EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2023

Authority

Subsection 23DNA(1) 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 2017* (the Principles).

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Purpose

The purpose of the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2023* (the Amending Instrument) is to amend the Principles to incorporate the revised accreditation standards that have been amended to address specific issues:

- incorporate the revised accreditation standard *Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022)*, which is a consolidation of the *Requirements for Medical Testing of Human Nucleic Acids (Second Edition 2013)* and *Requirements for Cytogenetic Testing (Third Edition 2013)*
- incorporate the revised accreditation standard *Requirements for Information Communication and Reporting (Fifth Edition 2022)*
- incorporate the revised accreditation standard *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)*
- incorporate the revised accreditation standard *Requirements for Transfusion Laboratory Practice (Fifth Edition 2022)*.

The Amending Instrument also:

- corrects the title of the accreditation standard titled *Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Fourth Edition 2018)*
- updates the note at the end of the table in Schedule 1 to advise that accreditation materials are accessible on the Australian Commission on Safety and Quality in Health Care's (the Commission) pathology accreditation standards webpage.

In accordance with s 14 of the *Legislation Act 2003*, the revised accreditation standards are not to be incorporated from time to time, but at the time of commencement of this Amending Instrument.

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 by or on behalf of an approved pathology practitioner, in an accredited pathology laboratory operated by an approved pathology authority. The Principles approved under section 23DNA operate to ensure that appropriate standards are met and maintained in pathology laboratories at which Medicare eligible pathology services can be provided.

The Principles set out the criteria for different categories of accredited pathology laboratories and specify the standards that must be met as part of the accreditation assessment for each category of laboratory and kinds of services provided in that laboratory. The overarching objectives of the Principles include promoting the delivery of reliable test results and reducing the risk of misdiagnosis in the provision of pathology services.

The Schedule to the Principles specifies accreditation materials that set out relevant quality standards against which applicants for accreditation are to be assessed. These documents are developed and maintained by National Pathology Accreditation Advisory Council (NPAAC) or endorsed by NPAAC as supplementary accreditation materials.

NPAAC and the National Pathology Accreditation Scheme are supported by the Commission under an arrangement with the Department of Health and Aged Care (the Department). The Department retains policy and regulatory responsibilities for pathology accreditation.

The process for the accreditation of pathology laboratories is administered by Services Australia, while the National Association of Testing Authorities, Australia (NATA) is the independent assessment body that conducts the accreditation assessment of pathology laboratories, in conjunction with the Royal College of Pathologists of Australasia, in accordance with the specified accreditation standards.

The revised accreditation standards follow on from NPAAC's consideration of quality standards and the ongoing refinement of the pathology requirements that are aimed to ensure pathology best practice and support the therapeutics regulatory framework. They should be read in conjunction with the pathology overarching standard titled the *Requirements for Medical Pathology Services*, which sets out the core elements of good laboratory practice, in addition to other materials that form the national pathology accreditation framework. This assists with the assurance of the quality of Australian pathology services.

***Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022*)**

To support the provision of safe and quality care to patients, the *Requirements for Medical Testing of Human Nucleic Acids (Second Edition 2013)* and the *Requirements for Cytogenetic Testing (Third Edition 2013)*, have been revised and consolidated into the *Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022).*

The revised accreditation standard sets out the expected level of practice required by laboratories for heritable and non-heritable human genetic variation medical testing, and includes revisions to:

- incorporate a risk-based approach
- provide guidance for laboratories on medical tests for heritable and non-heritable genetic/genomic changes associated with human disease

- provide guidance for several laboratory disciplines including (but not limited to) molecular, cytogenetic, and anatomical pathology laboratories
- align format and structure to the National Safety and Quality Health Service Standards for consistency in the health system.

Consolidating and streamlining these requirements will assist to reduce the compliance burden on pathology laboratories.

Requirements for Information Communication and Reporting (Fifth Edition 2022)

The *Requirements for Information Communication and Reporting (Fifth Edition 2022)* is a revised accreditation standard, that sets out the minimum standards to ensure the integrity of patient information during its transfer between pathology laboratories, requesters, consumers and other relevant parties.

In response to a public submission, commentary to clarify the standards for the secure messaging of electronic pathology requests and reports has been aligned with the current practice for the SMS reporting of COVID-19 test results. This amendment:

- minimises changes to the standards
- assists pathology services to streamline their registration processes - they will not be required to duplicate the registration process for people who have already provided their contact details.

Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)

The *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)* is a revised accreditation standard which sets out the expected level of practice that laboratories are to use when packaging and transporting pathology specimens and associated materials.

To support the system to provide safe and quality care to patients, the accreditation standard has been amended to:

- incorporate a risk-based approach
- provide guidance for laboratories and relevant parties on the appropriate transport and packaging requirements for pathology specimens
- support laboratories to address the different modes of transport
- include blood, blood products and haemoglobin within the scope of the document
- align format and structure to the National Safety and Quality Health Service Standards for consistency in the health system.

