

Transplantation and Anatomy Regulation 2017

Explanatory notes for SL 2017 No. 148

made under the

Transplantation and Anatomy Act 1979

General Outline

Short title

Transplantation and Anatomy Regulation 2017

Authorising law

Section 52 of the *Transplantation and Anatomy Act 1979*

Policy objectives and the reasons for them

The *Transplantation and Anatomy Act 1979* (the Act) regulates:

- donation of human tissue for transplantation, therapeutic, medical and scientific purposes
- authorisation of post-mortem examinations
- donation of bodies for anatomical purposes
- schools of anatomy at Queensland universities
- trade in human tissue, and
- determination of death.

The Act is supported by the *Transplantation and Anatomy Regulation 2004* (the 2004 Regulation) which:

- regulates how schools of anatomy receive, register and dispose of bodies
- prescribes tissue banks which are exempt from the general prohibition on trading in tissue in the Act for certain purposes, and
- prescribes the specialist qualifications required for a medical practitioner to co-certify brain death.

The 2004 Regulation is due to expire on 31 August 2017. The policy objective is to remake the 2004 Regulation as the *Transplantation and Anatomy Regulation 2017* (the 2017 Regulation).

The 2017 Regulation is being remade to be largely consistent with the 2004 Regulation. However, minor amendments have been included to ensure the regulation is up-to-date, supports the Act's objectives and aligns with modern drafting practice.

Achievement of policy objectives

The 2017 Regulation continues to support the Act's objectives by:

- regulating schools of anatomy in Queensland universities (the Act, part 5) by:
 - requiring the person in charge of a school of anatomy to obtain authorising documents before accepting the body of a deceased person donated under the Act
 - setting out requirements for the disposal of a body or part of a body by a school of anatomy, such as ensuring it is disposed of as soon as possible after the period for which it was authorised to be kept
 - requiring registers of bodies to be kept and records maintained to record the receipt, movement, lending, borrowing and disposal of bodies and the assignment of identifiers to bodies
- prescribing tissue banks which are exempt from the general prohibition on trading in tissue in the Act to enable them to recover reasonable costs associated with tissue removal and handling activities, including processing and storing donated tissue (the Act, section 42A(1))
- prescribing the Australian Bone Marrow Donor Registry as an entity which is exempt from the general prohibition on trading in tissue in the Act because it is a party to an agreement with the Commonwealth for trading in certain types of tissue (the Act, section 42AB), and
- prescribing the qualifications required for medical practitioners to co-certify the irreversible cessation of all function of the brain in order to establish the death of a person for the purposes of the Act (the Act, section 45(2)).

Clause 12 updates the list of prescribed tissue banks by removing the reference to the Queensland Skin Bank. It is no longer necessary to refer to the Queensland Skin Bank as, under Therapeutic Goods and Administration licencing arrangements, it forms part of the Queensland Bone Bank.

The 2017 Regulation also includes technical changes to reflect contemporary drafting practices.

Consistency with policy objectives of authorising law

The 2017 Regulation is consistent with the policy objectives of the authorising Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

The Act specifies that certain matters must be prescribed in regulations. As such, the 2017 Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

Implementation of the 2017 Regulation will be met within existing budget allocations.

Consistency with fundamental legislative principles

The 2017 Regulation is consistent with fundamental legislative principles.

Consultation

As the 2017 Regulation remakes the 2004 Regulation with no underlying policy changes, it was not considered necessary to undertake stakeholder consultation about the remake.

Notes on provisions

Part 1 Preliminary

Short title

Clause 1 provides the short title of the regulation is the *Transplantation and Anatomy Regulation 2017* (the 2017 Regulation).

Commencement

Clause 2 provides that the 2017 Regulation commences on 1 September 2017.

Definitions

Clause 3 provides that particular words are defined in the dictionary in schedule 1.

Part 2 Schools of anatomy

Division 1 Receiving bodies

Receiving a body at a school of anatomy

Clause 4 outlines the documents a person in charge of a school of anatomy that accepts donated bodies (an accepting school) must obtain before accepting the body of a deceased person for the school. The authorising documents are:

- a copy of the cause of death certificate (as defined in the *Births, Deaths and Marriages Registration Act 2003*, section 30) for the deceased person
- the authority for the retention of the body under part 5 of the *Transplantation and Anatomy Act 1979* (the Act). ‘Authority’ is defined in schedule 1 of the 2017 Regulation
- a Coroner’s consent under section 34(2) or (3) of the Act for retention of the body, if the Coroner has given a consent under those provisions, and
- any direction by a Coroner under section 34(4) of the Act that a consent under section 34(2) or (3) of the Act is not required.

If a Coroner has put a condition on a consent for the retention of a body, or on a direction that consent is not required, the person in charge of the accepting school must be satisfied the condition is complied with before accepting the body.

A maximum penalty of 10 penalty units (maximum \$1261.50 at commencement) applies if the person in charge of an accepting school does not obtain the correct documents before accepting a body of a deceased person.

