

Registration Scheme for A.R.T. Clinics



REGISTRATION OF ASSISTED REPRODUCTIVE TREATMENT PROVIDERS IN SOUTH AUSTRALIA

Registration Requirements for Providers of A.R.T. in South Australia

In South Australia, the *Assisted Reproductive Treatment Act 1988* (the Act), and *Assisted Reproductive Treatment Regulations 2010* set out:

- > Requirements for registration;
- > Mandatory conditions for registered assisted reproductive treatment (A.R.T.) providers;
- > Powers of the Minister for Health to suspend or cancel registration; and/or to remove a person from the register;
- > Reinstatement provisions; and
- > An appeals process to enable review of any decision relating to the above.

Registration

A person (or company) must not provide A.R.T. in South Australia unless they are registered by the Minister for Health. Failure to be registered may result in a maximum penalty of \$120,000.

To be registered an applicant must establish that he or she:

- > is a fit and proper person to be registered;
- > holds any licence, accreditation or other qualification required by the regulations for the purposes of registration; and
- > satisfies any other requirements prescribed by the regulations.

The 2010 regulations provide that 'a current Reproductive Technology Accreditation Committee (RTAC) license is required for the purposes of registration'.

Mandatory conditions for registered A.R.T. providers are placed by the Minister for Health, as set out in the Act and regulations. Such conditions include (but are not limited to) circumstances in which A.R.T. may be provided. (For further information on eligibility requirements, see Fact Sheet 5).

The Minister must also impose a condition on registration requiring that the person comply with National Health and Medical Research Council *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (NHMRC Guidelines). The Minister for Health can also impose any other condition of registration (see the A.R.T. provider register on the SA Health website for current conditions).

Suspension or Cancellation of Registration

The Minister may suspend or cancel registration if a person has failed to comply with or has contravened conditions of registration.

Removal from the Register

The Minister may remove a person from the register if they no longer meet registration requirements, or have had such registration cancelled or suspended.

Reinstatement to the Register

The Minister can reinstate registration subject to application and approval.

What requirements do registered A.R.T. providers have to meet?

Registered A.R.T. providers must:

- > comply with the Act, the regulations and any conditions imposed on their registration;
- > maintain RTAC accreditation and National Association of Testing Authorities accreditation;
- > comply with the NHMRC Guidelines;
- > ensure practice and research comply with any policies or guidelines issued from time to time; and
- > submit reports to the Minister for Health on request.

Registration requirements do not apply in relation to assisted insemination outside of a clinic

The registration requirements do not apply in relation to ‘assisted insemination’— which is defined as an assisted reproductive treatment (not being IVF or a surgical procedure) in which human sperm is introduced by artificial means, into the human female reproductive system—when provided outside of a clinic by a health professional (for example, a GP); or if provided for free (for example self-insemination, or the assisted insemination of a friend or partner). (Note insemination outside of a clinic may carry with it health risks if, for example, unscreened sperm is used).

Health professionals that provide such assisted insemination must nevertheless be ‘approved by the Minister’ for the purposes of the Act. Such approval may be conditional or unconditional—noting any breach of a condition placed upon approval may be subject to a maximum penalty of \$120 000.

There are currently no approved health professionals in South Australia providing artificial insemination.

Considerations

The regulatory system that now exists in South Australia is one that relies significantly upon self-regulation. That is, while there exists framework legislation requiring registration of A.R.T. providers, reliance is placed upon accreditation from the Reproductive Technology Accreditation Committee (RTAC).

The RTAC is a committee set up by the Fertility Society of Australia. The Fertility Society of Australia is the peak body representing clinicians practicing in the area of fertility.

The framework legislation also requires adherence to the NHMRC Guidelines.

The NHMRC Guidelines are promulgated at a national level, and are subject to change.



Subsequent to the 2010 amendments to the Act and the abolition of the South Australian Council of Reproductive Technology (SACRT), it was anticipated that the Ethics Health Advisory Council (EHAC) would provide advice to the Minister on health related ethical issues, including A.R.T.

The current review of the *Assisted Reproductive Treatment Act 1988 (SA)* will include consultation with the EHAC, and with members of the public, about how the EHAC has operated since 2010 in relation to A.R.T.

