insufficient, and enforcement powers are limited and under-utilised. Further, consumers find complaints avenues confusing and ineffective.

## Chapter 4: Consumer insights

In this chapter, we present some preliminary consumer insights on the current provision of ART in Australia. These include: barriers to making informed choices about ART treatment; profit-driven practices that adversely impact the consumer experience; difficulties making and resolving complaints; and concerns about donor gamete issues. While not exhaustive, the insights provide valuable consumer perspectives and offer an awareness of the concerns that matter most to those using ART, if only to suggest what issues would be worth exploring further.

## Chapter 5: System improvement

In this chapter, we outline ten opportunities to improve accreditation, regulation, and oversight of the ART sector, each with the intent of delivering better quality and safety of care, and better outcomes for consumers. These are:

1. Establishing an independent accreditation entity and process.
2. Developing and implementing more comprehensive national quality and safety standards for ART practice.
3. Improving oversight of and guidance for professional workers in the ART sector.
4. Harmonising registration and reporting requirements across jurisdictions.
5. Implementing more effective compliance monitoring.
6. Enabling more effective regulatory enforcement.
7. Sharing and publishing data on safety and quality improvement.
8. Improving transparency and guidance to enable informed consumer choice and consent.
9. Clarifying established complaints pathways and processes.
10. Sharing and using complaints data to support accreditation and regulatory activities.

In addition to progressing the above reform opportunities, we recommend that health ministers commission a project that engages a broad range of consumers to gain a deeper understanding of ART consumers' experiences. We also recommend that health ministers endorse a referral to the Australian Law Reform Commission to explore harmonisation opportunities in relation to donor issues.

## Chapter 6: Proposed implementation approach

Chapter 6 outlines a proposed three-phased approach to implementing the reform opportunities set out in this report with the first phase to be completed by January 2027.

# Summary of recommendations

These recommendations are discussed in detail in chapter 5.

We recommend that:

1. Independent accreditation be pursued through the existing national health care accreditation body, the Australian Commission on Safety and Quality in Health Care.
2. An updated Code of Practice or a suite of new ART standards be developed, aligned with the NSQHS Standards and including uniform minimum standards, performance monitoring metrics, and guardrails for adjuvant treatments and new technology.
3. Workforce requirements, including minimum qualifications, continuing professional development requirements, and staffing guidance, be embedded in the new standards.
4. Consistent registration and reporting requirements be imposed by individual State and Territory regulatory authorities.
5. State and Territory regulatory authorities take a proactive, risk-based approach to compliance monitoring.
6. State and Territory regulatory authorities draw on a spectrum of enforcement tools to enable decisive, proportionate action that more effectively deters misconduct.
7. The accreditor and State and Territory regulatory authorities share safety data, and that accreditation data and thematic analysis of safety and quality improvement data be published.
8. *YourIVFSuccess* be expanded to enable more informed consumer choice and consent.
9. Consumers are better supported to use existing complaints handling bodies and processes.
10. ART providers, the accreditor, regulators, and complaints handling bodies share complaints data.

We also recommend further work related to improving ART governance and oversight nationally but that was beyond the scope of this review:

- Commissioning consumer engagement to gain a deeper understanding of ART consumers' experiences and inform the design and implementation of future reform.
- Referral of donor issues to the Australian Law Reform Commission to explore opportunities to harmonise legislation in relation to donated gametes, and ensure integrated and effective legislation aligned with contemporary issues and community expectations.

# 1 Background and context

## 1.1 Context for this rapid review

Australia's Assisted Reproductive Technology (ART) sector has changed rapidly since *in vitro* fertilisation (IVF) was first pioneered as a treatment for infertility in the early 1980s. What began in the 1980s as a small, clinician-led sector that primarily delivered IVF services to heterosexual couples has grown to become a \$810 million a year industry<sup>1</sup> that now provides increasingly complex fertility services to diverse Australian communities in a largely private market.

From the beginning, ART providers sought to establish a regulatory framework that would ensure high quality, safe and ethical care. In 1987, this intent saw the establishment of the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA), now the Fertility Society of Australia and New Zealand (FSANZ). In many ways, this self-regulatory step was ahead of much of the rest of health care.

However, whether industry-based self-regulation remains sufficient to govern effectively the increased size and complexity of Australia's ART sector has been recently questioned, including by the industry itself.<sup>2</sup> Further, significant errors by some ART providers have raised broader concerns about the adequacy of current governance and oversight of the ART sector in Australia.

It is within this context that, at the joint Health and Mental Health Ministers Meeting on 13 June 2025, Health Ministers agreed to request the Health Chief Executives Forum to commission a rapid review of the regulatory and accreditation environment for the ART and IVF sectors and identify opportunities for improvement and action to be reported back within three months. The review was to include:

- options for implementation of an independent accreditation body and process
- consideration of how existing state based regulatory regimes could be strengthened
- consideration of whether a national regulatory approach would deliver benefit.

Victoria agreed to lead the commissioning of the review. Professor Euan Wallace AM was appointed as the independent reviewer, supported by a team from the Strategic Policy and Evidence (SPE) branch of the Victorian Department of Health. This report is the result of the rapid review.

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<sup>1</sup> Arna Richardson, *Fertility Clinics in Australia – Market Research Report (2015-2030)* (Report, January 2025).

<sup>2</sup> Greg Hunt and Rachel Swift, *Findings, Recommendations and Framework for an Australian 10 Year Fertility Roadmap* (Report, November 2024).

## 1.2 Previous reviews found a growing need for national reform of ART

This rapid review follows 12 reviews and inquiries into various aspects of ART legislation and care provision that have been undertaken in different states and territories since 2014 (see Table A1). Reviews of ART delivery in the Australian Capital Territory, Queensland, South Australia, Victoria, and Western Australia all identified the need for reform in the ART sector, including improvements to accreditation processes and regulatory oversight that:

- prioritise the health, safety, and welfare of people accessing ART and of those born as a result of ART
- improve the oversight, transparency, and safeguards in the ART sector
- enable increased oversight of ART clinic auditing, registration, and workforce standards
- provide more effective enforcement powers to regulators where lower-level compliance mechanisms fail.

Several jurisdictions have either already made amendments to their ART legislation and associated regulations or have reform underway. However, this is the first time that an independent review of ART accreditation and regulation has been undertaken at a national level.

In 2024, FSANZ commissioned the *Findings, Recommendations, and Framework for an Australian 10-Year Fertility Roadmap* (Framework for an Australian 10-Year Fertility Roadmap) that included consideration of the current ART legislative and regulatory landscapes.<sup>3</sup> The roadmap outlined a strategic vision focused on improving care, supporting ethical and sustainable practices, and fostering innovation across Australia and New Zealand. It also identified that current accreditation processes are no longer suitable for today's ART sector. In particular, the roadmap noted that the accreditation agency, RTAC, may not have the capacity to handle the growth in IVF services and that its lack of independence from FSANZ – as a sub-committee of this organisation – is problematic.<sup>4</sup>

## 1.3 ART in Australia is complex and demand is growing in volume and complexity

ART services in Australia are shaped by a complex and evolving landscape, marked by concentrated private sector delivery, rising demand, and expanding service offerings. While Medicare provides substantial funding support, significant out-of-pocket costs and limited access to public services continue to compromise equitable access.

Before considering the current accreditation and regulatory landscape, it is useful to briefly summarise the current demand and provision of ART in Australia, including consideration of trends in care demand and care provision.

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<sup>3</sup> Hunt and Swift (n 2).

<sup>4</sup> Hunt and Swift (n 2).

## Demand for ART services is increasing

Reflecting broader societal trends, both the demand for ART services and the complexity of ART services being sought continue to grow. In 2023, 104,000 ART treatment cycles were performed in Australia,<sup>5</sup> compared to 56,000 in 2010.<sup>6</sup> Australia has one of the highest *per capita* uptake rates of ART services in the world. One in 16 babies born in Australia are attributable to ART.<sup>7</sup>

A key driver of this growing demand is the evolving profile of consumers accessing ART services. The sector continues to serve heterosexual couples with subfertility or infertility. About one in six Australian couples experience infertility.<sup>8</sup> However, the uptake of ART in the community has progressively broadened over time, with an increasing number of single women and female-female couples accessing care. In 2023, 81% of ART cycles were provided to male-female couples, 14.6% were to single women, and 4.4% were to female-female couples.<sup>9</sup> For oocyte and embryo recipient cycles, almost 40% were provided to single women or female-female couples, indicating growing inclusivity in access to fertility services.<sup>10</sup> This is also reflected in a growing demand for donor gametes that exceeds supply.<sup>11</sup> This has resulted in increased importation of gametes from international gamete banks and the increased use of informal channels by consumers for gamete donations.<sup>12</sup>

## ART services are predominantly delivered by private providers

The number of ART providers and ART clinics in Australia continues to grow. As of 2024, there are 100 ART clinics nationally,<sup>13</sup> a 20% increase from the 83 clinics in 2017.<sup>14</sup> The majority of these clinics – about 95% of the clinics in market – are operated by private providers.<sup>15</sup>

Over the past two decades the ownership and company structures of private ART providers has progressively shifted from being predominantly small owner-operated units to large corporate ownership models.<sup>16</sup> Currently, the ownership structures for ART units include

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<sup>5</sup> Damian P Kotevski et al, *Assisted Reproductive Technology in Australia and New Zealand 2023* (Report, September 2025) ('2023 ART report').

<sup>6</sup> Alan Macalldowie et al, *Assisted Reproductive Technology in Australia and New Zealand 2010* (Report, 2012).

<sup>7</sup> 'IVF Statistics in Australia and New Zealand', *YourIVFSuccess* (Web Page) <<https://yourivfsuccess.com.au/national-statistics>>.

<sup>8</sup> Kotevski et al, *2023 ART report* (n 5) 1.

<sup>9</sup> Kotevski et al, *2023 ART report* (n 5) vii.

<sup>10</sup> Kotevski et al, *2023 ART report* (n 5) vii.

<sup>11</sup> Rozen G et al, 'Barriers to Reproductive Treatments in Australia' (2023) 52(3) *Australian Journal of General Practice* 109.

<sup>12</sup> Michael Gorton, *Helping Victorians Create Families with Assisted Reproductive Treatment: Final Report of the Independent Review of Assisted Reproductive Treatment* (Report, May 2019); Office of the Health Ombudsman (Qld), *Section 81 – Investigation of ART Providers in Queensland: Final Report* (Report, June 2024).

<sup>13</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023–2024* (Report, 2024) ('*Annual Report 2023-2024*').

<sup>14</sup> Jade E Newman et al, *Assisted Reproductive Technology in Australia and New Zealand 2017* (Report, September 2019).

<sup>15</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13) 12.

<sup>16</sup> Gorton (n 12) 6.

publicly listed entities, corporations owned by private equity firms, large private corporations, and some smaller doctor-owned and operated units. These ownership structures bring different public reporting obligations, such as reporting to the Australian Securities and Investment Commission and to shareholders for listed entities.

Four large ART providers currently account for about 80% of the Australian market share: Virtus Health (37%), Monash IVF (31%), Genea (12%), and City Fertility Centre (5%).<sup>17</sup> The emergence of these four providers reflects a progressive consolidation of the ART sector, with the major providers expanding their market share through mergers and acquisitions.<sup>18</sup> It is likely that the trend for consolidation will continue with the larger companies pursuing further clinic acquisitions.<sup>19</sup>

ART services are delivered in all states and territories. Largely reflecting population distribution,<sup>20</sup> about 80% of services are provided in New South Wales, Queensland and Victoria.<sup>21</sup> Access to ART services is limited for those living in rural and remote areas, with most located in large regional or metropolitan cities.<sup>22</sup> However, some metropolitan-based providers operate satellite units in regional and country areas.

Several ART providers operate clinics across multiple jurisdictions. The four largest providers occupy more than half of the market in each jurisdiction. Table 1.1 sets out the number of ART units in each State and Territory. There is greatest choice of provider in the larger jurisdictions.<sup>23</sup>

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<sup>17</sup> Richardson (n 1).

<sup>18</sup> Australian Competition and Consumer Commission, 'Monash IVF's Proposed Acquisition of Fertility North Not Opposed' (Media Release, 22 February 2024).

<sup>19</sup> Richardson (n 1).

<sup>20</sup> 77% of the nation's population are in New South Wales, Queensland, and Victoria: 'National, state and territory population', *Australian Bureau of Statistics* (Web Page, December 2024) <<https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/latest-release#cite-window1>>.

<sup>21</sup> Richardson (n 1).

<sup>22</sup> Amanda Mackay, Selina Taylor and Beverly Glass, 'Inequity of Access: Scoping the Barriers to Assisted Reproductive Technologies' (2023) 11(1) *Pharmacy* 17.

<sup>23</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13).

**Table 1.1: Number of private and public ART clinics by jurisdiction.<sup>24</sup>**

State	Private clinics	Public clinics	Total
ACT	3	0	3
NSW	31	3	34
NT	1	0	1
QLD	24	0	24
SA	4	0	4
TAS	2	0	2
VIC	22	1	23
WA <sup>25</sup>	8	1	9
<b>Total</b>	<b>95</b>	<b>5</b>	<b>100</b>

## ART services are increasingly complex

In addition to changing demand volume, the nature of ART services being sought is evolving. There is a growing demand for fertility preservation<sup>26</sup>, principally oocyte freezing, and advanced genetic screening, as well as an increasing range of infertility treatment options. For example, in addition to the common fertility treatments (such as intracytoplasmic sperm injection, IVF, frozen embryo transfer, and intrauterine insemination treatments), there is increasing demand for:

- **Fertility preservation services (oocyte/embryo freezing):** The number of fertility preservation cycles performed almost doubled over two years, from 3,642 in 2020 to 8,827 in 2023.<sup>27</sup>
- **Preimplantation genetic testing (PGT):** The number of cycles where PGT was performed increased from 7,697 in 2020 to 9,865 in 2023.<sup>28</sup>

Notably, 38% of the cycles performed for fertility preservation in 2022 were reported as being for non-medical reasons (e.g. not having a partner but seeking future fertility).<sup>29</sup> These trends are likely to continue further increasing ART demand.

## ART services receive public funding through Medicare and state programs

As detailed above, almost all ART services are provided by the private sector. ART services receive Commonwealth funding support through the Medicare Benefits Scheme (MBS). This

<sup>24</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13) 12.

<sup>25</sup> There is one public fertility clinic in Western Australia, however, it is not accredited by RTAC as it does not offer IVF services.

<sup>26</sup> In this report, we focus on fertility preservation services that fall under ART procedures. It is important to note that there are other types of fertility preservation services (e.g. collection of ovarian or testicular tissue) that are not considered as ART procedures.

<sup>27</sup> Jade E Newman, Repon C Paul and Georgina M Chambers, *Assisted Reproductive Technology in Australia and New Zealand 2020* (Report, October 2022) 17; Kotevski et al, *2023 ART report* (n 5) 17.

<sup>28</sup> Kotevski et al, *2023 ART report* (n 5) 46.

<sup>29</sup> Kotevski et al, *2023 ART report* (n 5) 17.

includes rebates for privately delivered ART services, subsidies for ART-related medications through the Pharmaceutical Benefits Scheme, and support for public patients in public hospitals. Currently, MBS funding is available without restriction of the number of cycles available to medically infertile patients undergoing non-surrogacy related fertility treatments. Prior to 2000, MBS funding was limited to six cycles per patient.<sup>30</sup> Medicare does not fund ART services provided in conjunction with surrogacy, hospital-based procedures, or diagnostic imaging and pathology services during an ART cycle, except for specific pathology services.<sup>31</sup>

On the pre-condition that the patient is infertile, specialists and fertility clinics can bill MBS items for ART services. Medicare rebates provide 75% of the fee for inpatient services and 85% for outpatient services.<sup>32</sup> Patients nonetheless face significant out-of-pocket costs due to the gap between clinic fees and Medicare coverage. For example, IVF Australia, a member of Virtus Health, projects the out-of-pocket costs for patients for an initial IVF cycle as of 1st June 2025 at \$6,711.65.<sup>33</sup> Once annual out-of-pocket medical expenses exceed the Extended Medicare Safety Net (EMSN) threshold of \$2,615.50 for general patients or \$834.50 for concessional patients, Medicare provides an additional rebate of 80% of the out-of-pocket cost or the EMSN cap for the item, whichever is lower.<sup>34</sup> Out-of-pocket costs for ART treatments can be compounded by multiple cycles of treatment, the cost of additional services such as genetic screening and adjuvant treatments like acupuncture,<sup>35</sup> and the cost of medications.

Public fertility services are available in New South Wales,<sup>36</sup> Victoria, and Western Australia<sup>37</sup> but access is limited by conditions such as age, means testing, and the number of cycles supported.

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<sup>30</sup> Sara Attinger et al, 'Addressing the consequences of the corporatization of reproductive medicine' (2024) 32(4) *Medical Law Review* 444.

<sup>31</sup> 'Assisted reproductive technology services', *Services Australia* (Web Page, 1 June 2025) <<https://www.servicesaustralia.gov.au/mbs-billing-for-assisted-reproductive-technology-services?context=20>>.

<sup>32</sup> Australian Government, *Understanding Medicare: Provider Handbook* (1 September 2024) 26.

<sup>33</sup> 'IVF Costs and Fees', *IVF Australia* (Web Page, 1 June 2025) <<https://www.ivf.com.au/ivf-cost/ivf-costs>>.

<sup>34</sup> This is based on the 2025 Medicare Safety Net thresholds: 'What are the thresholds', *Services Australia* (Web Page, 1 January 2025) <<https://www.servicesaustralia.gov.au/what-are-medicare-safety-nets-thresholds?context=22001>>.

<sup>35</sup> Gorton (n 12).

<sup>36</sup> In New South Wales, additional financial support is provided via a rebate scheme rather than offering a public fertility service.

<sup>37</sup> In Western Australia, public fertility services are provided by King Edward Memorial Hospital Fertility Clinic. Service offerings are limited to procedures preceding IVF, such as ovulation induction and surgery, with patients being referred to other fertility clinics for treatment: Western Australian Reproductive Technology Council, *Western Australian Reproductive Council Annual Report 2023–2024* (Report, 2024) 16; 'Reproductive Medicine Service – including Fertility Clinic', *Government of Western Australia* (Web Page 16 July 2024). <<https://www.kemh.health.wa.gov.au/For-Health-Professionals/Gynaecology/Reproductive>>.

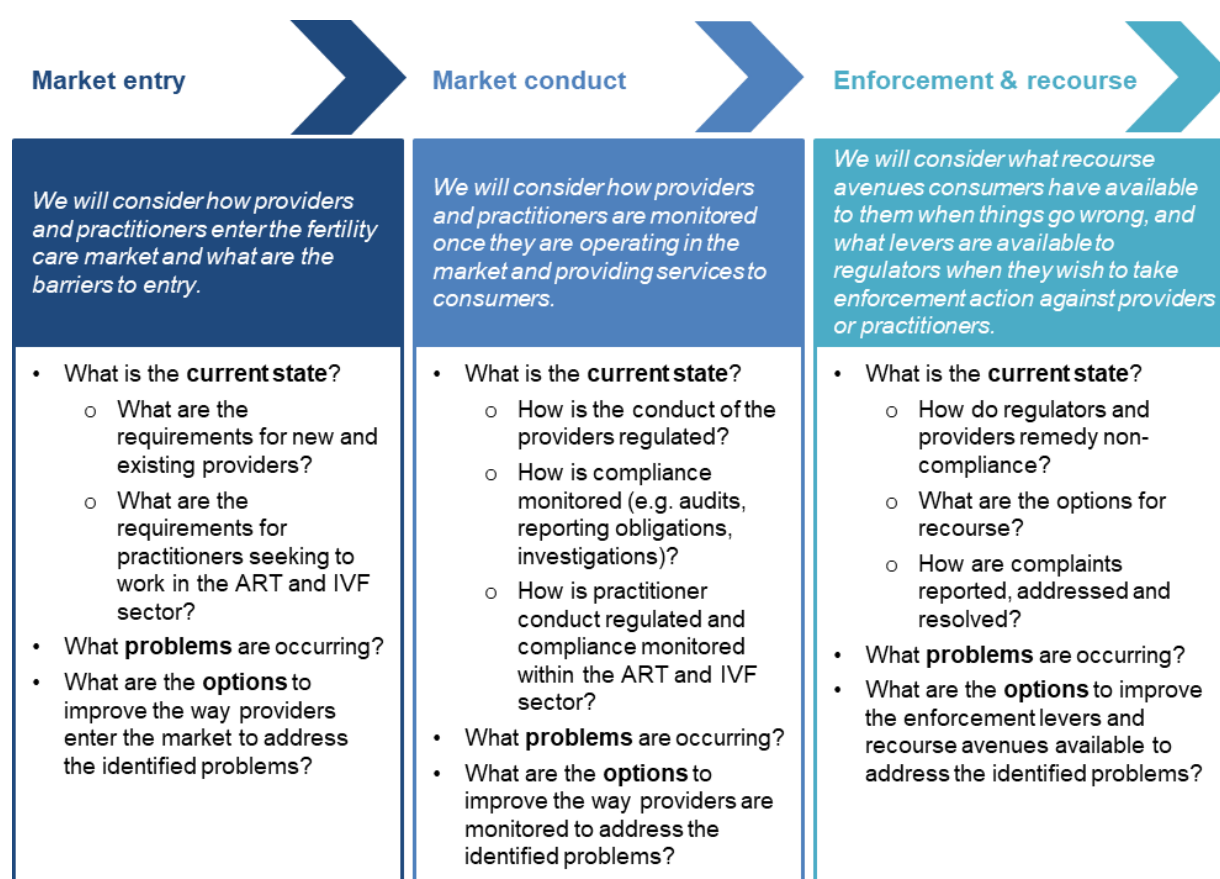
## 2 Current state of ART sector accreditation and regulation

In this chapter we outline the current state of accreditation and regulation of Australia's ART sector.

### 2.1 A conceptual framework for this rapid review

With the aim of providing clarity about ART accreditation and regulation, we structured the rapid review using a framework that conceptualises both elements – accreditation and regulation – into three phases: market entry (when a new ART provider seeks to operate), market conduct (oversight of existing ART providers), and enforcement and recourse (actions taken in response to provider non-compliance). Figure 2.1 provides an overview of this conceptual framework.

