

EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 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.2) 2023* (the Amending Instrument) is to amend the Principles to incorporate the revised pathology accreditation standard *Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Fourth Edition 2023)*.

In accordance with s 14 of the *Legislation Act 2003*, the revised accreditation standard is 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 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.

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 standard follows 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 Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Fourth Edition 2023)

The *Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Fourth Edition 2023)* is a revised pathology accreditation standard that provides minimum best practice standards for good pathology practice in Australia for testing for HIV and HCV.

This version of the accreditation standard reflects the updated Public Health Laboratory Network's (PHLN) case definition for confirmatory testing for HIV. The revised standard will enable pathology laboratories to employ nucleic acid amplification tests as an alternative to Western Blot assays for confirmatory testing for HIV and remain compliant with the standard.

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 website 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

The Commission which provides administrative support to NPAAC and its sub-committees, completed a short, targeted consultation on the proposed amendments to the standard. Consultation was open to key stakeholders from 15 November 2022 to 5 December 2022 and included:

- Royal College of Pathologists Australasia (RCPA)
- Royal College of Pathologists Australasia Quality Assurance Programs (RCPAQAP)
- PHLN

- Members of NPAAC and its subcommittees – Document Review and Liaison Committee (DRLC) and Strategy and Risk Committee.

NPAAC agreed that the feedback from the targeted consultation process would be considered by NPAAC and DRLC members out-of-session. Feedback from this process was incorporated into the revised standard and referred to NPAAC members for out-of-session consideration. The majority of NPAAC members endorsed the revised standard on 20 February 2023.

This Amending Instrument commences on 1 May 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.

Details of the Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 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.2) 2023* (the Amending Instrument).

2. Commencement

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

Schedule 1

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

Item 1

Item 1 repeals the accreditation standard listed in Item 5 of the table in Schedule 1 of the Principles and substitutes it with the revised standard titled “*Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Fourth Edition 2023).*”

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) 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 a revised version of a National Pathology Accreditation Advisory Council (NPAAC) accreditation standard currently listed in Schedule 1 of the Principles, namely the -

1. *Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Fourth Edition 2023)*.

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 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 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 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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