EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.3) 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.3) 2023* (the Amending Instrument) is to amend the Principles to incorporate the revised pathology accreditation standard *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)* (2023 Supervision Standard).

Consistent with subsection 14(2) of the *Legislation Act 2003*, the 2023 Supervision Standard is to be incorporated as it exists 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 where medicare eligible pathology services are 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 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. 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 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 2023 Supervision 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 Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)

The 2023 Supervision Standard re-issues the *Requirements for supervision in the clinical governance of medical pathology laboratories (Sixth Edition 2021)* (2021 Supervision Standard) which has been in effect since 1 August 2021. The 2023 Supervision Standard incorporates some reformatting and minimal changes to the content of the 2021 Supervision Standard and provides for the temporary continuation of the transitional workforce shortage provisions included in the 2021 Supervision Standard. These transitional provisions are being continued to address the ongoing national workforce shortages in the pathology disciplines of genomics (including cytogenetics and biochemical genetics), immunology and chemical pathology.

The transitional provisions provide laboratories with alternative pathways to demonstrate compliance with the 2023 Supervision Standard in certain circumstances to ensure patient safety and continued access to quality pathology services. The transitional provisions are temporary, applying until the 2023 Supervision Standard is re-issued or 2 years from the publication of the 2023 Supervision Standard, whichever occurs first. The transitional provisions extend the targeted arrangements included in the 2021 Supervision Standard for accredited pathology services existing at the date of effect of that Standard.

Any subsequent changes to, or replacement of the 2023 Supervision Standard will not apply unless further amendments are made to the 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 (https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards#national-pathology-accreditation-standards)**.**

Consultation

NPAAC agreed to re-issue the 2021 Supervision Standard as the 2023 Supervision Standard, with minimal changes including those required to extend the transitional provisions to address the ongoing national workforce shortages in the pathology disciplines of genomics (including cytogenetics and biochemical genetics) immunology and chemical pathology.

The National Association of Testing Authorities, Australia (NATA) is the independent body that conducts the accreditation assessment of pathology laboratories with the relevant pathology accreditation standards. NPAAC's decision to continue the transitional provisions accounted for NATA's findings that they are required to address ongoing national workforce shortages in three pathology disciplines. NATA has been advised on NPAAC's decision.

This Amending Instrument commences on 1 August 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.

ATTACHMENT A

Details of the Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.3) 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.3) 2023* (the Amending Instrument).

2. Commencement

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

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 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 August 2023.

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), which provided that S(FC) laboratory has the same meaning as in the "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)"* (2021 Supervision Standard).

The new definition provides that S(FC) laboratory has the same meaning as in the "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)"* (2023 Supervision Standard).

Item 2

Subsection 18(3) of the 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 2021 Supervision Standard.

Subsection 18(5) of the Principles currently provides that the responsibilities of the designated person for premises under section 18 may be delegated, but only in accordance with the 2021 Supervision Standard.

Item 2 amends these subsections to omit references to the 2021 Supervision Standard and instead refer to the 2023 Supervision Standard.

Item 3

The note to subsection 18(5) currently states that the 2021 Supervision Standard is listed in Schedule 1 of the Principles.

Item 3 amends this note to refer to the 2023 Supervision Standard, which will be listed in Schedule 1 of the Principles instead of the 2021 Supervision Standard (see item 4 below).

Item 4 – Clause 1 of Schedule 1 (table item 19)

The table in clause 1 of Schedule 1 of the Principles identifies documents that are accreditation materials. Item 19 of the table currently refers to the 2021 Supervision Standard.

Item 4 repeals the current item 19 and replaces it with an item listing the 2023 Supervision Standard as an accreditation material.

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.3) 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 *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)(2023 Supervision Requirements).*

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 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 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 2023 Supervision Standard addresses workforce limitations in the pathology sector so that patient access to pathology services in not affected whilst 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. 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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