Ethical issues in A.R.T.

A.R.T. raises ethical issues around numerous areas, including:

- > the paramountcy of the welfare of those born as a result of A.R.T.;
- > access to information by donors, recipients, and donor-conceived people;
- > the commercialization of reproductive capabilities (for example payment for egg, sperm, or embryo donation);
- > sex selection for 'social reasons';
- > egg or embryo freezing;
- > gene editing.

Questions

We are interested in hearing from people about their experience and views regarding the changes from the previous licensing system to the current registration scheme for assisted reproductive treatment in South Australia.

The following questions may help you to inform the review:

1. Are you satisfied with the current registration scheme?
2. Is the current registration scheme an improvement on the previous licensing scheme?
3. What are your views and/or experience of the industry-based RTAC accreditation scheme?
4. Is the requirement that registered people adhere to the NHMRC guidelines satisfactory? (See also Fact Sheet 4)
5. Do the NHMRC Guidelines adequately address ethical issues raised by A.R.T.?
6. From whom do you seek guidance if you are unsure of whether a registration requirement is being met or something may or may not be done?
7. Is there anything that isn't satisfactory and/or needs to be changed?

Please feel free to comment on anything else that is relevant.

The Review of the Act

The *Assisted Reproductive Treatment Act 1988* provides that a review must take place of the operation and effectiveness of the Act as soon as possible after the fifth anniversary of the changes that came into effect on or after 1st September 2010. The review will particularly focus upon the operation and effectiveness of the Act in relation to:

- > the requirement that the welfare of any child born as a consequence of A.R.T. is to be treated as being of paramount importance, and accepted as a fundamental principle, in respect of the operation of the Act, as well as in the provision of assisted reproductive treatment;
- > the replacement of the previous licensing scheme with a registration scheme for A.R.T. clinics;
- > the dissolution of the SA Council on Reproductive Technology and its Code of Ethical Clinical Practice;
- > amending eligibility for access to A.R.T. services—noting that such conditions relate to the circumstances in which, and to whom, A.R.T. may be provided;
- > allowing for the establishment of a donor conception register; and
- > provisions for record keeping and confidentiality.

The review will include examination of research and practice, and invite public submissions relevant to the above matters. It will lead to a report, which will include recommendations regarding the regulation of assisted reproductive treatment in South Australia. The report will be tabled in Parliament and made publically available. The recommendations will be considered by the Minister for Health.



Registration Scheme for A.R.T. Clinics Fact Sheet 3

Review of the *Assisted Reproductive Treatment Act 1988 (SA)*

We Invite You To Make a Submission



Complete the online submission form on the [YourSAy](#) website to provide your views in relation to the issues under review.

Email a submission to Associate Professor Sonia Allan at HealthPolicyLegislation@sa.gov.au with subject heading 'A.R.T. Act Review'



Post a submission to

A/Professor Sonia Allan
A.R.T. Act Review,
C/- Policy and Intergovernment Relations Unit,
SA Health, PO Box 287, Rundle Mall,
ADELAIDE SA 5000



Join the discussion on the [YourSAy](#) website.

Please note that all submissions are public unless marked 'confidential'. Public submissions will be posted on the [YourSAy](#) website, and the author may be cited in the final report. Authors of 'confidential' submissions will not be referred to by name. We cannot accept anonymous submissions.

Submissions close on Friday 15 April 2016.

More Information

For general information on topics relevant to the review of the *Assisted Reproductive Treatment Act 1988 (SA)* see the following Fact Sheets:

[Fact Sheet 1: Introduction to the Review](#)

[Fact Sheet 2: Paramourncy of the Welfare of the Child](#)

[Fact Sheet 3: Registration Scheme for A.R.T. Clinics](#)

[Fact Sheet 4: Dissolution of SA Council on Reproductive Technology, and its Code of Ethical Clinical Practice](#)

[Fact Sheet 5: Access to Assisted Reproductive Treatment](#)

[Fact Sheet 6: Establishment of a Donor Register](#)

[Fact Sheet 7: Record Keeping and Confidentiality](#)

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Prepared by Associate Professor Sonia Allan, for the *Assisted Reproductive Treatment Act 1988 (SA)* review, January 2016.

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