EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories – Approval) Amendment (Relevant Standards) Principles 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 2021* (the Amending Principles) is to amend the Principles to incorporate the following revised and new accreditation standards:

- *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)*
- *Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021)*
- *Requirements for the Communication of High Risk Pathology Results (First Edition 2020)*
- *Requirements for Information Communication and Reporting (Fourth Edition 2020).*

The Amending Principles also amend a number of sections of the Principles, most importantly those specifying the categories of accreditation of pathology laboratories and standards of direction, control and supervision of laboratories to reflect the new *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)*.

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 Department of Human Services, 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 issues drawn to attention by laboratories, or a request by the Minister for Health and Aged Care, or as part of the usual continued improvement of the pathology accreditation standards. Each of the revised and new accreditation standards must 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 Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)

Effective supervision of pathology laboratories is a key element for ensuring the safe operation of pathology laboratories. The provision of quality pathology services relies on the collaborative working relationship between pathologists, clinical scientists, scientists, technicians, and other laboratory staff.

The *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)* has been in effect since 1 August 2019. However, since the implementation of the standard, there have been several issues drawn to the attention of NPAAC. NPAAC, as the pathology accreditation standard setting body, has responded through a limited review of the accreditation requirements. The issues that have been addressed in the revised standards titled *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)* (the 2021 Supervision Requirements) include:

- Challenge with recruiting supervising pathologists in disciplines where there are recognised workforce shortages
- Pathology workforce shortage issues in the disciplines of genetics (including cytogenetics and biochemical genetics), immunology and chemical pathology
- Supervision arrangements for fertility control clinics (abortion clinics) that are a kind of Category S (Specialised) laboratories
- Revision of the definition of *Clinical Scientist* to cover clinical scientists in histocompatibility and immunogenetic laboratories
- Revision of the definition of *Technical Officer* to reflect the former definition, which recognised overseas qualifications
- Provision for Intensive Care Units (ICU) laboratories within hospital premises to be able to meet the description of a Category M laboratory for the purposes of supervision.

The new provisions in recognition of workforce limitations are not just limited to laboratories that were part of the previous transitional arrangements designed to assist laboratories to transition to new supervision requirements in the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)*. The 2021 Supervision Requirements are aimed at providing laboratories with alternative options to demonstrate compliance with the supervision requirements in certain circumstances. However, the requirements are still aimed at ensuring testing can be demonstrated to be safe and access to services is not curtailed.

Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021)

The *Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021)* sets out the minimum standards for the retention of laboratory records and materials.

In response to concerns raised by pathology laboratories in relation to the retention and storage of COVID specimens due to the volume of tests, a minor amendment to the standard has been made to address the retention of negative COVID specimens. Furthermore, there were other minor amendments to retention times and inclusion of additional reference materials made for the clarification of requirements.

Requirements for the Communication of High Risk Pathology Results (First Edition 2020)

The *Requirements for the Communication of High Risk Pathology Results (First Edition 2020)* is a new pathology accreditation standard that provides guidance and minimum best practice standards for the management and communication of high risk pathology results by the pathology services. The Requirements are aimed at minimising potential risks to patients and optimising the contribution of pathology testing towards improved patient outcomes.

The effective communication of patient test results is a shared responsibility between the pathology laboratory and treating clinicians. The pathology service is required to provide medical and scientific consultation on results when sought; but decisions about the management of the patient are made by the treating clinician.

Requirements for Information Communication and Reporting (Fourth Edition 2020)

As part of the usual review process of pathology accreditation standards, a review of the current information communication standard was undertaken and as a consequence the revised standard titled *Requirements for Information Communication and Reporting (Fourth Edition 2020)* has been developed. The revised Requirements outline best practice standards related to the electronic communication of pathology information between pathology laboratories, requesters, consumers and other relevant parties.

The Requirements have been revised to be more comprehensive, risk based and aims to ensure the integrity of patient information during the transfer of information the laboratory and relevant parties.

