

HUMAN TISSUE (AMENDMENT) BILL 1987

NEW SOUTH WALES



EXPLANATORY NOTE

(This Explanatory Note relates to this Bill as introduced into Parliament)

The Drug Misuse and Trafficking (Amendment) Bill 1987 is cognate with this Bill.

The object of this Bill is—

- (a) to provide that only authorised suppliers and exempt suppliers may carry on a business of supplying blood or blood products for blood transfusions or for other therapeutic purposes, or for medical or scientific purposes, involving the treatment of persons, or a business of supplying semen for the artificial insemination of women;
- (b) to provide legal protection against certain criminal and civil proceedings brought against—
 - (i) donors of blood provided for blood transfusions or for other therapeutic purposes, or for medical or scientific purposes, involving the treatment of persons and donors of semen provided for the artificial insemination of women;
 - (ii) suppliers of blood, blood products or semen for any of those purposes; and
 - (iii) persons carrying out blood transfusions or other medical treatment involving the use of blood or blood products or carrying out artificial insemination procedures on women;
- (c) to prohibit certain persons who are in possession of information or have custody of records which could identify donors of blood or semen from disclosing that information or publishing those records except in specified circumstances, such as for the purposes of court proceedings; and

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(d) to provide for other matters of a consequential or ancillary nature.

Clause 1 specifies the short title of the proposed Act.

Clause 2 provides that the proposed Act will, with minor exceptions, commence on a day to be appointed by the Governor-in-Council.

Clause 3 is a formal provision that gives effect to the Schedule of amendments to the Human Tissue Act 1983 ("the Principal Act").

Schedule 1 (1) amends section 4 of the Principal Act, which defines certain expressions for the purposes of that Act, by inserting into subsection (1) of that section definitions of "artificial insemination", "authorised supplier", "blood product", "donor", "exempt supplier", "premises", "record" and "supply". Schedule 1 (1) also amends that section so as to make it clear that the expression "tissue" includes blood and that the expression "transplantation" includes a transfusion of blood and an artificial insemination of semen. A definition of "prescribed contaminant" is also being inserted into the section and the Governor-in-Council will be empowered to make a regulation declaring an organism or substance to be a prescribed contaminant for the purposes of the Principal Act. The definition of "artificial insemination" and "donor" contained in the existing section 21A are being transferred to the section from section 21A of the Principal Act. Section 21A is to be repealed. (See Schedule 1 (4).)

Schedule 1 (2) amends section 21 of that Act, which prescribes the effect of a consent given under section 19 or 20 of that Act. The amendment is consequential on the insertion in section 4 of the Principal Act of the definition of "premises". (See Schedule 1 (1).)

Schedule 1 (3) changes the heading to Part IIIA of the Principal Act so as to reflect the contents of that Part as proposed to be amended.

Schedule 1 (4) repeals section 21A of the Principal Act, which defines certain expressions for the purposes of Part IIIA of that Act. The definitions of those expressions are being transferred to section 4 of the Principal Act. (See Schedule 1 (1).)

Schedule 1 (5) replaces section 21B of the Principal Act, which specifies the kinds of blood and semen to which Part IIIA of that Act relates. The substituted section 21B will express in a positive form the kinds of blood and semen to which the Part applies as opposed to the negative form in which the present section 21B is expressed.

Schedule 1 (6) amends section 21C of the Principal Act which requires donors of blood or semen to give certificates as to their medical suitability for giving their blood or semen. The amendments are consequential on the replacement of section 21B of the Principal Act. (See Schedule 1 (5).)

Schedule 1 (7) amends section 21D of the Principal Act, which makes it an offence for a person knowingly to sign for the purposes of Part IIIA of the Principal Act a certificate containing a false or misleading statement. The amendment makes it clear that for the offence to be committed the person concerned must have knowledge of the falsity or misleading nature of the statement.

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Schedule 1 (8) inserts proposed section 21DA into the Principal Act. The section will provide that, if a person who has become infected with a prescribed contaminant (such as the human immuno-deficiency virus (HIV)), or a disease attributable to such a contaminant, as a result of a transfusion of, treatment involving the use of, blood or a blood product, or, in the case of a woman, as a result of artificial insemination, no criminal proceedings or proceedings in tort or for a breach of contract may be brought against the donor of the blood or semen, unless it is proved that, when the blood was removed or the semen was obtained from the donor, the donor signed a certificate of a kind referred to in section 21C of the Principal Act knowing that the contents of the certificate were false or misleading. If criminal proceedings or civil proceedings in tort or for a breach of contract are brought against the supplier of the blood, blood product or semen, that supplier will have a good defence to those proceedings if it is proved that the provisions of the proposed subsection (3) were complied with. Proposed subsection (4) provides a similar defence in a case where such proceedings are brought against a person who was responsible for or carried out the transfusion, treatment or insemination that caused the infection or against the employer or a supervisor of that person. For example, a medical practitioner or nurse who transfuses contaminated blood to a patient would have a good defence in proceedings in tort for negligence arising out of the infection of the patient if, in those proceedings, the practitioner or nurse proved that the contaminated blood was received from an authorised or exempt supplier and the practitioner or nurse was not aware that the blood was contaminated or was likely to have been contaminated when the transfusion was carried out.

