EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2021

Authority

Section 23DNA of the *Health Insurance Act 1973* (the Act) provides for the Minister for Health 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) 2021* (the Amending Instrument) is to amend the Principles to incorporate the following revised and new accreditation standards:

- Requirements for Use of Digital Images as an Alternative to Direct Microscopy (First Edition 2021)
- Requirements for Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Sixth Edition 2021)
- Requirements for Point of Care Testing (Second Edition 2021).

In accordance with s 14 of the *Legislation Act 2003*, the revised and new accreditation standards are not to be incorporated from time to time, but at the time of commencement of this instrument on the specified dates.

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 the National Pathology Accreditation Advisory Council (NPAAC) or endorsed by NPAAC as supplementary accreditation materials. The accreditation process of pathology laboratories is administered by the Services Australia, while the National Association of Testing Authorities (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 and new accreditation standards follow from NPAAC's consideration of standards that would support the therapeutics regulatory framework or as a result of the ongoing refinement of the pathology requirements that are aimed at ensuring best pathology practice. 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 additional 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 Use of Digital Images as an Alternative to Direct Microscopy (First Edition 2021)

The *Requirements for Use of Digital Images as an Alternative to Direct Microscopy (First Edition 2021)* is a new pathology accreditation standard that provides minimum best practice standards for laboratories using digital technology for primary morphological diagnosis and second opinions. This primarily concerns the use of whole slide imaging but also encompasses use of telepathology where digital cameras, operated manually or remotely, transmit images.

The Requirements cover the use of digital microscopy in anatomical pathology, cytopathology, haematology morphology and microscopy in microbiology.

Requirements for Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Sixth Edition 2021)

The *Requirements for Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Sixth Edition 2021)* sets out the minimum standards for facilities involved in donor selection, collection, processing, storage or disposal of directed minimally manipulated:

- haemopoietic progenitor cells (HPC)
- cord blood; and
- donor lymphocytes which are used for haemopoietic reconstitution; and
- donor lymphocytes which are issued for subsequent manufacture of a TGA approved product or under an approved clinical trial.

CAR-T cells are novel therapies for some leukaemia and lymphoma patients who would otherwise currently have limited other treatment options. The Therapeutic Goods Administration raised concerns about the manufacture of CAR-T cell for genetic modification and cell expansion in the treatment of infusion patients that falls outside of the regulatory framework. In response, NPAAC revised the scope of the Requirements to include donor lymphocytes used for haemopoietic reconstitution and donor lymphocytes which are

issued for manufacture of a TGA approved product or under an approved clinical trial. This revision to the scope of the document ensures that CAR-T cells are addressed under the pathology accreditation framework.

Requirements for Point of Care Testing (First Edition 2021)

NPAAC published *Guidelines for Point of Care Testing* (PoCT) in 2015. The Guidelines were developed with the aim of providing a quality framework for the performance of PoCT that focussed on a laboratory setting, but also provided guidance for other healthcare settings.

As part of the document review, NPAAC considered the audiences for the accreditation standards, the quality framework for PoCT and potential risks for patients, and the comprehensiveness of the standards in consideration of the PoCT standards and healthcare standards more generally.

NPAAC and the Royal Australian College of General Practitioners have agreed on the incorporation of the General Practice Point of Care Standards into the new accreditation standard titled *Requirements Point of Care Testing (Second Edition 2021)*. The revised Requirements outline best practice standards for point of care tests used in all health care settings. The document describes the key steps to ensure users of PoCT technology provide safe, quality-assured testing, especially when the results are to be used for patient's healthcare management.

The aforementioned pathology standards are incorporated by the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017*. The *Requirements for Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Sixth Edition 2021)* and the *Requirements Point of Care Testing (Second Edition 2021)* are proposed to come into effect on 1 January 2022. The new *Requirements for Use of Digital Images as an Alternative to Direct Microscopy (First Edition 2021)* is proposed to come into effect on 1 February 2022.

Any subsequent changes or replacement to the above standards documents will not apply unless further amendments are made to the Principles.

Copies of pathology accreditation materials listed in the Schedule to the Principles are published on the NPAAC website and can be accessed readily and free of charge from - http://www.health.gov.au/internet/main/publishing.nsf/ Content/health-npaac-publication.htm.

Consultation

As part of the accreditation standards development process, all three accreditation standards were released for a public consultation phase to inform the finalisation of the accreditation standards. A broad range of stakeholders, including all pathology laboratories, peak pathology bodies, consumers, other relevant organisations with an interest in pathology were consulted on the on the new and revised standards. There was overall support for the accreditation standards and feedback was considered in the finalisation of the standards.

Peak pathology organisations and relevant pathology laboratories were consulted on the revised Supervision Requirements and Retention Requirements. There was overall support for the revised documents and the final versions take into consideration comments received from the consultation process.

The Amendment 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

Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2021

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) 2021* (the Amending Instrument).

2. Commencement

Subsection 2(1) provides for commencement date of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. Schedule 1 to the Amendment Instrument commences on the specified dates.

3. Authority

Section 3 provides for the authority for the Amendment 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 1 January 2022 and 1 February 2022.

Schedule 1 – Amendments commencing on 1 January 2022

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

Item 1

Item 1 repeals the standard listed in Item 12 of the Table and substitutes it with a new standard for the collection, processing, storage and issue of human haemopoietic progenitor cells titled "*Requirements for Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Sixth Edition 2021)"*.

Item 2

Item 2 amends Schedule 1 to the current Principles by adding a new item 23 to the list of standards in the Table. The new standard is titled "*Requirements for Point of Care Testing (Second Edition 2021).*"

Schedule 1 – Amendments commencing on 1 February 2022

Item 3

Item 3 amends Schedule 1 to the current Principles by adding a new item 24 to the list of standards in the Table. The new standard is titled "Requirements for the Use of Digital Images as an Alternative to Direct Microscopy (First Edition 2021)."

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) 2021

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 makes amendments to the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* ('Principles') to incorporate two new pathology accreditation standards and one revised version of National Pathology Accreditation Advisory Council (NPAAC) accreditation standards currently listed in Schedule 1 of the Principles, namely the -

1. Requirements for Use of Digital Images as an Alternative to Direct Microscopy (First Edition 2021)
2. Requirements for Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Sixth Edition 2021)
3. Requirements for Point of Care Testing (Second Edition 2021).

The Principles are made by the Minister under section 23DN of 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 the currently 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. 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 NPAAC website and can be freely accessed from - http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm.

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 quality, safe, clinically relevant and cost-effective Medicare eligible pathology services.

The revised and new accreditation standards set 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 or development 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.

Michael Ryan
Acting Assistant Secretary
Medical Benefits Division
Department of Health