



Western Australia

Human Tissue and Transplant Amendment Act 2022

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Human Tissue and Transplant Amendment Act 2022

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Western Australia

Human Tissue and Transplant Amendment Act 2022

No. 41 of 2022

An Act to —

- **amend the *Human Tissue and Transplant Act 1982*; and**
- **make consequential amendments to the *Anatomy Act 1930* and the *Health Legislation Administration Act 1984*.**

[Assented to 21 November 2022]

The Parliament of Western Australia enacts as follows:

Part 1 — Preliminary

1. Short title

This is the *Human Tissue and Transplant Amendment Act 2022*.

2. Commencement

This Act comes into operation as follows —

- (a) Part 1 — on the day on which this Act receives the Royal Assent (*assent day*);
- (b) Part 2 (but only Divisions 1 and 2) and Part 3 — on the day after assent day;
- (c) Part 2 Division 3 — on a day fixed by proclamation, and different days may be fixed for different provisions.

**Part 2 — *Human Tissue and Transplant Act 1982*
amended**

Division 1 — Preliminary

3. Act amended

This Part amends the *Human Tissue and Transplant Act 1982*.

Division 2 — General amendments

4. Long title replaced

Delete the long title and insert:

An Act to make provision —

- **for and in relation to the removal of human tissue for transplantation and other purposes; and**
- **for post-mortem examinations; and**
- **for related purposes.**

5. Part I heading amended

In the heading to Part I delete “**Part I**” and insert:

Part 1

6. Section 3 amended

In section 3(1) insert in alphabetical order:

human egg has the meaning given in the *Human Reproductive Technology Act 1991* section 3(1);

human embryo has the meaning given in the *Human Reproductive Technology Act 1991* section 3A;

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Division 2 General amendments

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human sperm has the meaning given in the *Human Reproductive Technology Act 1991* section 3(1);

7. Section 4 amended

- (1) In section 4(1) delete “by writing signed by him”.
- (2) After section 4(1) insert:
 - (1A) The nomination must be in writing signed by the chief medical administrator of the hospital.
- (3) In section 4(5) delete “notice of the revocation signed by him.” and insert:

signed notice of the revocation.

8. Section 5 amended

- (1) In section 5(1) delete “by writing signed by him, delegate to one or more persons any of his powers or duties” and insert:

delegate to 1 or more persons any powers or duties of the designated officer
- (2) After section 5(1) insert:
 - (1A) The delegation must be in writing signed by the designated officer.

(3) Delete section 5(3)(b) and insert:

- (b) has immediate effect, unless the instrument of delegation provides otherwise, and continues in force until revoked by writing signed by the designated officer and given to the delegate.

(4) Delete section 5(5) and insert:

- (5) The Chief Health Officer may require the designated officer to revoke a delegation made by the designated officer and the designated officer must immediately comply with the requirement.
- (5A) A requirement under subsection (5) must —
 - (a) be in writing signed by the Chief Health Officer; and
 - (b) be given to the designated officer.

9. Section 5A inserted

At the end of Part I insert:

5A. Delegation by Minister

- (1) The Minister may delegate to a person any power or duty of the Minister under another provision of this Act.
- (2) The delegation must be in writing signed by the Minister.
- (3) A person to whom a power or duty is delegated under this section cannot delegate that power or duty.

- (4) A person exercising or performing a power or duty that has been delegated to the person under this section is taken to do so in accordance with the terms of the delegation unless the contrary is shown.
- (5) Nothing in this section limits the ability of the Minister to perform a function through an officer or agent.

10. Part II heading amended

In the heading to Part II delete “**Part II**” and insert:

Part 2

11. Section 6 amended

In section 6 delete “shall not be read as including a reference to foetal tissue, spermatozoa or ova.” and insert:

does not include a reference to fetal tissue, a human embryo, human sperm or a human egg.

12. Section 8 amended

- (1) Delete section 8(1) and insert:

- (1) This section applies to a person who —
 - (a) has attained the age of 18 years; and
 - (b) is of sound mind; and
 - (c) is, in the light of medical advice furnished to the person, prepared to consent as referred to in subsection (1A).

