EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2025

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 **Approval 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 and operation

The purpose of the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2025* (the **Amending Instrument**) is to amend the Approval Principles to incorporate the following revised accreditation standards:

- *Requirements for Cervical Screening (Third Edition 2025)* (**2025 Cervical Screening Standard**); and
- *Requirements for supervision in the clinical governance of medical pathology laboratories (Eight Edition 2025)* (**2025 Supervision Standard**).

In accordance with section 14 of the *Legislation Act 2003*, the revised accreditation standards are to be incorporated as they exist at the time of commencement of this Amending Instrument.

Background

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 Approval Principles approved under section 23DNA of the Act:

- operate to ensure that appropriate standards are met and maintained in pathology laboratories at which Medicare eligible pathology services can be provided; and
- underpin the National Pathology Accreditation Scheme (**NPAS**), a compulsory accreditation scheme that requires pathology laboratories to meet specified quality standards for their services to be eligible for Medicare benefits.

The Approval 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 Approval 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 Approval 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, and they are intended to ensure pathology best practice, support the therapeutics regulatory framework and assure the quality of Australian pathology services. Individual accreditation standards should be read in conjunction with the overarching pathology accreditation standard, the *Requirements for Medical Pathology Services (Third Edition 2018)* which sets out the core elements of good laboratory practice.

The NPAAC is a committee established under subsection 9(1) of the *National Health Act 1953* whose responsibilities include making recommendations to the Australian Government and the states and territories on matters relating to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. Its membership includes pathology experts from various professional and scientific organisations, consumer representatives and representatives from the Australian Government and states and territories.

NPAAC and the NPAS are supported by the Australian Commission on Safety and Quality in Health Care (the **Commission**) under an arrangement with the Department of Health, Disability and Ageing (the **Department**). The Department retains policy and regulatory responsibilities for pathology accreditation and the National Association of Testing Authorities, Australia (**NATA**) is the independent assessment body that conducts the accreditation assessment of pathology laboratories with relevant accreditation standards.

Requirements for Cervical Screening (Third Edition 2025)

The 2025 Cervical Screening Standard replaces the *Requirements for Cervical Screening (Second Edition 2024)* (**2024 Cervical Screening Standard**) which came into effect on 1 February 2025. The 2025 Cervical Screening Standard will apply to accredited pathology laboratories providing pathology services as part of the National Cervical Screening Program (**NCSP**) from 1 July 2025. It provides a nationally consistent statement about the standard of care consumers can expect from pathology laboratories involved in the NCSP and supports the safe delivery of quality care to patients.

The 2025 Cervical Screening Standard has been revised to:

- refine the mandatory program indicators and numerical standards at Appendix 1 of the Standard to ensure they are accurate and unambiguous. The program indicators and numerical standards are set by the NCSP's Clinical Advisory Group (**CAG**) and provide a nationally consistent approach to performance measurement under the NCSP. These requirements will:
    - support laboratories to monitor the implementation of the safety and quality practices prescribed in the 2025 Cervical Screening Standard and undertake quality improvement activities where required;
    - enable NATA to revoke a laboratory's accreditation where it does not meet relevant standards; and
    - maintain clinical and participant confidence in the effectiveness of the NCSP.

- remove the transitional arrangements which permitted laboratories to report program indicator data in accordance with the requirements of the 2024 Cervical Screening Standard or the previous standards[1] from 1 February 2025 until 30 June 2025. Reporting in accordance with the requirements of the 2025 Cervical Screening Standard will be mandatory from 1 July 2025.
- update action "7.03 Reporting to the National Cancer Screening Register" to require laboratories to comply with the "Summary Guide for Pathology Laboratories reporting to the National Cervical Screening Register (**NCSR**) for the National Cervical Screening Program, Version 1.0." This document is published on the NCSR website and can be accessed readily and free of charge at:

  https://www.ncsr.gov.au/content/dam/ncsr/documents/NCSR-Summary-Guide-Pathology-Reporting-Requirements.pdf.

Requirements for supervision in the clinical governance of medical pathology laboratories (Eight Edition 2025)

The 2025 Supervision Standard continues to require a governance system where the designated person for an accredited pathology laboratory is accountable for the provision of accurate and timely test results. A designated person is a registered medical practitioner with appropriate qualifications, competence and relevant scope of practice, who is responsible for the:

- clinical governance of an accredited pathology laboratory; and
- oversight and management of staff and processes to ensure ethical patient care and the provision of accurate and timely test results.

This governance system must be clearly documented and understood to ensure that all testing is supervised by persons who are appropriately qualified, competent, operating within their scope of practice and accountable for their actions as the designated person. These arrangements minimise potential risks to patient safety and improve patient health outcomes.