Division 2 Disposing of bodies

Definition for division

Clause 5 provides a definition for **body** of a deceased person for part 2, division 2 of the 2017 Regulation. In this division, the term body includes a part of the body.

Disposal of a body by an accepting school

Clause 6 provides for the disposal of a body by an accepting school. The person in charge of the accepting school must dispose of the body as soon as possible after the period for which the body was authorised to be retained, or otherwise as soon as possible after the body has been used for the purpose for which the retention was authorised.

The disposal must include making arrangements for cremation or burial of the body.

The clause also provides that if a deceased person has given written instructions about the disposal of their body, the person in charge of the accepting school must, to the extent it is reasonably practicable, dispose of the body in accordance with the instructions.

A maximum penalty of 10 penalty units (maximum of \$1261.50 at the commencement) applies for failure by the person in charge of the accepting school to dispose of a body within the required timeframes, and for failure by the person in charge of the accepting school to, if reasonably practicable, dispose of the deceased person's body in accordance with the deceased person's instructions.

Returning a body or part to a lending school for disposal

Clause 7 requires a school of anatomy that borrowed a body or part of a body of a deceased person (described as a borrowing school), to return the body or the part of a body to the school of anatomy that loaned it when required to do so by the lending school.

A maximum penalty of 10 penalty units (maximum of \$1261.50 at the commencement) applies for failure to comply with the requirements of this clause.

Division 3 Records

Register of bodies – accepting schools

Clause 8 requires the person in charge of an accepting school to keep a register of bodies accepted at the school.

The register must include, in relation to each body:

- the name, age, sex and last address of the deceased person
- the day and place of death
- the day and time the body was received
- the name of the person or entity from whom the body was received
- the name of the individual who delivered the body

- the type of authority for the donation of the body
- the name of the individual who obtained the authorising documents ('authorising documents' is defined in clause 4(1)(a))
- the name of the individual who received the body
- the school of anatomy's unique identifier assigned to the body
- any specific period for which retention of the body is authorised, and
- a summary of any written instructions by the deceased person during their lifetime about the disposal of the person's body.

The person in charge of the accepting school must ensure these particulars are recorded in the register as soon as possible after the body is received at the school.

The register must also include:

- the day and time the body was removed from the accepting school for disposal
- the name of the individual who allowed the removal of the body for disposal
- the name of the person or entity who removed the body for disposal, and
- the name of the individual who removed the body for the above person or entity.

The person in charge of the accepting school must ensure these particulars are recorded in the register as soon as possible after the body is removed from the accepting school for disposal.

The register must also include the day, place and method of disposal of the body. The person in charge of the accepting school must ensure these particulars are recorded in the register as soon as possible after disposal of the body.

If the accepting school lends a body to a borrowing school, the register must also include:

- the name of the borrowing school
- the day and time the body was removed from the accepting school for the loan
- the name of the individual who allowed the removal of the body from the accepting school
- the day and time the body was received by the borrowing school, and
- the name of the individual from the borrowing school who received the body.

The person in charge of the accepting school that loaned a body must include these particulars in the register as soon as possible after the body is received by the borrowing school.

The register must also include:

- the day and time the body was returned to the accepting school
- the name of the individual from the borrowing school who allowed the return of the body, and
- the name of the individual from the accepting school who received the returned body.

The person in charge of the accepting school that loaned the body must include these particulars in the register as soon as possible after the body is returned.

A maximum penalty of 10 penalty units (maximum of \$1261.50 at the commencement) applies for failure of the person in charge of an accepting school to keep the register and for failure of the person in charge of an accepting school to comply with each of the requirements of clause 8.

Register of bodies – borrowing schools

Clause 9 requires the person in charge of a borrowing school to keep a register for the bodies it receives. The register must include, in relation to each body:

- the name of the school of anatomy that loaned the body (the lending school)
- the lending school's unique identifier for the body
- the name of the individual from the lending school who allowed the removal of the body
- the name of the individual from the borrowing school who received the body
- the day and time the body was received by the borrowing school.

The person in charge of the borrowing school must ensure these particulars are recorded in the register as soon as possible after the body is received at the borrowing school.

The register must also include:

- the day and time the body was returned to the lending school
- the name of the individual from the borrowing school who allowed the return of the body to the lending school, and
- the name of the individual from the lending school who received the body.

The person in charge of the borrowing school must ensure these particulars are recorded in the register as soon as possible after the body is returned to the lending school.

A maximum penalty of 10 penalty units (maximum of \$1261.50 at the commencement) applies for failure of the person in charge of a borrowing school to keep the register and for failure of the person in charge of an accepting school to comply with each of the requirements of clause 9.

Tracking records

Clause 10 requires records to be kept for tracking the location of bodies and parts of bodies. The person in charge of an accepting school must keep a record of:

- the school's unique identifier assigned to each body accepted by it
- the current location of each body accepted by it
- the unique identifier of any part of a body removed from a body accepted by it, and
- the current location of any part of a body removed from a body accepted by it.

