

2002

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

NATIONAL BLOOD AUTHORITY BILL 2002

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health and Ageing,
Senator the Honourable Kay Patterson)

NATIONAL BLOOD AUTHORITY BILL 2002

OUTLINE

The National Blood Authority Bill 2002 proposes to establish the National Blood Authority (NBA) to manage and coordinate Australia's blood supply in accordance with the National Blood Agreement agreed by the Commonwealth, States and Territories. The principal roles of the NBA will be to manage national blood arrangements, ensuring sufficient supply and to provide a new focus on the safety and quality of blood products and services.

The new national arrangements are a result of the 2001 *'Review of the Australian Blood Banking and Plasma Product Sector'*, chaired by Sir Ninian Stephen, which recommended inter alia, that a national blood authority be established to provide national management of Australia's blood supply.

The new national arrangements seek to preserve key principles that have served the national interests well to date, such as a continued policy of national self-sufficiency in blood and blood products, voluntary, unpaid donations of blood and plasma and the supply of such products free of charge to patients based on clinical needs and appropriate clinical practice. The new national arrangements also seek to ensure the highest quality, effectiveness and efficiency for the Australian blood sector.

The key features of the National Blood Agreement include:

- national policy leadership for the Ministerial Council (a continuation of the role of the Australian Health Ministers Conference) assisted by a new Jurisdictional Blood Committee to be established as a sub-committee of the Australian Health Ministers' Advisory Council (AHMAC);
- joint funding between the Commonwealth and each of the States and Territories on a 63:37 cost-share basis; and
- improved mechanisms to promote safety and quality of Australia's blood supply.

The NBA will be established as a Commonwealth Agency under the *Financial Management and Accountability Act 1997*. The Authority will be subject to the *Public Service Act 1999* and the *Auditor-General Act 1997*.

The Bill provides that the NBA will undertake a range of functions including:

- the annual supply and production planning of blood products and services;
- the entering into and management of contracts for the collection and distribution of blood products and services;
- the gathering of information regarding demand, supply and cost of blood products and services; and
- the facilitation and funding of research and policy development.

The Bill will establish the NBA Board and its role to provide advice to the NBA, through the General Manager, about the performance of the NBA's functions. The Bill also establishes, as a statutory office, the General Manager of the National Blood Authority. The Bill sets out appointment conditions for Board members and the General Manager of the NBA. The Bill also enables the NBA to gather information, other than personal information, in relation to the performance of the NBA's functions.

There are key elements of the new national arrangements that do not require legislation. These include the joint financing arrangements between the Commonwealth and each of the States and Territories, processes for national blood supply production and planning processes for evaluating proposals to make changes to the national blood supply. These arrangements are set out in the National Blood Agreement, which is to be tabled in both Houses of Parliament.

In addition, the role of the Ministerial Conference and the establishment of a Jurisdictional Blood Committee are set out in the National Blood Agreement. The Ministerial Council is charged with a number of functions including the general oversight and determination of national policy for the Australian blood sector, and oversight of the implementation of the National Blood Agreement.

The Jurisdictional Blood Committee's roles include the provision of advice to the Ministerial Council and settling of less significant issues as authorised by the Ministerial Council. The Jurisdictional Blood Committee also has responsibilities in relation to the national blood supply. These include referring proposed changes to the national blood supply for evidence based evaluation, participating in the development of NBA supply and production planning and budget, considering advice from and advising the NBA on matters related to the national blood supply and overseeing the NBA's role in relation to contracts.

Financial Impact Statement

There will be minimal financial impact from the introduction of the National Blood Authority Bill 2002. The Commonwealth government's share of funding for the new national arrangements is to be met from existing forward estimates.

NATIONAL BLOOD AUTHORITY BILL 2002

NOTES ON CLAUSES

PART 1 - PRELIMINARY

Clause 1: Short Title

Clause 1 is a formal provision specifying the short title of the Act as the National Blood Authority Act 2002.

Clause 2: Commencement

This clause is about the commencement of the Bill and provides for Sections 1 and 2 of the Bill to commence on the day they receive Royal Assent. This clause also provides that Sections 3 to 45 will commence on 1 July 2003 or on a single day to be fixed by Proclamation.

Sub-clause 2(2) provides for additional information to be specified, which is not part of this Bill, but that may be included in any subsequent printed version of this Bill.

Sub-clause 2(3) provides a mechanism to ensure that provisions 3 to 45 of the Bill commence no later than 6 months after the Bill receives Royal Assent. If, for example, provisions 3 to 45 do not commence on a date fixed by Proclamation within six months of Royal Assent, they will commence on the first day after the end of the six month period.

The effect of this is that the Bill will exist but will not commence operation until at least 1 July 2003.