- (1A) The person may, by writing signed by the person otherwise than in the presence of any member of the person's family or any of the person's friends, consent to the removal from the person's body of regenerative tissue, other than blood, specified in the consent —
- (a) for the purpose of the transplantation of the tissue to the body of another living person; or
 - (b) for use of the tissue for other therapeutic purposes or for medical or scientific purposes; or
 - (c) for use of the tissue for the purposes of training, education or quality assurance relating to a use referred to in paragraph (b).

- (2) In section 8(2) delete “subsection (1)” and insert:

subsection (1A)

13. Section 15 amended

In section 15:

- (a) in paragraph (b) delete “purposes.” and insert:

purposes; or
- (b) after paragraph (b) insert:

 - (c) for use of the tissue for the purposes of training, education or quality assurance relating to a use referred to in paragraph (b).

14. Section 18 replaced

Delete section 18 and insert:

18. Consent by adult to removal of blood

- (1) This section applies to a person who —
 - (a) has attained the age of 18 years; and
 - (b) is of sound mind.
- (2) The person may consent to the removal of blood from the person's body —
 - (a) for transfusion of the blood to another person;
or
 - (b) for use of the blood or of any of its constituents for other therapeutic purposes or for medical or scientific purposes; or
 - (c) for use of the blood or of any of its constituents for the purposes of training, education or quality assurance relating to a use referred to in paragraph (b).

15. Section 19 amended

In section 19 delete “section 18” and insert:

section 18(2)

16. Part III heading amended

In the heading to Part III delete “**Part III**” and insert:

Part 3

17. Section 21A inserted

At the beginning of Part III insert:

21A. No application to *Anatomy Act 1930*

Nothing in this Part applies to the removal of tissue for the purpose of the practice of anatomy under the *Anatomy Act 1930*.

18. Section 22 amended

In section 22(1):

(a) in paragraph (b) delete “purposes.” and insert:

purposes; or

(b) after paragraph (b) insert:

(c) for use of the tissue for the purposes of training, education or quality assurance relating to a use referred to in paragraph (b).

19. Section 24 amended

(1) Delete section 24(1) and insert:

(1) In this section —

permitted practitioner, in relation to an authority under this Part, means a medical practitioner other than —

(a) if subsection (2) applies — a medical practitioner who made a declaration under that subsection relating to the authority; or

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- (b) the designated officer for the hospital in which the authority was given or a person who has lawfully exercised the designated officer's powers under section 22;

permitted purpose or use, in relation to the removal of tissue, means —

- (a) the purpose of the transplantation of the tissue to the body of a living person; or
- (b) use of the tissue for other therapeutic purposes or for medical or scientific purposes; or
- (c) use of the tissue for the purposes of training, education or quality assurance relating to a use referred to in paragraph (b).

(1A) Subject to subsection (2), an authority under this Part is sufficient authority for the removal of tissue from the body of the deceased person referred to in the authority, for a permitted purpose or use, by —

- (a) if the tissue to be removed is ocular tissue —
 - (i) a permitted practitioner; or
 - (ii) a person appointed under section 24A(1) as an authorised person for the purposes of this paragraph;

or

- (b) if the tissue to be removed is musculoskeletal tissue —
 - (i) a permitted practitioner; or
 - (ii) a person appointed under section 24A(1) as an authorised person for the purposes of this paragraph;

or

- (c) if the tissue to be removed is skin —
 - (i) a permitted practitioner; or

(ii) a person appointed under section 24A(1) as an authorised person for the purposes of this paragraph;

or

(d) in any other case — a permitted practitioner.

(1B) An authority under this Part is subject to any restriction that applies in relation to the authority by reason of section 22(3).

(2) In section 24(2) delete “tissue shall not be removed from the body of the person for the purpose or a use specified in subsection (1)” and insert:

tissue must not be removed from the body of the person for a permitted purpose or use

(3) Delete section 24(4).

20. Section 24A inserted

At the end of Part III insert:

24A. Appointment of authorised persons

- (1) The Minister may, in writing, appoint a person, or a person in a class of person, to be an authorised person for the purposes of any 1 or more of section 24(1A)(a)(ii), (b)(ii) or (c)(ii).
- (2) A person cannot be an authorised person if the person is a medical practitioner.
- (3) The Minister may, in writing, revoke an appointment made under subsection (1) if the Minister considers it appropriate to do so.

