New South Wales

Assisted Reproductive Technology Regulation 2024

under the

Assisted Reproductive Technology Act 2007

Her Excellency the Governor, with the advice of the Executive Council, has made the following regulation under the *Assisted Reproductive Technology Act 2007*.

RYAN PARK, MP
Minister for Health

Explanatory note

The object of this regulation is to remake, with amendments, the *Assisted Reproductive Technology Regulation 2014*, which will be repealed on 1 September 2024 by the *Subordinate Legislation Act 1989*, section 10(2).

This regulation provides for the following—

(a) matters to be included in an application for registration as an ART provider,

(b) application and annual registration fees for ART providers,

(c) additional events or changes that registered ART providers must give notice of to the Secretary of the Ministry of Health (the ***Secretary***),

(d) infection control standards that certain ART providers must meet,

(e) qualifications required to provide counselling services to certain persons affected by ART treatment,

(f) reasonable steps an ART provider must complete in certain circumstances to establish whether a gamete provider is alive,

(g) information the Secretary must enter in the central register and disclose to certain persons,

(h) information an ART provider and certain other persons must provide to the Secretary in relation to women who have undergone ART treatment and persons born as a result of the ART treatment,

(i) other miscellaneous matters.

This regulation comprises or relates to matters set out in the *Subordinate Legislation Act 1989*, Schedule 3, namely—

(a) matters of a machinery nature, and

(b) matters that are not likely to impose an appreciable burden, cost or disadvantage on any sector of the public.

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Contents

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Part 1 Preliminary

1 Name of regulation

This regulation is the *Assisted Reproductive Technology Regulation 2024*.

2 Commencement

This regulation commences on 1 September 2024.

Note— This regulation replaces the *Assisted Reproductive Technology Regulation 2014*, which is repealed on 1 September 2024 by the *Subordinate Legislation Act 1989*, section 10(2).

3 Definitions

In this regulation—

ART legislation means—

(a) the Act and this regulation, and

(b) the following Acts, and regulations made under those Acts—

(i) the *Human Cloning for Reproduction and Other Prohibited Practices Act 2003*,

(ii) the *Prohibition of Human Cloning for Reproduction Act 2002* of the Commonwealth,

(iii) the *Research Involving Human Embryos Act 2002* of the Commonwealth,

(iv) the *Research Involving Human Embryos (New South Wales) Act 2003*.

federal accreditation means accreditation by—

(a) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia and New Zealand, or

(b) a body prescribed under the *Research Involving Human Embryos Act 2002* of the Commonwealth, section 8, definition of ***accredited ART centre***, paragraph (b).

relevant person, for Part 3—see section 11.

the Act means the *Assisted Reproductive Technology Act 2007*.

Note— The Act and the *Interpretation Act 1987* contain definitions and other provisions that affect the interpretation and application of this regulation.

Part 2 Registration as ART provider and provision of ART services

4 Registration application fee—the Act, s 7(2)

An application for registration must be accompanied by a fee of $3,342.

5 Matters to be included in registration application—the Act, s 7(3)(e)

An application for registration must state—

(a) whether or not the applicant has been convicted of contravening any ART legislation, and

(b) whether or not the applicant has ever been refused federal accreditation, and

(c) if the applicant has, or has ever had, federal accreditation—whether or not the applicant has had federal accreditation cancelled, revoked or suspended, and

(d) if the applicant is a corporation—

(i) the corporation's Australian Company Number, and

(ii) the address of the corporation's registered office, and

(iii) the address of the corporation's principal place of business.

6 Annual registration fee—the Act, s 7(8)

(1) The annual registration fee is $2,366.

(2) A registered ART provider must pay the annual registration fee before the anniversary of the registered ART provider's registration each year.

7 Notice of events or changes—the Act, s 8(1)(e)

A registered ART provider must give notice to the Secretary of the following events or changes—

(a) the ART provider is convicted of contravening any ART legislation,

(b) the ART provider is refused federal accreditation,

(c) the ART provider has its federal accreditation cancelled, revoked or suspended,

(d) if the ART provider is a corporation, changes to the following—

(i) the corporation's Australian Company Number,

(ii) the address of the corporation's registered office,

(iii) the address of the corporation's principal place of business.

8 Infection control standards—the Act, s 10

An ART provider that does not have federal accreditation must meet the infection control standards in—

(a) the document entitled *Infection Prevention and Control in Healthcare Settings* published by the Department on 15 September 2023, and

(b) paragraph 5.2.4 of the document entitled *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* published by the National Health and Medical Research Council, as in force from time to time.

9 Qualifications of counsellors—the Act, s 12(2C)

A person is qualified to provide counselling services if the person is—

(a) a psychologist, or

(b) a health practitioner who—

(i) is not providing ART services to which the counselling relates, and

(ii) has qualifications in—

(A) psychiatry recognised by the Royal Australian and New Zealand College of Psychiatrists, or

(B) general practice recognised by the Royal Australian College of General Practitioners, or

(c) eligible for membership of the Australian Association of Social Workers.

