

## HEALTH AMENDMENT BILL

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### EXPLANATORY NOTE

#### *General Policy Statement*

The key policy underlying this Bill is to—

- (a) Replace the Blood Transfusion Trust (“the Trust”) with entities appointed by the Minister of Health to carry out specified functions in relation to the collection and distribution of blood; and
- (b) Ensure that bone marrow is covered by the trading restrictions in the Health Act 1956 (“the principal Act”); and
- (c) Enable the Governor-General to apply those restrictions, by Order in Council, to other controlled human substances, to be specified as the need arises.

A Crown health enterprise, to be called the New Zealand Blood Service Limited (“NZBS”), is being established to be responsible, both operationally and strategically, for nationally consistent collection, processing, and testing of donated blood, as well as for distribution and associated clinical advice. The NZBS will carry out the functions of the Trust. It will be responsible for carrying out the blood service functions of the 23 Crown health enterprises.

Bone marrow has traditionally been thought to be part of blood for the purposes of the trading restrictions on blood in the principal Act. However, as the matter is not clear, the status of bone marrow is clarified in the Bill.

#### *Clause by Clause Analysis*

*Clause 1* deals with the Short Title and commencement. The commencement date will be appointed by Order in Council. The reason for this is that under the Bill the Trust’s responsibilities and assets need to be transferred to NZBS on the date the legislation comes into force. This will require co-ordination between the Trust and NZBS before the Bill can take effect.

### PART 1

#### AMENDMENTS TO PRINCIPAL ACT RELATING TO COLLECTION OF BLOOD

*Clause 2* substitutes a *new section 22E*, which re-enacts existing section 22E of the principal Act with changes that are consequential on the replacement of the Trust by entities appointed by the Minister of Health under *new section 92H* (“appointed entities”). Under the existing section the Minister of Health can require a Crown

health enterprise to supply information about the blood of donors to the Trust. Under *new section 22E* that information will be provided to appointed entities.

*Clause 3* repeals Part IIIA of the principal Act, and substitutes a *new Part 3A*, comprising *new sections 92A* to *92I*.

*New section 92A* defines the terms “appointed entity”, “blood”, and “controlled human substance”.

“Appointed entity” is an entity appointed by the Minister of Health under *new section 92H*.

The new definition of the term “blood” differs from the existing definition in including human bone marrow from which constituents of blood can be derived. Also included in the definition are human haematopoietic stem cells.

The term “controlled human substance” is defined to mean human bone marrow from which constituents of blood cannot be derived, but which may be used therapeutically. The Governor-General may, by Order in Council, include in the definition any other substance of the human body that can be used therapeutically.

*New section 92B* is similar to the current prohibition against trading in one’s own blood. The application of the prohibition is extended to the new constituents of the definition of “blood” set out in *new section 92A* and also to controlled human substances within the meaning of that section.

*New section 92C* prohibits persons from taking blood or controlled human substances for the purpose of administering it to other persons. The prohibition is similar to the prohibition contained in the current section 92C of the principal Act, but its application extends to “blood” as defined in *new section 92A* and to controlled human substances. The prohibition does not apply to appointed entities that are authorised to take blood and controlled human substances from persons. An appointed entity is authorised to take blood and controlled human substances, unless the notice appointing the entity states otherwise.

Every appointed entity that takes blood or a controlled human substance must give due recognition to the fact that the blood or the substance has been donated.

*New section 92D* continues the existing prohibition against charging for the administration of blood (within the extended meaning of *new section 92A*) and extends it to controlled human substances.

*New section 92E* authorises the Minister of Health to exempt persons from the prohibitions against trading in one’s blood and controlled human substances, and against charging for the administration of blood and controlled human substances. Every exemption given by the Minister must be published in the *Gazette*. The Minister’s power of exemption is similar to that currently conferred on the Minister by section 92E of the principal Act.

*New section 92F* re-enacts the current prohibition against advertisements relating to the sale or purchase of blood, and extends it to blood within the meaning of *new section 92A* and to controlled human substances.

*New section 92G* relates to the liability of employers, principals, and directors for offences against *new Part 3A* committed by employees, agents, and companies. The new section has the same effect as an existing provision in the principal Act (section 92H).

*New section 92H* authorises the Minister of Health to appoint 1 or more entities to be responsible for specified functions relating to blood and controlled human substances. An appointment may be subject to specified terms and conditions. The Minister may alter the terms and conditions of an appointment, and the functions for which an appointed entity is responsible.

