

EXPLANATORY STATEMENT
Issued by the Authority of the Minister for Regional Health, Regional
Communications and Local Government

Australian Organ and Tissue Donation and Transplantation Authority Act 2008

Australian Organ and Tissue Donation and Transplantation Authority Regulations
2020

Section 60 of the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (the Act) provides that the Governor-General may make regulations prescribing matters required or permitted to be prescribed by the Act; or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Act established the Australian Organ and Tissue Donation and Transplantation Authority (the Authority) on 1 January 2009, to implement a new national approach to provide access to transplants and improve transplant outcomes for Australians.

The *Australian Organ and Tissue Donation and Transplantation Authority Regulations 2009* (the AOTDTA Regulations), which are the Principal Regulations for the Authority, sunset on 1 April 2020. The purpose of the *Australian Organ and Tissue Donation and Transplantation Authority Regulations 2020* (the Regulations) is to remake the AOTDTA Regulations. No changes to the substantive meaning or operation of the AOTDTA Regulations are made apart from minor updates in the drafting style to align with current drafting practices. The Regulations specify exclusions to the definition of tissue, prescribe an alternative name for the Authority and specify additional individuals authorised to give consent to the publication or dissemination of patient information for a donor who is under 18 years of age, for the purposes of paragraph 58(2)(c) of the Act.

Details of the Regulations are set out in the [Attachment](#).

The Authority has been consulted on the content of the Regulations and agreed with remaking the Regulations without substantial amendment.

The Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after registration on the Federal Register of Legislative Instruments.

Details of the Australian Organ and Tissue Donation and Transplantation Authority Regulations 2020

1 Name of Regulations

Section 1 provides for the Regulations to be referred to as the *Australian Organ and Tissue Donation and Transplantation Authority Regulations 2020*.

2 Commencement

Section 2 provides that the Regulations commence on the day after they are registered on the Federal Register of Legislative Instruments.

3 Authority

Section 3 provides that the Regulations are made under the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008*.

4 Schedules

Section 4 provides that the Regulations repeal the existing *Australian Organ and Tissue Donation and Transplantation Authority Regulations 2009*.

5 Definitions

Section 5 provides that ‘Act’ means the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* in these Regulations.

6 Substances that are not tissue

Section 6 provides that the definition of *tissue* in section 4 of the Act does not include the following substances:

- (a) blood or blood products, including progenitor cells such as in cord blood and bone marrow;
- (b) reproductive tissue, including sperm and eggs;
- (c) foetal tissue;
- (d) stem cell tissue.

7 Alternative name for the Authority

Section 7 provides that the Authority may also be known as the ‘Organ and Tissue Authority’ in accordance with subsection 8(2) of the Act.

As the current name of the Authority is relatively long (noting that the legal title covers both the organ and tissue donation and transplantation sectors), section 8(2) of the Act provides that the Authority may also be commonly known by another shorter name. The name provided becomes the operational name of the Authority.

8 Patient confidentiality – authorised persons

Section 8 provides that if a donor is less than 18 years old, the parent or legal guardian of the donor is authorised to give consent to the publication or dissemination of information, in accordance with paragraph 58(2)(c) of the Act.

Currently the Act refers to individuals authorised to give consent if a donor is over 18 years old or deceased however does not identify individuals authorised to give consent if a donor is less than 18 years old.

Schedule 1 Repeals

Australian Organ and Tissue Donation and Transplantation Authority Regulations 2009

Item 1 – The whole of the Instrument

Item 1 repeals the existing *Australian Organ and Tissue Donation and Transplantation Authority Regulations 2009*.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Australian Organ and Tissue Donation and Transplantation Authority Regulations 2020

This Disallowable Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (the Act) established the Australian Organ and Tissue Donation and Transplantation Authority (the Authority) on 1 January 2009 to implement a new national approach to provide access to transplants and improved transplant outcomes for Australians.

Section 60 of the Act provides that the Governor-General may make Regulations prescribing matters required or permitted to be prescribed by the Act; or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Australian Organ and Tissue Donation and Transplantation Authority Regulations 2009* (the AOTDTA Regulations), which are the Principal Regulations for the Authority, sunset on 1 April 2020. The purpose of the *Australian Organ and Tissue Donation and Transplantation Authority Regulations 2020* (the Regulations) is to remake the AOTDTA Regulations. No changes to the substantive meaning or operation of the AOTDTA Regulations are made apart from minor updates in the drafting style to align with current drafting practices. The Regulations specify exclusions to the definition of tissue, prescribe an alternative name for the Authority and specify additional individuals authorised to give consent to the publication or dissemination of patient information for a donor who is under 18 years of age, for the purposes of paragraph 58(2)(c) of the Act.

Human rights implications

The Regulations do not engage any of the applicable rights or freedoms because the Regulations only prescribe the matters required to give effect to the Act.

Conclusion

The Regulations are compatible with human rights as they do not raise any human rights issues.

**The Hon Mark Coulton MP, the Minister for Regional Health, Regional
Communications and Local Government**