

## EXPLANATORY STATEMENT

### *HEALTH INSURANCE ACT 1973*

#### *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Principles 2015 (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 2015 (No. 1)* ('the Amending Principles') is to amend Schedule 1 of the Principles to incorporate the following revised versions of NPAAC accreditation materials currently listed in Schedule 1 of the Principles:

- a) *Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015)*; and
- b) *Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Fifth Edition 2015)*

The revision of these documents is part of the ongoing process of refining accreditation requirements to maintain their currency and to ensure they reflect contemporary clinical best practice. This helps assure the quality of Australian pathology services.

#### ***Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015)***

This document is a revision of the 2006 edition of the *Performance Measures for Australian Laboratories Reporting Cervical Cytology*. The document defines the key elements of the day-to-day performance of a laboratory reporting cervical cytology to ensure a high degree of accuracy in the reporting of results. These standards apply to cytology used as a primary screening test.

The document has been revised to be read in conjunction with the NPAAC overarching document, *Requirements for Medical Pathology Services*, which sets out key elements of good laboratory practice, and to reflect current best practice in consideration of current cytopathology data. In addition, the document, as revised, includes guidance for laboratories on how to achieve the performance measures and standards and the consequences of failure to meet the minimum best practice standards. Key changes include:

- revised date for laboratories to submit data to the Royal College of Pathologists of Australasia Quality Assurance Program (RCPA QAP) to allow adequate time to receive data from the Pap test registers.
- the standard for Performance Measure 3B, which describes the proportion of cytology specimens reported as a possible high-grade abnormality that must be confirmed on cervical histopathology at a slightly increased rate of 40%, which is achievable based on data collected by the RCPA QAP and desirable for the optimal patient outcome.
- lowering the acceptable negative cytology reports from 10% to 7%. A lower false negative rate is more desirable for better patient outcomes.
- inclusion of guidance on how to achieve the performance standards of repeated failure to meet the standards.

Based on expert advice, it is expected that there would be minimal to nil costs associated with the revised Requirements.

### ***Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Fifth Edition 2015)***

This document is a revision of the *Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells* (the Requirements) published in 2009 (noting that the 2013 edition was only a reformatted document that was to be read in conjunction with the NPAAC overarching document, *Requirements for Medical Pathology Services*). The document sets out the minimum requirements for competence and quality to be met by haemopoietic progenitor cell (HPC) transplant facilities.

The document has been revised to be more comprehensive and reflects current best practice, including harmonisation with the relevant international standards, for facilities involved in donor selection, collection, processing, storage and issue or disposal of HPCs and lymphocytes used for cellular therapy. Key changes include:

- inclusion of directed cord bloods (but not autologous or unrelated cord bloods) within the scope of the Requirements so as to provide a safety and quality framework for this material increasingly used in sibling paediatric recipients.
- harmonisation with Therapeutic Goods Order No 88, in that donor Nucleic Acid Testing (NAT) is now required for HIV-1, Hepatitis B and Hepatitis C.
- alignment of terminology, definitions and abbreviations with the International Society of Blood Transfusion standard terminology for Blood Cellular Therapy and Tissue Product description (ISBT 128).
- removal of the previous requirement for autologous donors to be subjected to a Blood Donation Questionnaire and Statement.

- strengthening the requirement that HPC processing facilities only accept products from NATA accredited or TGA licenced apheresis collection centres.
- provision of a process for the accreditation of new apheresis collection facilities.
- harmonisation of the Requirements with the current Foundation for the Accreditation of Cellular Therapy (FACT) standards.

The Requirements, as revised, are more comprehensive and do not include any new requirements that would have an additional compliance cost.

The Amending Principles also correct two administrative errors in the edition references of two other NPAAC accreditation materials currently listed in Schedule 1 of the Principles:

- a) *Requirements for Cytogenetic Testing*; and
- b) *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials*.

## CONSULTATIONS

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

- *Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015)* - stakeholders consulted included all pathology laboratories, state and territory representatives, cervical cancer screening registries, peak pathology organisations and consumers.
- *Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Fifth Edition 2015)* - stakeholders consulted included the Australian Red Cross Blood Service, hospitals, apheresis facilities, Australian Bone Marrow organisation, pathology laboratories and peak pathology and scientific organisations.

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.

No consultation was carried out in relation to the correction of the edition numbering for the two NPAAC materials noted above, given that these corrections are of an administrative nature and do not affect the content of the materials.

The Office of Best Practice Regulation (OBPR) has confirmed that the proposed amendments do not require a Regulation Impact Statement (OBPR reference number 18493).

All NPAAC documents are available on the NPAAC website – [www.health.gov.au/npaac](http://www.health.gov.au/npaac).

The Amending Principles commence on 1 August 2015.

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