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National Blood Authority Bill 2002

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National Blood Authority Bill 2002

Peter Prince
Law and Bills Digest Group
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National Blood Authority Bill 2002

Date Introduced: 11 December 2002

House: House of Representatives

Portfolio: Health and Ageing

Commencement: The main provisions commence either on 1 July 2003 if the Bill receives Royal Assent before that date, or on Proclamation. If the Bill is assented to on or after 1 July 2003, but is not proclaimed within six months of the date of assent, it will commence on the first day after that period.

Purpose

To establish a National Blood Authority as part of a coordinated national approach to management of the Australian blood sector.

Background

The National Blood Authority Bill 2002 (**'the current Bill'**) follows on from two major government reviews of Australia's blood sector.

The 1995 *Commonwealth Review of the Australian Blood and Blood Product System* resulted in

- The formation of a national Blood and Blood Products Committee to strengthen policy coordination in this area between the Commonwealth and the States and Territories
- The establishment of the Australian Red Cross Blood Service (ARCBS) allowing the free transfer of blood products across State and Territory boundaries.

Despite these measures, the then Minister for Health and Aged Care, Dr Wooldridge MP, said in 1999 that he was concerned that 'the demand for some processed blood products exceeds supply to the extent that effective treatment of some patients is being compromised'. In addition, Dr Wooldridge was concerned that improvements in overseas blood testing 'might not be implemented, or worse, implemented in a piecemeal manner

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across jurisdictions' due to 'the current split of roles and responsibilities between the Commonwealth and the States'.¹

According to Health Department spokeswoman, Kay McNiece

There are currently 30 different agreements on blood supply between the Commonwealth, States and Territories and the Red Cross....Every state has different regulations on things such as storage and donation as well. This means that there have been problems transferring blood between states and some blood has been sitting in one state's hospitals and may go unused when another state is desperately in need. The Red Cross has tried to move blood around the country but a national system will streamline the process.²

Because of such concerns, in 1999 the Minister established the *Review of the Australian Blood Banking and Plasma Product Sector*, chaired by former Governor-General, Sir Ninian Stephen ('**the Stephen Review**'). Completed in March 2001, the primary recommendation of the Stephen Review was the establishment of a National Blood Authority to draw together national blood supply planning and management within one organisation.³

In September 2001, the Minister announced that Australian Health Ministers had agreed on new national arrangements for the Australian blood sector.⁴ The new arrangements will retain key principles such as voluntary, non-remunerated donation; national self-sufficiency and provision of blood products free of charge to patients and other users such as the haemophiliac community.⁵

The new arrangements will be given effect through a National Blood Agreement that will be tabled in both Houses of Parliament.⁶ Key elements of the National Blood Agreement include:

- National agreement on the objectives of governments for the Australian blood sector;
- A primary policy setting role for the Ministerial Council (an extension of the Australian Health Ministers Conference), supported by a Jurisdictional Blood Committee of senior officials
- Joint funding of the national blood supply between the Commonwealth and the States and Territories on a 63:37 cost-share basis
- A national framework for the management of safety and quality issues within the Australian blood sector, and
- Establishment of a National Blood Authority as a statutory authority under Commonwealth legislation.⁷

The Second Reading Speech notes that the primary functions of the National Blood Authority will be 'to ensure continuity of supply of blood and blood products, and to

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facilitate and coordinate national safety, quality and related information systems on behalf of all governments'. The Authority will operate 'within policy approved by the Ministerial Council...and in full consultation with all governments through (the) Jurisdictional Blood Committee'.⁸

The current Bill establishes the National Blood Authority and its governing Board; provides for a General Manager (with the power to compel production of 'blood-related information') supported by staff and advisory committees; creates a National Blood Account under the *Financial Management and Accountability Act 1997* to fund the operations of the Authority; and stipulates accountability procedures that the Authority must comply with.

Main Provisions

Part 2 – The National Blood Authority

Clause 7 establishes the National Blood Authority as a Commonwealth statutory body.

Clause 8 sets out the functions of the Authority, including (inter alia):

- Liaising with governments and suppliers about blood products and services
- Planning and budgeting for the supply of blood products and services in accordance with the National Blood Agreement
- Funding the supply of blood products and services
- Entering and managing contracts for the collection and distribution of blood products and services to ensure a sufficient supply in all States and Territories
- Ensuring the safety and quality of blood products and services in accordance with the National Blood Agreement;
- Facilitating and funding research and policy development related to blood products and services, and
- Advising the Minister and the Ministerial Council on relevant matters.

Clause 10 gives the General Manager of the Authority the power to demand 'blood-related information' from managers of private hospitals, suppliers and importers of blood products and services, and any other person specified in regulations.