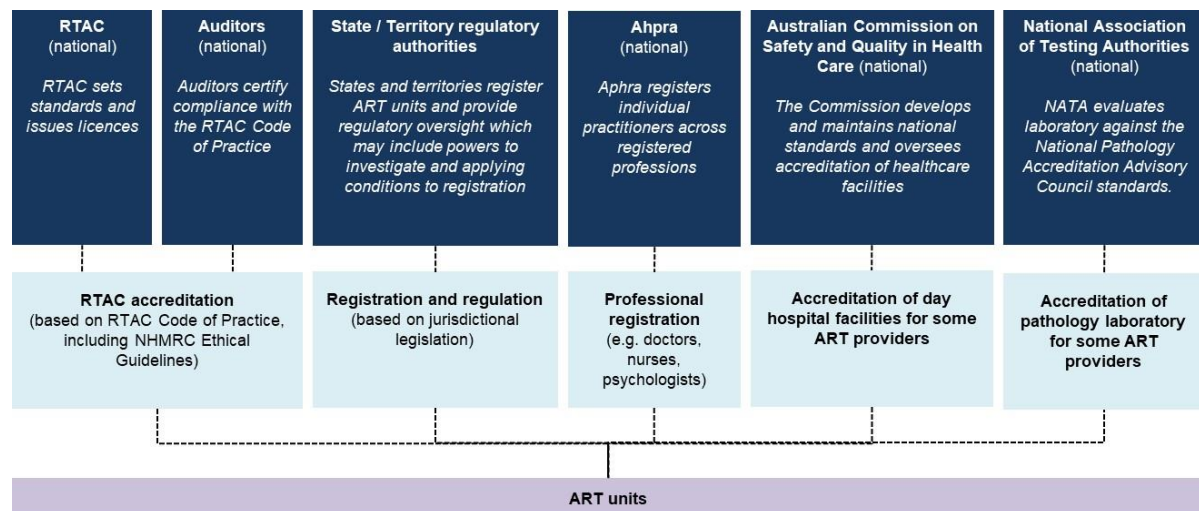
**Figure 2.1: Conceptual framework underpinning this review.**



## 2.2 Governance of ART accreditation and regulation is fragmented

There are principally six different entities involved in the accreditation and regulation of ART units in Australia. An ART unit is defined as a facility that includes a laboratory involved in collecting or preparing human gametes and/or embryos for therapeutic purposes.<sup>38</sup> Figure 2.2 summarises the six entities.

**Figure 2.2: Summary of the ART regulatory landscape in Australia.**



The role of these different accreditation and regulatory authorities is summarised below.

### Reproductive Technology Accreditation Committee

RTAC was established by the FSA, now FSANZ, in 1987 to set standards for ART care and to oversee the accreditation of ART units against those standards. RTAC is a committee of FSANZ and reports directly to the FSANZ board.<sup>39</sup> The members of RTAC are appointed by the representative professional groups within FSANZ: FSANZ Medical Directors Subcommittee, Australian and New Zealand Infertility Counsellors Association, Fertility Nurses of Australasia, Scientists in Reproductive Technology, and Access or fertility NZ.<sup>40</sup> There is currently a vacancy for a consumer representative on both RTAC and the FSANZ board.<sup>41</sup> The RTAC Chair is appointed by the FSANZ board and reports regularly to the board.

RTAC remains the national accreditation body for ART in Australia.

<sup>38</sup> Fertility Society of Australia and New Zealand, *Code of Practice For Assisted Reproductive Technology Units* (June 2025) s 1.4.1 ('RTAC Code of Practice').

<sup>39</sup> Reproductive Technology Accreditation Committee, *The Reproductive Technology Accreditation Committee: Terms of Reference* (Report, January 2020) s 1 ('RTAC Terms of Reference').

<sup>40</sup> Reproductive Technology Accreditation Committee, *RTAC Terms of Reference* (n 39) s 1.

<sup>41</sup> 'FSANZ Board', *Fertility Society of Australia and New Zealand* (Web Page, 2025) <<https://www.fertilitysociety.com.au/about/about-01/fsanz-board/>>.

As the national accreditation body, RTAC responsibilities include:

- setting and reviewing the accreditation standards (referred to as the Code of Practice)
- designing and overseeing the RTAC accreditation scheme, including effectiveness of certifying bodies<sup>42</sup>
- licensing ART providers to deliver ART services in Australia
- issuing, suspending and withdrawing RTAC licences
- promoting continuous improvement among ART providers
- supporting State and Territory ART regulatory functions.

Over time RTAC has codified the standards into a Code of Practice, against which ART units are certified by one of two independent certifying bodies (see section 2.3) for the purpose of RTAC accreditation.<sup>43</sup> The Code of Practice outlines requirements for governance, clinical practice, patient safety, data reporting and continuous improvement, divided into two sets of criteria:

1. 14 Critical Criteria that are audited annually, including requirements relating to compliance, adverse event reporting, and infection control<sup>44</sup>
2. Five Good Practice Criteria, a third of which is audited annually in a three-year cycle, including requirements relating to quality management systems.<sup>45</sup>

The Code of Practice also includes the requirement to comply with relevant sections of the National Health and Medical Research Council Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research.<sup>46</sup>

The Code of Practice is revised every three years through a peer review process led by RTAC.<sup>47</sup> Changes to the Code of Practice are recommended by RTAC for approval by the FSA board.<sup>48</sup> No independent agencies are involved in the development or revision of the Code of Practice.

It is also a requirement of the Code of Practice that all staff are authorised to perform the functions they have been employed to carry out,<sup>49</sup> with specific qualification, training, education and experience requirements for several key personnel, including professions that are not covered under the National Registration and Accreditation Scheme (NRAS) such as laboratory managers, counsellors and quality managers.<sup>50</sup> This includes a requirement for Medical and Clinical Directors to have a Certificate of Reproductive Endocrinology and

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<sup>42</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme – Requirements for bodies providing audit and certification to the Code of Practice for Assisted Reproductive Technology Units* (20 December 2021) ('RTAC Scheme Rules').

<sup>43</sup> 'Codes of Practice history and purpose', *Fertility Society of Australia and New Zealand* (Web Page, 2025) <<https://www.fertilitysociety.com.au/art-regulation/rtac/>>.

<sup>44</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.1.

<sup>45</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.1.

<sup>46</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.3.

<sup>47</sup> Reproductive Technology Accreditation Committee, *RTAC Terms of Reference* (n 39) s 4(d).

<sup>48</sup> Reproductive Technology Accreditation Committee, *RTAC Terms of Reference* (n 39) s 4(d).

<sup>49</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.5.

<sup>50</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.4.

Infertility, and recommendation for scientists to be certified with the Australian Council for Certification of the Medical Laboratory Scientific Workforce.<sup>51</sup>

## Accreditation certifying bodies

ART units may elect one of two independent certifying bodies registered by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) to conduct the primary and secondary audits:<sup>52</sup> Global-Mark and Certified Partner Global. The RTAC Scheme Rules specify the requirements for the JAS-ANZ accreditation of the certifying bodies, as well as certification criteria for ART units.<sup>53</sup>

Across the two certifying bodies, there are five individual auditors who deliver all audits of ART units across Australia. It is typical that an individual auditor will have undertaken all audits of a given ART unit over many years. RTAC advised auditors are approved to be involved in the certification process if they are certified by JAS-ANZ.

Certifying bodies are responsible for developing and submitting a final written audit report to RTAC. This details recommendations for granting certification or continuing certification, providing a basis for RTAC to make a licensing decision.<sup>54</sup> RTAC advised that these audit reports are only sighted by the RTAC Chair and are not shared with the RTAC board. Final audit reports are shared with the Queensland, South Australian, Victorian, and Western Australian regulatory authorities via ART providers as a condition of their registration (see section 2.4).

## State and Territory regulatory authorities

While accreditation standards are defined by RTAC and approved by the FSANZ board, and the auditors use those standards for accreditation audit purposes, regulation is, mostly, undertaken by jurisdictions.

Where present, State and Territory regulatory authorities are based within health departments<sup>55</sup> and are responsible for the registration and subsequent regulation of ART units operating in their jurisdiction under the relevant local legislation. For the purpose of this report, we use the term 'registration' to also encompass the concept of a licensing scheme (for example, the scheme recently established in Queensland). In all jurisdictions with ART regulatory arrangements, registration of an ART unit requires current accreditation by RTAC.

However, jurisdictional regulatory approaches vary widely in their scope and powers, reflecting differences in both State and Territory legislation and regulatory posture. Figure 2.3 outlines legislation regulating ART in each jurisdiction.

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<sup>51</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.5.2(c).

<sup>52</sup> Reproductive Technology Accreditation Committee, *RTAC* (Web Page, 2025) <<https://www.fertilitysociety.com.au/art-regulation/rtac/>>.

<sup>53</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42) s 7.4.15(c).

<sup>54</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42) s 7.4.15(c).

<sup>55</sup> The Northern Territory does not currently have a regulatory authority with regulatory powers to oversee the ART provider in the territory.

Further jurisdictional differences exist in the regulation of gamete and embryo use and transportation, donor conception registers, health information disclosure and the limits on the number of donor related families.<sup>56</sup>

**Figure 2.3: Legislation regulating ART in jurisdictions across Australia.**

Australian Capital Territory	New South Wales	Northern Territory	Queensland	South Australia	Tasmania	Victoria	Western Australia
<i>Assisted Reproductive Technology Act 2024 (ACT)</i>	<i>Assisted Reproductive Technology Act 2007 (NSW)</i>	No specific ART legislation	<i>Assisted Reproductive Technology Act 2024 (Qld)</i>	<i>Assisted Reproductive Treatment Act 1988 (SA)</i>	No specific ART legislation ART providers in Tasmania are regulated under the <i>Health Services Establishment Act 2006 (Tas)</i>	<i>Assisted Reproductive Treatment Act 2008 (Vic)</i>	<i>Human Reproductive Technology Act 1991 (WA)</i>

Legislative frameworks in some jurisdictions are evolving. The Australian Capital Territory, Queensland and Victoria underwent reform of their ART legislation in 2024. The new Australian Capital Territory legislation came into effect earlier this year, while the new Queensland legislation is commencing in stages, with its new licensing scheme to come into effect from March 2026. The Victorian reforms came into effect on 1 January 2025. Additionally, as of the date of this report, the Western Australian Parliament is debating the Assisted Reproductive Technology and Surrogacy Bill 2025, which would repeal current legislation.

## Australian Health Practitioner Regulation Agency

The Australian Health Practitioner Regulation Agency (Ahpra) is responsible for the nationwide registration and regulation of health professionals working in ART units, including medical practitioners, nurses, midwives, and psychologists. Regulation of registered health practitioners is undertaken by Ahpra through the NRAS that is legislated nationally. The NRAS defines which health professionals are regulated by Ahpra and does not extend to some key ART personnel, including embryologists, laboratory managers, counsellors, and quality managers.

For those workforces not regulated through Ahpra's NRAS, the ART sector relies on other mechanisms to ensure quality and safety:

- The Code of Practice requires ART units to ensure that all staff are authorised to perform the functions they have been employed to carry out,<sup>57</sup> with specific qualification, training, education, and experience requirements for several key personnel.<sup>58</sup> As with other Code of

<sup>56</sup> For example, Queensland, South Australia and Victoria have a limit of 10 donor related families, while Australian Capital Territory, New South Wales, and Western Australia have a five-family limit. There are no limits in the Northern Territory or Tasmania.

<sup>57</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.5.

<sup>58</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.4.

Practice requirements, adherence to these standards is audited annually by a certifying body.

- The National Code of Conduct for health care workers applies to all unregistered health care workers in Australia and sets out minimum practice and ethical standards.<sup>59</sup>
- Organisational policies specify necessary qualifications, experience and professional development obligations.<sup>60</sup>

## Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for overseeing the accreditation of healthcare facilities including health services; public, private and day hospitals; and cosmetic surgery clinics. The Commission is governed by the *National Health Reform Act 2011* (Cth) and is accountable to the Australian parliament through the Commonwealth Minister for Health, Disability and Ageing. It is funded jointly by the Australian Government and State and Territory governments.

The Commission develops and maintains the National Safety and Quality Health Service (NSQHS) Standards against which healthcare facilities are accredited. While ART units are not covered by the NSQHS Standards, ART providers that operate day hospital facilities fall within its remit.

Accreditation of healthcare facilities to the NSQHS Standards is undertaken by one of six accrediting agencies that are approved by the Commission, of which Global-Mark and Certified Partner Global are two. The Commission is responsible for overseeing the performance of these agencies, including checking on the quality of their assessment processes and reports. As part of the Australian Health Service Safety and Quality Accreditation Scheme, the Commission is also required to share accreditation failure or issues with jurisdictions and publish accreditation outcomes, including assessment results against the NSQHS Standards, on their website.<sup>61</sup> The Commission does not undertake this function for audits of ART units.

The Commission is not a regulator. The Commission develops the NSQHS Standards, which are implemented and enforced by jurisdictions. The Commission communicates with states and territories through the Inter-Jurisdictional Committee (IJC), comprising safety and quality officials from Commonwealth, State and Territory health agencies. The IJC meets regularly to provide advice to the Commission and discuss its policies, programs, standards and guidelines.<sup>62</sup>

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<sup>59</sup> See 'National Registration and Accreditation Scheme', *Australian Government Department of Health and Aged Care* (Web Page, 2024) <<https://www.health.gov.au/our-work/national-registration-and-accreditation-scheme>>.

<sup>60</sup> The RTAC Code of Practice requires ART units to provide evidence of personnel training policies and procedures and competency assessment protocols during the audit process. See Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.2.

<sup>61</sup> 'Australian Health Service Safety and Quality Accreditation Scheme', *Australian Commission on Safety and Quality in Health Care* (Web Page, 2025) <<https://www.safetyandquality.gov.au/our-work/accreditation/australian-health-service-safety-and-quality-accreditation-scheme>>.

<sup>62</sup> 'Committees', *Australian Commission on Safety and Quality in Health Care* (Web Page, 2021) <<https://www.safetyandquality.gov.au/about-us/our-people/committees>>.

## National Association of Testing Authorities

For an ART unit to deliver pathology services that are eligible for Medicare funding, Services Australia must approve its laboratory as an Accredited Pathology Laboratory.<sup>63</sup> This requires the laboratory to meet several criteria, including an advisory or assessment report from the National Association of Testing Authorities (NATA) that recommends Medicare accreditation. In undertaking this assessment, NATA evaluates the laboratory against the National Pathology Accreditation Advisory Council (NPAAC) standards. Generally, NATA accreditation must be renewed every four years following an on-site reassessment, with accredited laboratories also subject to an on-site surveillance visit during this period to ensure continued compliance with the NPAAC standards.<sup>64</sup>

## Other legislation

Other legislation, outside the scope of this rapid review, also interacts with the ART regulatory environment, including legislation relating to:

- corporations law
- family law (surrogacy, birth registration, discrimination)
- administrative procedures (information handling, complaints)
- clinical and research practices (customs regulations for importing gametes and embryos, human tissue and embryo handling, prohibitions against cloning)<sup>65</sup>
- competition and consumer law (providers are required to comply with obligations around guarantees of service quality, prohibition of misleading or deceptive conduct, and contracts and refunds).

## 2.3 Market entry – accreditation

Market entry refers to the requirements that an entity must meet to be able to commence service delivery. Accreditation is a process conducted by an external body that establishes whether an organisation meets the requirements of governing industry standards.

### Providers must be accredited by RTAC to operate in the sector

Most states and territories require a new ART unit to obtain RTAC accreditation prior to commencing provision of ART services. The *Research Involving Human Embryos Act 2002* (Cth) also prescribes that all new ART units must obtain initial RTAC accreditation.

As summarised above, RTAC accreditation involves the ART unit undergoing a primary audit by one of the two approved accreditation agencies (certifying bodies). The primary audit involves two stages: a document review and an onsite audit of facilities and equipment. On

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<sup>63</sup> National Association of Testing Authorities, *NATA Procedures for accreditation* (December 2024), 10.

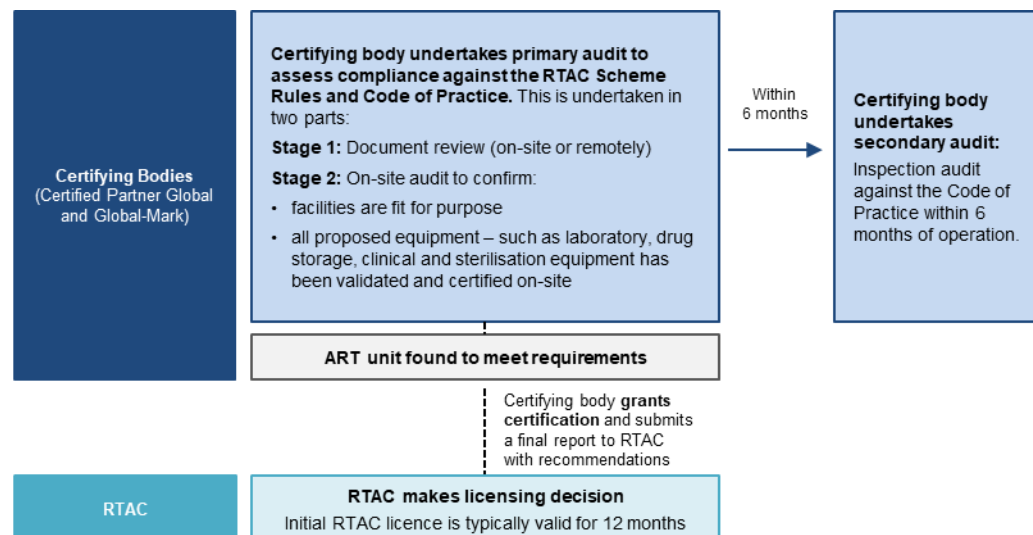
<sup>64</sup> National Association of Testing Authorities (n 63) 20–21.

<sup>65</sup> There is currently an ALRC review underway into surrogacy laws. 'Review of Surrogacy Laws', *Australian Law Reform Commission* (Web Page, 6 December 2024) <<https://www.alrc.gov.au/publication/review-of-surrogacy-laws-issues-paper-2025/>>.

passing the primary audit, the ART unit is certified by the auditor and granted an RTAC licence to operate, typically for 12 months.<sup>66</sup> A summary of the process is outlined in Figure 2.4 below.

Within six months of commencing operations, each new ART unit must then undergo a secondary audit involving inspection of unit operations.<sup>67</sup>

**Figure 2.4: RTAC accreditation process and auditing inclusions.**<sup>68</sup>



\* A new facility that is part of an established ART provider does not require a Stage 1 audit, provided the provider's existing quality management system is applied (Section 1.7 Code of Practice).

\*\* A satellite unit (i.e. an ART unit that operates for fewer than 180 days per year and lacks onsite storage for gametes or embryos) is subject to audit once every three years.

If an ART unit seeks to add a procedure from its scope of practice, a certifying body must first audit the procedure before RTAC may decide whether to amend the scope of practice.<sup>69</sup>

## 2.4 Market entry – regulation

Following RTAC accreditation, all jurisdictions – with the exception of the Northern Territory – require registration (or licensing) with the relevant state or territory regulatory authority. Regulation represents mandatory government oversight and rules that define minimum standards for safety and quality, enforced by law.

<sup>66</sup> ART units that have been certified by one of the two certifying bodies will be eligible for RTAC consideration for recognition as an RTAC licensed ART unit: Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.5.

<sup>67</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.7.

<sup>68</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.7; Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42) s 7.4.15(c).

<sup>69</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.1.1.

## Providers must be registered with a state or territory regulator

Table 2.1 sets out the registration requirements by jurisdiction. Note that Tables 2.1 – 2.8 are also consolidated in Appendix 2, which summarises State and Territory regulatory powers and jurisdictional features.

**Table 2.1: Registration requirements by jurisdiction.**

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
Registration required	✓	✓	✗	✓	✓	✓	✓	✓
Registration period	5 years <sup>70</sup>	12 months <sup>71</sup>	N/A	Up to 3 years <sup>72</sup>	Not specified	Not specified	Not specified – period aligns with RTAC accreditation <sup>73</sup>	Up to 5 years <sup>74</sup>

Following RTAC accreditation, a new ART unit must apply to the relevant state or territory regulatory authority (where appropriate) for registration prior to commencing ART operations in that jurisdiction. The registration period varies between jurisdictions, ranging from one to five years.<sup>75</sup> Under State and Territory legislation, regulatory authorities may impose conditions on the registration of ART units. These conditions vary between jurisdictions, reflecting differences in State and Territory legislation. For example, it is a condition of registration in Queensland, South Australia, Victoria, and Western Australia that ART providers submit a copy of their RTAC audit reports to the regulatory authority. (Note: RTAC does not provide the audit reports directly to regulatory authorities. See Table 2.2).

## ART providers with day hospitals require NSQHS accreditation

In addition to RTAC accreditation, if an ART provider operates a day hospital facility, that facility requires separate accreditation by the Commission using the Commission's national standards. Some ART units have day procedure facilities to conduct invasive procedures on-site, such as oocyte retrieval, and therefore fall within the remit of these standards. This would be in addition to other regulatory requirements that are imposed by State or Territory regulatory authorities.

Accreditation of day procedure facilities against the NSQHC Standards is undertaken by accrediting agencies approved and overseen by the Commission. The Commission reviews

<sup>70</sup> *Assisted Reproductive Technology Act 2024* (ACT) s 17.

<sup>71</sup> *Assisted Reproductive Technology Act 2007* (NSW) s 6.

<sup>72</sup> *Assisted Reproductive Technology Act 2024* (Qld) s 60.

<sup>73</sup> *Assisted Reproductive Treatment Act 2008* (Vic) ss 74–81.

<sup>74</sup> *Human Reproductive Technology Act (1991)* (WA) s 27.

<sup>75</sup> This is with exception to South Australia, which do not have a specified registration period in their ART legislation. SA's health department advised registration period for ART units in their state can range from one year to ongoing.

the performance of all approved accrediting agencies. The outcomes of assessments against the NSQHS standards for hospitals is publicly available on the Commission website.<sup>76</sup>

## Some ART practitioners are registered with Ahpra

Ahpra registration is a requirement for some professionals that deliver ART services, including medical practitioners, nurse managers and counselling managers who are clinical psychologists.<sup>77</sup> Other ART personnel, including laboratory supervisors, counselling managers (social workers), fertility scientists (embryologists) and quality managers, are not subject to Ahpra registration.

As outlined above in chapter 2, it is a requirement of the Code of Practice that key personnel meet qualification, training, education and experience requirements.<sup>78</sup> This includes a requirement for Medical and Clinical Directors to have a Certificate of Reproductive Endocrinology and Infertility,<sup>79</sup> and recommendation for scientists to be certified with the Australian Council for Certification of the Medical Laboratory Scientific Workforce.<sup>80</sup>

## 2.5 Market conduct – accreditation

RTAC provides ongoing oversight of ART units' conduct through its accreditation scheme, which involves periodic audits and reporting requirements.

### Annual RTAC audits are required to maintain accreditation

RTAC oversees the compliance of ART units with the Code of Practice through an annual re-accreditation process and a requirement to self-report any adverse events.<sup>81</sup>

To maintain RTAC accreditation, each ART unit must undergo an annual surveillance audit against the Code of Practice.

An audit typically takes one day on-site, although the RTAC certifying bodies advised that this would depend on the size of the ART unit and the complexity of the services it offers.

