EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles 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 2025* (the Amending Instrument) is to repeal three accreditation standards:

- *Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015);*
- *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019); and*
- *Requirements for Validation of Self-Collected Vaginal Swabs for use in the National Cervical Screening Program (First Edition 2019).*

The Amending Instrument will further:

- incorporate a new pathology accreditation standard, the *Requirements for cervical screening (Second edition 2024)* (the 2024 Cervical Screening Standard), in the Approval Principles to replace the repealed standards; and
- update the note at the end of the table in Schedule 1 to advise that in 2025, the accreditation materials are accessible on the Australian Commission on Safety and Quality in Health Care's (the Commission) pathology accreditation standards webpage.

Consistent with section 14 of the *Legislation Act 2003*, the 2024 Cervical Screening Standard is to be incorporated as it exists at the time of commencement of the 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 where Medicare eligible pathology services are 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 the 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 them as supplementary accreditation materials, and they are intended to ensure pathology best practice, support the therapeutic's 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 and Aged Care (the department). The department retains policy and regulatory responsibilities for pathology accreditation and the National Association of Testing Authorities, Australia (NATA) is the independent body that assesses the conformity of laboratories with relevant accreditation standards.

Requirements for cervical screening (Second edition 2024)

The 2024 Cervical Screening Standard is a new accreditation standard which will:

- apply to accredited pathology laboratories providing pathology services as part of the National Cervical Screening Program (NCSP); and
- support the safe delivery of quality care to patients. The primary aim of the 2024 Cervical Screening Standard is to protect women and people with a cervix from harm that may occur as a result of poor-quality screening processes, collection procedures (including self-collections), and the communication of results. The 2024 Cervical Screening Standard provides a nationally consistent statement about the standard of care consumers can expect from pathology laboratories involved in the NCSP. In particular it:
    - consolidates and revises three accreditation standards on cervical screening:
        - *Performance measures for Australian laboratories reporting cervical cytology (Third Edition 2015);*

- *Requirements for laboratories reporting tests for the National Cervical Screening Program (Second Edition 2019);* and
- *Requirements for validation of self-collected vaginal swabs for use in the National Cervical Screening Program (First Edition 2019).*

- sets out the current best-practice standards for using Human Papillomavirus (HPV) nucleic acid testing as the primary screening method for cervical cancer screening.
- prescribes mandatory program indicators and numerical standards at Appendix 1 of the Standard to provide a nationally consistent approach to performance measurement under the NCSP[1]. The numerical standards are set by the NCSP's Clinical Advisory Group. These arrangements will:
  - support laboratories to monitor the implementation of the safety and quality practices prescribed in the 2024 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.

The 2024 Cervical Screening Standard will come into effect on 1 February 2025, with transitional arrangements provided within the 2024 Cervical Screening Standard to assist laboratories to meet their reporting requirements. From 1 February 2025 until 30 June 2025, laboratories can report their program indicator data in accordance with the requirements of the existing cervical screening standards, or with the requirements of the 2024 Cervical Screening Standard. Reporting in accordance with the requirements of the 2024 Cervical Screening Standard will be mandatory from 1 July 2025.

Copies of the 2024 Cervical Screening Standard can be accessed readily and free of charge on the Commission's website under the subheading "Pathology accreditation standards" (https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards#national-pathology-accreditation-standards).

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 in 2025, the accreditation materials are published on the Commission's website and can be accessed there.

Consultation

The 2024 Cervical Screening Standard was endorsed by NPAAC on 18 November 2024. It reflects the outcome of consultations to draft the 2023 Cervical Screening Standard and amends it to address concerns relating to the omission of mandatory program indicators and numerical standards from "Appendix 1- Program Indicators". Stakeholders included the Australian Government, states and territories, private and public laboratories, anatomical

[1] The Approval Principles were amended to give effect to the Requirements for Cervical Screening (First Edition 2023) (2023 Cervical Screening Standard) from 1 August 2024. In response to concerns about the absence of mandatory program indicators and numerical standards in the 2023 Cervical Screening Standard, the Approval Principles were amended to repeal this standard and ensure continuity of the existing standards pending resolution of those concerns.

pathology experts including members of the drafting committee for the Standard, NATA and consumers.

Commencement

This Amending Instrument commences on 1 February 2025.

General

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

Details of the Amending 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 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 2025* (the Amending Instrument).