Clause 3: Definitions

Several key terms are defined in clause 3:

- “blood products and services” are those products and services that will be funded as part of the publicly funded blood supply and include:

“blood products” which are those products consisting of fresh human blood, components of human blood or products derived from human blood;

“blood related products” is defined to mean products which are alternative or complimentary to the use of blood products for therapeutic and diagnostic purposes and that are regarded as such for the National Blood Agreement;

“services, equipment or procedures that are regarded as blood related services for the National Blood Agreement” are defined to mean services, equipment or procedures, other than blood products or blood related products, which are used in the collection,

supply, and use of blood products. This is further defined to include alternatives to the use of blood products, or would reduce the need for blood products or otherwise affect the demand or supply of blood products and that are regarded as such for the National Blood Agreement.

These definitions are consistent with the definitions of blood products, blood related products and blood related services as set out in the National Blood Agreement. References to blood products and services ‘that are regarded as such for the National Blood Agreement’ are an important constraint upon those products and services that can be funded by the National Blood Authority. Only those blood products and services agreed by the Ministerial Council as constituting part of the publicly funded blood supply under the National Blood Agreement can be funded under this Bill.

- “blood related information” is defined by sub-clause 10(4) of this Bill and includes information relating to the demand and supply of blood products, forecasting donations and supplies of blood products, benchmarking, costs, risks and the safety of blood products and services. It does not include the collection of personal information.
- “Board” is defined to mean the National Blood Authority Board as established by section 12 of this Bill. The Board includes the Chair of the Board.
- “Chair” is defined to mean the Chair of the NBA Board who is appointed by the Minister in consultation with the Ministerial Council.
- “covered Territories” is defined to mean those Territories to which the NBA will ensure supply of blood products and services. The covered Territories are the Australian Capital Territory, the Northern Territory, the Territory of Christmas Island, the Territory of Cocos (Keeling) Islands, the Australian Antarctic Territory and the Jervis Bay Territory.
- “General Manager” is defined as the General Manager of the NBA who is appointed by the Minister after consultation with the NBA Board.
- “Ministerial Council is defined in Part 2 of the National Blood Agreement as being the Australian Health Ministers’ Conference unless the Parties to the Agreement (the Commonwealth, the States, the Northern Territory and the Australian Capital Territory) agree between them that another Ministerial Council will have responsibility for the Agreement or parts of the Agreement.
- “National Blood Agreement” is defined to mean the agreement, in force from time to time, between the Commonwealth, the States, the Northern Territory and the Australian Capital Territory, as represented by the Australian Health Ministers’ Conference, that relates to matters in this Bill and in particular, the supply of blood products and services.
- “national blood arrangements” is defined to mean all the arrangements specified in, or referred to in, the National Blood Agreement. They include arrangements specified in the National Blood Agreement in relation to, for example, the joint Commonwealth, State and Territory financing arrangements for the national blood supply and the process for national blood supply and production planning. They also include arrangements referred to in the National Blood Agreement, such as providing information and advice to the

Ministerial Council or the carrying out of certain functions by the Jurisdictional Blood Committee.

- “NBA” is defined as the National Blood Authority as established by this Bill and comprising the General Manager and the NBA Staff.
- “NBA Staff” are defined as being persons employed by the NBA and engaged under the operation of the *Public Service Act 1999*.

Clause 4: Main purpose of this Act

This clause provides that the purpose of the Bill is to establish the National Blood Authority in order to achieve a coordinated approach to the management of the Australian blood sector. This will be achieved in accordance with the mechanisms set out in the National Blood Agreement such as policy setting, financial arrangements and governance.

Clause 5: This Act binds the Crown

This clause provides that the Bill binds the Crown in right of the Commonwealth and the States and Territories and that the Crown may not be prosecuted for an offence against this Bill or Regulations.

Clause 6: Application to the external Territories

This clause provides that the Bill also applies to each of Australia’s external Territories, however, the obligations of the National Blood Authority to ensure supply of blood products and services applies only to covered Territories. Norfolk Island is not a covered Territory.

Part 2 – The National Blood Authority

Clause 7: Establishment

This clause provides for the establishment of the National Blood Authority (NBA) as a Commonwealth agency consisting of the General Manager and the staff of the NBA.

The note to this clause makes it clear that the NBA does not have a separate legal identity to that of the Commonwealth. The NBA will therefore undertake its functions on behalf of, and exercise the powers of, the executive of the Commonwealth government.

Clause 8: Functions

This clause establishes the functions that the NBA will undertake in managing the ‘national blood arrangements’ on behalf of the Commonwealth, States and Territories as agreed in the National Blood Agreement or otherwise determined by the Ministerial Council, and specified in writing by the Commonwealth Minister. References to the ‘national blood arrangements’ is a reference to the National Blood Agreement where it contains particular mechanisms or processes, for example supply planning, that the NBA is bound to follow in carrying out its functions.