The 2025 Supervision Standard replaces the *Requirements for supervision in the clinical governance of medical pathology laboratories (Seventh Edition 2023)* (**2023 Supervision Standard**), which came into effect on 1 August 2023. It will come into effect on 1 July 2025 and includes amendments to:

- extend the temporary workforce management provisions to provide laboratories with alternative pathways for demonstrating compliance with the 2025 Supervision Standard, in response to ongoing national workforce shortages in the pathology disciplines of genomics (including cytogenteics and biochemical genetics), immunology and chemical pathology, while ensuring patient safety and continued access to quality pathology services. In contrast to the *Requirements for supervision in the clinical governance of medical pathology laboratories (Sixth Edition, 2021)* and the 2023 Supervision Standard, these transitional workforce provisions will remain in

[1] Requirements for laboratories reporting tests for the National Cervical Screening Program (Second Edition 2019), Requirements for validation of self-collected vaginal swabs for use in the National Cervical Screening Program (First Edition 2019) and Performance measures for Australian laboratories reporting cervical cytology (Third Edition 2015).

effect until the 2025 Supervision Standard is repealed rather than being time limited; and
- enable accredited pathology laboratories existing at the date of effect of the 2025 Supervision Standard to access the temporary workforce management provisions. This will permit four additional Category GX laboratories to access those provisions.

Any subsequent changes to or replacement of the 2025 Cervical Screening Standard or the 2025 Supervision Standard will not apply unless further amendments are made to the Approval Principles.

Copies of the pathology accreditation materials listed in the Schedule to the Principles are published on the Commission's website and can be accessed readily and free of charge at:

https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards#national-pathology-accreditation-standards.

Consultation

NPAAC endorsed the 2025 Cervical Screening Standard on 2 June 2025 and the 2025 Supervision Standard on 14 March 2025 to ensure the suite of accreditation standards for laboratories providing Medicare eligible pathology services remain fit for purpose. The amendments to the:

- 2025 Cervical Screening Standard were made in consultation with the NCSP CAG and the Department; and
- 2025 Supervision Standard were made in consultation with the NATA and the Department.

Broader stakeholder engagement was not undertaken given the relatively minor nature of the amendments.

Commencement

This Amending Instrument commences on 1 July 2025.

General

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.

This Amending Instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in Attachment B.

ATTACHMENT A

Details of the Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2025

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.2) 2025* (the Amending Instrument).

2. Commencement

Subsection 2(1) provides that the Amending Instrument commences on 1 July 2025.

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).

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 Approval Principles) commencing on 1 July 2025.

Schedule 1

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

Item 1

Item 1 repeals the existing definition of S(FC) laboratory in subsection 5(2). The substituted definition provides that S(FC) laboratory has the same meaning as in the "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Eighth Edition 2025)"* (2025 Supervision Standard).

Item 2

Subsection 18(3) of the Approval Principles currently provides that the designated person is responsible for compliance with relevant standards of direction, control and supervision that apply to the relevant category of laboratory under the "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)*" (2023 Supervision Standard).

Subsection 18(5) of the Approval Principles currently provides that the responsibilities of the designated person for premises under section 18 may be delegated, but only in accordance with the 2023 Supervision Standard.

Item 2 amends these subsections to omit references to the 2023 Supervision Standard and instead refer to the 2025 Supervision Standard.

Item 3
The note to subsection 18(5) currently states that the 2023 Supervision Standard is listed in Schedule 1 of the Approval Principles.

Item 3 amends this note to refer to the 2025 Supervision Standard, which will be listed in Schedule 1 of the Approval Principles instead of the 2023 Supervision Standard (see item 4 below).

Item 4

Item 4 repeals the accreditation standard listed in Item 11 of the table in Schedule 1 of the Approval Principles and substitutes it with the revised standard titled "*Requirements for cervical screening (Third Edition 2025*)".

Item 5
Item 5 repeals the accreditation standard listed in Item 19 of the table in Schedule 1 of the Approval Principles and substitutes it with the revised standard titled *"Requirements for supervision in the clinical governance of medical pathology laboratories (Eight Edition 2025)".*

ATTACHMENT B

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.2) 2025

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* (Approval Principles) to incorporate revised versions of the National Pathology Accreditation Advisory Council (NPAAC) accreditation standards currently listed in Schedule 1 of the Approval Principles, namely the -

1. *Requirements for Cervical Screening (Third Edition 2025)*; and
2. *Requirements for supervision in the clinical governance of medical pathology laboratories (Eighth Edition 2025)*

The Approval Principles are made by the Minister under subsection 23DNA(1) of the *Health Insurance Act 1973* (the Act) and will be 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 Approval Principles approved under section 23DNA of the Act operate to ensure that appropriate standards are met and maintained in pathology laboratories at which Medicare eligible pathology services can be provided.

The Approval 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 Approval 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 Approval 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 NPAAC or endorsed by them 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, Disability and Ageing (the Department). The Department holds policy and regulatory responsibilities for pathology accreditation and the National Association of Testing Authorities, Australia (NATA) is the independent assessment body

that conducts the accreditation assessment of pathology laboratories with relevant accreditation standards.

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 are 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* (Third Edition 2018) 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 standard sets out the 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 in 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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