



New South Wales

# Assisted Reproductive Technology Regulation 2009

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*.

JOHN DELLA BOSCA, MLC  
Minister for Health

## Explanatory note

The *Assisted Reproductive Technology Act 2007* (*the Act*) regulates assisted reproductive technology services, including assisted reproductive technology treatment (*ART treatment*) such as artificial insemination and in-vitro fertilisation, and provides for the registration of assisted reproductive technology service providers (*ART providers*).

This Regulation makes provision with respect to the following:

- (a) the registration of ART providers, including additional matters to be included in applications for registration, application fees and annual registration fees,
- (b) the additional events and changes that registered ART providers must give notice of to the Director-General of the Department of Health,
- (c) the infection control standards that certain ART providers must meet,
- (d) the qualifications required to provide counselling services under the Act,
- (e) the steps required to be taken by an ART provider in certain circumstances to establish whether a person, who earlier provided a gamete, is still alive,
- (f) the information about a donated gamete, or embryo created using a donated gamete, that an ART provider must provide to another ART provider,
- (g) the collection of information about gamete providers and about offspring born as a result of ART, and the keeping of records of that information,
- (h) the matters to be entered in the central ART donor register and information required to be provided by ART providers for inclusion on that register,
- (i) the disclosure of information to a person born as a result of ART treatment using a donated gamete, to any such person's parents and to the donor of a gamete,

## **2009 No 323**

Assisted Reproductive Technology Regulation 2009

Explanatory note

---

(j) savings, transitional and formal matters.

This Regulation is made under the *Assisted Reproductive Technology Act 2007*, including sections 7 (2), (3) (e) and (8), 8 (1) (e), 10, 12 (2) (b), 24 (3) (b), 27 (4) (c), 30 (1), 31 (1) (a) (i) and (c), 33 (2) and (5), 37 (1) and (2) (a), 38 (1) (a) and (b), 39 (1) (a), 41 and 71 (the general regulation-making power) and clauses 1 (1) and 3 (2) of Schedule 1.

Parts 1 and 4 and clauses 4–8 of this Regulation comprise or relate to matters set out in Schedule 3 to the *Subordinate Legislation Act 1989*, namely matters of a machinery nature, matters of a savings or transitional nature and matters that are not likely to impose an appreciable burden, cost or disadvantage on any sector of the public.

---

## Contents

	Page
<b>Part 1 Preliminary</b>	
1 Name of Regulation	4
2 Commencement	4
3 Definitions	4
<b>Part 2 Registration and provision of services</b>	
4 Fee to accompany application for registration	6
5 Additional matters to be included in application	6
6 Annual registration fee	6
7 Notice to Director-General of event or change in particulars	6
8 Infection control standards	7
9 Qualifications of counsellors	7
10 Establishing whether gamete provider is still alive	7
<b>Part 3 Information and records</b>	
11 Information to be provided to another ART provider	8
12 Information to be collected when obtaining gametes	8
13 Records to be kept by ART provider	9
14 Information required to be provided by ART providers	9
15 Information to be entered in the central ART donor register	10
16 Disclosure of information from central ART donor register	11
17 Fees for applications or notices	11
<b>Part 4 Miscellaneous</b>	
18 Storage of gamete obtained before commencement of Act	12
19 Transitional provision—consent to create embryo	12
20 Transitional provision—maximum number of families	12

## 2009 No 323

Clause 1 Assisted Reproductive Technology Regulation 2009

Part 1 Preliminary

---

## Assisted Reproductive Technology Regulation 2009

under the

Assisted Reproductive Technology Act 2007

### Part 1 Preliminary

#### 1 Name of Regulation

This Regulation is the *Assisted Reproductive Technology Regulation 2009*.

#### 2 Commencement

This Regulation commences on 1 January 2010 and is required to be published on the NSW legislation website.

#### 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.

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

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

## **2009 No 323**

Clause 4 Assisted Reproductive Technology Regulation 2009

Part 2 Registration and provision of services

---

### **Part 2 Registration and provision of services**

#### **4 Fee to accompany application for registration**

For the purposes of section 7 (2) of the Act, the prescribed fee that must accompany an application for registration is \$2,500.