Where the Ministerial Council determines that the NBA will undertake further functions, and these are specified by the Commonwealth Minister by notice in writing, any such notice is a disallowable instrument for the purposes of s46A of the *Acts Interpretation Act 1901*.

Paragraph 8(1)(a) provides that the NBA is to liaise with and gather information from governments, suppliers of blood products and services and other persons. The NBA will gather relevant information from both national and international sources. The information gathered will include, for example, demand, supply, new technological and clinical developments, benchmarking, cost, performance evaluation, risk or other developments which may impact on the national supply of blood. The NBA will also provide information and advice to Commonwealth, State or Territory governments or government agencies, relevant non-government persons or bodies, and relevant international governments or other bodies, on matters relevant to the national blood supply.

Paragraph 8(1)(b) provides that the NBA is to undertake annual planning and budgeting for the production and supply of blood products and services. This function includes, for example, the process for national blood supply and production planning and budgeting as set out in Schedule 2 of the National Blood Agreement.

Paragraph 8(1)(c) provides that the NBA is to undertake national blood arrangements to ensure that there is a sufficient supply of blood products and services in all States and the covered Territories. The National Blood Agreement sets out that in undertaking this function the NBA is to ensure that States and covered Territories can obtain the volume and range of blood products and services they order, consistent with national product availability and good clinical practice.

Paragraph 8(1)(d) provides that the NBA is to carry out national blood arrangements relating to the funding of both the supply of blood products and services and the NBA's operating costs. Matters set out in the National Blood Agreement include developing the national price list for products for the joint Commonwealth funding arrangements and managing the Commonwealth, State and Territories financial contribution within the 63:37 cost share arrangements. The National Blood Agreement also provides for the NBA to participate in the process for national blood supply change proposals that may affect which products and services are a part of the publicly funded blood supply.

Paragraph 8(1)(e) provides that the NBA will enter into and manage contracts with suppliers of blood products and services and other necessary parties for the collection, production, safety and distribution of blood products and services. This paragraph also provides for the administration of financial arrangements including contractual payments and enforcement of contracts.

Paragraph 8(1)(f) provides that the NBA is to carry out national blood arrangements relating to safety, quality and contingency measures and risk mitigation strategies for the supply of blood products and services. For example, under the National Blood Agreement the NBA is required to establish and manage contingency and risk mitigation measures including those developed in consultation with the Jurisdictional Blood Committee and approved by the Ministerial Council. The NBA also has a specific role relating to the safety and quality of the Australian blood sector which it is to undertake in accordance with the National Blood Agreement.

Paragraph 8(1)(g) provides that the NBA is to provide information and advice to the Minister and the Ministerial Council on matters relating to blood products and services. This includes, for example, reporting on all significant developments for the national blood supply to the Ministerial Council and the Commonwealth Minister.

Paragraph 8(1)(h) provides for the NBA to carry out national blood arrangements to facilitate research, policy development and other action relating to blood products and services. This function includes, for example, facilitating and funding appropriate research or the development of clinical guidelines with other bodies such as the National Health and Medical Research Council. The Ministerial Council and the Jurisdictional Blood Committee are able to provide direction to the NBA in relation to this function.

Paragraph 8(1)(i) provides for the NBA to provide secretariat and other assistance to the Board of the NBA, the Jurisdictional Committee, and any advisory committees established under Division 3 of this Bill.

Paragraph 8(1)(j) provides for the NBA to assume other functions as decided by the Ministerial Council. Any such functions are to be specified in a written notice given to the General Manager by the Commonwealth Minister.

Sub-clause 8(2) provides that a determination made under paragraph 8(1)(j) is a disallowable instrument for the purposes of s46A of the *Acts Interpretation Act 1901*.

Clause 9: Policy principles about the NBA's functions

This clause provides that the Commonwealth Minister may give written policy principles to the NBA about the performance of its functions. Under the National Blood Agreement, the Ministerial Council can issue policy principles through the Commonwealth Minister to the NBA in relation to the performance of the NBA's functions, including in relation to safety and quality of the Australian blood sector.

The Commonwealth Minister may issue policy principles to the NBA without the approval of the Ministerial Council in emergency situations that are outside the normal planning and operational processes of the national blood supply and which require immediate action to ensure the availability of blood products and services to persons who need them. In these circumstances the Commonwealth Minister will consult with other members of the Ministerial Council prior to, or as soon as possible after, issuing such policy principles.

The Commonwealth Minister is required to table a copy of any policy principles in each House of Parliament within 15 sitting days after the day on which they were given to the NBA. The policy principles are not disallowable instruments.

The NBA is required to comply with any policy principles that are given by the Commonwealth Minister.

Clause 10: General Manager's power to obtain information and documents

Requirements to give information

This clause provides for the gathering of information related to Australia's blood supply by the NBA.

