

EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 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.2) 2024* (the Amending Instrument) is to:

- repeal the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2024*; 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.

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 (the 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.

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

The *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2024* is being repealed. This instrument was made to incorporate a new pathology accreditation standard, the *Requirements for Cervical Screening (First Edition 2023)* (the Cervical Screening Standard), into the Principles from 1 August 2024.

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 Cervical Screening Standard was due to take effect on 1 August 2024, at which time Australian pathology laboratories involved in the National Cervical Screening Program would need to comply with these requirements to be accredited to provide Medicare eligible pathology services.

In their preparation to comply with the Cervical Screening Standard, the pathology sector and the National Association of Testing Authorities, Australia (NATA), identified issues relating to the implementation of the Standard that may influence program performance. These matters require further consideration and have been referred to the NPAAC for a decision on whether the Cervical Screening Standard requires amendment before compliance with the standard becomes mandatory for pathology laboratories involved in the National Cervical Screening Program.

Repealing the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2024* will enable further consultation on the Cervical Screening Standard to occur. Meanwhile the three existing accreditation standards on cervical screening will remain in effect:

- *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 or a revised version of the Standard, will not apply unless further amendments are made to the Principles.

Amendments to the Principles

The note at the end of the table in Schedule 1 of the Principles will be amended. The existing note in the Principles will be repealed and replaced with a note to inform users that in 2024, the accreditation materials are published on the Commission's website.

Consultation

The pathology sector and the NATA, have identified issues with the Cervical Screening Standard that require further consideration before it comes into effect. These matters have been referred to the NPAAC for a decision on whether the Cervical Screening Standard is fit-for-purpose, or requires amendment before it is endorsed and compliance with the standard is mandatory for pathology laboratories involved in the National Cervical Screening Program.

Commencement

This Amending Instrument commences on 31 July 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.2) 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.2) 2024* (the Amending Instrument).

2. Commencement

Section 2 provides for the commencement date of the Amending Instrument on 31 July 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 are two Schedules in the Amending Instrument and both commence on 31 July 2024.

Schedule 1

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

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

Item 1 of the Amending Instrument repeals the note and substitutes it with “The documents mentioned in Schedule 1 could in 2024 be viewed on the Australian Commission on Safety and Quality in Health Care’s pathology accreditation standards webpage.”

Schedule 2

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

Item 1 - Repeal the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment (Relevant Standards) Principles (No.1) 2024*

Item 1 repeals the instrument that was made to give effect to the *Requirements for Cervical Screening (First Edition 2023)* from 1 August 2024. Australian pathology laboratories involved in the National Cervical Screening Program will be required to comply with the existing accreditation standards on cervical screening until further notice:

- *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).*

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) 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.2) 2024* (the Amending Instrument) amends the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* (the Principles) to:

- repeal the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2024*; 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 pathology accreditation standards webpage.

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 the National Pathology Accreditation Advisory Council (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 aim to ensure the quality and safety of pathology services that are eligible for Medicare benefits. Pathology laboratories are required to meet relevant standards for their services to be eligible for Medicare benefits. The 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.

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.

In this case, the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2024* is being repealed to enable further stakeholder consultation on the *Requirements for Cervical Screening (First Edition, 2023)*. Until further notice, Australian pathology laboratories involved in the National Cervical Screening Program will be required to continue to comply with the current 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)*.

Conclusion

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

Mary Warner
Assistant Secretary
Medicare Benefits and Digital Health Division
Health Resourcing Group
Department of Health and Aged Care