*New section 92I* empowers the Governor-General by Order in Council to exempt specified contracts relating to blood and controlled human substances from the

provisions of Part II of the Commerce Act 1986. The provision is in the same terms as existing section 92K of the principal Act, which applies to contracts relating to blood.

## PART 2

### PROVISIONS RELATING TO DISSOLUTION OF BLOOD TRANSFUSION TRUST

*Clause 4* relates to the vesting of assets and liabilities of the Trust in New Zealand Blood Service Limited. With the exception of employment contracts, all assets and liabilities of the Trust vest in NZBS. These assets and liabilities are to vest freed of all trusts. The vesting will take place when this Bill comes into force.

*Clause 5* requires NZBS, in managing any blood or controlled human substances vested in it by *clause 4*, to give due recognition to the fact that the blood or substances have been donated.

*Clause 6* dissolves the Blood Transfusion Trust.

*Clause 7* continues the application of section 92L of the principal Act in respect of former trustees of the Blood Transfusion Trust. Section 92L protects trustees of the Trust from liability.

*Clauses 8 to 10* enact consequential amendments and repeals.

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*Hon Bill English*

## HEALTH AMENDMENT

### ANALYSIS

Title		
1. Short Title and commencement		
PART 1		
AMENDMENTS TO PRINCIPAL ACT RELATING TO COLLECTION OF BLOOD		
2. Duty to provide information for purposes of blood collection	92G. Liability of employers, principals, and directors	
3. Part 3A substituted	92H. Appointed entities to collect and distribute blood and controlled human substances	
PART 3A		
TRADING IN HUMAN BLOOD AND CONTROLLED HUMAN SUBSTANCE		
92A. Interpretation	92I. Exemption from Part II of Commerce Act 1986	
92B. Trading in own blood or controlled human substance prohibited	PART 2	
92C. Collection of blood or controlled human substance	PROVISIONS RELATING TO DISSOLUTION OF BLOOD TRANSFUSION TRUST	
92D. Charging for administered blood or controlled human substance	4. Vesting of assets of blood transfusion trust	
92E. Exemptions	5. Respect for donated blood	
92F. Unauthorised advertising prohibited	6. Blood transfusion trust dissolved	
	7. Protection of former trustees	
	8. Consequential amendment to Ombudsmen Act 1975	
	9. Consequential amendment to Public Finance Act 1989	
	10. Consequential repeals	

### A BILL INTITULED

#### **An Act to amend the Health Act 1956**

BE IT ENACTED by the Parliament of New Zealand as follows:

5 **1. Short Title and commencement**—(1) This Act may be cited as the Health Amendment Act 1998, and is part of the Health Act 1956\* (“the principal Act”).

(2) This Act comes into force on a date to be appointed by the Governor-General by Order in Council.

\*R.S. Vol. 31, p. 467  
Amendments: 1994, Nos. 37, 133, 137

## PART 1

## AMENDMENTS TO PRINCIPAL ACT RELATING TO COLLECTION OF BLOOD

**2. Duty to provide information for purposes of blood collection**—The principal Act is amended by repealing section 22E, and substituting the following section: 5

“22E. The Minister may, at any time, by notice in writing, require a Crown health enterprise to provide to an entity appointed under **section 92H**, in such manner as the Minister specifies in the notice, such information as is specified in the notice, being health information of the kind referred to in paragraph (d) or paragraph (e) of the definition of that term in section 22B.” 10

**3. Part 3A substituted**—The principal Act is amended by repealing Part IIIA, and substituting the following Part: 15

## “PART 3A

## “TRADING IN HUMAN BLOOD AND CONTROLLED HUMAN SUBSTANCE

“92A. **Interpretation**—In this Part, unless the context otherwise requires,— 20

“‘Appointed entity’ means an entity appointed under **section 92H**:

“‘Blood’ means human blood; and—

“(a) Includes the following:

“(i) A substance derived from blood: 25

“(ii) A human organ, or human bone marrow, or human tissue, including the placenta, of a kind that is suitable as a source from which to derive a constituent of blood that may be used therapeutically or in the preparation of a substance for therapeutic use: 30

“(iii) A constituent of an organ, bone marrow, or tissue described in **subparagraph (ii)**:

“(iv) Human haematopoietic stem cells, or a constituent of human haematopoietic stem cells, that may be used therapeutically or in the preparation of a substance for therapeutic use; but 35

“(b) Does not include the following: 40

“(i) Any substance derived from blood, a human organ, human bone marrow, human

tissue, or human haematopoietic stem cells that is intended for use in quality control or as a diagnostic product:

