EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2013 (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 his or her powers under Section 23DN of the Act to approve in principle, or refuse 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').

Aside from some basic tests conducted by medical practitioners on their own patients or on patients of practitioners within their own medical practice, Medicare benefits for pathology services are only payable when they are rendered in an accredited pathology laboratory. The Principles operate to ensure minimum acceptable standards in pathology laboratories at which Medicare eligible pathology services are provided. The Principles specify a number of documents setting out relevant standards against which applicants for accreditation are to be assessed. These documents are issued by the National Pathology Accreditation Advisory Council (NPAAC) or endorsed by NPAAC for inclusion as supplementary accreditation materials, such as the National Association of Testing Authorities, Australia (NATA). Field Application Document. The Department of Human Services administers the accreditation process and NATA conducts the accreditation assessment, in conjunction with the Royal College of Pathologists of Australasia.

The purpose of the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2013 (No. 1)* ('the Amending Principles') is to amend the Principles to incorporate revised versions of a number of NPAAC documents and one new NPAAC document.

1. NPAAC accreditation materials

NPAAC has recently endorsed the new *Requirements for Medical Pathology Services (First Edition 2013)* which is an overarching document that sets out the core elements of good laboratory practice based on existing accreditation standards. This initiative was to remove any duplication and allow the technical documents to be more focussed on relevant technical requirements. No new requirements have been imposed.

The balance of the documents are revised versions of a number of the accreditation documents currently listed in Schedule 1 to the Principles, that have been updated to be read in conjunction with the *Requirements for Medical Pathology Services* document and to be more comprehensive:

- Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Fourth Edition 2013)

- Requirement for the Facilities and Operation of Mortuaries (Third Edition 2013)
- Requirements for Enrolment and Participation in External Quality Assessment (Fifth Edition 2013)
- Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection (Third Edition 2013)
- Requirements for the Performance of Anatomical Pathology Cut-Up (Third Edition 2013)
- Requirements for Medical Testing of Human Nucleic Acids (Second Edition 2013)
- Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Third Edition 2013)
- Requirements for Medical Testing of Microbial Nucleic Acids (Second Edition 2013)
- Requirements for Cytogenetic Testing (Second Edition)
- Requirements for Information Communication (Third Edition 2013)
- Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Third Edition 2013)
- Requirements for the Retention of Laboratory Records and Diagnostic Material (Sixth Edition 2013)
- Requirements for Transfusion Laboratory Practice (Second Edition 2013)

The proposed *Requirements for Medical Pathology Services* document will supersede the *Requirements for Pathology Laboratories* and *Requirements for Quality Management in Medical Laboratories* documents.

2. National Association of Testing Authorities Field Application Document

The document *Interpretation of NPAAC Requirements and ISO 15189 Medical Testing Field Application Document- Requirements for Accreditation, July 2013* has been reviewed by members of the –

- NATA Medical Testing Accreditation Advisory Committee
- Royal College of Pathologists Australasia; and
- NPAAC, including state and territory representatives.

The document includes minor revisions for clarification purposes and was endorsed by NPAAC with an implementation date of 1 December 2012.

All the NPAAC documents are available on the NPAAC website at www.health.gov.au/npaac. A copy of the NATA Field Application Document is available on the NATA website at www.nata.asn.au

The Amending Principles amend Schedule 1 to the Principles to refer to the above new and revised documents.

CONSULTATION

In accordance with established NPAAC public consultation and drafting process, the draft new and revised documents were circulated for comments to:

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

Submissions from the public consultation phase were considered by NPAAC in the finalisation of all documents. Feedback from stakeholders has been supportive of the proposed reformatted requirements.

The Amending Principles commence on 1 December 2013.

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

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2013 (No. 1)

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

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 his or her powers under Section 23DN of the Act to approve in principle, or refuse 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').

Aside from some basic tests conducted by medical practitioners on their own patients or on patients of practitioners within their own medical practice, Medicare benefits for pathology services are only payable when they are rendered in an accredited pathology laboratory. The Principles operate to ensure minimum acceptable standards in pathology laboratories at which Medicare eligible pathology services are provided. Schedule 1 of the Principles specifies a number of documents setting out relevant standards against which applicants for accreditation are to be assessed. These documents are issued by the National Pathology Accreditation Advisory Council (NPAAC) (NPAAC accreditation documents) or the National Association of Testing Authorities, Australia (NATA).

This Legislative Instrument makes amendments to the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* (the Principles) to incorporate revised versions of a number of NPAAC accreditation documents currently listed in Schedule 1 to the Principles and one new NPAAC accreditation document, the 'Requirements for Medical Pathology Services'. This has been developed as an overarching document that set out the core elements of good laboratory practice based on existing standards, guidelines and commentary within the accreditation framework.

This Legislative Instrument does not make any substantive changes to the law.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

The new and revised pathology accreditation documents do not impose any new requirements on laboratories seeking approval to provide Medicare eligible pathology services. The changes result from NPAAC producing a new overarching document setting out key elements of good laboratory practice, with other technical accreditation documents needing to be revised to be able to be read in conjunction with the new document.

Patient access to Medicare rebates for pathology services is not affected by these amendments.

Conclusion

This Legislative Instrument is compatible with the human rights as it does not engage any of the applicable rights or freedoms.

Richard Bartlett
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