EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2022

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.1) 2022* (the Amending Instrument) is to amend the Principles to incorporate the revised accreditation standard titled *Requirements for the Retention of Laboratory Records and Diagnostic Material (Ninth Edition 2022)* (the Retention Requirements).

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 accreditation 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. The standards are developed and maintained by the 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 (ACSQHC) under an arrangement with the Department of Health. The Department of Health retains policy and regulatory responsibilities related to pathology accreditation. The accreditation process of pathology laboratories is administered by Services Australia, while the National Association of Testing Authorities, Australia (NATA) is the current 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 is a result of the ongoing refinement of the pathology requirements that are aimed at ensuring best pathology practice and that 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 the Retention of Laboratory Records and Diagnostic Material (Ninth Edition 2022)

The Retention Requirements is a revised pathology accreditation standard that provides minimum best practice standards for laboratories on the minimum standards for the retention of laboratory records and materials. Laboratories may choose to exceed these minimum requirements based on their operations and practice.

In response to concerns raised by some laboratories experiencing issues with the retention and storage of COVID positive specimens, an amendment to the Retention Requirements has been made to reduce the retention period for COVID positive specimens to one week during the continued COVID-19 pandemic period. This measure is to support the continued operation of pathology laboratories during the high demand for services, limited workforce and storage capacity issues. In addition to the change in retention period for COVID positive specimens, other minor editorial amendments have been made to reflect that the document is the ninth edition of the Retention Standards and to acknowledge the role of the ACSQHC, including as the contact organisation for any queries in relation to 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 ACSQHC pathology webpage and can be accessed readily and free of charge from the NPAAC's website, maintained by the Department of Health (http://www.health.gov.au/npaac), or the Australian Commission on Safety and Quality in Health Care's pathology webpage (https://www.safetyandquality.gov.au/national-pathology-accreditation-scheme/resources#national-pathology-accreditation-standards).

Consultation

The ninth edition of the Retention Requirements is in response to concerns raised by some pathology laboratories with being able to meet the current retention requirements that apply to COVID positive specimens. The amendment reduces the retention period for COVID positive specimens from the usual applicable retention time for microbiology specimens during the COVID response period. This is expected to allow laboratories that perform COVID testing to be able to meet the accreditation standards for storage during a period of high volumes of tests.

The ACSQHC, who has administrative responsibilities to support the work of NPAAC, has advised that broader public consultation with pathology stakeholders was not considered necessary for this amendment given it was recommended by and done in consultation with NPAAC. NPAAC, as the ministerially appointed pathology expert committee has a broad membership of key pathology sector stakeholders. Additionally, the amendment to the accreditation standard was in response to concerns raised by the pathology sector and the aim was to implement timely change. The independent accrediting body for the accreditation of pathology laboratories, NATA was consulted on the proposed revised retention period for COVID positive specimens. There was no objection to the proposed change.

This Amending Instrument commences on the day after it has been registered.

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.1) 2022

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) 2022* (the Amending Instrument).

2. Commencement

Subsection 2(1) provides that the Amending Instrument commences on the day after it is registered on the Federal Register of Legislation.

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 Principles commencing on the day after this instrument is registered on the Federal Register of Legislation.

Schedule 1

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

Item 1

Item 1 repeals the accreditation standard listed in Item 21 of the table in Schedule 1 of the Principles and substitutes it with a revised accreditation standard for the retention of laboratory records and diagnostic materials titled "*Requirements for the Retention of Laboratory Records and Diagnostic Material (Ninth Edition 2022)".*

Item 2

Item 2 repeals the note at the end of the table at item 1 of Schedule 1 of the Principles and substitutes it with *"The documents mentioned could in 2022 be viewed on NPAAC's website, maintained by the Department of Health, or the Australian Commission on Safety and Quality in Health Care's pathology 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) 2022

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

1. Requirements for the Retention of Laboratory Records and Diagnostic Material (Ninth Edition 2022).

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. The accreditation process of pathology laboratories is administered by the Department of Human Services, 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 and can be accessed from NPAAC's website, maintained by the Department of Health (http://www.health.gov.au/npaac), or the Australian Commission on Safety and Quality in Health Care's pathology webpage (https://www.safetyandquality.gov.au/national-pathology-accreditation-scheme/resources#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 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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