Sub-clause 10(1) provides that the General Manager may write to a person, as described in sub-clause 10(3), and require that person to give answers or documents that are specified in the General Manager's written notice.

Sub-clause 10(2) provides that the General Manager's notice must contain the date by which the information is to be given and how the information is to be provided. The General Manager must allow the person providing the information at least 14 days from the date of the written notice to respond to the request for information.

Who may be required to give information

Sub-clause 10(3) specifies who may be required to give information. This includes persons with responsibility for the provision of hospital services in a private hospital, suppliers of blood products and services in Australia and importers of blood products and services into Australia. Other classes of persons may be specified by way of regulation as required.

Information that may be required to be given

Sub-clause 10(4) specifies the types of information the General Manager may request. The types of information that may be requested include the demand for, and supply of, blood products and services and forecasts of donation of human blood and plasma. It also includes:

- benchmarking performance in regard to blood products and services, for example, supplier practice and yields, supplier costs, clinical use of blood and blood products and product wastage;
- information regarding the fixed and variable costs of producing and supplying blood products and services, for example, determining actual product costs, research and development and capital costs;
- information relating to the safety and quality of blood products and services, for example, safety and quality of clinical use; and
- information related to any risks to the Australian blood supply, for example infectious agents and manufacturing problems.

The General Manager must not request personal information as defined in the *Privacy Act 1988*.

Offence for failing to comply with a requirement

Sub-clause 10(5) provides that if a person does not comply with a request for information by the General Manager, the person is deemed to have committed an offence for which the penalty is a maximum of 30 penalty points.

Self-incrimination

Sub-clause 10(6) provides that a person is not required to respond to the General Manager's written notice if, by giving that information, the person may incriminate himself or herself or expose themselves to other penalties or liabilities. The note to this provision indicates that a defendant bears the evidential burden if they rely on the excuse set out in this sub-clause.

Compensation for giving documents

Sub-clause 10(7) provides for the reasonable compensation of a person who is complying with the production of documents in response to the General Manager's written notice. Reasonable compensation is limited to the administrative and duplication costs incurred when responding to the General Manager's request.

Clause 11: Protecting confidentiality of information

This clause provides that the General Manager, NBA Board members, NBA staff members or any person performing services for the NBA (for example, consultants or contractors) must not disclose any fact or document gained in the course of their official employment. An exception is provided for information to be disclosed in the course of undertaking official employment.

Contravention of this section is an offence carrying a maximum penalty of imprisonment for 2 years.

This provision applies to a person who is currently or has been previously employed by the NBA.

Part 3 – The NBA Board

Clause 12: Establishment

This clause provides for the establishment of the NBA Board.

Clause 13: Functions

This clause sets out the functions that are to be undertaken by the NBA Board in its role to provide advice to the NBA on the strategic directions of the agency. The Board will have a key role in:

- (a) participating in consultation with the Commonwealth Minister on the appointment of the NBA's General Manager, for example, by making recommendations to the Commonwealth Minister on the appointment of a suitable person to the position of General Manager;
- (b) providing advice to the General Manager about the performance of the NBA's functions either at the request of the General Manager or of the Board's own volition; and
- (c) to liaise with governments, suppliers and others about matters relating to the NBA's functions.

The clause also provides that the Commonwealth Minister may give written notices to the Chair about other functions that the Board is to undertake.

Sub-clause 13(2) provides that any such notice is a disallowable instrument for the purposes of s46A of the *Acts Interpretation Act 1901*.

Clause 14: Membership

This clause sets out the membership of the Board as comprising:

- (a) a Chair; and
- (b) a person representing the interests of the Commonwealth; and
- (c) 1 or 2 persons representing the interests of the States and Territories; and
- (d) a person representing the community;
- (e) a person with expertise in public health issues relating to human blood; and
- (f) a person with financial or commercial expertise.

The membership of the Board, with its balance of expert and jurisdictional members, is intended to facilitate the Board in its advisory capacity to the NBA.

The role of the jurisdictional members is to represent the collective interests of the States and Territories and the interests of the Commonwealth. It is expected that the jurisdictional Board members will meet regularly with the Jurisdictional Blood Committee to assist them in this role.

Clause 15: Appointing members

This clause sets out that Board members are to be formally appointed by the Commonwealth Minister, on a part-time basis, by written instrument.

Before appointing Board members the Commonwealth Minister must be satisfied that all nominees have been selected by the Ministerial Council.

In relation to the Chair, the Commonwealth Minister must be satisfied that the person selected to be the Chair is considered by the Ministerial Council to be independent from the interests of the suppliers of blood products and services and the Commonwealth, States, and Territories. For example, consideration by the Ministerial Council in determining the independence of the Chair may include current or recent past employment with a supplier of blood products and services or ownership of shares in such a company. Relevant considerations may also include current employment by the Commonwealth, or a State or Territory Health Department.