Each annual audit assesses compliance with:<sup>82</sup>

- all Critical Criteria in the Code of Practice

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<sup>76</sup> 'Public Reporting on Hospital Performance: NSQHS Standards', *Australian Commission on Safety and Quality in Health Care* (Web Page, 2021) <<https://www.safetyandquality.gov.au/consumers/public-reporting-hospital-performance-nsqhs-standards>> ('ACSQHC website – NSQHS Standards: public reporting').

<sup>77</sup> Medical Directors are required to have RACP or RANZCOG membership. Counselling managers are required to have ANZICA membership, in addition to APS membership for those that are clinical psychologists.

<sup>78</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.4.

<sup>79</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.4.2.

<sup>80</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.4.3(e).

<sup>81</sup> Satellite units are subject to audit once every three years: see Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.4.2.

<sup>82</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42) s 7.9.7.

- at least one-third of the Good Practice Criteria (such that all criteria are audited over a three-year surveillance period)
- the effectiveness of internal audits plus a minimum of one-third of the quality management system (QMS) (such that all QMSs are audited over a three-year surveillance period).

The surveillance audit is arranged between the ART unit and the auditor. Audits are undertaken with significant notice periods and must be scheduled more than 30 days before the expiry date of the RTAC licence. ART units pay for the audit to be undertaken.

## Audit findings are reported to ART units and RTAC

Audit findings are provided by the certifying body to the ART unit and to the RTAC Chair. The RTAC Chair reviews all audit reports and prepares summaries and brief thematic analysis for the FSANZ board and the RTAC annual report. Audit reports are not sighted by other RTAC members. RTAC does not provide audit reports directly to state and regulatory authorities. There are varying arrangements for ART units to report audit outcomes to State and Territory regulatory authorities, as set out in Table 2.2 below.

**Table 2.2: Reporting arrangements for renewal of RTAC accreditation.**

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
Requirement to report whether RTAC licence has been renewed	ART units must advise	No requirement	No requirement	ART units must advise	ART units must advise	No requirement	ART units must advise	ART units must advise

Where a surveillance audit finds that the requirements of an item in the Code of Practice are not met or that the outcome is ineffective, a non-conformity will be raised and reported to RTAC. All non-conformities must be rectified by the ART unit. The type of corrective action required depends on whether the non-conformity is minor or major:<sup>83</sup>

- A minor non-conformity is raised when an unmet Code of Practice requirement leads to an ineffective outcome without patient risk. It can be closed out by the certifying body once it sights evidence of corrective action, or through a corrective action plan at the next audit.
- A major non-conformity is raised when an unmet Code requirement leads to an ineffective outcome with patient risk. Several related minor non-conformities may also constitute a major non-conformity. A major non-conformity requires the ART unit to present a corrective action plan to the certifying body within five business days, with immediate corrective action to address non-conformities related to high-risk activities that impact patient safety or patient identification and traceability. A major non-conformity will be closed out by the certifying body once it sights evidence of corrective action at a follow-up site audit within 30 days.

<sup>83</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42) ss 3, 7.4.13, 7.4.14.

The types and frequency of non-conformities identified at audit are reported, in a de-identified manner, in the RTAC annual report. In the 2024 Annual Report, one major non-conformity and 171 minor non-conformities were reported.<sup>84</sup>

Once the ART unit has met all the requirements of the audit and any major non-conformities have been closed out, the certifying body will provide RTAC and the ART unit with a final report. The report will include any recommendations to maintain, vary, suspend or withdraw accreditation. Based on this report, RTAC will decide whether to renew the licence.

RTAC advises that it has never challenged audit outcomes nor refused/revoked a licence. RTAC advises that this is principally due to high rates of compliance from ART providers in addressing non-conformities. However, RTAC does acknowledge that it has a reporting relationship to the FSANZ Board, and concerns about not having adequate resourcing to defend their decision to withhold or withdraw a licence has influenced their decision-making process.

FSANZ may, through RTAC, require the certifying body to conduct an exceptional circumstances audit if significant legislative, regulatory or clinical care concerns are identified.<sup>85</sup> RTAC advises that 12 exceptional circumstances audits have been undertaken since 2019, all of which were rectified.

## ART units must report adverse events to RTAC

The Code of Practice requires that ART units must investigate and review any serious adverse events and report these events to RTAC and the certifying body.<sup>86</sup> Reporting timeframes vary depending on the nature of the incident.<sup>87</sup> Under the Code of Practice, ART units are also required to implement a comprehensive incident reporting and response system to empower their workforce to identify and report incidents (see section 3.3).<sup>88</sup>

## ART units must report clinical outcomes data to RTAC

The Code of Practice requires ART units to report clinical outcomes data to the Australian and New Zealand Assisted Reproduction Database (ANZARD)<sup>89</sup>. This includes the reporting of up

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<sup>84</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13) 7.

<sup>85</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42) s 7.4.4.

<sup>86</sup> The Code of Practice defines a serious adverse event as any event which: causes a significant medical or surgical condition that occurs as a result of the ART treatment; result in the hospitalisation of the patient due to a complication of ART treatment; results or may result in the transmission of a communicable disease; result in a breach of legislation; arises from a gamete or embryo identification mix up; causes a loss of viability of gametes or embryos or suspected deterioration that renders them unsuitable for use or; arises from a systematic failure in the validation/verification of a diagnostic test and/or technology that has resulted in misdiagnosis and/or significant potential harm or loss to patients, their gametes or embryos. See Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.2.2.

<sup>87</sup> The Code of Practice states that incidents must be reported as soon as practical, but no later than six weeks after the provider becomes aware of the incident. However, a potential or actual breach of legislation must be reported within two weeks, and a sentinel event (e.g. death) must be reported within 48 hours. See Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.2.1.

<sup>88</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.2.5.

<sup>89</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.5.

to 110 data items for each ART cycle.<sup>90</sup> ANZARD is a clinical quality registry, held by the University of New South Wales (UNSW) and funded by ART units. It provides regular performance benchmarking and feedback to ART units and RTAC.<sup>91</sup> All ART units are required to provide de-identified patient and treatment information to ANZARD on IVF cycles, donor insemination cycles, pregnancy and birth outcomes as well as demographic details including sex, age, and infertility diagnosis.<sup>92</sup>

These data are used to inform benchmarking of each ART unit against the publicly available annual ANZARD Report.<sup>93</sup> If clinical outcomes (e.g. pregnancy rates) fall below the 25th percentile in an age group the ART unit must undertake a root cause analysis and address any issues during the audit process.<sup>94</sup> If clinical outcomes fall below three standard deviations,<sup>95</sup> the RTAC Chair will notify the unit. If clinical outcomes fall below three standard deviations for two consecutive years, the ART unit is required to submit an improvement plan to the RTAC Chair that will be audited at six-monthly intervals until there is sustained improvement.<sup>96</sup> RTAC advises that this power has been exercised 14 times between September 2019 and December 2024.

ANZARD provides some public reporting of ART unit performance via *YourIVFSuccess*, but ART units may opt out of this public reporting (see Table 2.3 below). Six (6%) ART units have chosen to opt out of public reporting.

### Non-conformities must be rectified through the audit process

Clinics are given 30 days to rectify any major non-conformities identified during an annual surveillance audit. If the clinic fails to resolve the issue within the required timeframe, the certifying body may vary, suspend or withdraw certification, which may have implications for the RTAC licensing decision.<sup>97</sup> Notably, the Code of Practice and RTAC Scheme Rules do not prescribe clear powers for RTAC to refuse, vary, suspend or cancel a licence (see section 3.3).

## Some clinical outcomes are reported publicly through *YourIVFSuccess*

Clinic-specific success rates are reported through the Commonwealth Government-funded *YourIVFSuccess* website. The website includes a personalised IVF success estimator and a searchable database of accredited ART clinics. Data are sourced from ANZARD, with the

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<sup>90</sup> National Perinatal Epidemiology and Statistics Unit, 'Australian and New Zealand Assisted Reproduction Database', *University of New South Wales* (Web Page) <<https://www.unsw.edu.au/research/npesu/clinical-registries/anz-assisted-reproduction-database>> ('*UNSW website - ANZARD*').

<sup>91</sup> National Perinatal Epidemiology and Statistics Unit, *UNSW website – ANZARD* (n 90).

<sup>92</sup> See the ANZARD Data Dictionary for a full list of fields required for reporting: Australian and New Zealand Reproductive Database, *ANZARD 3.0 Data Dictionary: Version 5.0* (November 2020).

<sup>93</sup> Kotevski et al, *2023 ART report* (n 5).

<sup>94</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.4.

<sup>95</sup> Using a funnel plot methodology to account for factors such as clinic size and female patient age.

<sup>96</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.4.

<sup>97</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42) s 7.6.

agreement of ART units. The aim is to provide transparent, objective information about IVF clinic success rates across Australia.<sup>98</sup>

Publication of outcomes on the ANZARD website requires ART unit agreement. Not all ART units participate (see Table 2.3). The ANZARD report shows that there is significant variation in success rates between the best performing and worst-performing clinics in Australia, with one measure ranging from 4% to 35% success.<sup>99</sup>

**Table 2.3: Clinics reporting on YourIVFSuccess.**

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
<b>Total units</b> <sup>100</sup>	3	34	1	24	4	2	23	8
<b>Reporting on YourIVFSuccess</b> <sup>101</sup>	3	33	1	22	4	2	21	8

## 2.6 Market conduct – regulation

The compliance of ART units with relevant regulatory requirements is overseen by State and Territory regulatory authorities through registration and compliance monitoring. Ahpra provides oversight of registered health practitioners.<sup>102</sup>

### Compliance monitoring and investigation powers vary between jurisdictions

Where registration requirements exist, State and Territory regulatory authorities are responsible for monitoring and investigating ART units' compliance with the conditions of their registration. The approach taken to compliance monitoring varies across jurisdictions, reflecting differences in scope, powers and regulatory posture. Some key examples are outlined below.

#### States and Territories may impose conditions on registration

In addition to general requirements of registration, State and Territory regulatory authorities may impose specific conditions on ART providers, either in response to specific issues or applied to all ART units to drive quality, safety and consumer protection. For example, consumer-driven requirements such as counselling are required as part of state-based regulation in Victoria and will form part of the regulatory approach in Queensland.

There is limited evidence of conditions being imposed in response to ART unit quality, safety, or conduct (see Table 2.4). This is in part due to new legislation and powers in Queensland,

<sup>98</sup> 'YourIVFSuccess', *YourIVFSuccess* (Web Page, 2025) <<https://yourivfsuccess.com.au>>.

<sup>99</sup> Kotevski et al, *2023 ART report* (n 5) 14.

<sup>100</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13).

<sup>101</sup> 'IVF Clinic Success Rates', *YourIVFSuccess* (Web Page, 2025) <<https://yourivfsuccess.com.au/clinics>>.

<sup>102</sup> Additionally, ART providers operating as private or public companies must comply with the *Corporations Act 2001* (Cth) requirements of company registration and reporting, director duties and responsibilities, financial disclosures and audits and recordkeeping and solvency.

which will commence in March 2026, and the Australian Capital Territory, and recent legislative changes and powers in Victoria.

**Table 2.4: Conditions imposed on ART units in response to ART unit quality, safety, or conduct the last 10 years by jurisdiction.**

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
Number of times conditions, in response to ART unit's quality, safety, or conduct, were applied in the last 10 years	0	N/A	N/A	N/A*	0	0	5**	3

\* Relevant powers under new Queensland legislation will not come into effect until March 2026.

\*\*The number of conditions applied in Victoria may not represent all conditions applied due to changes in reporting.

## Investigation powers vary between jurisdictions

Some jurisdictions have powers to undertake investigations in response to adverse events, complaints, or through own-motions powers. There is significant variation between jurisdictions in how adverse events are investigated and what regulatory actions, if any, are possible. For example, some jurisdictions have significant powers, through authorised officers, to undertake investigations and to compel ART units to provide information (see Table 2.5 below), while others rely on RTAC processes (see section 2.5 above).

Some jurisdictions have powers to commence own-motion investigations into service providers or sectors more broadly to investigate quality and safety concerns and to protect the public. For example, under Victorian legislation, the Victorian Health Regulator can act on a number of different pieces of evidence (such as complaints, RTAC reports, self-reporting or media) to investigate an ART unit, with authorised officers having extensive powers to enter and inspect facilities, ask questions and review documents. Similarly, from March 2026 Queensland will be able to undertake proactive compliance monitoring of ART providers, with a general power to secure compliance with the regulatory scheme for the safety and quality of the sector.

**Table 2.5: Investigatory powers by jurisdiction.**

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
<b>Power to undertake investigations</b>	✓	✗	✗	✓	~*	✓	✓	✓

\*South Australia does not have express powers of investigation under the *Assisted Reproductive Treatment Act 1988* (SA) and are limited to undertake investigations into a registered clinic using powers of an Authorised Person or relying on conditions of their registration which state they must provide specified information as requested to the Minister.

## Adverse event reporting requirements vary between jurisdictions

There are differences between jurisdictions in the reporting of adverse events. In the Australian Capital Territory, Queensland (from 1 March 2026), South Australia, Tasmania, Victoria, and Western Australia there are additional reporting obligations beyond the RTAC requirements (see Table 2.6). In other jurisdictions, adverse event reporting is to RTAC only. RTAC does not provide adverse event data to state or territory regulators.

**Table 2.6: Adverse event reporting requirements by jurisdiction.**

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
<b>Jurisdictional adverse event reporting requirements</b>	✗ <sup>#</sup>	✗	✗	~ <sup>^</sup>	✓	~*	✓	✓

<sup>#</sup>The Australian Capital Territory is yet to complete regulations to support the *Assisted Reproductive Technology Act 2024* (ACT), which may include prescribing other events that must be reported to the Australian Capital Territory Health and Community Services Directorate.

<sup>^</sup>Queensland will require mandatory adverse event reporting from 1 March 2026.

\*Tasmania requires reporting of injuries, transfers, deaths and other sentinel events, but does not impose an ART-specific adverse event definition.<sup>103</sup>

## Tasmania and Western Australian ART providers are subject to additional audits

ART units in Tasmania and Western Australia are subject to regulatory compliance audits by their local regulatory authority. These audits consider RTAC accreditation alongside a range of issues such as other statutory requirements, complaints management, and risk management. Other jurisdictions do not undertake additional compliance audits, relying on audits undertaken as part of the RTAC accreditation scheme and focussing regulatory attention on responding to adverse event reporting and complaints.

## Donor registries and donor limits vary between jurisdictions

Most jurisdictions maintain a registry of donors to enable tracking of genetic history for donor conceived people to access (see Table 2.7). There are mandatory registers and voluntary registers, with different operating models in place across the country. Consumer stakeholders

<sup>103</sup> *Health Service Establishments Regulations 2021* (Tas) Schedule 1, Part 4, Clause 10.

raised significant concerns about access to donor information when it is held by IVF providers (section 4.5).

**Table 2.7: Donor registries by jurisdiction.**

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
Donor registry	✓	✓	✗	✓	✓	✗	✓	✓

There is variation in the number of families allowed to be conceived by a given donor, and how family limits are applied (see Table 2.8). Most jurisdictions set limits for the number of families to whom a donor can provide gametes. In New South Wales the limitation is applied to the number of women accessing the donor gametes rather than families. An exception to this rule is if a woman (or her partner) receives further ART treatment using a donated gamete from the same donor's gametes.<sup>104</sup> It is unclear how limits are applied between jurisdictions.

**Table 2.8: Donor limits by jurisdiction.**

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
Donor limit	5 families in the ACT or 10 families Australia-wide.	5 women	No limit	10 families*	10 families	No limit	10 women^	5 families

\* The Queensland donor limit will come into effect from mid- to late-2026.

^ The Victorian limit includes an exemption to allow women in same-sex relationships to use the same donor to have a genetic sibling for their child/ren, even if the 10-women limit has been met. The exemption also applies to existing families (same sex or heterosexual) who use more than one surrogate mother to have a child who will be genetic sibling to their existing child/ren.

In addition to limits on the number of families, or women, a donor may donate to, there are limitations on the age of donors, and movement of genetic material.

Gamete and embryo donors cannot be paid to donate. They may be reimbursed for reasonable expenses incurred because of the donation. There are calls from some ART providers to enable payment for gametes to boost local availability.

## Ahpra regulates registered ART professionals

An additional level of regulation is provided by Ahpra's oversight of registered ART health professionals. In addition to its registration functions, Ahpra undertakes a range of compliance monitoring functions, such as audits, to ensure health practitioners are complying with their professional standards and any conditions or restrictions placed on registration.

Ahpra can receive complaints and notifications of conduct alleged to breach professional standards and undertake investigations. Anyone can make a notification to Ahpra or the

<sup>104</sup> *Assisted Reproductive Technology Act 2007* (NSW) s 27(1A).

relevant National Board if they believe a registered health professional has breached standards of professional conduct.

For each notification that is accepted, Ahpra will first assess the notification, which determines the next steps of the relevant National Board.<sup>105</sup> These may include:

- **taking immediate action**, which can include suspending registration, imposing a condition on registration, accepting an undertaking from the practitioner, or accepting the surrender of the practitioner's registration.
- **investigating a practitioner** if the National Board perceives risks to the public that are significant.<sup>106</sup> An investigation may be undertaken following an assessment or the immediate action process. The National Board also has the power to start an own motion investigation. All investigations are guided by nationally consistent policies, procedures and legal obligations.<sup>107</sup>

Ahpra assessment and investigation processes are strongly based in nationally harmonised legislation, policies and procedures, ensuring consistency across all registered professions and jurisdictions. Ahpra suggested that its system-level regulation, which focuses on organisational governance and culture, may have a greater impact on safety and quality than individual practitioner registration.

## 2.7 Enforcement and recourse

Enforcement action is the response taken when non-compliance has occurred, including action regulatory authorities can take to deter non-compliance or penalise those who do not follow regulatory requirements. Recourse refers to the way that consumers seek a remedy or compensation when something goes wrong with their ART treatment. Several avenues are available for consumers to make a complaint and report negative or unsatisfactory experiences with ART providers and practitioners.

### Enforcement powers vary between jurisdictions

When providers do not comply with regulatory requirements, the following enforcement mechanisms are available to State and Territory regulatory authorities:

- **Restriction, suspension or cancellation of jurisdictional registration:** ART units who have failed to comply with their conditions of registration may have their registration cancelled or suspended by the relevant state or territory regulatory authority. Additionally,

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<sup>105</sup> Each health profession that is part of the National Registration and Accreditation Scheme is represented by a National Board, which are responsible for registering practitioners and students as well as other functions for their professions. See, 'National Boards', *Australian Health Practitioner Regulation Agency* (Web Page, 2024) <<https://www.ahpra.gov.au/National-Boards.aspx>>.

<sup>106</sup> That is, because of a single, serious, one-off concern that has not been appropriately dealt with or appropriately managed without regulatory intervention; or series of concerns that represent that might represent a pattern of behaviour that requires our intervention. See 'Investigating practitioners', *Australian Health Practitioner Regulation Agency* (Web Page, 2023) <<https://www.ahpra.gov.au/Notifications/How-we-manage-concerns/Investigation.aspx>> ('Ahpra website – Investigating practitioners').

<sup>107</sup> Australian Health Practitioner Regulation Agency, *Ahpra website – Investigating practitioners* (n 106).

some jurisdictions have powers to vary registration including Queensland, South Australia, Tasmania, and Western Australia.

- **Other jurisdictional enforcement powers:** The Australian Capital Territory,<sup>108</sup> Queensland<sup>109</sup>, and Victoria<sup>110</sup> have the most comprehensive, scalable enforcement powers among jurisdictions, including additional powers to issue improvement notices and prohibition notices, among others. These powers are not available in New South Wales, South Australia, Tasmania, or Western Australia.
- **Offence provisions for ART units who continue to operate against the conditions of registration:** Beyond varying, suspending or cancelling registration, the type of offence provisions in jurisdictions varies considerably, from the ability to issue a fine in New South Wales and South Australia, to imprisonment in the Australian Capital Territory, Queensland, Victoria and Western Australia.

If Ahpra finds that a registered health practitioner has breached professional standards there are several scalable actions available – ranging from a caution or reprimand, the accepting of undertakings by the practitioner, and conditions on registration, to suspension or cancellation of registration or imposing fines. Some of these regulatory actions require referral to a civil and administrative tribunal.<sup>111</sup>

Health complaints bodies that have adopted the National Code of Conduct for Health Care Workers can take action against unregistered health practitioners. This provides health complaint bodies with powers to place conditions on or prohibit practice and take immediate action if a breach has taken place.

## Several complaints avenues are available to consumers

Several avenues are available to consumers who wish to make a complaint about an ART unit or individual practitioner. The most appropriate pathway will depend on the nature and subject of the complaint. However, there is no single national register or ART complaints agency and consumers often find themselves not knowing to whom they should direct a complaint.

RTAC and jurisdiction-based health complaints bodies recommend consumers first report their complaint to the service provider directly. This is consistent with complaints handling processes across health care more widely. If a complaint is not adequately resolved with the ART unit or by the individual provider, then RTAC recommends that the complainant contact

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<sup>108</sup> *The Assisted Reproductive Technology Act 2024* (ACT) includes scalable enforcement options in the event of legislative non-compliance by providers, including: improvement notices, prohibition notices, enforceable undertakings, information or document production notices and infringement notices.

<sup>109</sup> *The Assisted Reproductive Act 2024* (Qld) provides scalable enforcement options in the event of legislative non-compliance by providers, including: improvement notice, prohibition notices – applying to ART services of a stated kind, or all ART services, imposing and varying licence conditions, cancelling a licence and suspending a licence.

<sup>110</sup> *The Assisted Reproductive Treatment Act 2008* (Vic) include scalable enforcement options in the event of legislative non-compliance by providers, including: require provider to appoint an external auditor, notice to compel production of information or documents, power to enter premises to conduct an inspection of documents and records, improvement notice, suspending registration either in whole or in part, prohibition notice, accept an enforceable undertaking, infringement notice.

<sup>111</sup> Australian Health Practitioner Regulation Agency, *Ahpra website – Investigating practitioners* (n 106).

the relevant jurisdiction-based health complaints body. Only after that would RTAC agree to review a complaint about an ART unit.<sup>112</sup>

## ART providers are the primary complaints avenue

The Code of Practice requires ART units to acknowledge and investigate complaints, and implement and review policies and procedures that include: information on how patients make a complaint, acknowledgement and investigation of complaints, and systematic recording, review and corrective/preventive action of complaints.<sup>113</sup> ART units are also required to provide stakeholders with avenues that allow the escalation of complaints to external bodies.<sup>114</sup> Any correspondence relating to complaints about the ART unit must be provided to the certifying body as part of the audit process.<sup>115</sup>

## Jurisdictional health complaints bodies (or equivalent) are typically the secondary complaints avenue

Consumers may make a complaint to the relevant jurisdictional health complaints body about the conduct of both individual ART practitioners and ART providers.<sup>116</sup> Typically, these bodies will require the consumer to have approached their care provider first, only agreeing to handle the complaint if direct engagement did not resolve the matter. RTAC may also refer complaints to a health complaints body. In response to a complaint, the relevant body may conduct an assessment, investigation, mediation, or regulatory action.<sup>117</sup> Recourse options vary between jurisdictions and include assessment, investigation, conciliation and complaints resolution, referral to Ahpra or any other appropriate state or Commonwealth body, and system reviews.

