Assisted Reproductive Technology Regulation 2014

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New South Wales

Status Information

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Provisions in force

The provisions displayed in this version of the legislation have all commenced.

Authorisation

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New South Wales

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Part 1 Preliminary

1 Name of Regulation

This Regulation is the *Assisted Reproductive Technology Regulation 2014*.

2 Commencement

This Regulation commences on 1 September 2014 and is required to be published on the NSW legislation website.

Note—

This Regulation replaces the *Assisted Reproductive Technology Regulation 2009* which is repealed on 1 September 2014 by section 10 (2) of the *Subordinate Legislation Act 1989*.

3 Definitions

(1) In this Regulation:

ART legislation means the Act and this Regulation and the following Acts or the regulations made under those Acts:

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

(b) the *Research Involving Human Embryos (New South Wales) Act 2003*,

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

(d) the *Research Involving Human Embryos Act 2002* of the Commonwealth.

federal accreditation means accreditation by:

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

(b) any other body prescribed under paragraph (b) of the definition of ***accredited ART centre*** in section 8 of the *Research Involving Human Embryos Act 2002* of

the Commonwealth.

full name, in relation to a donor of a gamete, includes each name by which the donor is or has been known.

pre-Act gamete means a donated gamete that was obtained from a donor before 1 January 2010.

Note—

All provisions of the Act commenced on 1 January 2010, except for section 6 (1) which commenced on 1 March 2010.

Secretary means the Secretary of the Department.

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

(2) Notes included in this Regulation do not form part of this Regulation.

Part 2 Registration and provision of services

4 Registration application fee: section 7 (2)

The fee that must accompany an application for registration is $2,570.

5 Matters to be included in application: section 7 (3) (e)

An application for registration must include the following:

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

(b) a statement as to whether or not the applicant has been refused federal accreditation or has had federal accreditation suspended, cancelled or revoked,

(c) in the case of an applicant that is a corporation:

(i) the registered number (being the Australian Company Number or Australian Registered Body Number) of the corporation, and

(ii) the address of the registered office and principal place of business of the corporation.

6 Annual registration fee: section 7 (8)

(1) The annual registration fee is $1,820.

(2) In any year a registered ART provider must pay the annual registration fee before the anniversary of the registered ART provider's registration.

7 Notice of events or changes in particulars: section 8 (1) (e)

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

(a) the conviction of the ART provider for contravening any ART legislation,

(b) a refusal to grant federal accreditation to the ART provider,

(c) the suspension, cancellation or revocation of the federal accreditation of the ART provider,

(d) in the case where the registered ART provider is a corporation, any change in the address of the registered office and principal place of business of the corporation.

8 Infection control standards: section 10

An ART provider who does not have federal accreditation must meet the infection control standards in both of the following as in force from time to time:

(a) the *Infection Control Policy* published by the Department,

(b) paragraph 6.4 of the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* published by the National Health and Medical Research Council.

9 Qualifications of counsellors: section 12 (2) (b)

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

(a) a registered psychologist, or

(b) a medical practitioner who has qualifications in:

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

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

and who is not providing any ART services to which the counselling relates, or

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

10 Establishing whether gamete provider is alive: section 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 of which the ART provider is aware is in another State or Territory, and

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

(2) In this clause:

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 Information and records

11 Information to be provided to registered ART provider: section 27 (4) (c)

An ART provider must, if requested to do so by a registered ART provider for the purposes of complying with section 27 of the Act, provide the following information in relation to a donor:

(a) the number of women who are pregnant as a result of ART treatment provided by the ART provider using a gamete of the donor, but not including women referred to in section 27 (4) (a) of the Act,

(b) the number of women for whom an embryo has been created as a result of ART treatment provided by the ART provider using a gamete of the donor and placed in storage, but not including women referred to in paragraph (a) or section 27 (4) (a) of the Act,

(c) the number of women of whom the ART provider is aware who have given birth to offspring of the donor other than as a result of ART treatment, but not including women referred to in paragraph (a) or (b) or section 27 (4) (a) of the Act.