The Commonwealth Minister must also be satisfied that the person selected by the Ministerial Council to represent the interests of the Commonwealth was nominated by the Commonwealth and that the person or persons selected to represent the interests of the States and Territories were nominated by a State or Territory.

Clause 16 Term of appointment

The term of appointment for all board members will be set out in the written instrument of appointment and must not exceed 4 years.

Clause 17 Acting Appointments

This clause provides for the Commonwealth Minister to appoint an acting Chair or an acting Board member to the NBA Board if there is a vacancy, whether an appointment has been

made to the position previously or during a period when the Chair or Board member is absent from the Board or from Australia or is unable to perform the duties of the position for any reason.

Sub-clause 17(3) also provides that the Commonwealth Minister may only appoint a person to act as a Board member if the Minister is satisfied that the person is qualified under Clause 14 (b) to (f). This requires the Minister to maintain the balance of membership on the Board while any acting arrangements are in place.

Sub-clause 17(4) ensures that anything done by a person acting as a Board member is not invalid due to any procedural defect in the appointment.

Clause 18: Members' remuneration

Sub-clause 18(1) establishes that Board members are to be paid the remuneration that is determined by the Remuneration Tribunal or if no determination is in operation, the member is to be paid the remuneration that is specified in a written determination by the Commonwealth Minister.

Sub-clause 18(2) makes it clear that a Board member is not entitled to be paid remuneration if he or she is employed on a full-time basis by a State instrumentality (for example a State health department), other than a tertiary education institution.

The note to sub-clause 18(2) sets out that a Board member who is employed by the Commonwealth or a Territory is not entitled to be paid remuneration under sub-section 7(11) of the *Remuneration Tribunal Act 1973*.

Sub-clause 18(3) sets out that a Board member is entitled to be paid the allowances that are specified in a written determination made by the Commonwealth Minister. These allowances may include an annual allowance and a travelling allowance, subject to the *Remuneration Tribunal Act 1973*.

Determinations made under Clause 18 are disallowable instruments for the purposes of s46A of the *Acts Interpretation Act 1901*.

Sub-clause 18(5) sets out that Clause 18, with the exception of sub-clause 18(2), has effect subject to the *Remuneration Tribunal Act 1973*.

Clause 19 Leave of Absence

Sub-clause 19(1) provides that the Commonwealth Minister may grant leave of absence to the Chair of the NBA. Any leave granted may be subject to conditions and terms that the Minister determines.

Sub-clause 19(2) provides that the Chair of the NBA may grant leave of absence to any member of the NBA Board that may be subject to conditions and terms that the Chair determines.

Clause 20 Resignation

This clause provides for the resignation of any Board member, including the Chair, from the NBA Board by giving their resignation in writing to the Minister.

Clause 21 Termination of appointment

Sub-clause 21(1) provides that the Commonwealth Minister may terminate the appointment of a member of the NBA Board for misbehaviour or physical or mental incapacity.

Sub-clause 21(2) provides that the Commonwealth Minister must terminate a Board member's appointment if the Board member does any of the things listed in paragraphs 21(2)(a) to (c) inclusive. This includes: being absent from duty (except on leave of absence) for 3 consecutive Board meetings; becoming bankrupt; compounding with his or her creditors; assigning his or her remuneration for the benefit of his or her creditors; or engaging in employment outside the duties of his or her office which may or could conflict with the performance of his or her duties.

Sub-clause 21(3) provides that the Commonwealth Minister must terminate the appointment of the Chair of the NBA Board if the Ministerial Council considers that the Chair is no longer independent from suppliers of blood products and services or is no longer independent from the Commonwealth, States and Territories.

Clause 22: Board procedures

Sub-clause 22(1) provides that the Commonwealth Minister may determine in writing matters with regard to the operation of the NBA Board that include, but are not limited to:

- (a) the procedures to be followed in convening Board meetings;
- (b) the constitution of a quorum for Board meetings;
- (c) the procedures for conducting Board meetings which may include the manner in which the Board resolves matters and may also include other matters that the Minister may determine;
- (d) the manner in which Board members are to disclose any potential conflicts of interest
- (e) the manner in which the Board records the proceedings of its meetings and any resolutions it makes; and
- (f) any reporting requirements which may include reports to the Commonwealth Minister and to the public but may also include other reporting matters that the Minister may determine.

Sub-clause 22(2) provides that if the Commonwealth Minister has not made a determination in relation to the operation of the NBA Board, the Board may determine the way in which it operates with regard to the matters listed in paragraphs 16 (1)(a) to (f) inclusive.

Sub-clause 22(3) indicates that a determination made under sub-clause 22(1), is a disallowable instrument for the purposes of s46A of the *Acts Interpretation Act 1901*.