Requirements for Transfusion Laboratory Practice (Fifth Edition 2022)

The *Requirements for Transfusion Laboratory Practice (Fifth Edition 2022)* outlines practice standards that assure the safety, quality and efficacy of transfusion testing, associated transfusion laboratory practice, and non-transfusion related blood group immunohaematology testing. These requirements also apply to donor testing conducted by the Australian Red Cross Lifeblood (Lifeblood).

The revised accreditation standard includes commentary on the requirements for the pretransfusion testing of patients, that was potentially lost in the editorial process to develop the *Requirements for Transfusion Laboratory Practice (Fourth Edition 2019).*

This omission was identified in a public submission and the commentary has been reinstated and modified after consultation with key stakeholders. The exclusion of this commentary meant that the accreditor, NATA, would not permit the extension of validity for pretransfusion testing from 72 hours to 7 days in particular circumstances under direction of the supervising pathologist. Stakeholders advised that this commentary was important for the risk-based management of challenging cases, such as pregnant patients at ongoing high risk of sudden massive haemorrhage.

Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Fourth Edition 2018)

The title of the *Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Fourth Edition 2018)* has been amended to align with the name of the existing accreditation standard as published on the Commission's website. This has been achieved by including the word "Medical" and revising the year of edition to "2018."

Schedule 1 (note at the end of the table)

The note at the end of the table has been repealed and replaced with a note to inform users that the accreditation materials are published on the Commission's website.

Any subsequent changes or replacement to the above standards documents will not apply unless further amendments are made to the Principles.

A copy of the pathology accreditation material listed in the Schedule to the Principles is published on the Commission's pathology accreditation standards webpage and can be accessed readily and free of charge (https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards#national-pathology-accreditation-standards).

Consultation

Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022)

The Commission conducted public consultation on the draft *Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022)* between 20 April 2022 and 1 June 2022. The Commission received 182 submissions from stakeholders including NATA, state and territory government departments, pathology laboratories, peak bodies and industry organisations.

Most of the feedback received was neutral, with the main concern relating to consent issues and the onus on laboratories. These concerns were addressed by amending reference tables and examples to clarify these expectations. NPAAC endorsed the *Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022)* on 6 December 2022.

Requirements for Information Communication and Reporting (Fifth Edition 2022)

As the proposed amendments were relatively minor, the Commission conducted a targeted 2-week consultation on the draft *Requirements for Information Communication and Reporting (Fifth Edition 2022)* with:

- Public Pathology Australia, who represent public pathology services owned and operated by the state and territory governments
- Australian Pathology, who represent private pathology service providers
- NPAAC and Drafting Review and Liaison Committee members
- NATA

The Commission received 14 submissions. Most of the feedback was neutral and included suggested wording or grammatical changes. NPAAC endorsed the *Requirements for Information Communication and Reporting (Fifth Edition 2022)* on 6 December 2022.

Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)

The Commission conducted a public consultation process on the draft *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)* and associated materials from 20 April 2022 to 1 June 2022. The Commission received 71 submissions from stakeholders, including NATA, state and territory government departments, pathology laboratories and peak bodies.

Most stakeholder feedback received was neutral and included suggested wording or grammatical changes. NPAAC endorsed the Requirements for the *Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)* on 6 December 2022, which included amendment to address feedback from public consultation.

Requirements for Transfusion Laboratory Practice (Fifth Edition 2022)

As the proposed amendments were relatively minor, the Commission conducted a targeted 2-week consultation on the draft *Requirements for Transfusion Laboratory Practice (Fifth Edition 2022)* with:

- Public Pathology Australia
- Australian Pathology
- Members of NPAAC and its subcommittees
- Subject matter experts in transfusion and immunohaemotology practice
- NATA.

The Commission received 37 responses from stakeholders, collated the feedback and analysed the results. In consultation with NPAAC executives, feedback from the targeted consultation was incorporated into the draft where appropriate. A further amendment was made by NPAAC members in consultation with the Australasian New Zealand Society of Blood Transfusion to address a redundancy in the requirements for pre-transfusion testing.

The *Requirements for Transfusion Laboratory Practice (Fifth Edition 2022)* was referred to NPAAC and endorsed on 6 December 2022 with a minor amendment to the commentary on the requirements for transfusion in special circumstances.

No consultation was undertaken on the minor administrative amendments to:

- correct the title of the accreditation standard titled *Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Fourth Edition 2018)*
- update the note at the end of the table in Schedule 1 to advise that accreditation materials are accessible on the Australian Commission on Safety and Quality in Health Care's (the Commission) website.

This Amending Instrument commences on 1 March 2023.

The Amending Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Details of the legislative instrument are set out in Attachment A.

ATTACHMENT A

Details of the Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2023

1. Name of legislative instrument

Section 1 provides that the title of the legislative instrument is the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2023* (the Amending Instrument).