5 “(ii) Any substance containing a fraction of blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that the Governor-General by Order in Council declares not to be blood for the purposes of this Part:

10 “ ‘Controlled human substance’—

“(a) Means—

15 “(i) Human bone marrow (other than human bone marrow referred to in **paragraph (a) (ii)** of the definition of the term ‘blood’ in this section) that may be used therapeutically or in the preparation of a substance for therapeutic use; or

20 “(ii) A constituent of human bone marrow described in **subparagraph (i)**; or

25 “(iii) Any other substance of the human body that may be used therapeutically or in the preparation of a substance for therapeutic use and that the Governor-General by Order in Council declares to be included in this definition; but

“(b) Does not include—

30 “(i) A product derived from any controlled human substance that is intended for use in quality control or as a diagnostic product; or

35 “(ii) A substance containing a fraction of any controlled human substance that the Governor-General by Order in Council declares not to be a controlled human substance for the purposes of this Part.

40 “92B. **Trading in own blood or controlled human substance prohibited**—(1) No person may require or accept financial or other consideration for the blood or any controlled human substance of that person.

“(2) No person may provide financial or other consideration for the taking of blood or any controlled human substance from the body of a person for administration to another person.

“(3) Every person commits an offence and is liable to a fine not exceeding \$1,000 who contravenes **subsection (1)**.

“(4) Every person commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding \$5,000 who contravenes **subsection (2)**. 5

“92C. **Collection of blood or controlled human substance**—(1) No person may take blood or any controlled human substance from the body of a person for the purpose of obtaining that blood or that substance for administration to another person. 10

“(2) Every person commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding \$5,000 who contravenes **subsection (1)**.

“(3) **Subsection (1)** does not apply to—

“(a) An appointed entity that is authorised to take blood and controlled human substances from persons; or 15

“(b) An employee or agent of an appointed entity who is authorised by the entity to take blood or controlled human substances on behalf of the entity, if the entity has the power to authorise employees or agents to do so. 20

“(4) For the purposes of **subsection (3)**, an appointed entity is authorised to take blood and controlled human substances, and has the power to authorise employees and agents of the entity to do so, unless the notice by which the entity is appointed provides otherwise. 25

“(5) Every appointed entity described in **subsection (3) (a)** and every employee or agent described in **subsection (3) (b)** who takes blood or any controlled human substance must give due recognition to the fact that the blood or controlled human substance has been donated. 30

“92D. **Charging for administered blood or controlled human substance**—(1) No person who administers blood or any controlled human substance to another person may require or accept financial or other consideration for that blood or that substance from the person to whom it is administered. 35

“(2) Every person commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding \$5,000 who contravenes **subsection (1)**.

“92E. **Exemptions**—(1) The Minister may, in his or her discretion and on such terms and conditions (if any) as the Minister thinks fit, by notice in writing, exempt a person or persons or class of persons from compliance with any or all of 40

the provisions of **sections 92b (1), 92b (2), and 92d (1)**, and may in the same manner vary or revoke any such exemption.

5 “(2) Where a notice is given under **subsection (1)**, the Minister must as soon as practicable after giving the notice, publish in the *Gazette* and present to the House of Representatives a copy of the notice.

10 “**92F. Unauthorised advertising prohibited**—(1) No person may distribute an advertisement relating to the purchase or sale in New Zealand of blood or a controlled human substance.

“(2) For the purposes of **subsection (1)**, ‘distribute’ means—

15 “(a) To publish or otherwise disseminate, by newspaper, magazine, periodical, book, billboard, radio, television, cinematograph film, or any other means whatever; or

“(b) To exhibit to public view in any premises or place; or

“(c) To deposit in any area, yard, garden, or enclosure comprising part of or appurtenant to any premises.

20 “(3) Every person commits an offence and is liable to imprisonment for a term not exceeding 3 months or a fine not exceeding \$2,500 who contravenes **subsection (1)**.

25 “**92G. Liability of employers, principals, and directors**—(1) An act done by a person as the employee (‘the employee’) of another person (‘the employer’) is for the purposes of an offence against this Part to be treated as done by the employer as well as by the employee, if—

“(a) The employer approved of the act; or

30 “(b) The employer knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.

“(2) An act done by a person as the agent (‘the agent’) of another person (‘the principal’) is for the purposes of an offence against this Part to be treated as done by the principal as well as by the agent, if—

35 “(a) The principal approved of the act; or

“(b) The principal knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.