- (4) If, immediately before the day on which the *Human Tissue and Transplant Amendment Act 2022* section 20 comes into operation, a person is an authorised person for the purposes of section 24 —
- (a) the person is taken to have been appointed under subsection (1) to be an authorised person for the purposes of section 24(1A)(a)(ii); and
 - (b) for the purposes of subsection (3), the person’s appointment is taken to be an appointment made under subsection (1).

21. Part IV heading amended

In the heading to Part IV delete “**Part IV**” and insert:

Part 4

22. Section 28 amended

Delete section 28(2) and insert:

- (2) An authority under this Part is authority for the use of tissue removed from the body of the deceased person as part of the post-mortem examination for the following purposes —
- (a) therapeutic, medical, teaching or scientific purposes;
 - (b) training, education or quality assurance relating to a use referred to in paragraph (a).

23. Part V heading replaced

Delete the heading to Part V and insert:

Part 5 — Trading in tissue

24. Part VA heading amended

In the heading to Part VA delete “**Part VA**” and insert:

Part 6

25. Part VI heading amended

In the heading to Part VI delete “**Part VI**” and insert:

Part 7

26. Section 33 amended

(1) In section 33(1):

(a) in paragraph (b) delete “section 18” and insert:

section 18(2)

(b) in paragraph (e) delete “in conducting” and insert:

except as authorised under Part 4, in conducting

- (2) In section 33(3):
- (a) delete “to —” and insert:

to the following —
 - (b) in paragraphs (a) and (b) delete “or”;
 - (c) after paragraph (b) insert:

(ba) anything done under the *Anatomy Act 1930*;

27. Section 37 inserted

At the end of Part VI insert:

37. Regulations may adopt codes or legislation

- (1) In this section —
- code* means a code, standard, rule, specification, administrative procedure or other document, published in or outside Australia, that does not by itself have legislative effect in this State;
- subsidiary legislation* includes rules, regulations, instructions, local laws and by-laws.
- (2) Regulations may adopt, either wholly or in part or with modifications —
- (a) any code; or
 - (b) any subsidiary legislation made, determined or issued under any other Act or under any Act of the Commonwealth, another State or a Territory.

- (3) The adoption may be by —
 - (a) incorporating the code or subsidiary legislation in the regulations; or
 - (b) incorporating the code or subsidiary legislation by reference.
- (4) If the regulations adopt a code or subsidiary legislation by reference, then, unless the regulations specify that a particular text is adopted —
 - (a) the code or subsidiary legislation is adopted as existing or in force when the regulations are made; and
 - (b) any amendments made to the code or subsidiary legislation after the regulations are made have no legal effect as part of the regulations unless they are specifically adopted by later regulations or a later amendment to the regulations.
- (5) Particulars of any code or subsidiary legislation adopted by reference must be published on, or accessible through, the website of the department principally assisting in the administration of this Act.

28. Various references to gender removed

Amend the provisions listed in the Table as set out in the Table.

Table

Provision	Delete	Insert
s. 4(2)	his	
s. 23(1)		
s. 27(1) and (2)		

Human Tissue and Transplant Amendment Act 2022**Part 2** Human Tissue and Transplant Act 1982 amended**Division 2** General amendments**s. 28**

s. 4(3)	him	the chief medical administrator
s. 4(5)	his	the
s. 5(4)	him	the designated officer
s. 5(6)	he	the designated officer
s. 8(2) s. 9(1) and (2) s. 25(2) and (3)	his (each occurrence)	the person's
s. 9(1)	him (each occurrence)	the person
s. 14	his body	the child's body
s. 14 s. 17	his consent	the consent
s. 17	his agreement	the child's agreement
s. 21(1)(c)(ii)	has, before commencing the transfusion, assured himself	is, before commencing the transfusion, satisfied
s. 21(3)	satisfies himself	is satisfied
s. 21(5)	he	the medical practitioner
s. 22(2)(a) s. 26(2)(a) and (3)	his lifetime	the person's lifetime

s. 22(2)(a) and (b)	his death of tissue from his body	death of tissue from the body of the deceased person
s. 22(4)	he consents	the senior available next of kin consents
s. 23(2) s. 27(3)	his consent	the coroner's consent
s. 25(4)	he has	the senior available next of kin has
s. 26(2)(a) and (3)	his body	the person's body
s. 26(2)(a)	his objection	the objection
s. 31(2)(a) and (b)	he	the person
s. 33(2)	his	the designated officer's

29. Other minor amendments

Amend the provisions listed in the Table as set out in the Table.

