**EXPLANATORY STATEMENT**

***HEALTH INSURANCE ACT 1973***

***Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2014 (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 2014 (No. 1)* (the Amending Principles) is to amend Schedule 1 to the Principles to incorporate the following revised accreditation materials that have been issued by NPAAC:

a) *Requirements for Gynaecological (Cervical) Cytology (Second Edition 2014)*
b) *Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Third Edition 2014)*

These quality standards have been revised to be more comprehensive and reflect current best pathology practice. In addition, the format of the documents have been revised to be read in conjunction with the NPAAC overarching document, the *Requirements for Medical Pathology Services,* which sets out the core elements of good laboratory practice.

***Requirements for Gynaecological (Cervical) Cytology (Second Edition 2014)***

This document is a revision of the *Requirements for Gynaecological (Cervical) Cytology,* published in 2006, and merges the *Requirements for Gynaecological (Cervical) Cytology* document and *Guidelines for the use of Liquid Based Collection Systems and Semi-Automated Screening Devices in the Practice of Gynaecological*

*(Cervical) Cytology* currently listed in Part 1 of Schedule 1 of the Principle due to their complementary content.

The Requirements set out the minimum standards considered acceptable for good laboratory practice in relation to the provision of gynaecological cytology services in Australia. The Requirements are more comprehensive but do not include any new requirements that would have an additional compliance cost.

***Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Third Edition 2014)***

This document is a revision and renaming of the *Requirements for the Development and Use of In-House In Vitro Diagnostic Devices* published in 2007 currently listed in Part 1 of Schedule of the Principles.

The Requirements have been revised to reflect current best practice and in view of the Therapeutic Goods Administration's In Vitro Diagnostic Medical Device (IVD) regulatory framework. The Requirements set out the minimum quality standards for ensuring that all in-house tests are produced in a safe manner, assuring this by introducing strong requirements for the design, production, validation and monitoring of in-house IVDs

**CONSULTATION**

In accordance with established NPAAC public consultation and drafting process, the *Requirements for Gynaecological (Cervical) Cytology (Second Edition 2014)* and the *Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Third Edition 2014)* documents were circulated for comment to:

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

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

The documents have been revised to reflect current best practice. The Requirements are more comprehensive but do not contain any material that would have an additional compliance cost.

The Office of Best Practice Regulation has confirmed that the proposed amendments do not require a Regulation Impact Statement (OBPR reference number 16398).

All NPAAC documents are available on the NPAAC website – www.health.gov.au/npaac.

The Amending Principles commence on 1 June 2014.

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 2014 (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 to 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 endorsed by NPAAC (supplementary materials).

This Legislative Instrument makes amendments to the Principles to incorporate two recently revised NPAAC accreditation documents currently listed in Schedule 1 to the Principles, namely the –

a) *Requirements for Gynaecological (Cervical) Cytology (Second Edition 2014)*; and
b) *Requirements for the Development and Use of In House In Vitro Diagnostic Medical Devices (Third Edition 2014)*.

These documents have set out minimum acceptable standards for good laboratory practice based on current best practice.

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 revised NPAAC accreditation documents do not impose any new requirements on laboratories seeking approval to provide Medicare eligible pathology services. The changes result from ensuring the Requirements reflect current best practice and are set out in a more comprehensive manner. In addition, the format of the documents have been revised to be read in conjunction with the NPAAC overarching document, the *Requirements for Medical Pathology Services,* which sets out core elements of good laboratory practice.

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.

**The Hon Peter Dutton MP**
**Minister for Health**