The aforementioned new or revised Requirements are proposed to be incorporated into the Principles and come into effect as follows:

- *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)* – 1 August 2021;

- *Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021)* – 1 August 2021;
- *Requirements for the Communication of High Risk Pathology Results (First Edition 2020)* – 1 January 2022;
- *Requirements for Information Communication and Reporting (Fourth Edition 2020)* – 1 August 2022.

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

The aforementioned pathology standards are incorporated by the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* as existing on the day the Amending Principles commence. Any subsequent changes or replacement to the above standards documents will not apply unless further amendments are made to the Principles.

Consultation

As part of the accreditation standards development process, a public consultation process on the new and revised draft accreditation standards was undertaken. As part of its usual standards development process, NPAAC consulted with a broad range of stakeholders on the proposed High Risk and Information Communication standards, including all pathology laboratories, peak pathology bodies, consumers, other relevant organisations with an interest in pathology. There was overall support for the new and revised accreditation standard and feedback was considered in the finalisation of the standards.

Peak pathology organisations and relevant pathology laboraotories 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 Amending Principles commence as follows:
- Sections 1 to 4 – the day after registration on the Federal Register of Legislation;
- Part 1 of Schedule 1 - 1 August 2021;
- Part 2 of Schedule 1 – 1 January 2022;
- Part 3 of Schedule 1 – 1 August 2022.

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

Details of the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment (Relevant Standards) Principles 2021*

1. Name of legislative instrument

Section 1 provides that the title of this instrument is the *Health Insurance (Accredited Pathology Laboratories-Approval) Amendment (Relevant Standards) Principles 2021* (the Amending Principles).

2. Commencement

Section 2 provides for the commencement date of the Amending Principles as follows:

- Sections 1 to 4 – the day after the Amending Principles are registered;
- Part 1 of Schedule 1 – 1 August 2021;
- Part 2 of Schedule 1 – 1 January 2022;
- Part 3 of Schedule 1 – 1 August 2022.

3. Authority

Section 3 provides that the authority for the Amending Principles is 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 Principles 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)

Part 1 of Schedule 1 – Amendments commencing 1 August 2021

Item 1 – Subsection 5(2)
Item 1 amends subsection 5(2) to insert the following additional definitions:

- ***pathology discipline with a national workforce shortage***, meaning the disciplines of genomics (including cytogenetics and biochemical genetics), immunology and chemical pathology;
- ***S(FC) laboratory***, which has the same meaning as in as in the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)*.

These definitions are relevant for amendments being made to sections 17 and 18 of the Principles.

Item 2 – Subsection 17(1) (cell at table item 1, column headed "Criteria")
Section 17 of the Principles specifies the various categories in which a laboratory or a group of laboratories can be accredited.
Item 2 repeals the description of a Category GX laboratory in subsection 17(1), and substitutes with a new definition.

This new definition enables, in addition to the existing types of Category GX laboratories, premises of a recognised national blood service that are a laboratory or a number of co-located laboratories or a network of laboratories to be accredited as Category GX. Such laboratories must be under the full-time direction, control and supervision of a designated person, who is a pathologist with the relevant scope of practice, and also render a limited range of pathology testing under the full time supervision of a pathologist (whether or not the designated person) with the relevant scope of practice.

The new definition also specifies alternative supervision requirements that can be met for Category GX laboratories in the case of services rendered in groups of pathology testing that are in pathology disciplines with a national workforce shortage, if the laboratory or group of co-located laboratories is unable to recruit a full-time pathologist with the relevant scope of practice to provide full-time supervision. In this case, supervision can be offered by a pathologist (whether or not that pathologist is also the designated person for the laboratory or laboratories). The amendment is intended to ensure that national workforce shortages do not affect patient access by allowing laboratories providing testing in disciplines with a national workforce shortage to meet alternative supervision requirements if they are unable to recruit.

This definition is aligned with the amended supervision requirements for this category of laboratory in the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)* (2021 Supervision Requirements).