Table

Provision	Delete	Insert
s. 3(3)	shall be read as including	includes
s. 4(2)	shall be submitted	must be submitted
s. 4(2)	shall be the	is the
s. 4(2)	shall be subject	is subject

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s. 4(4) s. 22(4) s. 23(1) and (4) s. 24(3) s. 25(4) s. 27(1) and (5) s. 32B(2) and (5) s. 33(1) s. 34(1)	shall	must
s. 4(4b) s. 31(2)	shall be (each occurrence)	is
s. 5(4)	shall inform (each occurrence)	must inform
s. 5(4)	shall furnish	furnish
s. 11	shall not be read as including	does not include
s. 21(2)	shall be deemed	is taken
s. 32(2)	Part II	Part 2
s. 32A(4)	shall have	has
s. 32B(4) s. 33(1) and (2) s. 34(1)	Penalty:	Penalty for this subsection: a fine of
s. 33(1)(a)	Division 4 of Part II	Part 2 Division 4

s. 33(1)(b)	Division 5 of Part II	Part 2 Division 5
s. 33(1)(c)	Part III	Part 3
s. 33(1)(d)	Part IV	Part 4

Division 3 — Amendments relating to trading in tissue

30. Section 3 amended

In section 3(1) insert in alphabetical order:

Human Tissue Advisory Body means the body established under section 29F(1);

therapeutic goods has the meaning given in the Therapeutic Goods Act section 3(1);

Therapeutic Goods Act means the *Therapeutic Goods Act 1989* (Commonwealth);

31. Section 29 replaced

Delete section 29 and insert:

29. Part does not apply to trading regulated under *Human Reproductive Technology Act 1991*

This Part does not apply to or in relation to the sale or supply of a human embryo, human sperm or a human egg.

Note for this section:

The *Human Reproductive Technology Act 1991* section 53Q regulates the sale and supply of human embryos, human sperm and human eggs.

29A. Unauthorised trading in tissue prohibited

(1) In this section —

exempt entity, in relation to the sale or supply of tissue, means an entity prescribed by the regulations that is a party to an agreement with the Commonwealth or the State for the sale or supply of the tissue;

national product price list means the annual national product price list approved by the Ministerial Council under the National Blood Agreement (as defined in the *National Blood Authority Act 2003* (Commonwealth) section 3);

TGA provision means a provision of the Therapeutic Goods Act or any portion of regulations or rules made under that Act.

(2) Subject to subsection (4) and sections 29C, 29D(1) and 29E, a contract or arrangement is void if, under the contract or arrangement, a person agrees, for valuable consideration, whether given or to be given to that person or to another person —

(a) to the sale or supply of tissue from that person's body or from the body of another person, whether before or after that person's death or the death of the other person, as the case may be; or

(b) to the post-mortem examination or anatomical examination of that person's body after death or of the body of another person after the death of the other person.

(3) A person who enters into a contract or arrangement of the kind referred to in subsection (2) and to which that subsection applies commits an offence.

Penalty for this subsection: imprisonment for 12 months or a fine of \$12 000.

- (4) Except as provided in section 29D(2), subsection (2) does not apply to or in relation to the following contracts or arrangements —
- (a) a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with this Act;
 - (b) a contract or arrangement providing for the sale or supply of blood or any of its constituents included on the national product price list if the sale or supply is carried out by or with —
 - (i) an entity mentioned in the national product price list; or
 - (ii) the Commonwealth for the benefit of an entity mentioned in the national product price list;
 - (c) a contract or arrangement providing for the sale or supply of tissue if —
 - (i) the sale or supply is carried out by or with an exempt entity or the Commonwealth for the benefit of an exempt entity; and
 - (ii) the tissue is the subject of an agreement between the exempt entity and the Commonwealth or the State;
 - (d) a contract or arrangement providing for the sale or supply of therapeutic goods that comprise, contain or are derived from tissue if —
 - (i) the sale or supply is in accordance with an approval or authority given under a TGA provision; and
 - (ii) the TGA provision is prescribed by the regulations for the purposes of this paragraph;