'Blood-related information' includes any information relating to the supply of and demand for blood products and services; blood donations; the safety and quality of such products and services and their cost; and risks to a sufficient blood supply to States and Territories.

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It also includes information relating to 'benchmarking performance' with regard to blood products and services. The Explanatory Memorandum states that this phrase refers to 'supplier practice and yields, supplier costs, clinical use of blood and blood products and product wastage'.⁹

The General Manager cannot demand 'personal information' as defined in the *Privacy Act 1988*.

It is an offence not to comply with a demand for information made by the General Manager under **clause 10**¹⁰, although a person need not comply with such a demand if it would incriminate them or expose them to 'a penalty or other liability'. The Authority must provide 'reasonable compensation' for compelling a person to provide blood-related information.

Under **clause 11**, there is a penalty of 2 years imprisonment for improperly disclosing information obtained when serving as a member of staff of the Authority or in providing services to the Authority.

Part 3 – the National Blood Authority Board

Part 3 establishes the governing Board for the National Blood Authority. Board members serve for a maximum of 4 years and are appointed by the Minister after selection by the Ministerial Council. The Minister must be satisfied that the person selected by the Council as Chair of the Board is independent from interests of either blood product suppliers or the Commonwealth, States and Territories (**paragraph 15(1)(b)**).

The Board is to include a person representing the interests of the Commonwealth; one or two persons representing the States and Territories, and a representative of the community. It must also include someone with expertise in public health issues relating to human blood, and a person with financial or commercial expertise (**clause 14**). Payment for Board members will be determined by the Remuneration Tribunal (**clause 18**).

Part 4 – General Manager, staff and advisory committees

Part 4 Division 1 provides for the appointment of the Authority's General Manager by the Minister in consultation with the Board. The person appointed is to hold the position for a maximum term of 4 years. The General Manager must request the Board's advice on strategic matters, and must have regard to advice from the Board whether requested or not.

Part 4 Division 2 stipulates that the General Manager and Authority staff together constitute a Statutory Agency for the purposes of the *Public Service Act 1999*.

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Part 4 Division 3 allows the General Manager to establish advisory committees to assist the Authority. Payment for committee members will be determined by the Remuneration Tribunal.

Part 5 – the National Blood Account

Part 5 creates a National Blood Account as a Special Account for the purposes of the *Financial Management and Accountability Act 1997*. The Commonwealth is required to credit to the Account all monies appropriated for this purpose by the Parliament, and all amounts required to be paid by the Commonwealth under the National Blood Agreement. The Account can only be used to fund the operations of the Authority in carrying out its designated functions, and for paying remuneration and allowances under the current Bill.

Part 6 – Miscellaneous

Part 6 sets down reporting requirements for the Authority, including a corporate plan and an annual report. An annual report must also be prepared for the Board. The reports for the Authority and the Board must be presented to Parliament within 15 sitting days after they are received by the Minister.

Concluding Comments

A central role of the National Blood Authority will be to manage and fund contracts for the supply of blood products, including plasma.¹¹ A key concern addressed by the Stephen Review was the 'potential supply risks arising from Australia's dependence on a single plasma fractionator in an environment of strict import constraints'.¹² The plasma supplier in Australia is CSL Limited, the former Commonwealth Serum Laboratories, privatised in 1994 under the Keating Labor Government.

The Sydney Morning Herald reported in October 2001 that in its first six years of privatisation the Commonwealth paid CSL Limited more than \$570 million under a 10 year Plasma Fractionation Agreement¹³ plus a further \$33 million under a diagnostics contract, noting that 'together the figures represent almost twice the entire return the Government received when it sold the CSL'. The article stated that based on these two taxpayer funded agreements, CSL Limited

is now the darling of the Australian Stock Exchange and is valued at more than \$7 billion. Today it is among the 20 largest companies in Australia – almost twice as big, by market value, as Qantas, and just behind Coles Myer.¹⁴

In December 1999, the Commonwealth Auditor-General released a strongly critical report on [Commonwealth Management and Regulation of Plasma Fractionation](#),¹⁵ a function

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carried out by the then Department of Health and Aged Care (DHAC). The Auditor-General concluded that there was 'significant scope for improvement' in DHAC's contract management practices in relation to the Plasma Fractionation Agreement.

An important task for the new Authority will be to measure the extent of any improvement in management of the Plasma Fractionation Agreement since the Auditor-General's report, with a view to informing the Commonwealth's decision on whether to extend the existing agreement with CSL, or to negotiate a new agreement either with CSL or with one or more new suppliers.¹⁶

On a more technical level, the power of the Authority's General Manager under clause 10 of the current Bill to compel the production of blood-related information raises some issues.

The Explanatory Memorandum does not explain why managers of *private* hospitals can be required to provide information, but those running *public* hospitals have no equivalent obligation (**clause 10(3)(a)**).