Complaints relating to ART providers are not tracked and reported publicly in any jurisdiction. Most jurisdictions are unable to advise the number of complaints about ART providers or

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<sup>112</sup> 'RTAC', *Fertility Society of Australia and New Zealand* (Web Page, 2025) <<https://www.fertilitysociety.com.au/art-regulation/rtac/>>.

<sup>113</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.6.

<sup>114</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.6.

<sup>115</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42) s 4.1.2.1b.

<sup>116</sup> If a complaint is in scope of the *Assisted Reproductive Technology Act 2007* (NSW) or *Assisted Reproductive Technology Regulation 2024* (NSW), the Ministry for Health will manage it in accordance with its legislative powers. If it is outside the scope of the NSW legislation, it may refer the complainant to the NSW Health Care Complaints Commission.

<sup>117</sup> 'Information for people making complaints', *ACT Human Rights Commission* (Web Page) <<https://www.hrc.act.gov.au/complaints/information-for-people-making-complaints/>>; 'Possible Complaint Outcome' *Health Care Complaints Commission* (Web Page, 2 March 2023) <<https://www.hccc.nsw.gov.au/understanding-complaints/possible-complaint-outcomes/>>; 'Complaint Process', *Health and Community Services Complaints Commission* (Web Page, 31 October 2023) <<https://hcscc.nt.gov.au/complaint-process/>>; 'What happens when you make a complaint', *Office of the Health Ombudsman* (Web Page) <<https://www.oho.qld.gov.au/public/what-happens-when-you-make-a-complaint/>>; 'Consumers', *Health and Community Services Complaints Commissioner* (Web Page, 2025) <<https://www.hcsc.sa.gov.au/making-a-complaint/#are-there-exceptions/>>; 'Complaints Process', *Health Complaints Commissioner Tasmania* (Web Page, 24 June 2025) <<https://www.healthcomplaints.tas.gov.au/complaints#Complaint-process/>>; 'Our Process', *Health Complaints Commissioner* (Web Page) <<https://hcc.vic.gov.au/public/our-process/>>; 'Complaints Resolution Process', *Government of Western Australia* (Web Page, 25 June 2024) <<https://www.hadsco.wa.gov.au/For-Public/Complaint-Resolution-Process/>>.

practitioners lodged over the past 10 years.<sup>118</sup> Jurisdictional advice indicates that complaints information is not routinely shared between health complaints bodies and relevant state or territory regulatory authorities. Further, none of the health complaints bodies reported having a formal relationship with RTAC, with privacy identified as a potential barrier to information sharing. The health complaints bodies consulted as part of our review also advised that key themes in ART sector complaints have been issues with communication, fees and charges.

## RTAC handles complaints where an ART unit may have breached the Code of Practice

Following review of a complaint by the ART provider and the health complaints body, a consumer may lodge a complaint directly with RTAC if they believe an ART unit has breached the Code of Practice.<sup>119</sup> The number of complaints RTAC has received increased from six complaints in 2022–23<sup>120</sup> to 17 complaints in 2023–24.<sup>121</sup> RTAC advises that it is developing a complaints policy in response to the increasing number and complexity of complaints. This is currently under refinement.

## Health departments and health ministers' offices may handle complaints in some jurisdictions

While not a primary complaints avenue, jurisdictions advise that consumers in New South Wales, Queensland, South Australia, Tasmania, and Western Australia may direct their complaint about alleged breaches of ART regulatory requirements to health departments and/or ministers. In turn, these health departments may investigate complaints about ART services as the relevant regulatory authority under state legislation. State and Territory regulatory authorities may rely on investigation and enforcement powers to respond to a complaint.<sup>122</sup>

## Ahpra handles complaints about registered health professionals

Ahpra accepts a wide range of notifications (complaints) about individual registered health practitioners, primarily focused on public safety and professional conduct. These may be initiated by consumers, ART providers, other ART professionals or State and Territory regulatory authorities or health complaints bodies. However, Ahpra does not handle complaints about health services, organisations, or professions not regulated by Ahpra (e.g. embryologists, social workers), fees, charges, or dissatisfaction with service quality. Ahpra has extensive powers to investigate registered health practitioner conduct under the Health

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<sup>118</sup> The exceptions are South Australia, which advised that 25 complaints have been made to SA's Health and Community Services Complaints Commission; Victoria, which advised that 358 complaints had been made to the Health Complaints Commission between 2015-2025, and Queensland which advised that 304 matters were received by the OHO relating to possible ART treatment between 1 July 2014 and 15 May 2024: Office of the Health Ombudsman (Qld) (n 12) 98.

<sup>119</sup> 'RTAC', *Fertility Society of Australia and New Zealand* (Web Page, 2025) <<https://www.fertilitysociety.com.au/art-regulation/rtac/>>.

<sup>120</sup> Reproductive Technology Accreditation Committee, *Annual Report 2022–23* (2023) 10.

<sup>121</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023–24* (2024) 11.

<sup>122</sup> Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia have powers under their ART legislation to compel clinics to provide information or clarification around a matter.

Practitioner Regulation National Law. Ahpra advised that it does not receive many complaints regarding ART practitioners.

### Other complaints avenues

Under Australian Consumer Law, ART providers are required to comply with obligations around guarantees of service quality, prohibition of misleading or deceptive conduct, and contracts and refunds.<sup>123</sup> Consumers can file a complaint with their jurisdictional consumer protection agency if they believe an ART provider has breached its statutory guarantees, such as failing to provide the service with due care and skill, or providing gametes that are not fit for purpose.<sup>124</sup> Additionally, the Therapeutic Goods Association can investigate complaints about misleading or inappropriate advertising of therapeutic goods directed at consumers (including false or exaggerated health claims).<sup>125</sup> The Australian Competition and Consumer Commission (ACCC) also takes reports from people about possible issues under consumer law about false or misleading claims, but does not resolve individual disputes about misleading claims.<sup>126</sup>

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<sup>123</sup> *Competition and Consumer Act 2010* (Cth) sch 2 ss 18, 29, 60–62, 64, 67.

<sup>124</sup> 'Consumer Protection Agencies', *Australian Government* (Web Page) <<https://consumer.gov.au/consumers/consumer-protection-agencies>>.

<sup>125</sup> 'Report', *Therapeutic Goods Administration Care* (Web Page) <<https://compliance.health.gov.au/ac-report/>>.

<sup>126</sup> 'False or Misleading Claims', *Australian Competition and Consumer Commission* (Web Page) <<https://www.accc.gov.au/consumers/advertising-and-promotions/false-or-misleading-claims>>.

## 3 Strengths and weaknesses of current ART accreditation and regulation

In this chapter we describe our assessment of the strengths and weaknesses of the current ART accreditation and regulatory landscape. We have used the strengths and weaknesses that we have identified to inform the opportunities for improvement proposed in chapter 5.

### 3.1 Market entry – accreditation

This section outlines the issues identified with the RTAC accreditation scheme for new providers when they enter the ART market.

#### The RTAC accreditation scheme no longer meets current needs

This section outlines the issues identified with current accreditation processes, first as relevant to providers seeking a licence to operate (market entry).

#### RTAC is not independent of ART providers

As described in chapter 2, RTAC was first established by FSA (now FSANZ) in 1987 with the intent of establishing and maintaining clinical care standards in ART. This was a laudable initiative, recognising both the need for care standards and the absence of any other authority focussed on developing and overseeing standards for advanced infertility care. Indeed, in many ways, FSA's initiative to establish and empower RTAC was significantly ahead of health care regulation more broadly. However, nearly four decades on, that RTAC remains a committee of FSANZ, subordinate to the FSANZ board with a Chair appointed by the FSANZ board, means that it is unable to provide the independence that is the hallmark of contemporary accreditation processes elsewhere in health care, whether in public and private settings. This lack of independence has been identified as a key concern for all stakeholders. The majority of provider, workforce, and consumer stakeholders suggested that the accreditation agency should be independent of FSANZ. This is echoed by Recommendation 7 of the FSANZ-sponsored Framework for an Australian 10-Year Fertility Roadmap, published in November 2024,<sup>127</sup> that called for:

*“RTAC [to] be established as a body independent of FSANZ with its own independent constitution, funding and Board”.*

We found that the lack of independence of RTAC was not merely one of perception but that its actions, or more precisely its lack of actions, have been materially tempered by its close relationship with providers. Indeed, the Gorton Review<sup>128</sup> and the 2024 investigation into

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<sup>127</sup> Hunt and Swift (n 2).

<sup>128</sup> Gorton (n 12) 22–3.

Queensland ART providers<sup>129</sup> both raised concerns about the lack of an independent accreditation agency and the need for an independent and impartial authority to build public confidence in the ART sector.<sup>130</sup>

The current RTAC model for accreditation oversight also differs significantly with that of the Australian Commission for Safety and Quality in Healthcare. The Commission commenced as an independent statutory authority in 2011 to lead and coordinate national improvements in the safety and quality of health care. It is responsible for standard-setting and oversight of accrediting agencies for health care, in both private and public settings.

### RTAC's initial licensing and accreditation processes have some important limitations

Notwithstanding its lack of independence, RTAC's overall approach to the initial accreditation and licensing of new providers (market entry) appears sound. It requires an initial audit against defined standards, the Code of Practice, and then periodic surveillance audits against those same standards. As a process, this is consistent with the approach taken by the Commission in assessing health services against the NSQHS standards.

Further, the RTAC primary accreditation (audit) appears to be an appropriately comprehensive process that includes both document review and onsite attendance by an approved audit agency. This initial accreditation is then followed by a secondary audit, by the same approved agency, six months after a new clinic has commenced operations. This also appears to be an appropriate approach to ensure that providers are maintaining performance against RTAC requirements once they have entered the market.

That the accreditation audits are of individual ART clinics, rather than of an ART provider (i.e. companies with multiple clinics), is also appropriate because practices can differ significantly across ART units. It also makes it easier to identify any non-compliance with standards at an individual clinic level even if the remedies are the responsibility of the overarching provider/owner.

However, despite appropriate accreditation process structures, we identified some important limitations to the current RTAC accreditation approach that undermine the effectiveness of accreditation and licensing. These are in addition to the lack of clear and effective standards, discussed in more detail below.

#### **No oversight or quality checks of the auditing agencies**

First, RTAC does not oversee and review the performance of the two audit agencies (Global-Mark and Certified Partner Global) that perform all ART clinic audits on which RTAC accreditation and licensing is based. Review of the auditors by the accreditation agency – in this case RTAC – is required to ensure and maintain consistency and quality of the audits and to have confidence in an auditor's findings. RTAC has never reviewed the performance of its auditors, instead relying on the fact that they maintain certification by JAS-ANZ.

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<sup>129</sup> Office of the Health Ombudsman (Qld) (n 12) 98–100.

<sup>130</sup> Gorton (n 12) 22; Office of the Health Ombudsman (Qld) (n 12) 99.

While it is appropriate, indeed necessary, that the audit agencies approved by RTAC are certified by JAS-ANZ, such certification doesn't set aside the need for active oversight of the performance of the agencies by RTAC.

By way of comparison, the Commission employs several performance oversight and feedback mechanisms to monitor and improve the quality of assessments performed by the six approved accrediting agencies. These include post-assessment surveys by each health service, observation visits by the Commission at least annually to observe assessor performance, analysis of accreditation outcome data to identify anomalies or significant variation between agencies, accrediting agency compliance reports, and analysis of feedback from regulatory authorities and the public.<sup>131</sup> The Commission uses the data from these various oversight checks as the basis of an annual performance report for each accrediting agency.

RTAC reported to us that it was unable to undertake such oversight within its current resources.

### **Governance weaknesses underlying RTAC licensing decisions**

RTAC advised us that audit reports, both from initial audits (market entry accreditation) and annual audits (market conduct), are only sighted and reviewed by the RTAC Chair. The explanation for this was to maintain confidentiality, respecting potentially commercially sensitive audit findings. The flow-on of this arrangement is that only the RTAC Chair, a single person who is appointed by the FSANZ Board, is in a position to consider how a clinic will address audit findings if those findings include non-compliance. Audit reports are not made available to other members of the RTAC committee. However, it is the committee that approves licensing decisions.

It appears that there are two governance failures inherent in this approach. First, the sole decision maker, the RTAC Chair, has an overt conflict of interest because they are appointed by the FSANZ Board, a board whose membership includes representatives of the sector providers over whom they are making licensing decisions. Second, ultimately the RTAC licensing decisions are made by a committee on the recommendations of a single decision-maker without sighting or interrogating the audit reports and findings. It is difficult to see how the committee can be confident about its decisions without access to the primary report findings.

### **Limited information sharing between RTAC and jurisdictional regulatory authorities**

RTAC does not share the audit findings with jurisdictional regulatory authorities (see section 3.4 for further discussion of the use of regulatory intelligence). In Australian Capital Territory, Queensland, South Australia, Victoria and Western Australia the audit reports are provided to the regulator directly by the ART unit. In NT and Tasmania there is no routine sharing of the audit reports with the health department. This arrangement reflects very limited engagement between RTAC and jurisdictional regulatory authorities. RTAC reported to us that it has only ever met with Victoria and Western Australia, mostly for consultation on sector-wide matters rather than to discuss an individual ART clinic or provider. We believe that the lack of regular

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<sup>131</sup> Australian Commission on Safety and Quality in Health Care, *Fact Sheet 8: Accrediting Agency Performance Oversight and Feedback* (Fact Sheet, 25 July 2018) 2.

and systemised dialogue between RTAC and the regulators compromises effective accreditation and regulation.

Again, by way of comparison, the Commission regularly liaises with jurisdictional regulatory authorities, particularly on services of concern.

RTAC also told us that it has never met with the Commission. This was confirmed by the Commission. Given that the Commission oversees the accreditation of day surgery facilities, which some ART providers operate, this was surprising to us.

### **Inadequate transparency of accreditation outcomes**

The outcomes from accreditation assessments, whether at market entry or for ongoing market conduct are only published by RTAC, in summary form, in its annual report. Real-time accreditation outcomes are not available. In its annual report, RTAC provides tables detailing each ART clinic, the date of the audit visit(s), and the duration of the licence provided by RTAC.<sup>132</sup> However, while summary data on non-conformances are provided in the annual report, these are not provided by individual clinics. Neither providers nor state or territory regulatory authorities can see the audit outcomes for individual ART clinics.<sup>133</sup>

In addition to summary data from the national accreditation scheme,<sup>134</sup> the Commission publishes the individual accreditation outcomes for all health services, private and public, including detailing which standards were met and which, if any, were not met.<sup>135</sup>

Consumers expressed interest in accessing information about quality and safety performance of individual ART units, such as accreditation outcomes. Further, given that “identification and traceability” was the most common non-conformity reported in audits in 2023-24,<sup>136</sup> and in 2025 there have been two episodes of the wrong embryo being transferred in two different clinics owned by the same provider, improved visibility of audit outcomes, by clinic, in real-time would be expected to assist regulatory authorities.

### **Limited resourcing prevents RTAC from delivering its accreditation functions in full**

RTAC oversees and implements a national accreditation ART scheme, including the development of care standards – the Code of Practice. However, it appears to lack the resources necessary to deliver such accreditation functions in full.

The RTAC committee comprises seven members, all holding honorary positions with no, or nominal, financial compensation. The RTAC committee is supported by an administrative officer who is employed by FSANZ. This contrasts with the Commission which has

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<sup>132</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13) 12.

<sup>133</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13) 7.

<sup>134</sup> ‘NSQHS Standards Assessment Outcomes’, *Australian Commission on Safety and Quality in Health Care* (Web Page, 2025) < <https://www.safetyandquality.gov.au/standards/nsqhs-standards/nsqhs-standards-assessment-outcomes> >.

<sup>135</sup> Australian Commission on Safety and Quality in Health Care, *NSQHS Standards – public reporting* (n

<sup>136</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13) 7.

approximately 150 employees (albeit to deliver a far greater span of responsibility) and is funded jointly by the Australian Government and by State and Territory governments.<sup>137</sup>

The FSANZ-sponsored Framework for an Australian 10-Year Fertility Roadmap found that RTAC is not sufficiently resourced to allow for more comprehensive review functions, recommending reform to its funding model (Recommendation 10).<sup>138</sup> The 2024 Queensland investigation of ART providers also noted that the capacity of RTAC to undertake review of incidents may be constrained by a lack of resources.<sup>139</sup>

Many stakeholders expressed concern that, while it has done well with the resources available, RTAC is not adequately resourced to effectively perform the accreditation functions expected of it, especially given the growth in and complexity of Australia's ART sector.

The funding provided to RTAC, ultimately derived from ART providers, is determined and agreed to by FSANZ.

## RTAC appears to have limited power to deny or limit a provider's entry to market

The issuing or withholding of a licence to provide care is an essential accreditation power. The effectiveness of any accreditation scheme relies on the accrediting authority being able to determine whether a given provider is suitable to be licensed or not. However, the Code of Practice for ART units – the list of standards of care – does not provide clear criteria to guide RTAC licensing decisions. Accordingly, some stakeholders suggested that there may be risks of litigation or challenge should RTAC refuse accreditation to an ART unit that has been certified.<sup>140</sup> RTAC confirmed that it is concerned about litigation should a licence be withheld or withdrawn, citing the one and only example of a clinic's licence being withdrawn, in Western Australia, only to have that decision overturned by a court of law.

## RTAC accreditation standards lack sufficient rigour

### The RTAC Code of Practice could better support quality and safety

RTAC has developed the Code of Practice to take a risk-based approach to accreditation. That is, to outline requirements of care without being overly prescriptive. For example, Critical Criterion 3 requires ART units to undertake regular stakeholder feedback (including patients) and provide evidence of implementation and review of related policies and procedures. But the standard does not prescribe what should be included in those policies and procedures.<sup>141</sup>

The standards themselves are developed by RTAC in consultation with the various groups that make up FSANZ. The intent of this engagement is to ensure the involvement of

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<sup>137</sup> Australian Commission on Safety and Quality in Health Care, *Entity resources and planned performance* (Report, 2025).

<sup>138</sup> Hunt and Swift (n 2) recommendation 10.

<sup>139</sup> Office of the Health Ombudsman (Qld) (n 12) 98.

<sup>140</sup> ART units that have been certified by one of the two certifying bodies will be eligible for RTAC consideration for recognition as an RTAC licensed ART unit. See Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.5.

<sup>141</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.6.

appropriate expertise in standard development. However, one of the outcomes of this is that the standards are, in part, developed and agreed to by the very providers that are expected to abide to them. Indeed, changes to the Code of Practice require the approval of the FSANZ board.

By contrast, the Commission has established expertise in standard setting and accreditation oversight, including developing and implementing robust standards for health services, primary and community health providers, mental health providers, aged care providers, pathology and diagnostic imaging providers and, most recently, cosmetic surgery providers.<sup>142</sup> Over the past 10 years the Commission has also developed a suite of clinical care standards, of which there are now 20, that describe the care that patients can expect to be offered by clinicians and care providers in the relevant branch of health care.

The aim of these standards is to reduce unwarranted variation in health care or health outcomes by increasing evidence-based health care. Independent accrediting agencies use these standards to assess care provision across multiple domains as part of accreditation processes. For example, the National Safety and Quality Health Service (NSQHS) standards that are used to assess hospitals and health services include eight standards that cover clinical governance; partnering with consumers; preventing and controlling infections; medication safety; comprehensive care; communicating for safety; blood management; and recognising and responding to acute deterioration. Aligned with the NSQHS standards but recognising the differences in care settings, the Commission's standards for primary and community care include three standards addressing clinical governance; partnering with consumers; and clinical safety.

The independent development and maintenance of evidence-based standards that adequately cover ART care is not evident in current RTAC-based accreditation processes and the Code of Practice. Further, changes to the Code of Practice requires the approval of the FSANZ board. This is an overt conflict of interest.

From time-to-time RTAC issues technical bulletins to all ART units. These bulletins are intended to identify recurrent or emerging issues of concern, typically found through audit outcomes, bringing the issue to the attention of providers. The sector values these technical bulletins, suggesting that they help the Code of Practice keep pace with technological, medical and scientific advances in between more substantive updates. However, the bulletins are viewed by stakeholders as unenforceable educational communications to ART units and certifying bodies, not prescriptive or proscriptive requirements.

### *Opportunities to strengthen the Code of Practice*

Most stakeholders agreed that the Code of Practice has promoted high standards across the ART sector. It was apparent to us that providers took the Code of Practice seriously and, largely, abided by it. The most obvious example of this was, in 2002, the introduction of the recommendation for single embryo transfer to reduce the multiple pregnancy rate. Australia led the world in regard to this improvement in clinical care. Nonetheless, several stakeholders, including RTAC, ART providers, and auditors, identified that there are opportunities to

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<sup>142</sup> See 'Standards', *Australian Commission on Safety and Quality in Health Care* (Web Page, 2025) <<https://www.safetyandquality.gov.au/standards>>.

strengthen the Code of Practice to provide clearer standards of expected care, as outlined below.

### **The Code of Practice should be more prescriptive**

The Code of Practice lacks the prescriptive detail found in comparable national and international frameworks.<sup>143</sup> The Code of Practice contrasts with the Commission's NSQHS standards, which are more prescriptive in nature.<sup>144</sup> Auditors also suggested that their deep knowledge of the NSQHS standards was helpful to inform the practices of some ART units when the Code of Practice does not provide sufficient guidance.

### **The Code of Practice should define minimum standards and performance metrics**

The Code of Practice does not specify clear minimum standards or performance benchmarks. Some stakeholders reported that they would prefer the Code of Practice to be more detailed. For example, by clearly detailing the minimum standards required for good identification and traceability practices, beyond the current requirement which is simply to have relevant policies and procedures in place without specifying what those policies and procedures should be.

### **Updates to standards, as per in technical bulletins, should be incorporated into the Code of Practice**

ART units are not audited against updates provided in the technical bulletins, 16 of which have been published since 2009. The Code of Practice notes that from time to time, a technical bulletin will be incorporated into the Code of Practice and so become enforceable.<sup>145</sup> However, a reliance on unenforceable documents to maintain currency with technological, medical and scientific advancements in between Code of Practice updates may create confusion and inconsistent implementation across the ART sector.