12 Information to be collected when obtaining gametes: section 30 (1)

(1) An ART provider who obtains a gamete (other than a donated gamete) from a gamete provider must obtain the gamete provider's full name, date of birth and residential address.

(2) An ART provider who obtains a donated gamete from a donor must obtain the following information in relation to the donor:

(a) full name,

(b) residential address,

(c) date and place of birth,

(d) ethnicity and physical characteristics,

(e) any medical history or genetic test results of the donor or the donor's family that are relevant to the future health of:

(i) a person undergoing ART treatment involving the use of the donated gamete, or

(ii) any offspring born as a result of that treatment, or

(iii) any descendent of any such offspring,

(f) the name of each ART provider who has previously obtained a donated gamete from the donor and the date on which the gamete was obtained,

(g) the sex and year of birth of each offspring of the donor.

13 Gamete provider records: section 31 (1) (a) (i)

An ART provider must keep a record of the information required to be obtained under clause 12 and the date on which the ART provider obtained the information.

14 ART treatment offspring records: section 31 (1) (c)

An ART provider must keep a record of the following:

(a) the full name, sex and date of birth of each offspring born as a result of ART treatment provided by the ART provider,

(b) the name of the woman who gave birth to the offspring,

(c) if the offspring was born as a result of ART treatment using a donated gamete, the full name and date and place of birth of the donor.

15 Information required to be provided by ART providers: section 33 (5)

An ART provider must provide the following to the Secretary within 2 months after the birth of a live offspring born as a result of ART treatment provided by the ART provider using a donated gamete:

(a) the date and terms of the donor's consent (and of any modification or revocation of the donor's consent),

(b) the information referred to in clause 12 (2) and the date on which the ART provider obtained the information,

(c) the information referred to in clause 14 (a)–(c) in relation to the offspring.

Maximum penalty: 10 penalty units.

Note—

An ART provider is required to keep a record of:

(a) a gamete provider's consent—by section 31 (1) (a) (iii) of the Act, and

(b) the information in paragraph (b)—by clause 13, and

(c) the information in paragraph (c)—by clause 14.

Part 4 Central register

Division 1 Information about ART treatment

16 Information to be entered in central register: section 33 (2)

(1) The Secretary is to enter the following in the central register:

(a) information provided to the Secretary under clause 15 and the name of the ART provider that provided the information,

(b) any information provided voluntarily by a donor for the purposes of updating information provided by the donor under clause 12 (2) (a), (b), (e) or (g),

(c) any of the following information provided voluntarily by a donor of a pre-Act gamete:

(i) the information referred to in clause 12 (2) (a)–(e) or (g) in relation to the donor,

(ii) the name of the ART provider to whom the pre-Act gamete was provided,

(iii) the date on which the pre-Act gamete was provided,

(d) any of the following information provided voluntarily by the offspring of a donor:

(i) the full name, residential address, date and place of birth and sex of the offspring,

(ii) any medical history or genetic test results of the offspring or the offspring's family that are relevant to the future health of the donor or any descendants of the donor.

(2) The Secretary may, if satisfied that an entry in the register is incorrect, amend or add a notation to the entry.

17 Disclosure of information: sections 37 (1) and (2) (a), 38 (1) (a) and (b) and 39 (1) (a)

The Secretary must disclose to the following persons the following information as recorded on the central register if an application in an approved form is made:

(a) to an adult who was born as a result of ART treatment using a donated gamete—the information referred to in clause 12 (2) (a)–(e) in relation to the donor and the name of the ART provider who provided the information,

(b) to an adult offspring of a donor—the sex and year of birth of each other offspring of the donor,

(c) to the parent of a child born as a result of ART treatment using a donated gamete—the information referred to in clause 12 (2) (d) and (e) in relation to the donor and the sex and year of birth of each other offspring of the donor,

(d) to a donor—the sex and year of birth of each offspring born using a donated gamete of the donor.

