

EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2017 (No. 1)

Section 23DNA of the *Health Insurance Act 1973* ('the Act') provides for the Minister to determine the principles to be applied 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').

With the exception of some basic tests conducted by some medical 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 accreditation materials that set out relevant standards against which applicants for accreditation are to be assessed. These documents are developed and maintained by the National Pathology Accreditation Advisory Council (NPAAC) or endorsed by NPAAC as supplementary accreditation materials. The accreditation process is administered by the Department of Human Services, while the National Association of Testing Authorities (NATA) conducts the accreditation assessment of pathology laboratories, in conjunction with the Royal College of Pathologists of Australasia.

The purpose of the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2017 (No. 1)* ('the Amending Principles') is to amend Schedule 1 of the Principles to incorporate two new NPAAC accreditation materials and a revised accreditation standard that is currently listed in Schedule 1 of the Principles:

1. *Requirements for Transfusion Laboratory Practice (Third Edition 2017)*
2. *Requirements for Human Medical Genome Testing Utilising Massively Parallel Sequencing Technologies (First Edition 2017)*
3. *Requirements for Semen Analysis (First Edition 2017)*

These documents form part of the ongoing process of creating and refining the pathology accreditation requirements to maintain their currency and to ensure they reflect contemporary clinical best practice. They should 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, in addition to the other materials that form the national pathology accreditation framework. This helps assure the quality of Australian pathology services.

Requirements for Transfusion Laboratory Practice (Third Edition 2017)

This document is a revision of the 2013 edition of Transfusion Requirements, however, is the first full review since 2008. The Requirements outline minimum best practice standards for transfusion testing, associated transfusion laboratory practice and non-transfusion related blood group immunohaematology testing.

The document has been revised with a risk based approach to the safeguards for patients undergoing transfusion or immunohaematology testing and for the standards to reflect

contemporary practice. The standards have also been aligned with the recent review of the Australian New Zealand Society of Blood Transfusion *Guidelines for Transfusion, Pre and Postnatal Immunohaematology Testing* that provides further technical guidance on transfusion testing.

There are new standards to address the introduction of automated immunohaematology testing platforms and other technologies, the electronic laboratory environment, and a focus on storage and transport to support the management of inventory and minimisation of wastage of blood. The Requirements set out the role that Transfusion Laboratories play in stewardship of both patients and the blood supply and recognises the importance of patient blood management and haemovigilance programs.

Based on expert advice, it is expected that there will be minimal to nil costs associated with meeting the revised Requirements given that a majority of pathology laboratories performing transfusion services are already compliant with the ANZSBT Guidelines for Pre and Post Transfusion and the current accreditation Transfusion Requirements.

Requirements for Human Medical Genome Testing Utilising Massively Parallel Sequencing Technologies (First Edition 2017)

These Requirements set out the minimum best practice requirements for medical pathology laboratories undertaking the development and performance of human genome testing utilising massively parallel sequencing (MPS). The document takes a risk based approach to the development of standards for the implementation of these new technologies.

MPS testing is used within a broad spectrum of human genetic testing and includes testing of: a single gene; a panel of genes associated with a specific phenotype; somatic mutations in the cancer setting; the whole exome and the whole genome. Non-invasive prenatal screening (NIPS) performed using MPS technologies are also covered by these standards.

Assessment against the document will commence from 2 April 2017. The document will be published and available before this date.

Requirement for Semen Analysis (First Edition 2017)

Semen analysis is performed in different categories of laboratories including general pathology laboratories and specialised andrology laboratories. Furthermore, semen analysis is performed for several different clinical indications. The most common of these are the investigation of fertility and for confirmation of sterility following vasectomy. It was recognised by NPAAC that there is some variability of testing within the sector depending on clinical indication i.e. investigation of fertility or confirmation of sterility. Therefore, NPAAC developed these quality standards for use in pathology laboratories providing semen analysis services and to provide clearer guidance to the independent assessing body for the purposes of pathology laboratory accreditation.

