**EXPLANATORY STATEMENT**

**HEALTH INSURANCE ACT 1973**
**SECTION 23DNA**

**HEALTH INSURANCE (ACCREDITED PATHOLOGY LABORATORIES – APPROVAL) AMENDMENT PRINCIPLES 2009 (No. 2)**

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').

Apart from some basic tests conducted by treating medical practitioners on their own patients, Medicare benefits 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 three documents, which are revised versions of accreditation documents currently listed in Schedule 1 to the Principles:

(i) *Requirements for Participation in External Quality Assessment (Fourth Edition 2009)*
(ii) *Requirements for the Retention of Laboratory Records and Diagnostic Material (Fifth Edition 2009)*
(iii) *Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Second Edition 2009).*

The *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2009 (No. 2)* ('the Amending Principles') amend Schedule 1 to the Principles to refer to the revised versions of these three documents.

The Amending Principles commence on 1 January 2010.

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 Participation in External Quality Assessment (Fourth Edition 2009)*

In accordance with the established NPAAC public consultation and drafting process, the draft document *Requirements for Participation in External Quality Assessment (Fourth Edition 2009)* was circulated for comments to:

- all laboratories and pathology professional organisations within Australia;
- state and territory health departments; and
- NPAAC members, including state and territory representatives.

Submissions from the public consultation phase for this draft document were considered by NPAAC in the finalisation of the document. Feedback from stakeholders has been supportive of the proposed requirements. The Requirements document supersedes the previous external quality assessment standards but there are no requirements that would have associated additional compliance costs. Hence, it is presumed that stakeholders already comply with the proposed requirements and there will be minimal, if any, additional compliance costs.

### *(ii) Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Second Edition 2009)*

In accordance with the established NPAAC public consultation and drafting process, the draft document *Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Second Edition 2009)* was circulated for comments to:

- all laboratories within Australia;
- state and territory health departments; and
- NPAAC members, including state and territory representatives.

Submissions from the public consultation phase for this draft 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 so there would be minimal, if any, additional compliance costs.

### *(iii) Requirements for the Retention of Laboratory Records and Diagnostic Material (Fifth Edition 2009)*

The fifth edition of the requirements is substantially the same as the fourth edition, with only minor amendments. This was a short-cycle review to correct a specific issue – namely, the retention times for semen and urine samples. As such, it was not considered necessary to go out to public consultation for such a minor change. It is anticipated that the document will undergo a full review in 2010/2011.

There are no additional compliance costs associated with the corrections to the document.

**ATTACHMENT**

**DETAILS OF THE *HEALTH INSURANCE (ACCREDITED PATHOLOGY LABORATORIES – APPROVAL) AMENDMENT PRINCIPLES 2009 (No. 2)***

**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. 2)*.

**2 Commencement**

This section provides that the Principles commence on 1 January 2010.

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

> *Standards for Pathology Laboratory Participation in External Proficiency Testing Programs*, published in 2004 ('the Standards').

The Standards have recently been revised and renamed, and are now the '*Requirements for Participation in External Quality Assessment (Fourth Edition 2009)'* ('the External Quality Assessment Requirements').

Item 1 of Schedule 1 to the Amending Principles replaces the reference to the Standards with a reference to the External Quality Assessment Requirements.

This means that the External Quality Assessment Requirements will be included in the list of accreditation materials ("NPAAC materials") on and from 1 January 2010.

The External Quality Assessment Requirements outline the general features that an external quality assessment program must have in order to provide an effective monitoring strategy for the various pathology disciplines. The ongoing participation to

an acceptable standard in appropriate external quality assessment programs is an essential aspect of good laboratory practice.

External quality assessment is usually conducted by an external agency and is primarily designed to determine the performance of the laboratory for specific tests or test procedures, and to monitor a laboratory's continuing performance.

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

An assessment has been completed for the External Quality Assessment Requirements and the document has been assessed as having low impact or no compliance costs.

**Item 2**

Table item 11 of Part 1, Schedule 1 to the Principles currently lists the following document as an accreditation material ("NPAAC material"):

> *Standards and Guidelines for Laboratory Testing of Antibodies to the Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)*, published in 2006 ('the HIV/HCV Standards').

The HIV/HCV Standards have been revised and renamed and are now the *Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Second Edition 2009)* ('the HIV/HCV Requirements').

Item 2 of Schedule 1 to the Amending Principles replaces the reference to the HIV/HCV Standards with a reference to the HIV/HCV Requirements.

This means that the HIV/HCV Requirements will be included in the list of accreditation materials ("NPAAC materials") on and from 1 January 2010.

The HIV/HCV Requirements outline the minimum standards for good pathology laboratory practice in Australia for testing for HIV and Hepatitis C. These requirements have been developed with reference to current and proposed Australian legislative regulations and other relevant International standards. The implementation of these requirements is to assist medical and scientific laboratory professionals and to avoid public health risks.

The review of the document was limited to address a specific issue and also took the opportunity to ensure that the document aligned with international requirements that are fundamental to the quality management system of a pathology laboratory. The new requirements do not include any new additional requirements.

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

An assessment has been completed for the HIV/HCV Requirements and the document has been assessed as having low impact or no compliance cost.

**Item 3**

Table item 20 of Part 1, Schedule 1 to the Principles currently lists the following document as an accreditation material ("NPAAC material"):

> *Requirements for the Retention of Laboratory Records and Diagnostic Material*, published in 2007 ('the current Retention Requirements').

The Retention Requirements have been revised and are now the *Requirements for the Retention of Laboratory Records and Diagnostic Material (Fifth Edition 2009)* ('the revised Retention Requirements').

The fifth edition of the requirements is substantially the same as the fourth edition, with only minor amendments. These requirements outline the minimum standards for retention of records and materials. Most of the retention times are aligned with international practice. Individual laboratories may choose to exceed these minimum requirements based on local circumstances or historical practice.

Item 3 of Schedule 1 to the Amending Principles replaces the reference to the current Retention Requirements with a reference to the revised Retention Requirements.

This means that the revised Retention Requirements will be included in the list of accreditation materials ("NPAAC materials") on and from 1 January 2010

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

An assessment has been completed for the revised Retention Requirements and the document has been assessed as having low impact or no compliance cost.