#### **5 Additional matters to be included in application**

For the purposes of section 7 (3) (e) of the Act, 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**

For the purposes of section 7 (8) of the Act:

- (a) the prescribed annual registration fee is \$1,770, and
- (b) the annual registration fee for a year must be paid before the anniversary, in that year, of the registration of the ART provider.

#### **7 Notice to Director-General of event or change in particulars**

For the purposes of section 8 (1) (e) of the Act, a registered ART provider must give notice 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

For the purposes of section 10 of the Act, an ART provider who does not have federal accreditation must meet the infection control standards set out in:

- (a) the *Infection Control Policy* (ISBN 9781 1 74187 204 0) published by the Department in 2007, or
- (b) a publication of the Department that replaces that Policy.

## 9 Qualifications of counsellors

For the purposes of section 12 (2) (b) of the Act, a person is qualified to provide counselling services if the person is:

- (a) registered as a 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 still alive

- (1) For the purposes of section 24 (3) (b) of the Act, 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 a Territory, and
  - (b) the ART provider obtains a certificate from the registering authority of that State or Territory under a corresponding registration law as to whether the death of the gamete provider has been recorded in the register kept under that corresponding registration law.
- (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.

## 2009 No 323

Clause 11 Assisted Reproductive Technology Regulation 2009

Part 3 Information and records

---

### Part 3 Information and records

#### 11 Information to be provided to another ART provider

For the purposes of section 27 (4) (c) of the Act, an ART provider must provide the following information in relation to a donor of a gamete:

- (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 which 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

- (1) For the purposes of section 30 (1) of the Act, 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) For the purposes of section 30 (1) of the Act, an ART provider, who obtains a donated gamete from a donor, must obtain the following:
  - (a) the full name of the donor,
  - (b) the residential address of the donor,
  - (c) the date and place of birth of the donor,
  - (d) the ethnicity and physical characteristics of the donor,
  - (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.



- (3) For the purposes of section 30 (2) or (3) of the Act, an ART provider is taken to have obtained any information required to be obtained by those subsections in relation to a donated gamete that was obtained from a donor before the commencement of section 30 of the Act if:
- (a) an embryo was created using the donated gamete before that commencement and the embryo is used to provide ART treatment to a woman within 5 years after that commencement, or
  - (b) the gamete is used to provide ART treatment to a woman within 3 years after that commencement and the woman has, before that commencement, already conceived an offspring as a result of ART treatment using a donated gamete from the donor.

### **13 Records to be kept by ART provider**

- (1) For the purposes of section 31 (1) (a) (i) of the Act, an ART provider must keep a record of the information required to be obtained under clause 12 and the date on which the information was obtained.
- (2) For the purposes of section 31 (1) (c) of the Act, an ART provider must keep a record of:
- (a) the full name, sex and date of birth of each offspring born as a result of ART treatment, provided by the ART provider, and
  - (b) the name of the woman who gave birth to the offspring, and
  - (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 of the gamete.
- (3) An ART provider is not required to keep records under section 31 of the Act, in relation to the following gametes or embryos:
- (a) an embryo that was created using a donated gamete before the commencement of that section if the embryo is used to provide ART treatment to a woman within 5 years after that commencement, or
  - (b) a donated gamete that was obtained from a donor before the commencement of that section if the gamete is used to provide ART treatment to a woman within 3 years after that commencement and the woman has, before that commencement, already conceived an offspring as a result of ART treatment using a donated gamete from the donor.

### **14 Information required to be provided by ART providers**

For the purposes of section 33 (5) of the Act, an ART provider must provide to the Director-General, 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:

## 2009 No 323

Clause 15 Assisted Reproductive Technology Regulation 2009

Part 3 Information and records

---

- (a) the records in relation to the gamete that the ART provider is required to keep under section 31 (1) (a) (i) and (iii) of the Act, and
- (b) the records in relation to the offspring that the ART provider is required to keep under section 31 (1) (c) of the Act.