Item 3 - Subsection 17(1) (table item 2, column headed "Criteria", paragraphs (a) and (b))
Item 3 makes a consequential amendment to paragraphs (a) and (b) of the definition of a Category GY laboratory in subsection 17(1) by omitting the word "is" and substituting with "are".

Item 4 - Subsection 17(1) (table item 2, column headed "Criteria", paragraph (c))
Item 4 repeals paragraph (c) of the definition of a Category GY laboratory in subsection 17(1) and substitutes with a new definition. This revised definition reflects amended supervision requirements for this category of laboratory in the 2021 Supervision Requirements which can be met in the case of services rendered in groups of pathology testing that are in pathology disciplines with a national workforce shortage, if the laboratory or group of co-located laboratories are unable to recruit a full-time onsite pathologist with the relevant scope of practice to provide on-site supervision.

Similarly for GX laboratories, in this case supervision can be offered by a pathologist (whether or not that pathologist is also the designated person for the laboratory or laboratories). The amendment is intended to ensure that national workforce shortages do not affect patient access by allowing laboratories providing testing in disciplines with a national workforce shortage to meet alternative supervision requirements if they are unable to recruit.

Item 5 - Subsection 17(1) (table item 3, column headed "Criteria", paragraphs (a) and (b))
Item 5 amends paragraphs (a) and (b) of definition of a Category B laboratory in subsection 17(1) by omitting the word "is" and substitutes with "are". This is a consequential change necessitated by the amendments made by items 3 and 4.

Item 6 - Subsection 17(1) (table item 3, column headed "Criteria", paragraph (c))
Item 6 makes a minor drafting correction to paragraph (c) of the definition of a Category B laboratory in subsection 17(1) by omitting the word "renders" and substituting with "render". This is a consequential change necessitated by the amendments made by item 5.

Item 7 - Subsection 17(1) (table item 5, column headed "Criteria")
Item 7 amends the definition of a Category S laboratory in subsection 17(1) omitting "either of the following" and substitutes with "any of the following". This is a consequential change necessitated by the amendments made by item 8.

Item 8 - Subsection 17(1) (at the end of the cell at table item 5, column headed "Criteria")
Item 8 amends the description of a Category S laboratory in section 17(1) to include a new description for fertility control clinics, being premises comprising an S(FC) laboratory that:

- is under the full time direction, control and supervision of a designated person, who is a medical practitioner with a specialised scope of practice but not a pathologist; and
- renders a limited range of pathology testing that is restricted to tests related to fertility control testing and is under the full-time supervision of the designated person.

The amendments also specify alternative designated person requirements that can be met for Category S laboratories in the case of services rendered in groups of pathology testing that are in pathology disciplines with a national workforce shortage. In this case, the designated person can be a medical practitioner (who is not a pathologist) without a relevant scope of practice. The amendment is intended to ensure that national workforce shortages do not affect patient access by allowing laboratories providing testing in disciplines with a national workforce shortage to meet alternative supervision requirements.

These amendments to the definition of Category S laboratories have been made in recognition of the amended supervision requirements for this category of laboratory in the 2021 Supervision Requirements.

Item 9 - Subsections 18(3) and (5)
Item 9 amends subsections 18(3) and (5) to omit "*Requirements for Supervision of the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)*" and substitute with reference to the 2021 Supervision Requirements.

Item 10 - Subsection 18(5) (note)
Item 10 amends the note to subsections 18(5) to omit "*Requirements for Supervision of the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)*" and substitute with reference to the 2021 Supervision Requirements.

Item 11 - At the end of section 18
Section 18 of the Principles deals with required standards of control, direction and supervision for accredited laboratories.

Item 11 inserts a new subsection 18(6) which provides that paragraph 18(1)(c) and subsection 18(4) do not apply to a designated person of a category S laboratory in which services are rendered in 1 or more groups of pathology testing that are in 1 or more pathology disciplines with a national workforce shortage.

Paragraph 18(1)(c) and subsection 18(4) together require that accredited premises must be under the direction, control and supervision of a designated person who has a relevant scope of practice and that the designated person only supervises testing within their scope of practice. A scope of practice is relevantly defined in subsection 5(2) to mean the discipline and areas of testing in which a person has met certain training or credentialling requirements.