2. Commencement

Subsection 2(1) provides that the Amending Instrument commences on 1 March 2023.

3. Authority

Section 3 provides for the authority for the Amending Instrument and that it is made under subsection 23DNA(1) of the *Health Insurance Act 1973* (the Act).

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

4. Schedules

Section 4 provides that each instrument that is specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the instrument has effect according to its terms.

There is one Schedule in the instrument. This Schedule provides for the amendments to the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* (the Principles) commencing on 1 March 2023.

Schedule 1

Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017.

Item 1

Item 1 repeals the accreditation standard listed in Item 3 of the table in Schedule 1 of the Principles and substitute it with the revised standard titled "*Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022).*"

Item 2

Item 2 repeals the accreditation standard listed in Item 4 of the table in Schedule 1 of the Principles and substitutes it with the revised standard titled "*Requirements for Information Communication and Reporting (Fifth Edition 2022).*"

Item 3

Item 3 repeals the accreditation standard listed in Item 6 of the table in Schedule 1 of the Principles.

Item 4

Item 4 repeals the accreditation standard listed in Item 9 of the table in Schedule 1 of the Principles and substitutes it with the revised standard titled *"Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)."*

Item 5

Item 5 repeals the accreditation standard listed in Item 16 of the table in Schedule 1 of the Principles and substitutes it with the revised pathology accreditation standard *"Requirements for Transfusion Laboratory Practice (Fifth Edition 2022)."*

Item 6

Item 6 repeals and substitutes the item in order to amend the title of the accreditation standard listed in Item 20 of the table in Schedule 1 of the Principles to "*Requirements for the Development and Use of In-Vitro Diagnostic Medical Devices (Fourth Edition 2018).*" This rectifies previous typographical errors in the name of the accreditation standard.

Item 7

Item 7 repeals the note at the end of the table in Schedule 1 of the Principles and substitutes it with *"The documents mentioned could in 2023 be viewed on the Australian Commission on Safety and Quality in Health Care's pathology accreditation webpage."*

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 (Relevant Standards) Principles (No.1) 2023

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

This Legislative Instrument amends the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* ('Principles') to incorporate four revised versions of National Pathology Accreditation Advisory Council (NPAAC) accreditation standards currently listed in Schedule 1 of the Principles, namely the -

1. *Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022)*
2. *Requirements for Information Communication and Reporting (Fifth Edition 2022)*
3. *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)*
4. *Requirements for Transfusion Laboratory Practice (Fifth Edition 2022).*

The Principles are made by the Minister under subsection 23DNA(1) of the *Health Insurance Act 1973* (the Act) and applied in exercising the Minister's powers to approve in principle, or refuse to approve, premises as an accredited pathology laboratory.

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 by or on behalf of an approved pathology practitioner, in an accredited pathology laboratory operated by an approved pathology authority. The Principles approved under section 23DNA operate to ensure that appropriate standards are met and maintained in pathology laboratories at which Medicare eligible pathology services can be provided.

The Principles set out the criteria for different categories of accredited pathology laboratories and specify the standards that must be met as part of the accreditation assessment for each category of laboratory and kinds of services provided in that laboratory. The overarching objectives of the Principles include promoting the delivery of reliable test results and reducing the risk of misdiagnosis in the provision of pathology services.

The Schedule to 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 NPAAC or endorsed by NPAAC as supplementary accreditation materials.

NPAAC and the National Pathology Accreditation Scheme are supported by the Australian Commission on Safety and Quality in Health Care (the Commission) under an arrangement with the Department of Health and Aged Care (the Department). The Department holds policy and regulatory responsibilities for pathology accreditation.

The process for the accreditation of pathology laboratories is administered by the Services Australia, while the National Association of Testing Authorities (NATA) is currently the recognised independent assessment body that conducts the accreditation assessment of pathology laboratories, in conjunction with the Royal College of Pathologists of Australasia.

The review of these pathology accreditation standards is part of the ongoing process of refining the pathology accreditation requirements to maintain their currency and to ensure they reflect contemporary clinical best practice and to be responsive to operational requirements for the pathology sector. 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. Copies of the pathology accreditation materials are published on the Commission's pathology accreditation standards webpage (https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards#national-pathology-accreditation-standards).

The pathology accreditation standards are aimed at assuring the quality of Australian pathology services.

Human rights implications

This instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the *'highest attainable standard of health'* takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The Committee reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or

groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

Analysis

The Legislative Instrument advances the right to health and the right to social security by ensuring appropriate accreditation requirements are in place to maintain access to quality, safe, clinically relevant and cost-effective Medicare eligible pathology services.

The revised accreditation standards set out minimum acceptable standards for good laboratory practice, so that patient access is not affected whilst still maintaining appropriate requirements for quality, safe, clinically relevant and cost-effective Medicare eligible pathology services.

The revision of pathology accreditation standards 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.

Conclusion

This Legislative Instrument is compatible with human rights as it advances the right to health and the right to social security.

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