## **ART accreditation could be aligned with broader healthcare accreditation standards**

Currently, and largely for historical reasons, the ART sector operates outside the national healthcare safety and quality architecture, with an accreditation scheme not linked to the national scheme run by the Commission. The exception is those ART providers that operate day hospitals. Those facilities are subject to accreditation by the Commission. More generally though, RTAC and the Commission do not have an established relationship as healthcare accreditation bodies. Indeed, both RTAC and the Commission confirmed that the two agencies do not communicate with each other.

We believe that this is an important weakness of the RTAC scheme. The Commission are experts in the development and use of standards, and in the implementation of a sophisticated accreditation scheme with quality and safety improvement as the principal goal. Lessons learned from the Commission's recent work in the accreditation of cosmetic surgery, including the development of clear, defensible standards that can be used to make licensing decisions,

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<sup>143</sup> For example, UK's Human Fertilisation and Embryology Authority Code of Practice outlines the specific information that is needed to be given to patients, specifically requiring details on the centre, treatment, risks, data and success rates, costs and contracts be given prior to consent.

<sup>144</sup> For example, the NSQHS standards require providers to have a healthcare record system in line with relevant regulations and steps out key elements that are required, such as using national patient and provider identifiers. In contrast, the RTAC Code of Practice takes a more general approach, requiring a records system that aligns with applicable regulations and guidelines without detailing specific elements.

<sup>145</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.8.

show how accreditation requirements for a specialist area of practice can be aligned with the NSQHS standards while addressing its unique risks and priorities.

## 3.2 Market entry – regulation

In this section we outline issues we identified with the State and Territory registration process.

### State and Territory registration is perceived as burdensome

As described in chapter 2, ART units must be registered with the jurisdiction in which they wish to practice. Where it exists, jurisdictional ART legislation outlines registration requirements. All jurisdictions with the exception of the Northern Territory require ART units to be accredited with RTAC as a registration requirement.<sup>146</sup> Thus, jurisdictional registration relies on the RTAC accreditation process.

Some jurisdictions have other registration conditions in addition to RTAC accreditation. This enables those jurisdictions to address any perceived gaps in the RTAC accreditation scheme. For example, South Australia and Western Australia requires ART units to provide the regulatory authority with a copy of their RTAC surveillance audit reports and any corrective action plans. This seeks to correct a weakness in the information flow between RTAC and regulatory authorities. Additionally, from March 2026, Queensland will be able to consider a range of factors in issuing a licence to an ART provider, none of which are bound to RTAC accreditation. In contrast, the Australian Capital Territory and Victorian legislation only permit registration conditions for a provider that are consistent with any conditions of RTAC accreditation.

Providers that operate clinics in multiple jurisdictions reported that the variation in regulatory requirements across jurisdictions creates an unnecessary regulatory burden. Our review of the relevant State and Territory legislation suggests that, with the exception of providers operating in Western Australia and Tasmania who are subject to jurisdictional audits,<sup>147</sup> the market entry regulatory burden is more associated with the process of applying for registration in separate jurisdictions – which have varying registration periods and may impose different conditions – rather than particularly onerous registration requirements in any jurisdiction.

### Registration requirements of the ART workforce are broadly appropriate

Most stakeholders were satisfied with the current requirements for medical and nursing practitioners to be registered with Ahpra. As noted in chapter 2, of those key personnel that do not fall within Ahpra's NRAS, the Code of Practice requires all staff to be authorised to

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<sup>146</sup> The Northern Territory does not currently have a regulatory authority with or regulatory powers to oversee the ART provider in the territory.

<sup>147</sup> In Tasmania and Western Australia, clinics undergo audits as part of their re-registration process and are required to submit documentation, including annual RTAC audit reports, to their jurisdiction's regulatory authority for review.

perform the functions for which they have been employed, with specific requirements for most non-NRAS professions, including laboratory managers, counsellors and quality managers.

However, the role of the embryologist is not defined in the Code of Practice. It was apparent to us that there was significant variation in the experience required of embryologists, particularly senior embryologists, between clinics. This variation is enabled by a lack of professional requirements for embryologists. In this regard, Australia's regulatory approach to embryologists differs from that of New Zealand and the United Kingdom (UK). In New Zealand clinical embryologists must be registered with the Medical Science Council.<sup>148</sup> In the UK, clinical scientists, including embryologists, must be registered with the Health and Care Professions Council.<sup>149</sup> Unlike Australia, both councils require minimum qualifications and continuing professional development (CPD) from embryologists to ensure that this profession meets minimum standards. These requirements do not exist in Australia, although many embryologists are members of the Australian Institute of Medical and Clinical Scientists (AIMS) and/or the Australian Council for the Certification of the Medical Laboratory Scientific Workforce (CMLS).

There was not widespread support among stakeholders to extend Ahpra registration to embryologists and other ART professions that are not currently party to Ahpra's NRAS. We agree with that position. We see little, if any, benefit of adding embryologists to the NRAS. Nonetheless, some stakeholders recognised that more prescriptive qualification requirements for embryologists, such as requiring fellowship of AIMS or equivalent, could improve standards of care. We agree that there is merit in considering such requirements.

Some stakeholders also advised that the Code of Practice could usefully include more prescriptive guidance on staffing requirements.

### 3.3 Market conduct – accreditation

In this section we outline the issues we identified with the ongoing accreditation of licensed providers through RTAC audits and use of accreditation data.

#### Re-accreditation processes require improvement

##### RTAC surveillance audits lack independence and quality

Currently, RTAC requires each ART unit to undergo an annual audit to maintain accreditation.<sup>150</sup> This approach seeks to offer regular opportunities to identify and report non-conformities with the Code of Practice. Annual auditing is commendable. Although it could be argued that with stronger and more effective standards and more robust accreditation processes with transparent outcomes, less frequent auditing may be just as effective and significantly less burdensome for all.

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<sup>148</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.5.2.

<sup>149</sup> Human Fertilisation and Embryology Authority, *Code of Practice* (October 2023) s 2.19.

<sup>150</sup> Satellite units are subject to audit once every three years: see Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 1.4.2.

In that regard, RTAC's reaccreditation (market conduct) processes for ART units have the same weaknesses as its market entry accreditation processes – lack of independence, inherent conflicts of interest, reliance on an individual's decision making, lack of performance monitoring of audit agencies, the lack of clear, defensible standards for decision making, lack of transparency of outcomes, and inadequately resourced functions. In addition, we identified some other weaknesses, outlined below.

### **Lack of audit independence**

Due to the very small pool of auditors, there is a risk of regulatory capture and lack of independence. The same auditors, and in many cases the same auditing individuals, have been undertaking ART unit audits year after year after year.

### **Insufficient audit quality**

Concerns around the quality, and lack of transparency, of RTAC audits were raised in the 2024 investigation into Queensland ART providers.<sup>151</sup> The Gorton Review also heard mixed views on the audit processes from stakeholders.<sup>152</sup> While some stakeholders told us the audits were comprehensive and a valuable opportunity for improvement, others expressed concerns about the rigour and quality of the surveillance audits. The lack of assessment of audit quality undermines the ability of RTAC and regulators to have confidence in audit quality. This contrasts with the Commission's approach to maintaining audit performance.

### **Limited audit capacity**

It was apparent that the very small pool of part-time auditors restricts their availability to conduct audits. However, we found no evidence to suggest that this is preventing audits from being completed in a timely manner.

### **Audit timing**

Some stakeholders expressed concern that some ART units could potentially "game" the audit process by lowering the number of cycles occurring in the ART laboratory on the day of the audit. Most provider stakeholders reported to us that they prepared at length for audit visits. This is not unique to ART accreditation processes. Indeed, over recent years the Commission introduced short notice assessments, at 24 hours' notice, specifically to prevent similar gaming but also to reduce preparative burden on providers and to more accurately reflect care as routinely provided.

## **RTAC makes limited use of accreditation data for continuous improvement**

Many stakeholders reported that RTAC does not routinely analyse audit data to inform accreditation processes or to support providers in continuous improvement. We found that this was partially true. If an ART unit reports a high rate of notifications of serious adverse events or non-conformities, RTAC advised that they will write to the ART unit for further information and to support remediation. However, RTAC does not undertake benchmarking or define 'reasonable' levels of adverse event reporting and notifications in the Code of Practice. It also does not review reporting data to identify or investigate potential under-reporting by ART providers.

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<sup>151</sup> Office of the Health Ombudsman (Qld) (n 12) 100–2.

<sup>152</sup> Gorton (n 12) 21–2.

RTAC does not share audit outcomes, including non-conformance reports, adverse events or complaints data, with jurisdictional regulatory authorities. In comparison, the Commission shares accreditation outcomes routinely with jurisdictional regulatory authorities.

However, RTAC does issue Technical Bulletins that raise matters of concern that have typically been identified through audit findings.

### *Data reported by ART providers to ANZARD are not sufficiently used*

The Code of Practice requires ART units to provide a significant volume and detail of clinical data to ANZARD.<sup>153</sup> Many stakeholders raised concerns that ANZARD data are not used to support benchmarking or performance improvement at the provider level, despite its depth and national coverage. While aggregate data are published, clinic-level insights are not made available through ANZARD. We believe this to be a major weakness and missed opportunity.

Specifically, there is an opportunity to use the data that are currently routinely collected and reported to make visible unwarranted variations in practice and outcomes and thereby drive continuous improvement. Such functions are provided by the Commission, through their Safety and Quality Advice Centre, for other areas of health care. It is also a feature of high functioning clinical registries – ANZARD is a clinical registry – such as the Prostate Cancer Outcomes Registry<sup>154</sup> or the Australian Orthopaedic Association National Joint Replacement Registry.<sup>155</sup>

There is also opportunity to better use outcome data to inform a risk-based approach to accreditation frequency, potentially reducing the burden on providers. Some sectors apply a risk-based approach to reduce the frequency of accreditation audits to a two or three yearly cycle, based on risk factors. For example, hospitals and health services must be re-accredited every three years against the NSQHS standards.<sup>156</sup> Similarly, aged care providers must be re-accredited by the Aged Care Quality and Safety Commission every three years, although this may be longer for providers who consistently meet their obligations or shorter for those who are new to the sector or have a record of non-compliance.<sup>157</sup>

### *Adverse events are not analysed by RTAC and may be under-reported by providers*

Under the Code of Practice, providers are required to report serious adverse events directly to RTAC.<sup>158</sup> Stakeholders raised several concerns with current reporting arrangements:

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<sup>153</sup> See the ANZARD Data Dictionary for a full list of fields required for reporting: National Perinatal Epidemiology and Statistics Unit (UNSW), *ANZARD 3.0 Data Dictionary: Version 5.0* (Report, November 2020).

<sup>154</sup> *Prostate Cancer Outcomes Registry Australia and New Zealand Website* (Web Page, 2023) <<https://prostatecancerregistry.org>>.

<sup>155</sup> *Australian Orthopaedic Association National Joint Replacement Registry Website* (Web Page) <<http://aoanjrr.sahmri.com>>.

<sup>156</sup> Australian Commission on Safety and Quality in Health Care, *Fact Sheet 2: Accreditation of Health Service Organisations in Australia* (Fact Sheet, November 2021).

<sup>157</sup> Australian Government Department of Health and Aged Care, *How the New Model for Regulating Aged Care Works* (Web Page, 2025) <<https://www.health.gov.au/our-work/new-model-for-regulating-aged-care/how-it-works>>.

<sup>158</sup> ART units must report instances of serious adverse events to RTAC as soon as practical, but no later than six weeks after the provider becomes aware of the incident. These timeframes are compressed to within two weeks for a potential or actual breach of legislation, and within 48 hours for a sentinel event (e.g. death): Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.2.1.

### **Under-reporting of adverse events may be commonplace**

The majority of industry-based stakeholders told us that RTAC adverse event reporting is robust and effective. However, some expressed concern that there is a culture of under-reporting across the sector. The significant variation in the rates of adverse events, for example of ovarian hyperstimulation syndrome, would suggest that this concern is valid, with industry-based stakeholders pointing out that some units reporting of OHSS is lower than credible. Indeed, in the 2024 investigation into Queensland ART providers, non-conformities were inconsistently classified across different providers, suggestive of differential reporting of similar events during the auditing process.<sup>159</sup> Many stakeholders felt this could be attributed to the definition of “serious adverse event” being too broad and imprecise, allowing providers a generous latitude of interpretation. A 2020 inquiry into the Victorian ART sector noted that patients reported a higher number of adverse events than were reported by providers, particularly in relation to ovarian hyperstimulation syndrome. It was suggested that commercial pressures and “blame culture” contributed to the underreporting.<sup>160</sup>

### **RTAC does not scrutinise adverse event reports by individual ART units**

As outlined in chapter 2, ART units are required to document serious adverse events and provide auditors with evidence of corrective actions undertaken in response.<sup>161</sup> However, the 2024 Queensland investigation of ART providers identified inconsistencies and deficiencies in this process. Adverse event notifications supplied to RTAC by ART providers were not cross-checked with the adverse event actions reported to auditors.<sup>162</sup>

### **RTAC does not work with jurisdictional regulatory authorities to address adverse event reporting**

Despite limited capacity within RTAC to investigate adverse events, we found no evidence that RTAC works with jurisdictional regulatory authorities to address adverse events. The result is that providers may report adverse events to RTAC but there is a limited, if any, response to them and no systemised visibility of those events or responses to them by jurisdictional regulatory authorities. This approach to adverse event reporting contrasts with the approach adopted for hospital-based care, where both public and private health services typically report at a jurisdictional level to the relevant quality and safety authority, for example, Safer Care Victoria or Clinical Excellence Queensland.

### ***Findings from RTAC surveillance audits and adverse events reports are not used to inform sector-wide continuous improvement***

Many stakeholders noted that findings from RTAC surveillance audits and adverse event reports are not consistently used to inform sector-wide learning. Audit outcomes are provided to individual providers and to the RTAC Chair, but there is no mechanism to share lessons learned or identify systemic risks.<sup>163</sup> This lack of transparency and coordination was seen by

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<sup>159</sup> Office of the Health Ombudsman (Qld) n (12) 93–4.

<sup>160</sup> Health Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria: Final Report* (Report, 3 March 2020) 62–70 (*‘Inquiry into Victorian ART sector’*).

<sup>161</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.2.

<sup>162</sup> Office of the Health Ombudsman (Qld) n (12) 94–7.

<sup>163</sup> ANZARD provides ART units with a Feedback Report describing their clinical outcomes. ART units are required to identify opportunities for improvements based on this report. Where clinical outcomes fall below the 25th percentile, the unit must undertake a root cause analysis as to why its results fall in this range and either

most stakeholders as a missed opportunity to strengthen clinical governance and improve consumer outcomes.

### Public information available on *YourIVFSuccess* could be improved

The *YourIVFSuccess* website<sup>164</sup> was acknowledged by many as a useful initiative and an important step toward improved transparency for consumers. However, we heard that the data provided are too limited to be useful to consumers in making individual decisions about providers or treatments.

The voluntary nature of reporting on the *YourIVFSuccess* website limits consumer information and informed decision making. Five ART units currently choose not to share their data. Nonetheless, *YourIVFSuccess* is a key enabler of informed decision making for consumers. It presents data on a consistent basis as well as personalised success probability. The requirement to report outcomes publicly could be established through an amendment to the Code of Practice.

The Human Fertilisation and Embryology Authority (HFEA) in the UK presents a range of information for the purposes of consumer information (see the HFEA case study in chapter 5). Some stakeholders engaged through this project recommended the use of these data to enable more informed decision-making by consumers. Suggestions included mandatory information sheets and using the personalised outcome probability infographics available on *YourIVFSuccess* as a mandatory attachment to quotes for service provision.

There is an opportunity to better use the considerable data that are currently collected and reported by ART units to ANZARD to further improve transparency of outcomes and performance for consumers, regulators, and providers.

### RTAC does not have clearly defined powers to withhold, vary, or withdraw accreditation

The two documents that underpin the RTAC accreditation scheme – the Code of Practice<sup>165</sup> and the RTAC Scheme Rules<sup>166</sup> – do not clearly define the powers for RTAC to withhold, vary, or withdraw accreditation in response to an unaddressed major non-conformity. This is reflected in the 2024 FSANZ-sponsored Framework for an Australian 10-Year Fertility Roadmap, that recommends that RTAC should have the power to withhold, grant or vary licences depending on compliance with the Code of Practice.<sup>167</sup> FSANZ confirms that, to date, no ART clinic in Australia has failed to rectify a major non-conformance identified via an audit

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provide a corrective action plan or provide a rationale for not doing so during the audit process: Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 4.4.

<sup>164</sup> *YourIVFSuccess* is an Australian Government funded website developed by the University of New South Wales (UNSW) to provide transparent, independent information about ART and IVF. It contains information on clinic-specific success rates using data from the Australian and New Zealand Assisted Reproduction Database (ANZARD). See: Your IVF Success, *Homepage* (Web Page, 2025) <<https://yourivfsuccess.com.au/>>.

<sup>165</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38).

<sup>166</sup> Fertility Society of Australia and New Zealand, *RTAC Scheme Rules* (n 42).

<sup>167</sup> Hunt and Swift (n 2) recommendation 15.

within 30 days.<sup>168</sup> This is also reflected in RTAC's 2023–24 Annual Report.<sup>169</sup> RTAC confirmed with us that, apart from one clinic in Western Australia in the 1980s, it has never cancelled a provider's licence. Indeed, the questionable authority by which it may do that has led it to be very cautious about ever exercising that power. As with the power to refuse accreditation (see section 3.1), these are essential accreditation powers and the lack of clarity regarding their use appears to fundamentally undermine the effectiveness of RTAC's accreditation scheme.

## 3.4 Market conduct – regulation

In this section we outline the issues we identified with State and Territory regulatory activities, including compliance monitoring.

### State and Territory compliance monitoring should be strengthened

#### Regulatory role and posture vary between states and territories

Currently regulatory roles and posture across jurisdictions can be best described as variable and in evolution. There is significant variation in regulatory and investigation powers and approaches to compliance monitoring and regulatory actions across jurisdictions. For example, there are no regulatory powers in the Northern Territory, with no registration requirement or powers for the Territory government to investigate or sanction. New South Wales relies on RTAC audits to identify and manage compliance issues with limited, if any, visibility of adverse events. New legislation in the Australian Capital Territory and Queensland is being implemented progressively and, as of March 2025, the Victorian Health Regulator has new compliance powers to conduct investigations, issue directions, and enforce standards across ART providers.<sup>170</sup> Additionally, as noted earlier, the Western Australian Parliament is currently debating the Assisted Reproductive Technology and Surrogacy Bill 2025, which would repeal current legislation.

The variation in powers and approaches to ART regulation risks undermining public confidence in the regulation of ART services. The reliance on accreditation *in lieu* of comprehensive regulatory oversight is not consistent with the approaches taken across the rest of the health sector. The health sector is supported by a clear separation of accreditation and regulatory functions. The Commission provides robust standard setting and accreditation, and jurisdictional regulatory authorities with significant powers provide regulatory oversight and, where required, apply regulatory actions.

While regulatory powers across State and Territory regulatory authorities vary considerably, most jurisdictions with regulatory powers have established them only recently and they continue to evolve. The Australian Capital Territory, Queensland, and Victoria are in the process of implementing new arrangements. As such, it is too early to report on the

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<sup>168</sup> Fertility Society of Australia and New Zealand, 'Media Statement' (Media Release, 2 May 2025) 1.

<sup>169</sup> Reproductive Technology Accreditation Committee, *Annual Report 2023-2024* (n 13) 7.

<sup>170</sup> Victorian Department of Health, *Assisted Reproductive Treatment Reforms – Amendments to the Act and Regulations* (Guide, December 2024).

effectiveness of jurisdiction-based regulation of the ART sector. That said, this is the approach taken to healthcare regulation more broadly, including the regulation of cosmetic surgery, and there is no reason to expect that the effectiveness of jurisdiction-based regulation should be any different for ART

### There is little evidence that jurisdictions use their compliance powers, or that these powers influence provider conduct

Jurisdictional regulatory authorities have described ART providers as a “black box”. This is perhaps not surprising given that, as described earlier, RTAC does not routinely share audit or adverse event data with regulatory authorities. This is perhaps compounded by the use of non-disclosure agreements (NDAs) for consumers who have experienced poor outcomes. Consumer representatives suggest that the use of NDAs is widespread. Civil law remedies appear to be preferred by, at least some, consumers instead of engagement with regulatory authorities and health complaints bodies.

Unsurprisingly, we found only a few examples of regulatory action taken against ART providers by jurisdictional regulatory authorities. Indeed, it appears that more effective modifiers of provider conduct lie with other regulatory schemes, such as ASIC, and litigation, as demonstrated recently in a record-breaking \$56 million settlement reached between Monash IVF and 700 patients. This conduct related to the use of a genetic testing process from May 2019 to October 2020 that was found to be flawed. There appears to have been little regulatory oversight of the conduct in question.

### Variation between jurisdictions can affect provider conduct and consumer protection

Variation in registration requirements and associated compliance and enforcement powers between jurisdictions also creates the risk of regulatory arbitrage.<sup>171</sup> ACT Health identified that ART service provision rates were much higher in the Australian Capital Territory compared to other jurisdictions before the introduction of their ART legislation in 2024. This suggests that some providers may have been operating in the Australian Capital Territory to avoid ART regulatory burdens in other jurisdictions.

The different regulatory postures between jurisdictions affects reporting requirements, with varying levels of information and reporting formats required by different bodies. The impact of these arrangements is that larger providers operating in multiple jurisdictions require several different reporting approaches to meet the needs of RTAC and jurisdictions when reporting on the same event.

### Information sharing between RTAC and regulatory authorities is limited

Some jurisdictions, such as Victoria and Western Australia, have legislative requirements for ART providers to report adverse events to their jurisdiction’s regulatory authority. However, these obligations are not national and there is no formal mechanism for integrating this information with RTAC’s accreditation processes.

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<sup>171</sup> Regulatory arbitrage refers to a legal planning technique used to avoid regulatory costs.

As discussed earlier, several stakeholders pointed out the absence of structured communication between RTAC and jurisdictional regulatory authorities. While both entities collect data relevant to safety and quality, there is no formalised process to share information, coordinate responses, or align compliance activities. This disconnect materially limits the ability of regulatory authorities to act on emerging risks and undermines the potential for regulatory intelligence to inform continuous improvement across the sector. It is also in distinct contrast to the relationships between the Commission and jurisdictions.

We believe that the lack of formalised and regular dialogue between RTAC, the accreditation agency, and the jurisdictions significantly undermines effective quality and safety governance of Australia's ART services.

### Inconsistency in donor limits and gamete movement is a key issue for stakeholders

Regulatory inconsistencies in donor limits and gamete movement may give rise to consumer protection and safety risks for individuals seeking care, and for donor-conceived individuals. Concerns raised by stakeholders include the inability for donor-conceived individuals to access important medical and genetic information, risks of consanguineous relationships, and growing presence of unregulated private donor markets accessed through social media or word of mouth in certain community groups.