Some Category S laboratories delivering testing in disciplines with a national workforce shortage have experienced difficulties recruiting a designated person with a scope of practice. The revised 2021 Supervision Requirements provide alternative arrangements for these laboratories, necessitating consequential changes to section 18.

Item 12 – Schedule 1
Item 12 amends Schedule 1 to clarify that the table of NPAAC materials in Schedule 1 has effect for the purposes of the definition of accreditation materials in subsection 5(2) of the Principles. This is a technical drafting improvement.

Item 13 - Schedule 1 (table item 19)
Item 13 repeals the standard listed in Item 19 of the table in Schedule 1 of the Principles and substitutes it with a new standard in relation to the supervision requirements for pathology laboratories titled "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)"*.

Item 14 – Schedule 1 (table item 21)
Item 14 repeals the standard listed in Item 21 of the table in Schedule 1 of the Principles and substitutes it with a new standard in relation to the retention and storage of pathology laboratory records and specimens titled "*Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021)"*.

Item 15 - Schedule 1 (note at the end of the table)
Item 15 amends the note to the table in Schedule 1 of the Principles to omit "2018" and substitute "2021". This note informs readers where copies of the NPAAC materials specified in Schedule 1 can be viewed, and indicates that in 2021 the materials can still be viewed on NPAAC's website (http://www.health.gov.au/npaac).

Item 16 – At the end of Schedule 1
Item 16 amends Schedule 1 to include new clause 2 specifying that for the purposes of the Principles, the *Requirements for Medical Pathology Services (Third Edition 2018)* mentioned in the table in Schedule 1 apply as if the definition of 'designated person' in those requirements did not include a reference to relevant scope of practice. New clause 2 only applies in relation to the designated person of a ategory S laboratory that renders services in groups of pathology testing in disciplines with a national workforce shortage.

This modification to the application of the definition ensures that the definition is not inconsistent with amendments to section 17 and 18 of the Principles made by the Amending Principles, and revisions to supervision standards in the 2021 Supervision Requirements.

Part 2 of Schedule 1 – Amendments commencing 1 January 2022

Item 17 – Schedule 1 (at the end of the table)
Item 17 makes an addition to Schedule 1 (at the end of the table) to include a new Item 23 incorporating *Requirements for the Communication of Hight Risk Pathology Results (First Edition 2020)* as accreditation material that must be met by laboratories.

Part 3 of Schedule 1 – Amendments commencing 1 August 2022

Item 18 – Schedule 1 (table item 4)
Item 18 repeals the standard listed in Item 4 of the table in Schedule 1 of the Principles and substitutes it with the revised standard titled "*Requirements for Information Communication and Reporting (Fourth Edition 2020)".*

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 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 one new pathology accreditation standard and three revised versions of National Pathology Accreditation Advisory Council (NPAAC) accreditation standards currently listed in Schedule 1 of the Principles, namely the -

a) *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)*

b) *Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021)*

c) *Requirements for the Communication of High Risk Pathology Results (First Edition 2020)*

d) *Requirements for Information Communication and Reporting (Fourth Edition 2020).*

This Legislative Instrument also amends section 5 (definitions), section 17 (allocation of categories of accreditation of pathology laboratories) and section 18 (Standards of direction, control and supervision of premises required) and Schedule 1 (Accreditation materials) of the Principles to reflect the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth 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 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 *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories* (together with related amendments to the Principles) and revised *Requirements for the Retention of Laboratory Records and Diagnostic Material* address workforce limitations and other issues across the pathology sector (including concerns raised by pathology laboratories in relation to the retention and storage of COVID specimens due to volume of tests) 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 new *Requirements for the Communication of High Risk Pathology Results* and revised *Requirements for Information Communication and Reporting* provide best practice standards for the communication of pathology information, aimed at minimising potential risks to patients and optimising the contribution of pathology testing towards improved patient outcomes.

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.

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