EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2024

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 and operation

The purpose of the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2024* (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for cervical screening (First edition 2023)* (the Cervical Screening Standard), in the Principles to replace the repealed standards; and
- update the note at the end of the table in Schedule 1 to advise that in 2024, 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 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 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.

- 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 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 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. 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 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 Cervical Screening Standard results 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. It 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 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 cervical screening (First edition 2023)

The Cervical Screening Standard is a new accreditation standard which consolidates three existing accreditation standards and includes revisions to support the safe delivery of quality care to patients. The primary aim of the 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 Cervical Screening Standard provides a nationally consistent statement about the standard of care consumers can expect from pathology laboratories involved in the National Cervical Screening Program. In particular it:

- sets out sets out the current best-practice standards for using Human Papillomavirus nucleic acid testing as the primary screening method for cervical cancer screening.
- 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).*

The Cervical Screening Standard will take effect on 1 August 2024, by which time, Australian pathology laboratories involved in the National Cervical Screening Program will need to comply with these requirements for accreditation purposes and to ensure best practice. Any subsequent changes to, or replacement of the Cervical Screening Standard will not apply unless further amendments are made to the Principles.

A copy of the Cervical Screening Standard can be accessed readily and free of charge on the Commission's website under the NPA Scheme news and announcements subheading (https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards#npa-scheme-news-and-announcements).

The Cervical Screening Standard will also be available by 1 August 2024, free of charge on the Commission's website under the National pathology accreditation standards subheading (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 2024, the accreditation materials are published on the Commission's website.

Consultation

The Cervical Screening Standard was developed by NPAAC in collaboration with the Australian Government, states and territories, private and public laboratories, anatomical pathology experts and consumers. This included a public consultation on a draft version of the Cervical Screening Standard throughout June and July 2023. The feedback was analysed by the Commission and referred to relevant NPAAC sub-committees for consideration. Wherever appropriate, this feedback was included in the draft version of the Cervical Screening Standard that was referred to NPAAC for endorsement. NPAAC endorsed the Cervical Screening Standard on 20 November 2023.

Commencement

This Amending Instrument commences on 1 August 2024.

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 (No.1) 2024

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) 2024* (the Amending Instrument).

2. Commencement

Section 2 provides for the commencement date of the Amending Instrument on 1 August 2024.

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 Principles) commencing on 1 August 2024.

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 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 (First edition 2023)*" 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 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 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 2024 be viewed on the Australian Commission on Safety and Quality in Health Care's pathology accreditation standards 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) 2024

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 (No.1) 2024* (the Amending Instrument) amends the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* (the Principles) to incorporate a new National Pathology Accreditation Advisory Council (NPAAC) accreditation standard in Schedule 1 of the Principles, namely the *Requirements for cervical screening (First edition 2023)* (the Cervical Screening Standard). The introduction of this standard will replace the three existing standards related to cervical screening.

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 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 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 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.

Pathology accreditation standards are reviewed as part of an ongoing process to refine the 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 (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 Cervical Screening Standard can be accessed readily and free of charge on the Commission's website under the NPA Scheme news and announcements subheading (https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards#npa-scheme-news-and-announcements).

The Cervical Screening Standard will also be available by 1 August 2024, free of charge on the Commission's website under the National pathology accreditation standards subheading (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

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 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. It sets out sets out the current best-practice standards for using Human Papillomavirus nucleic acid testing as the primary screening method for cervical cancer screening.

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. This helps assure the quality of Australian pathology services.

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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