While there are some sound policy rationales as to why jurisdictional restrictions differ,<sup>172</sup> this variability may ultimately result in 'jurisdiction shopping' by prospective parents, undermining the original policy intent.<sup>173</sup> Several stakeholders reported that donor limits and inconsistencies in those limits lead people to look outside the regulated system, to 'informal' donor arrangements such as those arranged through Facebook groups or other unregulated environments. This presents significant risks for the people involved in informal sperm donation and increases the likelihood of donors exceeding donor limits. Some stakeholders called for regulation to extend to informal donations and protected practice regulation for sperm donation.

In addition to risks from informal donations, there are significant barriers to the movement of gametes within Australia. Many stakeholders have reported that it is easier to import gametes from international donor banks than it is to move material between states. These stakeholders raised concerns about the donor limits applied to donors through these international banks and also the traceability of donors when reliant on international banks. Ensuring the quality and safety of protocols used by overseas gamete banks is also more difficult for local ART providers, as is evident from the recently reported case of a mis-identified sperm donor.<sup>174</sup>

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<sup>172</sup> For example, the risk of consanguineous relationships is higher in smaller jurisdictions: Sonia Allan, *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008: Report Part 1* (Report, January 2019) 119–28.

<sup>173</sup> Gorton (n 12) 118.

<sup>174</sup> Grace Tobin and Kirsten Robb, 'IVF Clinic Queensland Fertility Group Silenced White Couple Who Gave Birth To Biracial Baby In Sperm Mix-up', *ABC News* (online, 1 September 2025) <<https://www.abc.net.au/news/2025-09-01/white-couple-biracial-baby-in-ivf-clinic-sperm-mix-up/105716654>>.

The limitations and inconsistency in requirements for donors also limits donor gamete availability, further driving demand for international gamete imports or people travelling internationally to access donor material.

Consumer and government stakeholders also raised concerns about access to donor information, with different requirements for retaining information adding confusion and difficulty for consumers in particular.

Further discussion of consumer perspectives on access to donor material and information is outlined in chapter 4. However, if the intent of current, albeit differing, regulations is to provide safer outcomes to both consumers of ART and those conceived through donor gamete pregnancies, we believe that consideration of harmonisation of regulations would be worthwhile.

## Clearer requirements about staff qualifications and workforce staffing levels would be beneficial

Stakeholders regarded Ahpra as an established and effective regulator of health professionals through the NRAS. However, concerns were raised about the level of professional regulation for key ART roles that do not fall within the NRAS. Stakeholders expressed concern that non-NRAS roles have the potential to contribute to adverse clinical outcomes without stronger regulation. That said, adherence to Code of Practice staffing requirements – a key mechanism in RTAC’s scheme to drive quality and safety– is reviewed annually through the RTAC surveillance audit process.

One stakeholder felt that commercial incentives were driving low staffing levels in laboratories, with higher workloads potentially increasing the risk of human error, and non-compliance with manual witnessing requirements. It was suggested that ART standards that prescribed staffing levels in laboratories could help drive improved quality and safety outcomes.

Some stakeholders raised concerns that inexperienced staff were able to secure senior positions in some ART laboratories, creating clinical risk. We recommend that consideration be given to minimum qualifications, certifications or experience alongside staffing levels.

## 3.5 Enforcement and recourse

In this section we outline the issues we identified with the enforcement powers and recourse options available for the ART sector.

### Enforcement powers are limited and under-utilised

#### Most jurisdictions have enforcement powers but rarely use them

Victoria and Western Australia are the only jurisdictions that reported issuing any sanctions to ART providers over the past 10 years, all of which were in the form of specific conditions of registration. Given recent quality and safety incidents in the ART sector, this lack of enforcement activity by State and Territory regulatory authorities suggests gaps in current regulatory schemes.

Indeed, comprehensive, scalable powers appear to be available only in the Australian Capital Territory, Queensland (commencing March 2026), and Victoria. And only there following recent legislative reform. The powers available to other jurisdictional regulatory authorities are limited to the variation, suspension, or cancellation of registration, with the exception of New South Wales which only has a cancellation power, and South Australia and Tasmania which also has the power to issue monetary penalties. Such unscalable powers are inconsistent with contemporary, risk-based regulatory practices, particularly given the impact on consumers if a clinic's registration were to be cancelled in the absence of any other regulatory options.

### The mechanisms for enforcing workforce compliance are appropriate

Ahpra has a clear and effective process for taking action against regulated health professionals, with a range of scalable actions available. For other non-NRAS professionals, enforcement options are limited to corrective action requirements under the Code of Practice and National Code of Conduct for Health Care Workers. We did not hear significant concerns about regulatory action against individual health professionals.

## Complaints avenues are confusing and confronting for consumers

### Avenues to make complaints are difficult for consumers to navigate

While there are several avenues for consumers to make a complaint about an ART provider or practitioner, consumers advised that these are often confusing and difficult to navigate. It is often unclear which pathway is the most appropriate for their specific complaint. For example, a layperson may not realise that misleading and deceptive conduct should be referred to the ACCC, while an allegation from a consumer that an ART unit might be in breach of the Code of Practice should first be raised directly with the provider, followed by the relevant health complaints body, before RTAC will consider it.<sup>175</sup> We explore this further in chapter 4.

The Code of Practice requires ART units to acknowledge and investigate complaints<sup>176</sup> and provide patients with information about a range of other issues relating to their treatment.<sup>177</sup> It does not, however, require ART units to provide patients with information about how to make a complaint, beyond advising them of external escalation avenues.<sup>178</sup> Several reviews have found that consumers are often unaware of complaint handling procedures and that clearer pathways and information are needed.<sup>179 180 181</sup>

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<sup>175</sup> Fertility Society of Australia and New Zealand, *RTAC* (Web Page, 2025) <<https://www.fertilitysociety.com.au/art-regulation/rtac/>>.

<sup>176</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.6.

<sup>177</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 3.2.1.

<sup>178</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.6.

<sup>179</sup> Office of the Health Ombudsman (Qld) n (12) 98.

<sup>180</sup> Gorton (n 12) xi.

<sup>181</sup> Health Complaints Commissioner (Vic), *Inquiry into Victorian ART sector* (n 160) 71.

## Lack of national harmonisation has led to inconsistency in complaints handling

In the absence of clear complaints handling guidance, ART providers have developed different complaints processes. Together with differences in approaches between jurisdictional health complaints bodies, there is inconsistency in complaints handling across providers and jurisdictions.<sup>182</sup>

## Low levels of complaints may indicate potential under-reporting

Most jurisdictional health complaints bodies have been unable to confirm the number of ART sector complaints received in recent years, with the exception of RTAC and the Queensland, South Australia, Victoria and Tasmanian bodies. Anecdotally, complaints bodies told us that complaints are relatively few. However, data provided by the Victorian Health Complaints Commissioner show the number of complaints has tripled over the past decade, with the most common issues raised relating to treatment and communication.

Given the power imbalance between consumers and their ART provider, the common requirement to raise a complaint with the provider in the first instance may be contributing to under-reporting. The Gorton review heard that patients receiving ongoing services, including gamete or embryo storage with the clinic, can fear that a complaint may adversely affect their care, and that some consumers may be reluctant to engage with a generic health complaints body given the sensitivity inherent in infertility issues.<sup>183</sup> Health complaints bodies and Ahpra also told us that they do not typically receive complaints from the ART workforce.

Understandably, some stakeholders expressed concern that the RTAC complaints handling function is undermined by its lack of financial and operational independence from FSANZ and ART providers. This perception may also contribute to a reluctance by some consumers to report a complaint to RTAC.

## Insights from complaints data are not leveraged by RTAC and regulatory authorities

There is currently no jurisdictional or national collation of ART sector complaints across the different avenues. No jurisdictional health complaints bodies reported a formal relationship with RTAC for information sharing, and only two of the complaints bodies advised that they have an established relationship with their state- or territory- regulator. While this is consistent with handling of broader healthcare complaints, these relationships would enable the very low number of complaints currently recorded to be analysed for emerging trends and risks more effectively and would reflect the cross-jurisdictional operations of the large ART providers.

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<sup>182</sup> Gorton (n 12) 22.

<sup>183</sup> Gorton (n 12) 33.

## 4 Consumer insights

“Nothing about us without us”

The Sejm (Polish parliament), 1505

### 4.1 Introduction

In this chapter we present some preliminary consumer insights on the current provision of ART in Australia. The insights are not intended to be exhaustive or comprehensive. Rather, we wished the patient/consumer voice to be presented in a manner that made visible the issues that appear to be a priority for those using ART services. In this way, should improvements to ART accreditation and/or regulation be planned, consumer needs will inform those changes from the outset.

The insights summarised here were drawn from the two consumer roundtables that involved 18 consumers, and including those who have accessed ART services, with and without donors, and donor-conceived adults, and from a review of previous inquiries, recent media coverage, and other lay materials. We hope that the insights provide valuable consumer perspectives and offer an awareness of the concerns that matter most to those using ART, if only to suggest what issues would be worth exploring further. We recommend that broader consumer consultation is commissioned as part of the design and implementation stages of any future reform.

### 4.2 Consumers highlighted barriers to making informed choices

A recurrent observation of recent inquiries and the roundtables undertaken as part of this review was that many consumers find it is difficult to make informed choices about ART. This appears largely because the information they receive is all too often incomplete and inconsistent. For example, the 2024 Queensland investigation into ART providers found that inadequate information provision, and therefore compromised informed consent to care, is one of the most concerning issues in the ART sector.<sup>184</sup>

#### Limited information on treatment efficacy and outcomes is a barrier to informed consent

More specifically, consumers consistently raised concerns about the lack of information from providers about treatment efficacy and outcomes. Many reported that this meant they were unable to make informed choices or give informed consent. Examples include:

- Many consumers reported that success rates advertised by clinics were overly optimistic and misleading. One consumer shared that when she asked about her chances of being pregnant after embryo transfer, her doctor provided the average pregnancy success rate for women of

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<sup>184</sup> Office of the Health Ombudsman (Qld) n (12) 10.

all ages rather than an average for her own (older) age group. This exaggerated her likelihood of a successful pregnancy.

- Many consumers felt that the options for managing their stored embryos or gametes were not adequately explained to them prior to treatment. Some reported being told that it was something to think about later, only to discover later that their choices were limited to either disposal or ongoing storage that incurred additional fees.
- Some consumers reported that they were encouraged by clinics to undergo adjuvant (add on) treatments, each with additional cost, without being informed of the limited evidence about their effectiveness.<sup>185</sup>

Despite the above experiences, one consumer noted that the *YourIVFSuccess* website is a valued resource and that expanding the information provided on the platform would greatly assist consumers to make informed and better choices.

## Limited transparency of treatment costs creates stress for consumers

Several consumers advised that treatment costs are not adequately explained by providers. Some felt that disclosure of costs was confusing and misleading. In particular, the total cost of procedures, including any payments gaps, are not clearly communicated. This resulted in costs higher than expected.

A few consumers expressed concern about providers encouraging debt-facilitated treatment, reporting that they are aware of several providers that offer ways for their patients to take out loans or access their superannuation to pay for ART services.

## Counselling services provided during treatment are inadequate

Consumers engaged through our review and through other recent inquiries have highlighted that more supportive and informative counselling would assist them to make fully informed decisions about their treatment.<sup>186</sup> For example, many consumers indicated that they did not have access to sufficient counselling during their treatment. They also raised concerns about inadequate or partial information being provided by counsellors, which they attributed to potential conflicts of interest given that most counsellors are employed directly by ART clinics. Some consumers felt unable to speak openly with counsellors, particularly when they had negative experiences with a clinic, for fear that their care would be compromised.

Several consumers engaged during this review reported that donor conception counselling is particularly lacking. Some consumers suggested that clinics may avoid offering comprehensive information about this topic to avoid discouraging patients from proceeding with treatment.

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<sup>185</sup> Health Complaints Commissioner (Vic), *Inquiry into Victorian ART sector* (n 160) 10.

<sup>186</sup> Health Complaints Commissioner (Vic), *Inquiry into Victorian ART sector* (n 160) 45; Gorton (n 12) 39.

## Misleading advertising practices create confusion for consumers

Consumers consistently told us that it was difficult to make sense of ART advertising and marketing materials. This was especially the case for information that was central to their decision making, such as comparative success rates of ART providers and/or different treatment options. Consumers reported that such information was often presented in confusing and non-comparable ways.

Several consumers also reported that some materials used by providers offered an overly optimistic, and potentially misleading, view of the efficacy of ART services. This led some people with unrealistic expectations and made it difficult to assess the merits of different treatment options. Many consumers described the advertising of ART services in Australia as aggressive and unlike any other area of medicine, suggesting that more regulation is needed so that patients can make better informed decisions.

### 4.3 Profit-driven practices adversely impact consumer experience

As described in section 1.3, most ART services are provided by the private sector. There is limited access to publicly funded fertility services and such funded services are not available in all states and territories. The Gorton Review and Queensland's 2024 investigation into ART both highlighted consumer concerns about the increase in for-profit private providers, such as those publicly listed on the Australian Securities Exchange or owned by private equity. In particular, consumers were concerned that these providers may be more focused on maximising profit than patient care.<sup>187</sup>

The consumers we engaged as part of this review also highlighted the tension between profit-driven practices and patient-centred care. Some examples include:

- **Lack of consumer agency:** consumers described feeling sidelined in decisions that directly affected their care, with ART providers prioritising clinical and commercial interests over the lived experiences and emotional needs of patients. One consumer highlighted this as part of a broader power imbalance between providers and patients, where individuals undergoing treatment often feel they must defer to clinical advice, even when those interests may not align with their values or needs.
- **Pressure to donate gametes/embryos:** several consumers described feeling pressured by clinics to donate, rather than destroy, their unused gametes/embryos. They presumed that this was because the demand for surplus gametes/embryos is high and that they can be used by the provider to help another patient conceive. One consumer who wanted her stored eggs to be destroyed reported that she felt pressured by her provider to donate her eggs instead. The 2024 Queensland investigation into ART providers also identified instances of unexpected delays or lengthy turnaround times for the disposal of gametes and embryos.<sup>188</sup>
- **Incentives encourage more treatment cycles:** a few stakeholders reported instances of doctors being offered incentives by the providers they work for to have patients complete more

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<sup>187</sup> Office of the Health Ombudsman (Qld) n (12) 65; Gorton (n 12) 169.

<sup>188</sup> Office of the Health Ombudsman (Qld) n (12) 12–13.

treatment cycles. One consumer advised that because of this practice they had been encouraged to complete more IVF cycles after several failed, even when their chances of success were low given their (older) age. This consumer reported that their experience was reflective of a sector that appears to disregard the potential harm to consumers of ART treatment.

## 4.4 Consumers experience difficulties making and resolving complaints

We have touched upon confusing complaints pathways in earlier chapters. While there are several established avenues for patients to make a complaint about ART care, consumers report that they find complaints processes confusing and difficult to navigate.

The Code of Practice requires ART providers to give patients information on how they can make a complaint. The Code also requires providers to acknowledge and investigate complaints when received.<sup>189</sup> However, several reviews have found that consumers are often unaware of complaint handling procedures and have called for clearer complaints pathways.<sup>190</sup> Most consumers consulted as part of this review confirmed the previous findings, telling us that complaints handling remains inadequate. Many reported having limited or no success resolving their complaints directly with clinics, even with assistance from RTAC. They also noted that they did not make a complaint through existing state-based complaints systems – which accords with the limited number of complaints reported by those agencies (see section 3.5) – instead seeking legal advice to pursue a remedy.

Of note, many consumers engaged through this review reported to us that they did not feel that changing providers midway through their treatment was a realistic option. They advised us that even when they had complaints about their provider, they never considered changing provider because it was too time consuming and stressful to start again.

## 4.5 Consumers raised concerns about donor gamete issues

As described earlier (sections 2.2 and 3.4), varied legislation across jurisdictions has created a fragmented ART regulatory environment. This is particularly apparent in relation to who can donate gametes and how that information is recorded and accessed by donor conceived people.

Several issues were highlighted by consumers:

- **Increased reliance on overseas donors and ‘black market’ donations:** several consumers noted that the increasing demand for donor gametes has resulted in demand exceeding local supply. Anecdotally, this has resulted in a growing reliance on overseas donors and ‘black market’ donations. Consumers raised concerns about the quality and traceability of donor material, and the absence of consumer protection rights for individuals conceived from such

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<sup>189</sup> Fertility Society of Australia and New Zealand, *RTAC Code of Practice* (n 38) s 2.6.

<sup>190</sup> Health Complaints Commissioner (Vic), *Inquiry into Victorian ART sector* (n 160) 71; Office of the Health Ombudsman (Qld) n (12) 98; Gorton (n 12) xi.

donations. Queensland's investigation of ART providers in 2024 noted these themes, highlighting the increased risks of consanguinity and transmission of inherited diseases.<sup>191</sup>

- **Inconsistent definitions and restrictions:** several consumers raised concerns about inconsistent restrictions on who can donate genetic material and about jurisdictional differences regarding the number of families that can be created using a single donor's gametes.<sup>192</sup> These differences are contributing, directly or indirectly, to donor "tourism", where donors living in one jurisdiction may donate in another, and "black market" donations.
- **Absence of a national donor register and information sharing between jurisdictions:** donor conceived individuals consulted during the review process stressed the risks of unregulated donations and the absence of a national donor register. While some jurisdictions have a donor register these databases are each managed independently and are not linked to each other. This means that a single donor can exceed legislated family limits by donating in multiple jurisdictions. The lack of a nationally linked resource also compromises the ability of donor conceived individuals to identify or verify donors, siblings, or medical information.

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<sup>191</sup> Office of the Health Ombudsman (Qld) n (12) 111–12.

<sup>192</sup> Family limits and definitions vary significantly across jurisdictions. For example, in the Australian Capital Territory clinics must ensure the number of "families" born from a single donor is limited to five. Whereas in New South Wales, a donated gamete cannot be used for ART treatment in more than five families, with reference to the number of "women" rather than families: *Assisted Reproductive Technology Act 2024 (ACT)* s 40; *Assisted Reproductive Technology Act 2007 (NSW)* s 27.

## 5 System improvement

“Every system is perfectly designed to get the results it gets”

W Edwards Deming

As we outlined in chapter 1, Health Ministers instructed the Health Chief Executives to commission a rapid review of the accreditation and regulatory environment for ART and IVF, with the request that the review included:

1. options for implementation of an independent accreditation body and process
2. consideration of how existing state-based regulatory regimes could be strengthened
3. consideration of whether a national regulatory approach would deliver benefit.

As described elsewhere in this review, the current accreditation and regulatory environment is confused and confusing, for providers, consumers, and regulatory authorities. This confusion has contributed to undermining the very intent of accreditation and regulation – the continuous improvement in the quality and safety of services being provided. However, it is not just the blurred lines of responsibility that underlie the compromised accreditation and regulatory processes and outcomes that we found. The lack of a skilled, independent accreditation agency, appropriately resourced, and the still evolving legislative and regulatory instruments that differ significantly across jurisdictions all contribute to a less than effective system and unsatisfactory outcomes.

In this chapter we outline ten opportunities to improve accreditation and regulation, each with the intent of delivering better quality and safety of care, and better outcomes for consumers. Reform ideas that would deliver a system that is designed to get the results that are wanted.

Of the ten opportunities, we believe that establishing an appropriately resourced independent accreditation authority capable of developing and implementing evidence-based standards of care is the priority. We also propose that better regulation could be most readily achieved through strengthening and harmonisation of existing state- and territory-based regulatory regimes rather than through the establishment of a standalone national regulator. We believe this approach would deliver stronger regulation more quickly and for significantly less cost than building a new national body.

Below, we have purposefully separated accreditation reform opportunities from regulatory improvement. We have done so with the intent of improving understanding of these two separate but dependent components of effective clinical governance.

## 5.1 Accreditation reform opportunities

We identified three key improvement opportunities in relation to accreditation, both at market entry and during market conduct:

1. Establishing an independent accreditation entity and process.
2. Developing and implementing more comprehensive national quality and safety standards for ART practice.
3. Improving oversight of and guidance for professional workers in the ART sector.

Each is discussed in turn.

### Reform opportunity 1: Establishing an independent accreditation entity and process

As outlined in chapter 3, the lack of independence of the current accreditation agency, RTAC, from the sector's peak body FSANZ fundamentally undermines good governance, demonstrably constrains accreditation powers, and weakens consumer and government confidence. There is an opportunity to reform accreditation to ensure the accreditor and its processes are independent of providers.

We identified three alternative options that would each provide independent accreditation:

**Option A: Authorise the Australian Commission on Safety and Quality in Health Care to deliver ART accreditation.** Expand and utilise the Commission's capacity as an existing national accreditor to include ART providers.

**Option B: Establish a new accreditation body.** Establishment of a new independent national entity to oversee ART accreditation.

**Option C: Reform the existing industry accreditor, RTAC.** Expand capacity and upskill an existing industry accreditor.

#### Option consideration

Option A would involve tasking the Commission to acquire responsibility for accreditation of ART providers, as it has for the rest of health care. This would require the Commission receiving additional resources and developing new capabilities, including the development of new ART standards. However, we anticipate that this would be less expensive and more readily implemented than establishing an entirely new accreditation body (Option B). Indeed, the industry-specific insights gained by the Commission over recent years in establishing accreditation processes for cosmetic surgery would serve it well should it be tasked with ART accreditation.

Option A would also readily enable reform opportunity 2 – the development and implementation of more effective national standards for ART. The Commission is the national expert in the development of healthcare standards for accreditation purposes. Appropriately resourced, it would have the expertise to develop a new set of standards for the ART sector, using an approach like that taken for cosmetic surgery. This would also enable better alignment with the national safety and quality standards and afford the ART sector robust accreditation processes, including short notice assessments and effective oversight of audit performance. The heightened

rigour of accreditation that the Commission would bring to the sector would be expected to reduce the accreditation burden on providers over time.

Establishing a new accreditation body (Option B) would address the need for an independent agency. However, we believe that this would require substantially more resources and a longer implementation timeline than either Option A or Option C. Further, the ART sector is a small part of the health care overall. Whether the sector justifies the ongoing investment in a standalone accreditation body when those functions could, most likely, be provided more effectively and efficiently by the Commission is questionable. We also believe that a small, independent accreditation agency would be less able than the Commission to maintain contemporary accreditation standards and practices over time. That said, a dedicated ART accreditation agency, whether Option B or C, may be more responsive to emerging technologies or service models, than a larger entity such as the Commission.

Option C – reforming RTAC – is relatively straight forward to pursue. It builds on existing structures and industry knowledge. However, as outlined in chapter 3, there is widespread concern among stakeholders about RTAC’s lack of independence from industry. Whether reform of RTAC could assuage those concerns would depend on the extent of the reform. Even with reform and establishment of new governance and a professional board, there is a risk that RTAC would still be perceived as captured by industry, and certainly more so than the Commission. This option also has the same weaknesses as Option B – a small, standalone accreditation entity that will be relatively expensive to run and still likely struggle to maintain contemporary standards of care and accreditation practices. However, a reformed RTAC may be more agile in responding to emerging technologies or service models than the Commission.

