EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973
SECTION 23DNA

HEALTH INSURANCE (ACCREDITED PATHOLOGY LABORATORIES – APPROVAL) AMENDMENT PRINCIPLES 2009 (No. 1)

Section 23DNA of the *Health Insurance Act 1973* ('the Act') provides for the Minister to determine the principles to be applied by the Minister in exercising powers under section 23DN of the Act to approve in principle, or not to approve, premises as an accredited pathology laboratory. The current principles determined under section 23DNA are the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* ('the Principles').

Medicare benefits, apart from some basic tests conducted by treating medical practitioners on their own patients, are not payable in respect of pathology services unless they are rendered in an accredited pathology laboratory. The Principles operate to ensure minimum acceptable standards in pathology laboratories. The Principles make reference to accreditation materials (National Pathology Accreditation Advisory Council ('NPAAC') materials and other materials), which are standards, guidelines and other assessment aids that must be taken into account during the accreditation process. Medicare Australia administers the accreditation process and the National Association of Testing Authorities, Australia ('NATA') conducts the accreditation assessment, in conjunction with the Royal College of Pathologists Australasia ('RCPA').

NPAAC has recently endorsed the following two documents, which are revised versions of two accreditation documents currently listed in Schedule 1 to the Principles:

(i) Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Third Edition 2009); and
(ii) National Association of Testing Authorities, Australia AS 4633 (ISO 15189) Field Application Document – Supplementary Requirements for Accreditation in the Field of Medical Testing, July 2009.

The *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2009* ('the Amending Principles') amend Schedule 1 to the Principles to refer to the revised versions of these two documents.

The Amending Principles commence on 1 July 2009.

Details of the Amending Principles are set out in the Attachment.

The Amending Principles are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

CONSULTATION

(i) Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Third Edition, 2009)

In accordance with the established NPAAC public consultation and drafting process, the draft document 'Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Third Edition 2009)' was circulated for comments to:

- all laboratories and apheresis facilities within Australia;
- state and territory health departments;
- hospitals and bone marrow transplant units; and
- NPAAC members, including state and territory representatives.

Submissions from the public consultation phase for this document were considered by NPAAC in the finalisation of the document. Feedback from stakeholders has been supportive of the proposed requirements. Most respondents indicated that they already comply with the proposed requirements or that they intend to utilise other networks to ensure they are in compliance with the proposed requirements and minimise their compliance costs.

The draft requirements have been developed over a number of years and stakeholders are anticipating the introduction of the new standards and have commenced implementing systems to ensure they will be compliance with the requirements when they come into effect.

(ii) National Association of Testing Authorities, Australia AS 4633 (ISO 15189) Field Application Document – Supplementary Requirements for Accreditation in the Field of Medical Testing, July 2009.

The document 'National Association of Testing Authorities, Australia AS 4633 (ISO 15189) Field Application Document – Supplementary Requirements for Accreditation in the Field of Medical Testing, July 2009' has been reviewed by members of the –

- Medical Testing Accreditation Advisory Committee
- RCPA; and
- NPAAC, including state and territory representatives.

The document incorporates comments from those expert groups and was endorsed by NPAAC at its 23 April 2009 meeting with an implementation date of 1 July 2009.

ATTACHMENT

DETAILS OF THE *HEALTH INSURANCE (ACCREDITED PATHOLOGY LABORATORIES – APPROVAL) AMENDMENT PRINCIPLES 2009 (No. 1)*

1 Name of Principles

This section provides that the title of the Principles is the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2009 (No. 1)*.

2 Commencement

This section provides that the Principles commence on 1 July 2009.

3 Amendment of *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002*

This section provides that Schedule 1 amends the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002*.

Schedule 1 Amendments

Item 1

Table item 1 of Schedule 1, Part 1 to the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* currently lists the following document as an accreditation material ("NPAAC material"):

> '*Guidelines for Laboratory Procedures Related to the Processing, Storage and Infusion of Cells for Transplantation or Cell Therapy*', published in 2004 ('the Guidelines').

The Guidelines have recently been revised and renamed, and are now the '*Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Third Edition 2009)*' ('the HPC Requirements').

Item 1 of Schedule 1 to the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2009 (No. 1)* replaces the reference to the Guidelines with a reference to the HPC Requirements.

This means that the HPC Requirements will be included in the list of accreditation materials ("NPAAC materials") on and from 1 July 2009.

The HPC Requirements outline the minimum requirements for the competence and quality to be met by facilities and individuals preparing Human Haemopoeitic Progenitor Cells (HPCs) and/or lymphocytes for infusion, and for providing assured safety and quality of the product. The collection, processing, storage and issue of HPCs is a highly specialised and complex clinical activity which sits within the clinical field of haematology. HPCs are cells capable of bone marrow repopulation and can be collected by laboratories or other facilities involved in donor selection, collection, processing, storage and issue or disposal of HPCs and lymphocytes used for infusion or cellular therapy, such as bone marrow transplantation.

Apheresis unit clinical activity does not fall within the usual scope of pathology laboratory activity. However, independent expert advice indicates that having quality management procedures for collection, processing, storage and issue of HPCs is important in ensuring quality and patient safety. A deficiency in the collection of material could affect the quality of the resultant product and their fitness for purpose and could also present a risk to donor safety or the safety of the product with a downstream risk to patient safety.

Although the cell collection activity that occurs in apheresis units is in many ways similar to laboratory-based activity, it is not controlled by laboratories and there is no other relevant accreditation framework available to guide the quality of the collection process.

The HPC Requirements have been developed in consultation with Therapeutic Goods Administration and are complementary to their regulatory framework.

A copy of the HPC Requirements is available on the NPAAC website – www.health.gov.au/npaac

A costing of the possible financial impact has been done through a Business Cost Calculator in consultation with the Office of Best Practice Regulation (OBPR Reference no 9575.)

Item 2

Schedule 1, Part 2 to the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* currently lists the following document as an accreditation material ("other material"):

> '*National Association of Testing Authorities, Australia AS 4633 (ISO 15189) Field Application Document – Supplementary Requirements for Accreditation in the Field of Medical Testing, August 2007*' ('the current NATA Field Application Document').

The current NATA Field Application Document has recently been revised and is now the '*National Association of Testing Authorities, Australia AS 4633 (ISO 15189) Field*

Application Document – Supplementary Requirements for Accreditation in the Field of Medical Testing, July 2009' ('the revised NATA Field Application Document').

Item 2 of Schedule 1 to the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2009 (No. 1)* replaces the reference to the current NATA Field Application Document with a reference to the revised NATA Field Application Document.

This means that the revised NATA Field Application Document will be included in the list of accreditation materials ("other materials") on and from 1 July 2009.

The NATA Field Application Document is developed by NATA and provides interpretive detail of the NPAAC standards and guidance for the quality and competence of medical testing, in particular an explanation of the applications of *ISO 15189: 2003 Medical laboratories – Particular requirements for quality and competence* to the various disciplines of pathology testing and also a description of the NATA/RCPA accreditation procedures applied in this field. Medical testing laboratories must comply with this document, all relevant clauses of ISO 15189 and NPAAC Standards and relevant statutory requirements for accreditation to be granted and/or continued.

The NATA Field Application Document is reviewed every two years to ensure that the document reflects the current applications of ISO 15189. As part of the accreditation framework to ensure pathology laboratories perform to best practice guidelines and are competent to undertake specific testing, the document is included in Schedule 1, Part 2 to the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002.*

A copy of the revised NATA Field Application Document is available on the NATA website – www.nata.asn.au

The changes made to the current NATA Field Application Document have been assessed as being low impact or no compliance cost.