Part 4 – The NBA General Manager, staff and advisory committees

Division 1 – The General Manager

Subdivision A – Establishment and role

Clause 23: General Manager

Clause 23 establishes that there is to be a General Manager of the NBA.

Clause 24: Function

Clause 24 establishes that the General Manager is to be responsible for managing the NBA. This responsibility includes carrying out the functions of the NBA in Clause 8.

Clause 25: Working with the Board

Sub-clause 25(1) provides that the General Manager must request the Board's advice on strategic matters that relate to the performance of the NBA's functions. Strategic matters may include, for example, supply and demand planning, budgetary matters, blood supply change proposals or other matters.

Sub-clause 25(2) sets out that the General Manager must have regard to the advice provided by the Board, whether or not the advice given by the Board was in response to a request. This Clause contemplates that the Board, in undertaking its functions specified in Clause 13, may of its own volition provide advice to the General Manager. However, the General Manager is not bound to follow the advice provided by the Board.

Sub-clause 25(3) requires the General Manager to keep the Board informed of the NBA's operations and to give to the Board such reports, documents and information in relation to those operations as the Chair requires.

Sub-clause 25(4) provides that the General Manager may attend Board meetings as an observer either in person or by telephone or other means, for example, videoconference. This provision gives the General Manager the right to attend Board meetings.

Clause 26: Delegation

Sub-clause 26(1) provides a power for the General Manager to delegate, in writing, any or all of his or her functions or powers to a member or members of the NBA staff.

Sub-clause 26(2) sets out that where a member of the NBA staff performs a delegated function or exercises a delegated power, he or she must comply with any written directions of the General Manager.

Subdivision B – Appointing the General Manager

Clause 27: Appointing the General Manager

Sub-clause 27(1) provides that the General Manager is to be appointed by the Commonwealth Minister. This appointment is to be made in writing.

Sub-clause 27(2) sets out that before appointing the General Manager the Commonwealth Minister must first consult the Board about a proposed appointment. This is in line with the Board's function under paragraph 13(1)(a) to participate in consultation with the Commonwealth Minister about the appointment of the General Manager, for example, by making recommendations to the Commonwealth Minister on the appointment of a suitable person to the position of General Manager.

Clause 28 Term of appointment

Clause 28 provides that the term of appointment for the General Manager is to be set out in the written instrument of appointment and must not exceed 4 years.

Clause 29 Acting Appointments

This clause provides for the Commonwealth Minister to appoint a person to act as General Manager if there is a vacancy, whether an appointment has been made to the position previously or during a period when the General Manager is absent from duty or from Australia or is unable to perform the duties of the position for any reason.

Sub-clause 29(2) ensures that anything done by the person acting as General Manager is not invalid due to any procedural defect in the appointment.

Clause 30: General Manager's Remuneration

Sub-clause 30(1) provides that the General Manager is to be paid the remuneration that is determined by the Remuneration Tribunal. If there is no determination by the Remuneration Tribunal in place, the General Manager is to be paid the remuneration that is specified in a written determination by the Minister.

Sub-clause 30(2) provides that the General Manager is to be paid the allowance that are specified in a written determination made by the Commonwealth Minister. These allowances may include an annual allowance and a travelling allowance, subject to the *Remuneration Tribunal Act 1973*.

Sub-clause 30(3) sets out that determinations made under this Clause are disallowable instruments for the purposes of s46A of the *Acts Interpretation Act 1901*.

Sub-clause 30(4) provides that Clause 30 has effect subject to the *Remuneration Tribunal Act 1973*.

Clause 31 Outside employment

This clause provides that the General Manager must not engage in employment outside the NBA without the express permission of the Commonwealth Minister.

Clause 32 Leave of Absence

Sub-clause 32(1) provides that the General Manager of the NBA is entitled to recreation leave as determined by the Remuneration Tribunal.

Sub-clause 32(2) provides that the Commonwealth Minister may grant leave of absence, other than recreation leave, to the General Manager may be subject to conditions and terms that the Minister determines. A determination under this sub-clause is not a disallowable instrument.

Clause 33 Disclosure of interests

This clause provides that the General Manager must disclose by way of written notice to the Commonwealth Minister all interests, financial or otherwise, that the General Manager has, or acquires during his or her appointment as General manager, which could conflict with the proper performance of his or her functions as General Manager.

Clause 34 Resignation

This clause provides for the resignation of the General Manager from the NBA by giving his or her resignation in writing to the Minister.

Clause 35 Termination of appointment

Sub-clause 35(1) provides that the Commonwealth Minister may terminate the appointment of the General Manager for misbehaviour or physical or mental incapacity.

Sub-clause 35(2) provides that the Commonwealth Minister must terminate the General Manager's appointment if the General Manager does any of the things listed in paragraphs 35(2)(a) to (c) inclusive. This includes: being absent from duty (except on leave of absence) for 14 consecutive days or for 28 days in any 12 months commencing from the date of appointment; becoming bankrupt; compounding with his or her creditors; assigning his or her remuneration for the benefit of his or her creditors; or engaging in employment outside the duties of his or her office without the expressed approval of the Commonwealth Minister or does not comply with Clause 33 "Disclosure of interests".