The *Requirements for Semen Analysis* sets out the minimum acceptable standards for good laboratory practice in relation to the performance of pathology-based semen analysis for these varied indications. This document defines points in the request-test-reporting cycle where requirements for semen analysis, when performed for the purpose of post-vasectomy clearance, may be varied.

For additional technical guidance on recommended methodologies, laboratories should refer to the World Health Organisation (WHO) *Laboratory Manual for the Examination and*

Processing of Human Semen. The methods described in the WHO publication are regarded as best practice.

Assessment against the document will commence from 2 April 2017. The document will be published and available before this date.

CONSULTATIONS

In accordance with established NPAAC public consultation and drafting processes, the revised documents were circulated for comment as follows:

- *Requirements for Transfusion Laboratory Practice (Third Edition 2017)* - stakeholders consulted included all pathology laboratories, particularly those that provide transfusion services, state and territory representatives, peak pathology, scientific and medical organisations and consumers.
- *Requirements for Human Clinical Genome Testing Utilising Massively Parallel Sequencing Technologies (First Edition 2017)* – stakeholders consulted included all pathology laboratories, state and territory representatives, peak pathology, scientific and medical organisations and consumers.
- *Requirements for Semen Analysis (First Edition 2017)* – stakeholders consulted included all pathology laboratories, particularly those that perform fertility and sterility testing, state and territory representatives, peak pathology, scientific and medical organisations and consumers.

Submissions were received from a broad range of stakeholder groups and the revised documents take into consideration the comments received. Feedback from stakeholders was supportive of the proposed requirements.

The final draft of the accreditation materials were endorsed by NPAAC in October 2016 for publication and inclusion in the Principles.

The Office of Best Practice Regulation (OBPR) has confirmed that the proposed amendments do not require a Regulation Impact Statement (OBPR reference number 21665).

All NPAAC documents are available free of charge from the NPAAC website – www.health.gov.au/npaac.

Schedule 1 of the Amending Principles, which replaces reference to the second edition of the *Requirements for Transfusion Laboratory Practice* with reference to the third edition, commences on the day after the Instrument is registered. Schedule 2 of the Amending Principles, which adds reference to the new *Requirements for Human Clinical Genome Testing Utilising Massively Parallel Sequencing Technologies* and *Requirements for Semen Analysis*, commences on 2 April 2017.

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 2017 (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 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').

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Schedule 1 of the Principles specifies accreditation materials that set out relevant standards against which applicants for accreditation are to be assessed. These documents are developed and maintained by the National Pathology Accreditation Advisory Council (NPAAC) or endorsed by NPAAC as supplementary accreditation materials. The accreditation process is administered by the Department of Human Services, while the National Association of Testing Authorities (NATA) conducts the accreditation assessment, in conjunction with the Royal College of Pathologists of Australasia.

This Legislative Instrument makes amendments to the Principles to incorporate two new pathology accreditation materials and a revised version of NPAAC accreditation documents currently listed in Schedule 1 of the Principles, namely the -

- a) *Requirements for Transfusion Laboratory Practice (Third Edition 2017)*
- b) *Requirements for Human Clinical Genome Testing Utilising Massively Parallel Sequencing Technologies (First Edition 2017)*; and
- c) *Requirements for Semen Analysis (First Edition 2017)*

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

Human rights implications

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

The revision of the NPAAC accreditation documents is part of the ongoing process of refining accreditation requirements to maintain their currency and to ensure they reflect contemporary clinical best practice and with a comprehensive format. This helps assure the quality of Australian pathology services. The revised accreditation materials do not impose any new requirements on pathology laboratories seeking approval to provide Medicare eligible pathology services. The new accreditation materials are aligned with international best practice however; there may be some minimal costs for some laboratories associated with meeting these Requirements. The standards do not impose any obligations on

individuals. The standards promote the right to health as they are aimed at ensuring pathology laboratories providing Medicare-eligible pathology services provide safe and high quality services.

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

Conclusion

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

Natasha Ryan
First Assistant Secretary (A/g)
Medical Benefits Division
Department of Health