- (e) a contract or arrangement providing for the sale or supply of therapeutic goods that comprise, contain or are derived from tissue if —
 - (i) the therapeutic goods are exempt under a TGA provision from the operation of Part 3.2 or Part 3.2A Division 4 of the Therapeutic Goods Act; and
 - (ii) the sale or supply does not breach a condition of the exemption; and
 - (iii) the TGA provision is prescribed for the purposes of this paragraph;
 - (f) a contract or arrangement providing for the sale or supply of tissue where the sale or supply of the tissue meets the requirements set out in section 29B(3).
- (5) Nothing in this section renders inoperative a consent or authority given or purporting to have been given under this Act in relation to tissue from the body of a person or in relation to the body of a person if a person acting in pursuance of the consent or authority did not know and had no reason to know that the tissue or the body was the subject matter of an unauthorised contract or arrangement.

29B. Recovery of certain costs by authorised suppliers

- (1) In this section —
- authorised supplier* means —
- (a) a person who supplies therapeutic goods that —
 - (i) comprise, contain or are derived from tissue; and
 - (ii) are included in the Register under the Therapeutic Goods Act or are registered goods under that Act;

or

- (b) a person who owns or controls a tissue bank;

tissue bank means a facility that is —

- (a) established for the purposes of the removal, evaluation, processing, storage and distribution of tissue, or any of those purposes; and
 - (b) prescribed by the regulations.
- (2) Regulations prescribing a facility as a tissue bank cannot be made unless —
- (a) the Human Tissue Advisory Body has recommended the making of the regulations; and
 - (b) the Minister has approved the recommendation.
- (3) For the purposes of section 29A(4)(f), the requirements for the sale or supply of the tissue are as follows —
- (a) the person selling or supplying the tissue must be an authorised supplier of the tissue;
 - (b) the authorised supplier must be satisfied, after making reasonable enquiries, that the first sale or supply of the tissue was not for valuable consideration other than reimbursement of any expenses necessarily incurred in relation to the removal of the tissue;
 - (c) the tissue must have been subjected to processing or treatment;
 - (d) the sale or supply of the tissue must be for the purpose of enabling the tissue to be used —
 - (i) for therapeutic, medical or scientific purposes; or
 - (ii) for the purposes of training, education or quality assurance relating to a use referred to in subparagraph (i);

- (e) the consideration given to the authorised supplier for the sale or supply of the tissue must consist only of an amount (a ***cost-recovery amount***) that —
 - (i) is necessarily incurred by the authorised supplier in relation to the removal, evaluation, processing, storage or distribution of the tissue or in relation to any other matter prescribed by the regulations; and
 - (ii) complies with regulations (if any) made for the purposes of subsection (4).
- (4) The regulations may set out the components of a cost-recovery amount for a matter or otherwise regulate the charging of the cost-recovery amount.

29C. Recovery of certain costs by authorised school of anatomy

- (1) In this section —
 - authorised school of anatomy*** has the meaning given in the *Anatomy Act 1930* section 2;
 - donated body*** means the body of a deceased person received or possessed by an authorised school of anatomy in accordance with the *Anatomy Act 1930*.
- (2) An authorised school of anatomy may charge an amount to recover the reasonable costs associated with supply of a donated body (including a prosected donated body) or portion or specimen part of a donated body —
 - (a) to another authorised school of anatomy; or
 - (b) to a person to whom the proviso to the *Anatomy Act 1930* section 18 applies; or

- (c) for the purposes of the *Anatomy Act 1930* section 10A.
- (3) For the purposes of subsection (2), ***reasonable costs associated with supply*** include reasonable costs for the following —
 - (a) administration in respect of the supply;
 - (b) the preparation, handling, transfer, receipt, embalming, plastination, storage, maintenance and disposal of the body or portion or specimen part of the body;
 - (c) security in respect of the body or portion or specimen part of the body.
- (4) Section 29A(2) does not apply to a contract or arrangement entered into for the purposes of subsection (2).