Sub-clause 35(3) provides for the Commonwealth Minister, with the consent of the General Manager, to retire the General Manager from office on the grounds of physical or mental incapacity if the General Manager is an eligible employee for the purposes of the *Superannuation Act 1976* or is a member of a superannuation scheme established by deed under the *Superannuation Act 1976*

Sub-clause 35(4) provides for the retirement of the General Manager on grounds of invalidity only if the General Manager is retired on grounds of mental or physical incapacity and if the Commonwealth Superannuation Scheme (CSS) Board have certified that the General Manager is eligible to be retired on grounds of invalidity and is therefore eligible to receive his or her superannuation entitlements.

This sub-clause would apply in cases where the General Manager is not able to give consent as required in sub-clause 35(4) and where the General Manager has superannuation entitlements under the Commonwealth Superannuation Scheme.

Sub-clause 35(5) provides for the retirement of the General Manager on grounds of physical or mental incapacity only if the General Manager is retired on grounds of mental or physical incapacity and if the Public Sector Superannuation (PSS) Board have certified that the General Manager is eligible to be retired on grounds of physical or mental incapacity and is therefore eligible to receive his or her superannuation entitlements, under the Public Sector Superannuation Scheme.

This sub-clause would apply in cases where the General Manager is not able to give consent as required in sub-clause 35(5) and where the General Manager has superannuation entitlements under the Public Sector Superannuation Scheme.

Division 2 – Staff and Consultants

Clause 36: Staff

Sub-clause 36(1) provides that staff of the NBA are persons engaged under the *Public Service Act 1999*.

Sub-clause 36(2) establishes that the General Manager and the NBA staff together constitute a Statutory Agency within the meaning of the *Public Service Act 1997* and that the General Manager is the Head of that Statutory Agency.

Clause 37: Consultants

Clause 37 provides a power for the General Manager, on behalf of the NBA, to engage consultants to perform services for the NBA that are related to the NBA's functions.

Division 3 – Advisory Committees

Clause 38: Advisory Committees

Sub-clause 38(1) provides a power for the General Manager to establish advisory committees to assist with the performance of the NBA's functions.

Sub-clause 38(2) provides that an advisory committee consists of persons appointed by the General Manager.

Sub-clause 38(3) provides that the General Manager may give an advisory committee written directions about the way in which the committee is to carry out its task and the procedures to be followed in relation to its meetings.

Clause 39: Committee members' remuneration

Sub-clause 39(1) provides that a person appointed to an advisory committee is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination by the Remuneration Tribunal is in operation then the person is to be paid the remuneration that is specified in a written determination by the Commonwealth Minister.

Sub-clause 39(2) makes it clear that an advisory committee member is not entitled to be paid remuneration if he or she is employed on a full-time basis by a State instrumentality (for example a State health department, a public statutory corporation, or a company beneficially owned by a State or Territory Government), other than a tertiary education institution.

The note to sub-clause 39(2) sets out that an advisory committee member who is employed by the Commonwealth or a Territory is not entitled to be paid remuneration under subsection 7(11) of the *Remuneration Tribunal Act 1973*.

Sub-clause 39(3) sets out that an advisory committee member is entitled to be paid the allowances that are specified in a written determination made by the Commonwealth Minister. These allowances may include a travelling allowance, subject to the *Remuneration Tribunal Act 1973*.

Determinations made under clause 39 are disallowable instruments for the purposes of s46A of the *Acts Interpretation Act 1901*.

Sub-clause 39(5) sets out that clause 39, with the exception of sub-clause 39(2), has effect subject to the *Remuneration Tribunal Act 1973*.

Part 5 – The National Blood Account

Clause 40: National Blood Account

Clause 40 establishes the National Blood Account as a Special Account for the purposes of the *Financial Management and Accountability Act 1997*.

Clause 41: Credits to the Account

Clause 41 sets out the moneys and amounts that must be credited to the Special Account as follows:

- (a) all money appropriated by the Commonwealth Parliament for the purposes of the Account. This covers all money appropriated by the Commonwealth Parliament through the normal budget estimates and annual appropriation processes for the purposes of the special account. This includes, for example, money appropriated for the NBA's operating costs under paragraph 8(1)(d)(ii);