10 Establishing whether gamete provider is alive—the Act, s 24(3)(b)

(1) An ART provider takes reasonable steps to establish whether a gamete provider is alive if—

(a) the last address of the gamete provider known by the ART provider is in another State or Territory, and

(b) the ART provider obtains a certificate from the registering authority of the other State or Territory as to whether the gamete provider's death is recorded in the register kept under the corresponding registration law of the other State or Territory.

(2) In this section—

corresponding registration law means a law of another State or Territory that provides for the registration of deaths.

registering authority means an authority responsible under a corresponding registration law for the registration of deaths.

Part 3 Central register—surrogacy information

11 Definition

In this part—

relevant person means an adult—

(a) who was born as a result of a surrogacy arrangement, and

(b) whose parentage has been transferred by a parentage order.

12 Information to be entered in central register—the Act, s 41B(1)

(1) For a surrogacy arrangement that results in the birth of a child, the Secretary must enter in the central register—

(a) the following information about the child—

(i) full name,

(ii) date of birth,

(iii) place of birth,

(iv) sex, and

(b) the following information about each birth parent or gamete provider under the surrogacy arrangement—

(i) full name,

(ii) residential address,

(iii) date of birth,

(iv) place of birth,

(v) ethnicity and physical characteristics,

(vi) medical history or genetic test results in relation to the following persons that are relevant to the future health of the child or the child's descendants—

(A) the birth parent,

(B) the gamete provider,

(C) members of the birth parent's family,

(D) members of the gamete provider's family, and

(c) the sex and year of birth of each biological sibling of the child.

(2) If provided voluntarily by a relevant person, the Secretary must also enter the following information about the relevant person in the central register—

(a) residential address,

(b) medical history or genetic test results in relation to the person that are relevant to the future health of—

(i) the birth parent, or

(ii) the gamete provider, or

(iii) the birth parent's descendants, or

(iv) the gamete provider's descendants.

13 Disclosure about birth parents and gamete providers—the Act, s 41F(1) and (2)

The Secretary must, on application by a relevant person, disclose the following information held on the central register about each birth parent, or gamete provider under the surrogacy arrangement, of the relevant person—

(a) residential address,

(b) date of birth,

(c) place of birth,

(d) ethnicity and physical characteristics,

(e) medical history or genetic test results in relation to the following persons that are relevant to the future health of the relevant person or the relevant person's descendants—

(i) the birth parent,

(ii) the gamete provider,

(iii) members of the birth parent's family,

(iv) members of the gamete provider's family.

Note— The Act, section 41F also requires the name of the birth parent or gamete provider to be given. Information may be disclosed under section 41F only to a person who is an adult.

14 Disclosure about biological siblings—the Act, s 41F(3)(a)

The Secretary must, on application by a relevant person, disclose the sex and year of birth of each of the relevant person's biological siblings.

15 Disclosure to birth parent and gamete provider—the Act, s 41G(1)(a)

The Secretary must, on application by a birth parent, or a gamete provider under a surrogacy agreement, of a relevant person, disclose the sex and year of birth of the relevant person.

Part 4 Miscellaneous

16 Secretary must take into account psychological report—the Act, s 40A(3)

(1) In forming an opinion under the Act, section 40A(3) that contact between the applicant and the person whose information is proposed to be disclosed is justified, the Secretary must take into account a report that—

(a) has been prepared by—

(i) a medical practitioner with expertise in mental health, or

(ii) a psychologist, and

(b) considers whether the contact is justified to protect the welfare and best interests of the applicant and the person whose information is proposed to be disclosed.

(2) The report must—

(a) be obtained by the applicant at the applicant's cost, and

(b) accompany the application.

17 Time within which notice to applicant must be given—the Act, s 41U(1)

For the Act, section 41U(1), the time prescribed is 28 days.

18 Information to be given to Secretary—the Act, s 41U(3)(b)

An ART provider must, when giving the Secretary information about a donor under the Act, section 41U, also give the Secretary identifying information that the ART provider has about—

(a) each woman who has undergone ART treatment using a gamete donated by the donor, and

(b) each offspring born as a result of the ART treatment.

19 Information to be given in response to written direction—the Act, s 41V(1)(d)

(1) The Secretary may require a person to give the Secretary information about—

(a) a woman who has undergone ART treatment using a gamete donated by a specified donor, and

(b) offspring born as a result of the ART treatment.

(2) A reference to information in subsection (1) includes identifying information.

20 Savings

An act, matter or thing that, immediately before the repeal of the *Assisted Reproductive Technology Regulation 2014*, had effect under that regulation continues to have effect under this regulation.