## Recommendation

**We recommend that independent accreditation be pursued through the existing national health care accreditation body, the Australian Commission on Safety and Quality in Health Care (Option A).**

This recommendation reflects consideration of both the feasibility of implementation and the need for independence from industry.

### **The Commission takes a continuous improvement approach to accreditation**

As outlined in chapter 2, the Commission is responsible for overseeing the accreditation of health services and hospitals, underpinned by the NSQHS standards. The Commission is responsible for designing and administering national accreditation schemes for healthcare services that relate to healthcare safety and quality matters. This involves developing standards of care; designing the accreditation scheme; providing oversight of the accreditation process through the approval and performance management of accrediting agencies; ensuring consistent, high-quality assessments across accrediting agencies; and evaluating the effectiveness of accreditation schemes using assessment outcome data.<sup>193</sup>

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<sup>193</sup> ‘Accreditation’, *Australian Commission on Safety and Quality in Health Care* (Web Page, 2025) <<https://www.safetyandquality.gov.au/our-work/accreditation>>.

## Reform opportunity 2: Developing and implementing more comprehensive national quality and safety standards for ART practice

Irrespective of the accreditation agency itself, there is a need for a revised set of quality and safety standards in ART practice. Specifically, standards that would more effectively set minimum expected standards of care against which care can be audited. There is a need to set standards that are clear, directive, evidence-informed and readily understood by providers, auditors, regulators, and consumers. Such standards would better support a strengthened and independent accreditation process, more effective continuous improvement by ART providers, and consumer protection.

We identified four complementary options to strengthen and enhance the current national standards for ART practice:

### **Option A: Update Code of Practice with uniform minimum standards.**

Ensure standards are clear and prescriptive across all areas, including details on identification and traceability, informed consent, partnering with consumers, and adverse event reporting requirements.

### **Option B: Update the Code of Practice to include performance monitoring metrics.**

Include key metrics to track ART unit performance and outline associated data reporting criteria. For example, metrics could include 'exceeds expectations', 'meets expectations' and 'does not meet expectations'.

### **Option C: Refresh the Code of Practice to align with NSQHS Standards.**

Ensure the Code of Practice aligns with existing national safety and quality standards that healthcare facilities are subject to and address any identified gaps.

### **Option D: Update Code of Practice to include guardrails for adjuvant treatments and new technology.**

Introduce processes for the adoption of new interventions or technologies with the objective that it is clear to providers and consumers when adjuvant treatments and new technology are evidence-based or when the evidence is emerging and it should be considered a clinical trial.

## Option consideration

An improved Code of Practice would increase transparency and consistency across the ART sector and set a baseline for quality and safety. It allows for private market innovation and acknowledges varying levels of provider maturity by setting minimum required standards and encouraging providers to perform above the baseline. Clearer, minimum standards would better enable the other reforms outlined in this chapter, such as performance monitoring, complaints handling, data transparency and more effective performance benchmarking.

Implementation of these options will require resources for careful design, including stakeholder engagement, and expertise in the development of effective quality and safety standards. There is a risk that more detailed standards will increase costs of compliance burden. However, stakeholders, including ART providers and RTAC, recognised the need for improved standards and were supportive of a suite of minimum standards of care. Consumer and industry consultation would be important to inform the development of an updated Code of Practice.

## Recommendation

**We recommend that an updated Code of Practice or a suite of new ART standards be developed aligned with the NSQHS Standards and including uniform minimum standards, performance monitoring metrics, and guardrails for adjuvant treatments and new technology (Options A, B, C and D).**

While all of the above options should be progressively adopted, we believe that Options A and B are the immediate priorities. Option C would be a necessary step should the Commission assume accreditation responsibilities for the ART sector but would still be worthwhile if it didn't. While Option D would also be beneficial, it will likely require further consultation to ensure the guardrails are future-proofed and do not prevent innovative safe practices that would benefit consumers.

In the event that the Commission becomes the ART sector accreditor (as proposed in opportunity 1), then the Commission should use the updated and refreshed Code of Practice as a basis for a set of accreditation standards for the ART sector. This would be similar to the approach they took for the cosmetic surgery sector.

### **Cosmetic surgery standards provide a model for sector-specific standards embedded in health sector standards and accreditation**

In September 2022, Australian Health Ministers announced urgent reforms to the cosmetic surgery sector. These reforms were delivered in response to concerning reports of patient harm. As part of these reforms the Commission developed a National Licensing Framework and the National Safety and Quality Cosmetic Surgery Standards. The standards were launched on 14 December 2023.

The development of the Cosmetic Surgery Standards involved consultation with consumers, clinicians, services, professional and peak bodies, regulatory authorities and other representatives of the sector. The standards are designed to be person-centred, focusing on informed decision-making, patient suitability assessments, and post-operative care.

To support implementation, the Commission introduced two accreditation pathways: one for services seeking standalone accreditation to the Cosmetic Surgery Standards, and another for those already accredited under the NSQHS Standards, which can adopt a supplementary Cosmetic Surgery Module. These pathways aim to reduce compliance burdens while ensuring rigorous oversight.

### **Essential performance metrics are a critical element of the NSQHS standards**

The NSQHS standards comprise 8 core standards, each of which include a series of specific, numbered actions.<sup>194</sup> These actions define what health services must do to meet the standard. This structure provides clarity and consistency across the sector, ensuring all services understand what is required of them. Because each action is linked to a specific outcome, they serve as a roadmap for continuous improvement. Services can identify gaps, implement changes and track progress over time. This approach supports quality improvement and accountability.

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<sup>194</sup> Australian Commission on Safety and Quality in Health Care, *National Safety and Quality Health Service Standards* (2021) 1–2.

Actions are linked to performance metrics that are publicly reported. Accreditation bodies evaluate health services on their implementation of these actions through audits and the results are publicly reported on the Commission website, showing what actions were met, where improvements were recommended or required or where the actions were not applicable.<sup>195</sup> This allows for benchmarking across services and supports transparency for consumers. Public reporting also incentivises services to meet standards.

### Reform opportunity 3: Improving oversight of and guidance for professional workers in the ART sector

Most stakeholders consulted were satisfied that most of the ART sector workforce is registered with Ahpra. However, many noted that embryologists, laboratory managers, counsellors, and quality managers are not registered with Ahpra and that the Code of Practice does not include minimum qualifications or CPD requirements. While several stakeholders noted that improved oversight for professional workers should not displace effective regulation of providers and their systems and processes, there remains an opportunity to promote individual practitioner responsibility to support quality and safety.

We identified two options that may enhance oversight of professional workers in the ART sector:

#### **Option A: Introduce workforce and staffing guidance in the Code of Practice.**

Embed workforce requirements for all professions working within ART units within an updated Code of Practice for service-level oversight of professional workers. This would include minimum qualifications, CPD requirements, and staffing guidance. For example, staffing guidance could include requirements about the need for more than one person working in a laboratory to ensure manual witnessing can occur.

#### **Option B: Introduce Ahpra registration for embryologists, laboratory managers, counsellors and quality managers.**

Seek to enhance individual accountability and national consistency through formal registration of ART workforces as registered health professionals under the National Registration and Accreditation Scheme.

#### Option consideration

Option A offers improved oversight and professional requirements of ART workers that are not registered with Ahpra. It is proportionate and ensures that those staff have the appropriate skills and knowledge and that providers ensure that the systems and processes they operate within maintain quality and safety. This option could be implemented in the near term as part of the updates to the Code of Practice outlined in opportunity 2.

Option B could offer enhanced oversight of individual workers. However, creating a new group of registered practitioners within Ahpra, with the required practitioner board and dedicated registration standards, does not appear well justified. Further, lessons from recent incidents indicate that errors made in laboratories were less of an issue of individual behaviour, and more

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<sup>195</sup> Australian Commission on Safety and Quality in Health Care, *ACSQHC website – NSQHS Standards: public reporting* (n 76).

of an issue of a lack of effective systems and processes that providers are accountable for. Accordingly, we do not believe that adding ART laboratory workforces to Ahpra's NRAS would necessarily enhance the safety of ART services. We do suggest that further consideration be given to the professional requirements and CPD of embryologists, including whether participation in laboratory-based professional bodies, such as AIMS, be a future condition for employment.

## Recommendation

**We recommend that workforce requirements, including minimum qualifications, continuing professional development requirements and staffing guidance, be embedded in the new standards (Option A).**

Option A should be implemented in the immediate term as part of the broader reforms and updates to the Code of Practice outlined in opportunity 2.

It appropriately balances the need for more oversight of staff not registered with Ahpra without creating unwarranted administrative burden and costs on individuals and Ahpra. It also emphasises the need for providers to ensure sufficient staffing to enable safe practices, particularly in laboratories.

### **NZ and UK have greater oversight of embryologists and medical scientists**

In the UK, clinical embryologists are registered and regulated as clinical scientists through a structured process and a professional body. Clinical scientist is a protected title in the UK, meaning that professionals must be registered to use it.<sup>196</sup> The Health and Care Professions Council (HCPC) is the regulator responsible for maintaining the register of clinical scientists. To be eligible for HCPC registration, embryologists have usually completed a postgraduate-level work-based training program.<sup>197</sup> Once registered, clinical embryologists must undertake CPD to keep their knowledge and skills up to date.

In New Zealand, embryologists are currently regulated under the *Health Practitioners Competence Assurance Act 2003* falling under the broader category of medical laboratory scientists which is a regulated profession overseen by the Medical Sciences Council of New Zealand (MSCNZ).<sup>198</sup> To be registered under the MSCNZ, embryologists must obtain their qualification from an accredited education program. Once registered, recertification requires professionals to have an annual practicing certification and to engage in CPD.

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<sup>196</sup> 'Professions and Protected Titles', *Health and Care Professions Council* (Web Page, 2025) <<https://www.hcpc-uk.org/about-us/who-we-regulate/the-professions/>>.

<sup>197</sup> 'How to become clinical scientist in embryology', *NHS Scotland Careers* (Web Page, 2023) <<https://www.careers.nhs.scot/explore-careers/healthcare-science/clinical-scientist-in-embryology/>>.

<sup>198</sup> *Health Practitioners Competence Assurance Act 2003* (NZ) sch 2; New Zealand, *Notice of Scopes of Practice and Prescribed Qualifications for the Practice of Medical Laboratory Science*, No 2021-gs2023, 1 June 2021.

## 5.2 Regulation reform opportunities

We identified three improvement opportunities in relation to regulation, both at market entry and during market conduct:

4. Harmonising registration and reporting requirements across jurisdictions
5. Implementing more effective compliance monitoring.
6. Enabling more effective regulatory enforcement.

Each is discussed in turn.

### Reform opportunity 4: Harmonising registration and reporting requirements across jurisdictions

As outlined in chapters 2 and 3, several providers are required to apply for registration in separate jurisdictions, and each jurisdiction has different registration periods and may impose different conditions. Providers reported that this creates regulatory burden and confusion for those operating across multiple jurisdictions. We acknowledge that requiring providers to be registered enables states and territories to regulate the sector. However, it would be beneficial if these registration and reporting requirements were consistent across jurisdictions. This would ensure alignment of minimum legal standards for safety, quality, and ethical practice, and reduce administrative burden on regulatory authorities. This would also support a coherent national approach to ART regulation and promote public confidence.

We identified two alternative options:

**Option A: Consistent registration and reporting requirements imposed by individual State and Territory regulatory authorities.**

**Option B: Establish a national ART regulator to deliver national registration and reporting requirements.**

#### Option consideration

Both options have the same objective – to provide consistent registration and reporting requirements so that all ART providers are held to the same requirements and providers operating in multiple jurisdictions are subject to the same registration conditions. This reduces administrative burden for providers and better supports each jurisdiction to have the same regulatory levers available to them to support compliance monitoring and enforcement (as outlined in opportunities 5 and 6).

Option A can be implemented through a shared framework and progressive harmonisation of registration requirements. Jurisdictions with a small number of ART providers could potentially rely upon the registration requirements of another jurisdiction rather than establish their own regulatory authority and legislation. This option leverages existing arrangements but seeks to harmonise them, whereas Option B requires the establishment of a new standalone national regulator. Establishing a national regulator would be a lengthy process requiring coordinated

legislative reform, intergovernmental negotiation and system redesign.<sup>199</sup> While some stakeholders cited examples of standalone regulators, such as the Aged Care Commission, aged care is a \$36 billion industry compared to the much smaller \$810 million ART sector.<sup>200</sup>

## Recommendation

Both options provide consistent registration and reporting requirements.

**We recommend that consistent registration and reporting requirements be imposed by individual State and Territory regulatory authorities (Option A).**

This approach is more feasible and less costly than establishing a new national ART regulator (Option B). Option A also builds on existing regulatory capability and aligns ART regulation with the rest of health care. While there may be some benefit in a national regulator, the ART sector is a relatively small part of the health sector. We believe that it is difficult to justify a standalone regulator. This is discussed further in opportunities 5 and 6.

## Reform opportunity 5: Implementing more effective compliance monitoring

As discussed in chapter 3, there is significant variation in State and Territory compliance powers, compliance monitoring, and regulatory posture. Many jurisdictions rely on RTAC's accreditation process to identify non-compliance. This is inconsistent with the rest of the health sector where the national accreditor (the Commission) role is distinct from State and Territory regulatory authorities who monitor compliance and regulate conduct.

This opportunity would improve the oversight of provider conduct across jurisdictions. It includes drawing on regulatory intelligence from audits and other available data to identify risks and proactively investigate where providers are non-compliant.

The two alternative options (as outlined in opportunities 4 and 6):

**Option A: State and Territory regulatory authorities take a proactive, risk-based approach to compliance monitoring with consistent tools.**

**Option B: A centralised national regulator that adopts a proactive, risk-based approach to compliance monitoring.**

## Option consideration

As outlined above, we identified the potential benefit of a national regulatory approach to be achieved through strengthening and harmonising existing state-based regulatory regimes, rather than through the establishment of a standalone national regulator.

Under Option A, individual State and Territory regulatory authorities would be responsible for monitoring compliance of ART providers, as they are for hospitals and health services.<sup>201</sup> A

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<sup>199</sup> Each jurisdiction would be required to pass sequenced bills, and changeovers would need to be carefully staged across nine parliaments. This would be time-intensive and complex.

<sup>200</sup> 'GEN fact sheet 2023–24: Spending on aged care', *Australian Institute of Health and Welfare* (Fact Sheet, 2025) 1; Richardson (n 1).

<sup>201</sup> This includes strengthening through introducing increased penalty units, modern regulatory tools such as improvement notices, enforceable conditions and suspension powers.

resourcing uplift may be required for some jurisdictions to enforce regulations, particularly in New South Wales and the Northern Territory. However, resourcing requirements may vary across jurisdictions depending on the local scale of providers. Queensland Health currently has 5 FTE dedicated towards regulating the 24 ART clinics in their state. This could serve as a guide for other jurisdictions. Generalist staff as part of a broader health compliance/regulation team may also be considered to balance regulatory oversight with local demand and available resourcing.

Further investment would also be required to implement case management systems, data analytics, and operational capacity to support effective monitoring and enforcement.

## Recommendation

**We recommend that State and Territory regulatory authorities take a proactive, risk-based approach to compliance monitoring with consistent tools (Option A).**

This is more consistent with health regulation practices more broadly and is more proportionate to the size of the ART sector than establishing a standalone national regulator (Option B).

## Reform opportunity 6: Enabling more effective regulatory enforcement

As outlined in chapter 3, currently regulatory powers are limited and under-utilised. Most jurisdictions have blunt enforcement powers that are not being optimally used.

There are two alternative options to address this issue:

**Option A: State and Territory regulatory authorities draw on a spectrum of enforcement tools to enable decisive, proportionate action that deters misconduct**

**Option B: A centralised national regulator with a spectrum of enforcement tools that takes decisive, proportionate action that deters misconduct**

## Option consideration

Under both options, the regulator/s would have a graduated set of enforcement tools that enable a series of escalating series of actions. In both scenarios, regulatory authorities take enforcement action to address immediate non-compliance and to deter other providers from engaging in similar conduct. Both scenarios would also rely on strengthened communication and sharing of regulatory intelligence between regulatory authorities and the accreditation body to inform compliance monitoring and enforcement activity. Enforcement action requires resources particularly when sanctions and application of penalties result in litigation and appeals.

Option A can be implemented through a shared framework and harmonisation of enforcement powers. This option leverages existing arrangements but seeks to harmonise them, whereas Option B requires the establishment of a new standalone national regulator. As outlined in opportunity 4, establishing a national regulator would be a lengthy process requiring coordinated legislative reform, intergovernmental negotiation and system redesign.<sup>202</sup>

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<sup>202</sup> Each jurisdiction would be required to pass sequenced bills, and changeovers would need to be carefully staged across nine parliaments. This would be time-intensive and complex.

## Recommendation

**We recommend that State and Territory regulatory authorities draw on a spectrum of enforcement tools to enable decisive, proportionate action that deters misconduct (Option A).**

This recommendation is consistent with maintaining jurisdiction-led regulation (opportunities 4 and 5). We believe that Option A is more feasible than developing enforcement tools within a national regulator (Option B). While there may be some benefit in a national regulator, the ART sector is a relatively small part of the health sector, and it is difficult to justify a standalone regulator.

## 5.3 Enablers of reform opportunities

We identified four further opportunities that will strengthen oversight of the ART sector:

7. Sharing and publishing data on safety and quality improvement.
8. Improving transparency and guidance to enable informed consumer choice and consent.
9. Clarifying established complaints pathways and processes.
10. Sharing and using complaints data to support accreditation and regulatory activities.

### Reform opportunity 7: Sharing and publishing data on safety and quality improvement

As discussed in chapter 3, ART providers already collect and report a significant volume of process and outcome data to ANZARD. However, these data are not used by RTAC or jurisdictional regulatory authorities to inform regulatory activities or support continuous improvement. This is particularly the case for safety and quality improvement data. These are missed opportunities. Better use of data already collected and reported, including publication of the data in the public domain, would significantly enhance accreditation and regulatory functions, and consumer decision making (as outlined in Reform opportunity 8: Improving transparency and guidance to enable informed consumer choice and consent).

We identified three potential options:

**Option A: Share safety data (e.g. audit and adverse events) between the accreditor and regulators to inform standards, accreditation, and regulatory activities.**

This would support a risk-based approach to regulation and oversight of the sector and support proactive compliance monitoring and continuous improvement where data reveals pockets or trends of non-compliance.

**Option B: Publish accreditation data for public transparency.**

This would involve publishing provider assessment results, undertaken as part of the accreditation process.

**Option C: Share and publish thematic analysis of safety (e.g. audit and adverse events) and quality improvement data to support providers to continuously improve.**

This would involve the accreditation agency, regulators and/or ANZARD regularly undertaking analysis and publishing reports on topical issues to drive continuous improvement.

## Option consideration

The sharing of safety data to support accreditation and regulatory activities (Option A) would require systems for managing and categorising information between the accreditor and regulators. It would likely require a memorandum of understanding that clearly establishes the type of information that should be shared and in what timeframes. Ideally information would be shared in a seamless and automated way rather than manual data entry.

Option B would involve the publication of accreditation results via the accreditor's website. Providers may not be supportive of this approach. However, this approach is currently used by the Commission which publishes assessment outcomes for hospitals.<sup>203</sup> The ART sector could adopt the same approach. This would improve performance transparency and benefit consumers seeking further information about a provider's safety standards.

Option C would require leveraging existing data collected by ANZARD, the accreditor, and regulators to identify themes relating to safety and quality improvement. Given the type of data analysis required, it may be preferable for ANZARD to be responsible for this analysis and its publication. The organisation would likely require additional resourcing and capability uplift to undertake this analysis and publication of data on a regular basis. There was strong appetite from providers engaged as part of this review to gain access to information that supports benchmarking and quality improvement.

## Recommendation

**We recommend that the accreditor and State and Territory regulatory authorities share safety data, and that accreditation data and thematic analysis of safety and quality improvement data be published (Options A, B and C).**

We recommend that all of these options are pursued given the benefits to oversight of the ART sector and also the potential for it to inform continuous improvement by providers. Each of the options has potential to be implemented in the near term as they leverage existing data and platforms.

### **HFEA in the UK regularly publishes ART sector data**

HFEA, the UK's independent ART regulator, publishes reports on adverse events and non-compliance to support transparency and continuous improvement of UK's ART sector. This includes:

1. Annual state of the fertility sector reports which include information on HFEA licensed clinics, offering national and clinic-level data on treatment cycles, success rates and adverse events reported.
2. Quarterly Clinical governance updates that are shared via HFEA's clinic newsletter 'Clinic Focus'. These reports give providers an overview of most common non-compliances in the reported quarter. Insights into non-compliances support clinics to address areas of non-compliance as they emerge across the sector.<sup>204</sup>

<sup>203</sup> Australian Commission on Safety and Quality in Health Care, *ACSQHC website – NSQHS Standards: public reporting* (n 76).

<sup>204</sup> Human Fertilisation and Embryology Authority, *Clinical Governance Quarterly Update*, (Report, June 2025).

Report data is compiled from information gathered by HFEA's inspections throughout the year and other sources of information including incident reports, patient feedback and patient complaints.<sup>205</sup>

### **The Commission publishes accreditation results for Australian hospitals**

Information about how hospitals performed at their last assessment against the NSQHC standards are published on the Commission's web page.<sup>206</sup> Consumers and stakeholders can search and view how individual hospitals performed.

The Commission is responsible for collecting assessment outcomes from accrediting agencies, then compiles, interprets and develop reports on hospital performance data, enabling monitoring of safety and quality across the health system.

## **Reform opportunity 8: Improving transparency and guidance to enable informed consumer choice and consent**

As discussed in chapter 4, consumers consistently report barriers to making informed choices about ART treatment. Ensuring there is improved transparency about treatment efficacy and outcomes would assist consumers to make informed choices and give informed consent.

We identified four potential options to improve transparency and guidance for consumers:

### **Option A: Expand *YourIVFSuccess*.**

An expansion could include additional information such as treatment success rates, evidence for adjuvant treatments, and treatment costs.

### **Option B: Introduce a provider star rating system including quality and performance domains to rate clinics.**

These ratings could be included on the *YourIVFSuccess* website.

### **Option C: Deliver a targeted public fertility education campaign in partnership with the ART sector.**

This would draw on industry expertise and drive accountability of providers to promote evidence-based information to prospective consumers.

### **Option D: Deliver a public health campaign.**

This would provide the general population with information about fertility care and treatment options via digital platforms and media coverage.

## **Option consideration**

Expanding *YourIVFSuccess* to include additional information (Option A) and a provider star rating system (Option B) would provide consumers with more information to make informed choices

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<sup>205</sup> Human Fertilisation and Embryology Authority, *State of the fertility sector 2023/24* (Report, 1 October 2024).