Maximum penalty: 10 penalty units.

**Note.** Section 31 (1) (a) (i) and (iii) of the Act requires an ART provider to keep, in relation to each gamete or embryo in the ART provider's possession, records of:

- (a) the identity of each gamete provider and any other prescribed information (being the information required to be obtained under clause 12) about the gamete provider, the gamete provider's spouse (if any) and any offspring of the gamete provider, and
- (b) the gamete provider's consent in relation to any such gamete or embryo.

Section 31 (1) (c) of the Act requires an ART provider to keep a record of the identity and any other prescribed information (being the information required to be recorded under clause 13 (2)) about each offspring born as a result of ART treatment provided by the ART provider.

### 15 Information to be entered in the central ART donor register

- (1) For the purposes of section 33 (2) of the Act, the Director-General is to enter the following in the central ART donor register:
  - (a) information provided to the Director-General under clause 14 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 that is provided voluntarily by a donor in relation to a gamete that was donated before the commencement of section 33 of the Act:
    - (i) information referred to in clause 12 (2) (a)–(e) or (g),
    - (ii) the name of the ART provider to whom the gamete was provided,
    - (iii) the date on which the gamete was provided,
  - (d) any of the following information that may be provided voluntarily by the offspring of a donor:
    - (i) the sex, full name, residential address and date and place of birth 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 Director-General may, if satisfied that an entry in the register is incorrect, amend or add a notation to the entry.

**16 Disclosure of information from central ART donor register**

For the purposes of sections 37 (1) and (2) (a), 38 (1) (a) and (b) and 39 (1) (a) of the Act, the Director-General is to disclose, to the following persons, the following information as recorded on the central ART donor register:

- (a) to an adult who was born as a result of ART treatment using a donated gamete—information specified in clause 12 (2) (a)–(e) in relation to the donor of the gamete and the name of the ART provider who supplied 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—information specified in clause 12 (2) (d) and (e) in relation to the donor of the gamete 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.

**17 Fees for applications or notices**

For the purposes of section 41 of the Act, the prescribed fee in relation to an application or notice under Part 3 of, or clause 4 of Schedule 1 to, the Act is \$50.

## 2009 No 323

Clause 18 Assisted Reproductive Technology Regulation 2009

Part 4 Miscellaneous

---

### Part 4 Miscellaneous

#### 18 Storage of gamete obtained before commencement of Act

- (1) For the purposes of clause 3 (2) of Schedule 1 to the Act, an ART provider must not store a donated gamete that was obtained from a donor before the commencement of section 25 of the Act for any longer than 10 years after the date the gamete was obtained from the donor or such longer period as may be authorised by the Director-General under this clause.

Maximum penalty: 10 penalty units.

- (2) The Director-General may give written authorisation for a donated gamete to be stored for a period longer than 10 years, if satisfied that there are reasonable grounds for doing so having regard to any relevant guidelines issued by the Director-General from time to time.

#### 19 Transitional provision—consent to create embryo

- (1) Consent is taken to be provided for the use of a donated gamete, obtained from a donor before the commencement of section 18 of the Act, to create an embryo outside the body of a woman, if:
  - (a) the embryo is used to provide ART treatment to a woman within 3 years after that commencement, and
  - (b) the woman has, before that commencement, conceived an offspring as a result of ART treatment using a donated gamete from the donor.
- (2) Consent that is taken to be provided under subclause (1) may be modified or revoked in accordance with section 17 of the Act.

#### 20 Transitional provision—maximum number of families

Section 27 (1) of the Act does not prevent the ART treatment of a woman if the gamete used in the treatment of the woman is a donated gamete that was obtained from a donor before the commencement of that subsection and:

- (a) an embryo was created using the donated gamete before that commencement and the embryo is used to provide the ART treatment to the woman within 5 years after that commencement, or
- (b) the gamete is used to provide the ART treatment to the woman within 3 years after that commencement and the woman has, before that commencement, already conceived an offspring as a result of ART treatment using a donated gamete from the donor.