- (b) amounts required to be credited to the Account by the Commonwealth under the national blood arrangements that relate to the funding of the supply of blood products and services. This sub-clause creates a standing appropriation for these purposes. This clause operates by reference to the ‘national blood arrangements’ which means the arrangements in, or referred to in, the National Blood Agreement. The amounts which the Commonwealth is required to contribute are set out in Part 4 and Schedule 3 of the National Blood Agreement. Accordingly, the amounts that the Commonwealth is required to credit to the special account are those amounts the Commonwealth is required to pay under the National Blood Agreement. This sub-clause specifically excludes from the standing appropriation arrangements any amounts other than those relating to the supply of blood products and services under paragraph 8(1)(d)(i);
- (c) amounts equal to those received by the Commonwealth in connection with the performance of the NBA’s functions. This includes amounts received from the States, the Australian Capital Territory and the Northern Territory for the supply of blood products and services and the NBA’s operations under clause 8(1)(d);
- (d) amounts equal to interest received by the Commonwealth from the investment of money from the Account;
- (e) amounts equal to those received by the Commonwealth in relation to property paid for with money from the account; and
- (f) amounts equal to the amounts of any gifts or bequests made for the purposes of the Account.

Clause 42: Purposes of the Account

Clause 42 sets out that the purposes for which money in the Special Account may be expended are:

- (a) in payment or discharge of the costs, expenses and other obligations incurred by the Commonwealth in the performance of the NBA’s functions; or
- (b) in payment of any remuneration or allowances payable to any person.

The NBA’s functions are those set out in clause 8 as follows:

- a. to liaise with, and gather information from, governments, suppliers and others about matters relating to blood and blood products;
- b. to carry out national blood arrangements relating to annual plans and budgets for the production and supply of blood products and services
- c. to carry out national blood arrangements to ensure that there is a sufficient supply of blood products and services in all the States and covered Territories;
- d. to carry out national blood arrangements relating to the funding of:
 - (i) the supply of blood products and services (the Commonwealth’s share of which is funded under the standing appropriation); and
 - (ii) the NBA’s operations (the Commonwealth’s share of which is funded under the annual appropriation);

- a. to enter and manage contracts and arrangements for the collection, production and distribution of the blood products and services necessary to ensure a sufficient supply of blood products and services in the States and covered Territories;
- b. to carry out national blood arrangements relating to safety measures, quality measures, contingency measures and risk mitigation measures for the supply of blood products and services;
- c. to provide information and advice to the Minister and the Ministerial Council about matters relating to blood products and services;
- d. to carry out national blood arrangements relating to the facilitation and funding of research, policy development and other action about matters relating to blood products and services;
- e. to provide assistance:
 - (i) in accordance with national blood arrangements to a committee referred to in those arrangements; and
 - (ii) to the Board; and
 - (iii) to the advisory committees (if any) established under clause 38;
- a. such other functions (if any) as are determined by the Ministerial Council and specified in a written notice given by the Minister to the NBA.

This clause makes it clear that the only function that is to be funded out of the standing appropriation created under Clause 41 is that of the supply of blood products and services in accordance with the national blood arrangements.

Sub-clause 42(b) enables the payment of any remuneration or allowances to any person under this Act. This would include any remuneration and allowances paid to:

- a. Board members who are not employed by State or Territory instrumentalities as set out in clause 18;
- b. the NBA's General Manager under clause 30;
- c. members of any advisory committees established by the General Manager under clause 38 of the Act, where those members are not employed by State or Territory instrumentalities.

Part 6 – Miscellaneous

Clause 43: Corporate Plans

Clause 43 provides that the NBA must, at all times after the first year of its operation, have a corporate plan that sets out its current objectives and business strategies that has been approved by the Commonwealth Minister.

A corporate plan may include, for example, a vision and mission statement and a statement regarding the values of the NBA. The corporate plan may also include specific information on strategic planning, corporate management, information management, people management, financial management and a business plan for reporting.

The Minister may approve a corporate plan provided by the NBA if the Plan has been endorsed by the Ministerial Council.

Clause 44: Annual Reports

Sub-clause 44(1) provides an obligation for the General Manager to prepare and give to the Ministerial Council and the Commonwealth Minister a report of the NBA's operation during the year ending on each 30 June. The report must be prepared and given as soon as practicable after 30 June in each year. The General Manager's report will include matters on which the General Manager is required to report on under the *Public Service Act 1999* and the *Financial Management and Accountability Act 1997*.

Sub-clause 44(2) provides an obligation on the Chair of the NBA Board to prepare and give to the Ministerial Council and the Minister a report of the Board's operation during the year ending on each 30 June. The report must be prepared and given as soon as practicable after 30 June in each year.

Sub-clause 44(3) sets out that both the General Manager's and the NBA Board's report must be presented to each House of Parliament within 15 sitting days of that House after the day the Minister is given the report.

A combined annual report from the General Manager and the NBA Board is not precluded by this section.

Clause 45: Regulations

Clause 45 provides that the Governor-General may make regulations prescribing matters required or permitted to be prescribed by the Bill, or necessary or convenient to be prescribed for carrying out or giving effect to the Bill.