Division 2 Information about surrogacy arrangements

18 Information to be entered in central register: section 41B (1)

(1) The Secretary is to enter the following in the central register in relation to each surrogacy arrangement that results in the birth of a child:

(a) the full name, date and place of birth and sex of the child,

(b) the following information in relation to each gamete provider or birth parent under the surrogacy arrangement:

(i) full name,

(ii) residential address,

(iii) date and place of birth,

(iv) ethnicity and physical characteristics,

(v) any medical history or genetic test results in relation to the gamete provider or birth parent, or members of the gamete provider's or birth parent's family, that are relevant to the future health of the child or the child's descendents,

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

(2) If provided voluntarily by a person born as a result of a surrogacy arrangement who is an adult and whose parentage is transferred by a parentage order, the Secretary is also to enter the following information in the central register in relation to the person:

(a) residential address,

(b) any medical history or genetic test results in relation to the person that are relevant to the future health of a birth parent or gamete provider under the surrogacy arrangement or the birth parent's or gamete provider's descendents.

19 Disclosure about birth parents and gamete providers: section 41F (1) and (2)

The Secretary must, on application by a person who is an adult and whose parentage was transferred by a parentage order, disclose the following information held on the central

register about each birth parent of the applicant or gamete provider under the surrogacy arrangement:

(a) residential address,

(b) date and place of birth,

(c) ethnicity and physical characteristics,

(d) any medical history or genetic test results in relation to the birth parent or gamete provider, or members of the birth parent's or gamete provider's family, that are relevant to the future health of the applicant or the applicant's descendents.

Note—

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

20 Disclosure about biological siblings: section 41F (3) (a)

The Secretary must, on application by an adult person whose parentage has been transferred by a parentage order, disclose the sex and year of birth of each of the applicant's biological siblings.

21 Disclosure to birth parent and gamete provider: section 41G (1) (a)

The Secretary must, on application by a birth parent, or a gamete provider under a surrogacy arrangement, of a person whose parentage is transferred to another person as a result of a parentage order, disclose the sex and year of birth of the person whose parentage is transferred.

Part 5 Miscellaneous

22 Pre-Act gamete exemptions: clause 1 (1) of Schedule 1

(1) This clause applies to the following uses of a gamete or embryo:

(a) the use of a pre-Act gamete to provide ART treatment to a woman who, before 1 January 2010, conceived an offspring as a result of ART treatment using a donated gamete from the donor of the pre-Act gamete,

(b) the use of an embryo, created before 1 January 2010 using a pre-Act gamete, to provide ART treatment to any woman.

(2) For the purposes of section 18 of the Act, the donor is taken to consent to the use of the pre-Act gamete to create an embryo outside the body of a woman, but that consent may be modified or revoked in accordance with section 17 of the Act.

(3) Sections 26 (1) and 27 (1) of the Act do not prevent a use to which this clause applies.

(3A) Section 25 of the Act does not prevent the storage of a gamete or embryo for the purposes of any use to which this clause applies.

(4) An ART provider is taken to have obtained any information required to be obtained under section 30 (2) or (3) of the Act in relation to the pre-Act gamete or embryo.

(5) An ART provider is not required to keep records under section 31 (1) (a) of the Act in relation to the pre-Act gamete or embryo.

Note—

Section 18 of the Act prohibits use of a gamete to create an embryo without the gamete provider's consent. Section 27 (1) limits the use of a donated gamete if its use will result in the donor's offspring being born to more than 5 women. Section 30 (2) and (3) prohibits the use of gametes without obtaining particular information. Section 31 requires the keeping of records relating to gametes and embryos in an ART provider's possession.

23 Storage of pre-Act gametes: clause 3 (2) of Schedule 1

(1) Subject to clause 22, an ART provider must not store a pre-Act gamete for any longer than 15 years after the date the pre-Act gamete was obtained from the donor or such longer period as may be authorised by the Secretary under this clause.

Maximum penalty: 10 penalty units.

(2) The Secretary may give written authorisation for a pre-Act gamete to be stored for a period longer than 15 years, if satisfied that there are reasonable grounds for doing so having regard to any relevant guidelines issued by the Secretary from time to time.

24 Savings

Any act, matter or thing that, immediately before the repeal of the *Assisted Reproductive Technology Regulation 2009*, had effect under that Regulation continues to have effect under this Regulation.