A maximum penalty of 10 penalty units (maximum \$1261.50 at the commencement) applies for failure of the person in charge of an accepting school to record these details.

The clause also places responsibility on the person in charge of a borrowing school to record the following details if they have received a body or part of a body from a lending school:

- the lending school's unique identifier of the body or the part of a body, and
- the current location of the body or the part of the body.

A maximum penalty of 10 penalty units (maximum \$1261.50 at the commencement) applies for failure of the person in charge of a borrowing school to record these details.

Production of documents for inspection

Clause 11 gives an inspector of a school of anatomy the power to require the person in charge of the school of anatomy to produce an authorising document, a register required to be kept under section 8 or 9 or a record required to be kept under section 10.

The person in charge must produce the requested document, register or record unless they have a reasonable excuse. A maximum penalty of 10 penalty units (maximum \$1261.50 at the commencement) applies for failure to comply with the inspector's requirement.

Part 3 Miscellaneous

Prescribed tissue banks

Clause 12 prescribes the following entities for the definition of 'tissue bank' in section 42A(6) of the Act:

- Queensland Bone Bank
- Queensland Eye Bank
- Queensland Heart Valve Bank
- Australian Red Cross Blood Service – for blood and blood products derived from blood, for medical and scientific purposes.

These entities are prescribed as tissue banks for the purposes of section 42A of the Act. The effect is that these entities can, despite the Act's prohibition on trade in tissue:

- charge an amount to recover their reasonable costs associated with removing, evaluating, processing, storing or distributing donated tissue (a 'cost-recovery amount')
- sell, agree to sell, offer to sell or hold themselves out as being willing to sell donated tissue for a cost-recovery amount, and
- inquire whether a person is willing to buy donated tissue for a cost-recovery amount.

Exempt entity – Act, s 42AB

Clause 13 prescribes the Australian Bone Marrow Donor Registry as an 'exempt entity' for section 42AB(2) of the Act.

The Act prohibits buying tissue (including advertising to buy) and selling tissue (including holding out to sell), but makes provision for certain exceptions.

Section 42AB of the Act provides, in part, that trading in tissue is permitted if carried out by an exempt entity and the tissue is the subject of an agreement between the exempt entity and the Commonwealth or State government. Prescribing the Australian Bone Marrow Donor Registry as an exempt entity for section 42AB ensures it can fulfil its agreement with the Commonwealth Department of Health in relation to trading in tissue.

Prescribed qualifications for medical practitioners certifying death

Clause 14 prescribes the specialist qualifications required by a medical practitioner in order to co-certify brain death, for section 45(2) of the Act.

For the purposes of the Act, section 45(1) provides that a person dies when there is either irreversible cessation of circulation of blood in the person or irreversible cessation of all function of the brain of the person. Irreversible cessation of all function of the brain must be certified by two medical practitioners. One of these medical practitioners must be a specialist neurologist or neurosurgeon, or otherwise must be registered under the Health Practitioner Regulation National Law as a specialist health practitioner in one of the medical specialties or specialty fields prescribed in this clause.

Part 4 Transitional provisions

Definitions for part

Clause 15 defines the terms ‘former regulation’ and ‘new’ for the purpose of this part.

Registers and records kept under former regulation

Clause 16 provides that:

- a register kept by an accepting school under section 8 of the *Transplantation and Anatomy Regulation 2004* is taken to be a register kept under section 8 of this regulation
- a register kept by a borrowing school under section 9 of the *Transplantation and Anatomy Regulation 2004* is taken to be a register kept under section 9 of this regulation
- a record kept by an accepting school for a body or a part of a body under section 10(1) of the *Transplantation and Anatomy Regulation 2004* is taken to be a record kept under section 10(1) of this regulation, and
- a record kept by a borrowing school for a body or a part of a body under section 10(2) of the *Transplantation and Anatomy Regulation 2004* is taken to be a record kept under section 10(2) of this regulation.

Application of transitional provisions under expired regulation

Clause 17 continues the operation of sections 15 and 16 of the *Transplantation and Anatomy Regulation 2004*, despite their expiry. The effect of this is that the register requirements under clause 8 (for an accepting school) and clause 9 (for a borrowing school) of the 2017 Regulation do not apply if a school of anatomy still has in its possession a body or part of a body accepted or borrowed under the *Transplantation and Anatomy Regulation 1994*.

References to former regulation

Clause 18 provides that a reference to the *Transplantation and Anatomy Regulation 2004* in any document may, if the context permits, be taken to be a reference to the 2017 Regulation. This does not limit the application of section 14H of the *Acts Interpretation Act 1954*.

Schedule 1 Dictionary

Schedule 1 defines terms for the purposes of the 2017 Regulation.

© The State of Queensland 2017