More significantly, **sub-clause 10(6)** states that production of information demanded by the General Manager is not required if it 'might tend to...expose the person to a penalty or other liability'. Apart from managers of private hospitals, persons who may be required to give information to the General Manager include suppliers and importers of blood products. Such people will be carrying on their business under commercial contracts that usually include confidentiality clauses. Therefore they will be able to claim exposure to liability for breach of contract as a reason for not complying with a demand for information. Although the person receiving a demand for information will have the evidential burden of proving exposure to liability,¹⁷ such confidentiality clauses have the potential to undermine the General Manager's power to obtain relevant information on the supply of blood products and services in Australia.

In addition, those who receive demands from the National Blood Authority for information that is the subject of a commercial contract may find themselves in an invidious position. If they refuse to provide the information, they risk not being able to establish exposure to liability, making them liable for an offence under **sub-clause 10(5)**. If they avoid this risk by complying with the demand, they face being sued by the other party to the contract for breach of its confidentiality provisions.

Sub-clause 10(7) of the current Bill states that the Authority must pay a person 'reasonable compensation' for complying with a demand for information. The Explanatory Memorandum states that such compensation 'is limited to the administrative and duplication costs incurred when responding to the General Manager's request'.¹⁸ However, no such limit is stated in the current Bill itself. While a court may have regard to the Explanatory Memorandum, the National Blood Authority could potentially find itself liable to pay compensation for legal claims resulting from compliance with its demands for blood-related information.

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Endnotes

- 1 Minister for Health and Aged Care, Michael Wooldridge MP, *Media Release*, 'Review of the Australian Blood Banking and Plasma Product Sector', 10 May 1999.
- 2 *The Australian*, 1 October 2001.
- 3 The full review is available on the Department of Health and Ageing [website](http://www.health.gov.au/hsdd/bodt/pdf/report.pdf) (<http://www.health.gov.au/hsdd/bodt/pdf/report.pdf>).
- 4 Minister for Health and Aged Care, Michael Wooldridge MP, *Media Release*, 'Australian Health Ministers Agree on National Blood Scheme', 28 September 2001.
- 5 Minister for Ageing, National Blood Authority Bill, Second Reading Speech, House of Representatives, *Debates*, 11 December 2002, p. 10078.
- 6 Explanatory Memorandum, p. 2.
- 7 Minister for Ageing, National Blood Authority Bill, Second Reading Speech, House of Representatives, *Debates*, 11 December 2002, p. 10078; Explanatory Memorandum, p. 1.
- 8 Minister for Ageing, National Blood Authority Bill, Second Reading Speech, House of Representatives, *Debates*, 11 December 2002, p. 10078.
- 9 Explanatory Memorandum, p 8.
- 10 Such an offence carries a penalty of '30 penalty units'. A 'penalty unit' currently means \$110 (section 4AA *Crimes Act 1914*).
- 11 Proposed paragraphs 8 (1) (d) and (e).
- 12 Department of Health and Ageing, '[Review of the Australian Blood Banking and Plasma Product Sector](http://www.health.gov.au/hsdd/bodt/review.htm)' (<http://www.health.gov.au/hsdd/bodt/review.htm>).
- 13 The contract covers an initial term commencing on 1 January 1994 and ending on 30 June 2004 but may be extended a further five years or longer at the Commonwealth's discretion. Source: [Auditor-General's report](#) at: <http://www.anao.gov.au/WebSite.nsf/Publications/4A256AE90015F69B4A25690300072819>.
- 14 *Sydney Morning Herald*, 'Blood trail behind a stockmarket darling', 6 October 2001.
- 15 <http://www.anao.gov.au/WebSite.nsf/Publications/4A256AE90015F69B4A25690300072819>. See eg Finding 2.37: 'There has been an absence of adequate financial controls over payments made by DHAC under the PFA. Between 1 January 1994 and April 1999, DHAC paid out more than \$400 million of Commonwealth funds under the PFA without a formal process in place to confirm that the products it was invoiced for had actually been received by the designated recipients.'

This was the second inquiry by the Auditor-General into the Plasma Fractionation Agreement, the first being in 1995, see Audit Report No.14 1995-96, *The Sale of CSL-Commonwealth Blood Product Funding and Regulation*, which was tabled in Parliament in November 1995.
- 16 As the Auditor-General's report notes, apart from relying on taxpayer funded contracts, CSL's operations are based on blood supplies voluntarily donated to the Australian Red Cross

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(<http://www.anao.gov.au/WebSite.nsf/Publications/4A256AE90015F69B4A25690300072819>
Summary paragraph 2).

- 17 See note to clause 10(6) in the current Bill.
- 18 Explanatory Memorandum, p. 9.

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