2. Commencement

Section 2 provides for the commencement date of the Amending Instrument on 1 February 2025.

3. Authority

Section 3 provides that the Amending Instrument 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 Amending Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

There is one Schedule in the Amending Instrument. This Schedule provides for the amendments to the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* (the Approval Principles) commencing on 1 February 2025.

Schedule 1

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

Item 1 – Clause 1 of Schedule 1 (table item 11)

The table in clause 1 of Schedule 1 of the Approval Principles identifies documents that are accreditation materials.

Item 11 of the table currently refers to the "*Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015).*" Item 1 of the Amending Instrument repeals the current item 11 and replaces it with an item listing the "Requirements for cervical screening (Second edition 2024)*"* as the accreditation material.

Item 2 – Clause 1, Schedule 1 (table item 14)

Item 2 of the Amending Instrument repeals the accreditation material listed in item 14 of the table in Schedule 1 of the Approval Principles, *"Requirements for laboratories reporting tests for the National Cervical Screening Program (Second Edition 2019)."*

Item 3 - Clause 1, Schedule 1 (table item 22)

Item 3 of the Amending Instrument repeals the accreditation material listed in item 22 of the table in Schedule 1 of the Approval Principles, *"Requirements for validation of self-collected vaginal swabs for use in the National Cervical Screening Program (First Edition 2019)."*

Item 4 – Schedule 1 (Note at the end of the table)

Item 4 of the Amending Instrument repeals the note and substitutes it with "The documents mentioned could in 2025 be viewed on the Australian Commission on Safety and Quality in Health Care's pathology accreditation standards webpage."

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 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

The *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles 2025* (the Amending Instrument) amends the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* (the Approval Principles) to incorporate a new National Pathology Accreditation Advisory Council (NPAAC) accreditation standard in Schedule 1 of the Approval Principles, namely the *Requirements for cervical screening (Second edition 2024)* (the 2024 Cervical Screening Standard). The introduction of this standard will replace the three existing standards related to cervical screening.

The Approval 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 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 NPAAC or endorsed by them as supplementary accreditation materials, and they are intended to ensure pathology best practice, support the therapeutic's regulatory framework and assure the quality of Australian pathology services.

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 representative and representatives from Australian Government and states and territories.

Copies of the 2024 Cervical Screening Standard can be accessed readily and free of charge on the Commission's website under subheading "Pathology accreditation standards" (https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards#national-pathology-accreditation-standards).

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

This Amending 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 primary aim of the 2024 Cervical Screening Standard is to protect women and people with a cervix from harm occurring as a result of poor-quality screening processes, from collection, including self-collections, to the communication of results. It provides a nationally consistent statement about the standard of care consumers can expect from pathology laboratories involved in the National Cervical Screening Program (NCSP).

The 2024 Cervical Screening Standard sets out the current best-practice standards for using Human Papillomavirus (HPV) nucleic acid testing as the primary screening method for cervical cancer screening and prescribes mandatory program indicators and numerical standards to provide a nationally consistent approach to performance measurement under the NCSP[2]. The numerical standards are set by the NCSP's Clinical Advisory Group, and these arrangements will:

- support laboratories to monitor the implementation of the safety and quality practices prescribed in the 2024 Cervical Screening Standard and undertake quality improvement activities where required;
- enable a laboratory's accreditation to be revoked where it does not meet relevant standards; and
- maintain clinical and participant confidence in the effectiveness of the NCSP.

The 2024 Cervical Screening Standard will come into effect on 1 February 2025, with transitional arrangements provided within the 2024 Cervical Screening Standard to assist laboratories to meet their reporting requirements. From 1 February 2025 until 30 June 2025, laboratories can report their program indicator data in accordance with the requirements of the existing cervical screening standards, or with the requirements of the 2024 Cervical Screening Standard. Reporting in accordance with the requirements of the 2024 Cervical Screening Standard will be mandatory from 1 July 2025.

Conclusion

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

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[2] The Approval Principles were amended to give effect to the Requirements for Cervical Screening (First Edition 2023) (2023 Cervical Screening Standard) from 1 August 2024. In response to concerns about the absence of mandatory program indicators and numerical standards in the 2023 Cervical Screening Standard, the Approval Principles were amended to repeal this standard and ensure continuity of the existing standards pending resolution of those concerns.