29D. Minister may make order as to application of section 29A

- (1) The Minister may, by order published in the *Gazette*, declare that section 29A(2) does not apply to or in relation to the sale or supply in accordance with the order of a specified class or classes of product derived from tissue that has been subjected to processing or treatment.
- (2) The Minister may, by order published in the *Gazette*, declare that section 29A(2) applies to a specified contract or arrangement, or a contract or arrangement of a specified class, to which section 29A(4) would otherwise apply.
- (3) An order published under subsection (1) or (2) is subject to the conditions, if any, specified in the order.

- (4) The Minister may, by order published in the *Gazette*, amend or revoke an order published under subsection (1) or (2).
- (5) An order in effect under section 29(4) as in force immediately before the day on which the *Human Tissue and Transplant Amendment Act 2022* section 31 comes into operation has effect as if it were an order published by the Minister under subsection (1) of this section, and subsection (4) applies accordingly.

29E. Minister may approve certain contracts

- (1) The Minister may, if the Minister considers it desirable by reason of special circumstances, approve in writing the entering into of a contract or arrangement that would, but for the approval, be void under section 29A(2).
- (2) Nothing in section 29A(2) or (3) applies to or in relation to a contract or arrangement entered into in accordance with an approval under subsection (1).
- (3) The Minister must not give an approval under subsection (1) unless —
 - (a) in the case of a contract or arrangement in relation to non-regenerative tissue for the purposes of transplantation to the body of a living person —
 - (i) the entering into of the contract or arrangement has been recommended by a body of medical practitioners prescribed by the regulations for the purposes of this paragraph; and
 - (ii) the Minister is reasonably satisfied that no monetary payment or reward will be made, given or received for or in

consideration of the contract or
arrangement;

or

- (b) in the case of any other contract or arrangement (irrespective of whether any monetary payment or reward will be made, given or received for or in consideration of the contract or arrangement) — the entering into of the contract or arrangement has been recommended by the Human Tissue Advisory Body.

29F. Human Tissue Advisory Body

- (1) The Minister must, by instrument signed by the Minister, establish the Human Tissue Advisory Body to provide advice and recommendations to the Minister for the purposes of sections 29B(2)(a) and 29E(3)(b).
- (2) The instrument establishing the Human Tissue Advisory Body must —
 - (a) identify the members of the Advisory Body or provide for the manner of appointing members of the Advisory Body; and
 - (b) provide for the length and conditions of appointment; and
 - (c) set out the duties and responsibilities of the Advisory Body and its members; and
 - (d) set out any other matters in relation to the constitution, operation and procedures of the Advisory Body that the Minister considers appropriate.
- (3) The Minister may, by instrument signed by the Minister, amend or revoke the instrument establishing the Human Tissue Advisory Body.

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- (4) Except to the extent that its procedures are set out in an instrument under subsection (2), the Advisory Body may determine its own procedures.
- (5) The members of the Advisory Body are entitled to any remuneration and allowances that the Minister may determine on the recommendation of the Public Sector Commissioner.

32. Section 30 amended

(1) In section 30:

(a) delete “A person shall” and insert:

(1) A person must

(b) delete the Penalty and insert:

Penalty for this subsection: imprisonment for
12 months or a fine of \$12 000.

(2) At the end of section 30 insert:

(2) Subsection (1) does not apply in relation to an advertisement if the advertisement —

(a) has been approved in writing by the Minister and contains a statement to that effect; or

(b) belongs to a class of advertisement approved in writing by the Minister for the purposes of this section.

Part 3 — Consequential amendments

33. *Anatomy Act 1930* amended

- (1) This section amends the *Anatomy Act 1930*.
- (2) Delete section 20(c) and insert:
 - (c) the removal of tissue from a human body for a purpose authorised under the *Human Tissue and Transplant Act 1982*.

Note. The heading to amended section 20 is to read:

Post mortem examination, and activity under *Human Tissue and Transplant Act 1982*, not prohibited

34. *Health Legislation Administration Act 1984* amended

- (1) This section amends the *Health Legislation Administration Act 1984*.
- (2) In section 9(7)(a) delete “1911” and insert:

1911, the Human Tissue and Transplant Act 1982