<sup>206</sup> Australian Commission on Safety and Quality in Health Care, *ACSQHC website – NSQHS Standards: public reporting* (n 76).

about their treatment and has the benefit of leveraging an existing platform. These options would rely on data collection and sharing with the platform. There would likely be an increased cost associated with *YourIVFSuccess* including more information on the website. An implementation challenge could be providers' resistance to submit data, and to ensure data quality and comparability across clinics. Providers will likely also not be supportive of a star rating system that could have a potentially negative impact on their business.

Options C and D both offer opportunities to support informed reproductive choices and reduce stigmatisation and misinformation around infertility and ART. While public health campaigns (Option D) may achieve a wider reach, they can be costly and need to have a critical mass for messages to land. Option C has the benefit of targeting prospective consumers and linking their personal circumstances to probability of success. It would draw on industry expertise and driving provider accountability to ensure key messages are evidence-based and accurate. Both options would require funding.

To be successful, all options require careful monitoring to ensure available information is not outdated or misleading.

## Recommendation

**We recommend that *YourIVFSuccess* be expanded in the near term to enable more informed consumer choice and consent (Option A).**

The review team recommends further exploration of a provider star rating system (Option B) as a recognisable indicator of a clinic's performance.

Option C may warrant further exploration subject to funding to support the initiative and industry buy-in. Option D is not recommended given expense and it not being as targeted as Option C.

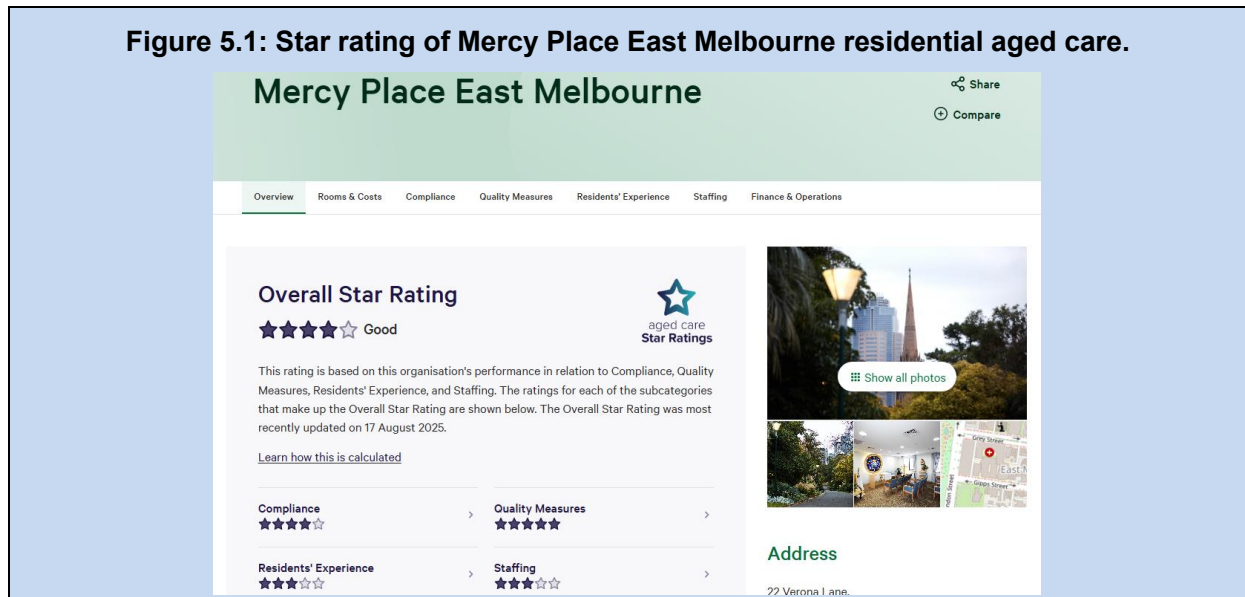
### **Aged care star ratings are a useful tool to inform consumer choice**

Provider rating systems are used in the residential aged care sector (see Figure 5.1). The ratings assist older people, their families and carers to compare the quality of aged care homes. Aged care homes receive an overall star rating and a rating against four sub-categories: residents' experience, compliance, staffing and quality measures. These are calculated using data from aged care residents, aged care providers, and the Aged Care Quality and Safety Commission – which are updated at least every quarter.<sup>207</sup> Transparent information about the quality, safety, and services of residential aged care homes help people compare options and encourages providers to improve their care standards.

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<sup>207</sup> 'How Star Ratings works', *Australian Government* (Web Page, 6 June 2025) <<https://www.health.gov.au/our-work/star-ratings-for-residential-aged-care/how-star-ratings-works#star-ratings-updates>>.

**Figure 5.1: Star rating of Mercy Place East Melbourne residential aged care.**



## Reform opportunity 9: Clarifying established complaints pathways and processes

As outlined in chapter 4, consumers consistently told us that they have difficulties making and resolving complaints with ART providers.

We propose two alternative options to address this:

### **Option A: Better enable consumers to use existing complaints handling bodies and processes.**

The accreditor, providers, and regulators should all provide consumers with clear and accessible information about how they can make a complaint, and which entity can assist them with different issues. For example, if a complainant is unable to reach a resolution with their provider and their complaint relates to a practitioner, they should be referred to Ahpra. However, if the complaint relates to a provider, the consumer should be referred to the relevant state-based health complaints body.

### **Option B: A dedicated ART complaints ombudsman.**

An independent, specialised authority would be responsible for investigating and resolving complaints related to services, conduct or practices within the ART sector. The independent review of complexity in the NRAS is considering a reduction in the number of complaints bodies within the NRAS, which could be leveraged to improve pathways for ART consumers.<sup>208</sup>

## Options consideration

Option A involves better use of existing complaints handling processes and bodies. It requires the accreditor, providers and regulators to ensure consumers receive clear and accessible information about how to make and resolve complaints. This option leverages existing entities

<sup>208</sup> Australian Government, *Consultation Paper 2: Consultation Outcomes and Reform Directions* (Report, May 2025) 95–9.

such as Ahpra, and State and Territory health complaints bodies, rather than establishing a new entity. It should be noted that some consumers may not be satisfied with this option given their experiences with current processes.

Establishing a dedicated ART ombudsman to handle ART complaints (Option B) would be welcomed by consumers because it would create a single, dedicated pathway to make a complaint. Additionally, the creation of a dedicated complaints body for the ART sector would mean that staff would have subject matter expertise about ART services and treatments. However, at present, we believe that the volume of complaints makes it difficult to justify a standalone ombudsman for the ART sector.

## Recommendation

**We recommend that consumers are better supported to use existing complaints handling bodies and processes (Option A).**

## Reform opportunity 10: Sharing and using complaints data to support accreditation and regulatory activities

Regulators and accreditors can use complaints data to gain insights into potential harms, identify trends and systemic issues, and inform their audit, compliance, enforcement, and policy-making activities. At present, complaints data in the ART sector are not collected in a systemised manner. This is a missed improvement opportunity, both for the ART sector and health care more broadly.

## Recommendation

**We recommend that providers, the accreditor, regulators and complaints handling bodies share complaints data.**

Insights from complaints data could usefully inform accreditation and regulatory activities. For example, if a provider is subject to multiple complaints, this could prompt proactive compliance monitoring by the regulator.

A network of reporting arrangements across the various complaints handling, accreditation and regulatory authorities would need to be established. This would need to consider privacy protections so that consumers are not identifiable. Consideration would need to be given to how entities would share and report data to minimise manual data entry and enable analysis and trends to be identified.

### **Australian Securities and Investments Commission (ASIC) uses complaints data to inform compliance monitoring activities**

Internal dispute resolution data reporting to ASIC is a mandatory and ongoing obligation for all in-scope financial firms.<sup>209</sup> Firms are required to report detailed data about their complaints management processes twice a year.<sup>210</sup> This allows ASIC to use reports of misconduct to inform its surveillance activities and investigations and allocate finite resources.

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<sup>209</sup> 'Internal dispute resolution data reporting', *Australian Securities and Investment Commission* (Web Page, 2025) <<https://www.asic.gov.au/regulatory-resources/financial-services/dispute-resolution/internal-dispute-resolution-data-reporting/#handbook>> ('ASIC website – Internal dispute resolution data reporting').

<sup>210</sup> Australian Securities and Investment Commission, *ASIC website – Internal dispute resolution data reporting* (n 209).

## 5.4 Further work to be commissioned

During our review we identified some further work related to improving ART governance nationally but that was beyond the scope of this review.

### Commissioning of consumer engagement

The review team recommends that health ministers commission consumer engagement.

We were not able to conduct widespread consumer engagement due to this review's short timeframe. While we did glean consumer insights during our desktop review and facilitated two consumer roundtables with 18 consumers, we recommend health ministers commission a project that engages a broader range of consumers to gain a deeper understanding of ART consumers' experiences.

These insights would be critical to inform the design and implementation of future reform. Insights from this engagement would be useful to inform improvements to the Code of Practice, publication of performance data, guidance to support community understanding and informed consent, and improvements to complaints processes.

### Referral of donor issues to the Australian Law Reform Commission

As outlined above, both providers and consumers engaged during this review repeatedly highlighted the risks of unregulated donations and the absence of a national donor register where individuals can access important information. While some jurisdictions have their own donor registers, these databases are managed independently which means a single donor can exceed family limits by donating in multiple jurisdictions. One example cited was the Australian Organ Donor Register, currently operated by Services Australia.

Opportunities that seek to create more consistency in laws and regulations<sup>211</sup> across jurisdictions for donations should be considered in the future to address this issue. This process however should not delay implementation of legislative reform in Queensland and Western Australia.

The Australian Law Reform Commission (ALRC) is currently conducting two reviews of related matters, including a Review of Human Tissue Laws inquiry<sup>212</sup> and a Review of Surrogacy Laws.<sup>213</sup>

We recommend that health ministers endorse a referral to the ALRC to explore opportunities to harmonise legislation in relation to donated gametes. The review could explore:

- whether who can be a donor is too restrictive and should be expanded to facilitate more local donations and deter 'black market' donations
- ways to more effectively monitor family donation limits to minimise consanguinity risks

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<sup>211</sup> Including family limits and regulations for movement and control of donor material nationally.

<sup>212</sup> Commenced on 6 February 2025 with the report to the Attorney-General by 16 August 2026: 'Review of Human Tissue Laws: Issue Paper Released', *Australian Law Reform Commission* (Web Page, 2025) <<https://www.alrc.gov.au/news/review-of-human-tissue-laws-issues-paper-released/>>.

<sup>213</sup> Commenced on 6 December 2024. The ALRC providing its final report to the Attorney-General by 29 July 2026. 'Review of Surrogacy Laws: Issues Paper Released', *Australian Law Reform Commission* (Web Page, 2025) <<https://www.alrc.gov.au/news/review-of-surrogacy-laws-issues-paper-released/>>.

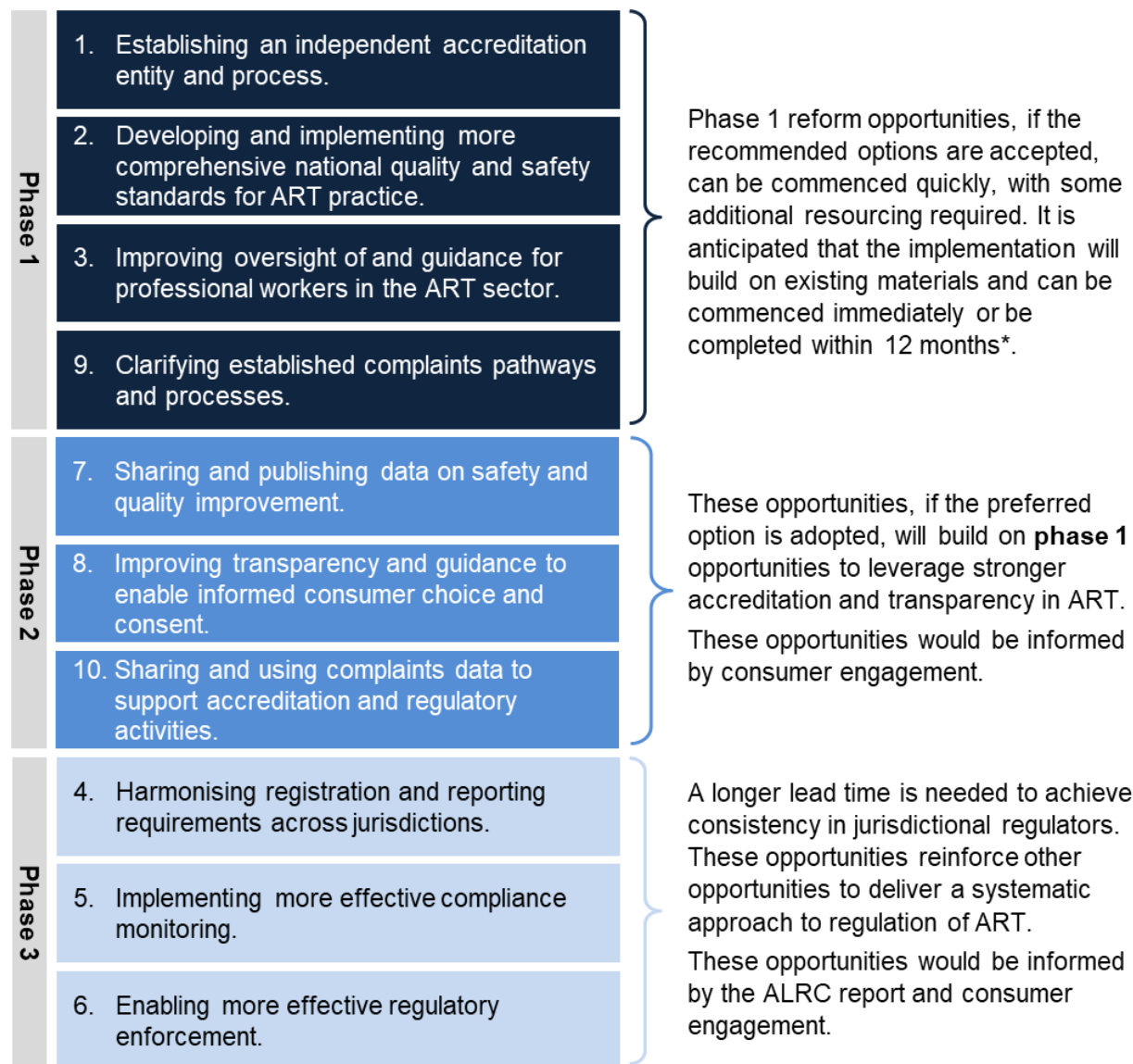
- effective regulation of the movement of donor material
- ways to enable greater access to information for donor-conceived people.

The objective of the review would be to ensure integrated and effective legislation aligned with contemporary issues and community expectations. We recommend that a broad cross-section of consumers is engaged as part of this process.

# 6 Proposed implementation approach

In addition to the opportunities, options, and recommendations above, we propose a three-phased approach to implementing the reform recommendations set out in this report. This is outlined in Figure 6.1.

Figure 6.1: Proposed prioritisation and phasing of reform opportunities.



*\*Establishing an independent accreditation entity and process will be in place by January 2027.*

In addition to progressing the above reform opportunities, and as outlined in section 5.4, we recommend that health ministers commission a project that engages a broad range of consumers to gain a deeper understanding of ART consumers’ experiences. We also recommend that health ministers endorse a referral to the ALRC to explore harmonisation opportunities in relation to donor issues.

# Appendix 1

**Table A1: Chronology of ART sector reviews and inquiries conducted since 2014.**

Published	Relevant jurisdiction(s)	Title
<b>November 2024</b>	All	Findings, Recommendations and Framework for an Australian 10 Year Fertility Roadmap.
<b>July 2024</b>	Qld	Section 81 – Investigation of ART Providers in Queensland.
<b>December 2022</b>	WA	Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy: Final Report.
<b>August 2022</b>	Qld	Inquiry into matters relating to donor conception information: Report No. 33, 57 <sup>th</sup> Parliament.
<b>August 2022</b>	ACT	Assisted Reproductive Technology: Regulation and Access – ACT Government Response.
<b>March 2020</b>	Vic	Inquiry into Assisted Reproductive Treatment Practices in Victoria: Final Report.
<b>May 2019</b>	Vic	Final Report of the Independent Review of Assisted Reproductive Treatment.
<b>October 2018</b>	Vic	Interim Report of the Independent Review of Assisted Reproductive Treatment.
<b>2019</b>	WA	The Review of the Western Australian <i>Human Reproductive Technology Act 1991</i> and the <i>Surrogacy Act 2008</i> (Report: Part 1).
<b>January 2017</b>	SA	Report on the review of the <i>Assisted Reproductive Treatment Act 1988</i> (SA).
<b>May 2014</b>	NSW	Report on the Statutory Review of the <i>Assisted Reproductive Technology Act 2007</i> (NSW)
<b>February 2014</b>	WA	Position on the Posthumous Collection and Use of Gametes.

## Appendix 2

**Table A2: Summary of State and Territory regulatory powers and jurisdictional features (Tables 2.1 – 2.8).**

	ACT	NSW	NT	QLD	SA	TAS	Vic	WA
<b>Registration required</b>	Yes	Yes	No*	Yes	Yes	Yes	Yes	Yes
<b>Registration period</b>	5 years	12 months	N/A	Up to 3 years	Not specified	Not specified	Not specified – registration period aligns with RTAC accreditation	Up to 5 years
<b>Requirement to report whether RTAC licence has been renewed</b>	ART units must advise	No requirement	No requirement	ART units must advise	ART units must advise	No requirement	ART units must advise	ART units must advise
<b>ART clinics participating in <i>YourIVFSuccess</i> reporting</b>	3 of 3	33 of 34	1 of 1	22 of 24	4 of 4	2 of 2	21 of 23	8 of 8
<b>Number of times conditions, in response to ART unit's quality, safety, or conduct, were applied in the last 10 years</b>	0	N/A	N/A	N/A**	0	0	5 <sup>#</sup>	3
<b>Power to undertake investigations</b>	Yes	No	No	Yes	~##	Yes	Yes	Yes
<b>Jurisdictional adverse event reporting requirements</b>	No~	No	No	~~	Yes	~^	Yes	Yes
<b>Donor registry</b>	Yes	Yes	No	Yes~	Yes	No	Yes	Yes

<b>Donor limits</b>	5 families in the ACT or 10 families Australia-wide.	5 women	No limit	10 families^^	10 families	No limit	10 women	5 families
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\* There is a sole ART/IVF provider in Northern Territory: Repromed Darwin. While Repromed Darwin is a separate entity to Repromed SA and has unique RTAC licences, both clinics operate under a similar operational model and use the same policies and procedures where possible. Repromed Darwin is however not regulated under South Australia or any other ART legislation.

\*\* Relevant powers under new Queensland legislation will not come into effect until March 2026.

# The number of conditions applied in Victoria may not represent all conditions applied due to changes in reporting.

## South Australia does not have express powers of investigation under the *Assisted Reproductive Treatment Act 1988* (SA) and are limited to undertake investigations into a registered clinic using powers of an Authorised Person or relying on conditions of their registration which state they must provide specified information as requested to the Minister.

~ The Australian Capital Territory is yet to complete regulations to support the *Assisted Reproductive Technology Act 2024* (ACT), which may include prescribing other events that must be reported to the Australian Capital Territory Health and Community Services Directorate.

~~ Queensland will require mandatory adverse event reporting from 1 March 2026.

^ Tasmania requires reporting of injuries, transfers, deaths and other sentinel events, but does not impose an ART-specific adverse event definition.

^^ The Queensland donor limit will come into effect from mid- to late-2026.

# Glossary

Term	Definition
<b>Adjuvant (or ‘add on’) treatments</b>	Procedures or medications that are added to ART treatment to try to improve a patient’s chance of success to conceive.
<b>Assisted reproductive treatment (ART)</b>	A range of treatment or procedures that aim to achieve pregnancy.
<b>ART provider</b>	A person or organisation that is registered under their jurisdiction’s ART legislation to provide ART services. ART providers may operate multiple ART units/clinics across different locations.
<b>ART units/clinics</b>	These terms are used interchangeably to refer to the regulated entity that is authorised to deliver ART services. ART units/clinics are a subset of fertility clinics and encompasses associations, agencies, groups, independent practitioners, and individuals responsible for providing ART services to patients.
<b>Donor conception</b>	The process of achieving conception through using donated sperm, eggs, or embryos.
<b>Embryo</b>	A biological entity created when a human egg is fertilised by sperm after which time it begins to grow and divide into more cells and is up to eight weeks old or 10 weeks gestation.
<b>Gamete</b>	An egg or sperm.
<b>Health complaints body</b>	An independent organisation set up in each state or territory to support people to resolve concerns about health services or health practitioners. Health complaints bodies are governed by their local jurisdiction legislation which outlines powers for them to investigate, resolve and manage complaints.
<b>Intracytoplasmic sperm injection (ICSI)</b>	ICSI is a form of ART procedure where a single sperm is injected into the inner cellular structure of an egg using a microscopic needle to achieve fertilisation.
<b>In-vitro fertilisation (IVF)</b>	IVF is a form of ART procedure. IVF treatment includes all fertility treatments where embryos or eggs and sperm are combined and handled outside of the body with the goal of achieving a pregnancy.
<b>Oocyte</b>	A cell that provides maternal genetic material for embryo formation. Oocytes can be fertilised by a sperm to create an embryo. They are released from a woman’s ovary usually one per monthly cycle and can be fertilised by a sperm to create an embryo.
<b>Ovarian hyperstimulation syndrome</b>	A potential complication of fertility treatment that can occur when injectable hormone medication to stimulate the ovaries to produce eggs causes an excessive response. This causes the ovaries to swell and become painful.
<b>Ovulation induction</b>	A fertility treatment that uses medication to stimulate the ovaries to produce and release eggs in larger quantities.
<b>Preimplantation genetic testing (PGT)</b>	A scientific technique to test embryos for a specific genetic condition or chromosomal abnormalities. This is done to allow the selection of

	chromosomally healthy embryos for transfer during an IVF cycle, increasing the likelihood of a healthy baby.
<b>Registration</b>	Formal process through which an ART unit is authorised by their state or territory regulator to legally operate and offer ART services in their jurisdiction, which may include the granting of a licence to provide ART services.
<b>State and Territory regulatory authority</b>	State and Territory regulatory authorities are typically based in health departments and responsible for the registration and subsequent regulation of ART units operating in their jurisdiction under the relevant local legislation.
<b>Surrogacy</b>	An arrangement where one woman (the surrogate) agrees to carry an implanted embryo through pregnancy and childbirth on behalf of another person or couple (the intended parent/s).
<b>Transfer</b>	A procedure whereby one or more embryos, created through IVF, is placed into a person's uterus.