Schedule 1 (9) inserts in the Principal Act a Part IIIB which will provide for the regulation of persons who carry on businesses of supplying blood or blood products for blood transfusions or other therapeutic purposes, or for medical or scientific purposes, involving the treatment of persons or of supplying semen for the artificial insemination of women. Proposed Part IIIB contains the following provisions:

Proposed section 21F defines certain expressions for the purposes of the Part.

Proposed section 21G prohibits a person from carrying on a business of supplying blood or semen unless an authorisation is in force in respect of the business. The section will not apply to an exempt supplier. (The expression "exempt supplier", in relation to blood or blood products, includes the Australian Red Cross Society and the Commonwealth Serum Laboratories Commission, and in relation to blood, blood products and semen, includes a public or private hospital and an area health service.)

Proposed section 21H enables persons who wish to carry on a business of supplying blood, blood products or semen to apply to the Secretary of the Department of Health for an authorisation for that purpose.

Proposed section 21I provides for the issue or refusal of an authorisation and, in particular, specifies the grounds on which an application for an authorisation may be refused. The section also empowers the Secretary to impose conditions or restrictions when issuing an authorisation.

Proposed section 21J enables the conditions or restrictions of an authorisation to be varied or revoked.

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Proposed section 21K provides for the revocation or suspension of an authorisation on the grounds that the holder of the authorisation has failed to comply with or has contravened a condition or restriction of the authorisation.

Proposed section 21L prescribes certain offences for the purposes of the Part. The maximum penalty for such an offence will be \$10,000.

Proposed section 21M prescribes certain presumptions in relation to legal proceedings arising out of an alleged contravention of proposed section 21G.

Proposed section 21N provides that, if a person who is a director of or concerned in the management of a corporation authorised or permitted a contravention of a provision of the proposed Part IIIB or of a regulation made for the purposes of that Part, the person shall be deemed to have contravened the same provision.

Proposed section 21O provides that a decision of the Secretary relating to an authorisation held by a supplier is to take effect on the day after the date on which it is served on the supplier or on such later date as may be specified in the notice.

Proposed section 21P provides for the appointment of inspectors for the purposes of the proposed Part IIIB.

Proposed section 21Q prescribes the powers of inspectors under the proposed Part IIIB. Those powers include—

- (a) a power of entry to premises for the purposes of ascertaining whether or not a provision of that Part or regulations made for the purposes of that Part are being complied with or have been contravened;
- (b) the power to inspect blood, blood products, semen and certain other items kept on those premises;
- (c) the power to inspect records;
- (d) the power to make and take away copies of records;
- (e) the power to take samples of blood, blood products or semen;
- (f) the power to seize and detain blood, blood products or semen and certain other items in relation to which an offence may have been committed; and
- (g) the power to take away records and other documents in certain circumstances.

Proposed section 21R makes it an offence—

- (a) to prevent or attempt to prevent an inspector from gaining entry to premises in the exercise of a power conferred by proposed section 21Q;
- (b) to obstruct or hinder an inspector in the exercise of a power conferred by that section; or

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(c) to refuse or fail to comply with a requirement made by an inspector under that section.

Such an offence will be punishable by a fine not exceeding \$1,000 or imprisonment for a term not exceeding 3 months. The proposed section also provides that a person is not guilty of such an offence unless certain matters are proved in proceedings for the offence.

Proposed section 21s provides for the disposal of articles seized under proposed section 21Q. In general, such articles are to be forfeited to the Crown after a specified period unless in the meantime an order disallowing the seizure is made under proposed section 21T. The section also makes provision for the immediate destruction of blood, blood products or semen which is found to contain a prescribed contaminant.

Proposed section 21T enables a person claiming to be entitled to blood, blood products, semen, containers or equipment seized under proposed section 21Q to apply to the District Court and obtain an order disallowing the seizure and ordering the return of the seized articles to the applicant.

Proposed section 21U empowers the Supreme Court, on the application of the Secretary, to grant an injunction restraining a person from engaging in conduct involving a contravention of proposed section 21G.

Proposed section 21v provides for the service of documents on authorised suppliers.

Schedule 1 (10) amends section 36 of the Principal Act, which prescribes certain offences for the purposes of that Act. Subsection (3) of that section makes it an offence for a person knowingly to sign for the purposes of the Principal Act (Part IIIA excepted) a certificate containing a false or misleading statement. The amendment makes it clear that, for the offence to be committed, the person concerned must have knowledge of the falsity or misleading nature of the statement.

Schedule 1 (11) amends section 37 of the Principal Act, which, with certain exceptions, prohibits medical practitioners and others from disclosing or giving information or documents relating to persons who have donated tissue for transplantation or for a therapeutic, medical or scientific purpose. As a result of the amendment, the prohibition will extend to the Australian Red Cross Society, employees and members of the Society and other prescribed persons who have been involved in removing blood from persons for the purpose of transfusion to patients or the purpose of treating patients in some other way.

Schedule 1 (12) amends section 38 of the Principal Act which prescribes the manner in which offences against that Act are to be dealt with. The amendment is consequential on the enactment of the Local Courts Act 1982.