40 “(3) Where a body corporate is convicted of an offence against this Part, a director of the body corporate is to be treated as having committed the same offence if—

“(a) The director approved of the act that constituted the offence; or

“(b) The director knew the offence was to be or was being committed and failed to take all reasonable steps to prevent it.

“(4) In **subsection (3)**, the term ‘director’ includes a person who is concerned in the management of a body corporate. 5

“92H. **Appointed entities to collect and distribute blood and controlled human substances**—(1) The Minister may from time to time, by notice in writing, appoint 1 or more entities to be responsible for the performance of such functions in relation to blood and controlled human substances as are specified in the notice. 10

“(2) An appointment under **subsection (1)** may be subject to such terms and conditions as are specified in the notice appointing the appointee.

“(3) The Minister may from time to time, by notice in writing, revoke, vary, or add to— 15

“(a) Any of the functions for which an appointee is responsible:

“(b) Any of the terms or conditions of the appointment.

“(4) The Minister may, at any time, by notice in writing, revoke an appointment made under **subsection (1)**. 20

“(5) A notice given under this section takes effect on the date specified for the purpose in the notice or, if no date is specified for that purpose, on the day after the date on which it is issued.

“(6) As soon as practicable after the Minister gives a notice under **subsection (1)** or **subsection (3) (a)** or **subsection (4)**, the Minister must— 25

“(a) Publish a copy of it in the *Gazette*; and

“(b) Present a copy of it to the House of Representatives.

“92I. **Exemption from Part II of Commerce Act 1986**— Nothing in Part II of the Commerce Act 1986 applies to— 30

“(a) Any contract, arrangement, understanding, or covenant in relation to blood or controlled human substances that—

“(i) At the time it is entered into is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or 35

“(ii) Is entered into by a person who (at the time it is entered into) is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or 40

“(b) Any act done to give effect to a provision of any contract, arrangement, understanding, or covenant to which **paragraph (a)** applies.”

PART 2

PROVISIONS RELATING TO DISSOLUTION OF BLOOD TRANSFUSION TRUST

5       **4. Vesting of assets of blood transfusion trust**—(1) In this section and in **sections 6 and 7**, the term “the Trust” means the blood transfusion trust established under section 92J of the principal Act (as in force before the commencement of this Act).

10       (2) On the date that this Act comes into force, the assets and the liabilities of the Trust (other than assets and liabilities described in **subsection (3)**) vest in the Crown health enterprise known as New Zealand Blood Service Limited freed of all trusts affecting those assets or liabilities.

15       (3) The assets and liabilities vested by **subsection (2)** do not include any contract of service that is binding on the Trust or on a trustee of the Trust.

      (4) Sections 6, 8, and 9, and the First Schedule, of the Health Reforms (Transitional Provisions) Act 1993 apply in respect of the vesting of assets and liabilities by **subsection (2)** as if—

20       (a) Those assets and liabilities were transferred under section 5 of that Act; and

      (b) The Trust were the transferor and New Zealand Blood Service Limited were the transferee under a proposal approved by an Order in Council made under that section.

25       (5) In this section, unless the context otherwise requires, the terms “assets”, “liabilities”, and “transfer” have the same meaning as they have in section 2 of the Health Reforms (Transitional Provisions) Act 1993.

30       **5. Respect for donated blood**—(1) New Zealand Blood Service Limited must, in managing any blood or controlled human substance vested in it by **section 4**, give due recognition to the fact that the blood or controlled human substance has been donated.

35       (2) In this section, the terms “blood” and “controlled human substance” have the same meaning as they have in **section 92A** of the principal Act.

**6. Blood transfusion trust dissolved**—(1) On the date that this Act comes into force the Trust is dissolved.

40       (2) On the date that this Act comes into force every trustee of the Trust ceases to hold office as trustee of the Trust.

**7. Protection of former trustees**—Section 92L of the principal Act (as in force before the commencement of this Act) continues to apply to former trustees of the Trust as if this Act had not been passed.

**8. Consequential amendment to Ombudsmen Act 1975**—The Ombudsmen Act 1975 is consequentially amended by omitting from Part II of the First Schedule the item relating to the blood transfusion trust established under section 92J of the Health Act 1956. 5

**9. Consequential amendment to Public Finance Act 1989**—The Public Finance Act 1989 is consequentially amended by omitting from the Fourth, Fifth, and Sixth Schedules the item relating to the blood transfusion trust established under section 92J of the Health Act 1956. 10

**10. Consequential repeals**—The following enactments are consequentially repealed: 15

(a) Section 27 of the Health Amendment Act 1993:

(b) Section 2 of the Health Amendment Act (No. 3) 1994.