EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories – Approval) Amendment (Transitional Arrangements) Principles 2020

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).

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.

Purpose

The purpose of the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment (Transitional Arrangements) Principles 2020* (this instrument) is to amend the Principles to include further transitional arrangements for the listed laboratories and specialised category S laboratories that perform In-vitro Fertilisation (IVF) testing related to the diagnosis and treatment of fertility issues to meet the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)* (the 2018 Supervision Requirements).

The further transitional arrangements for these laboratories will commence on 1 January 2021 and allow them to continue operations whilst making the necessary arrangements to meet the 2018 Supervision Requirements before 1 August 2021.

The further transitional arrangements have been provided to these laboratories to ensure that they have appropriate supervision arrangements in place, including ensuring that their medical specialists' have adequate time to have their scope of practice credentialed for the purposes of supervision of testing rendered in their pathology laboratories. Following the end of the further transitional arrangements, it is expected that all accredited pathology laboratories meet the 2018 Supervision Requirements in order to be able to provide pathology services eligible for Medicare benefits.

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. Accredited pathology laboratories are premises approved by the Minister under section 23DN of the Act. The Principles, made under section 23DNA of the Act, set out the principles the Minister must apply in exercising his or her powers to approve premises as accredited pathology laboratories and operate to ensure that appropriate standards are met and maintained in

pathology laboratories at which Medicare eligible pathology services can be provided. Decisions to approve premises as an accredited pathology laboratory (or refuse, vary, or revoke approvals) are reviewable by the Administrative Appeals Tribunal (see subsection 23DO(5) of the Act).

The Principles include criteria for different categories of accreditation and specify the relevant standards for pathology services that must be met by each accredited pathology laboratory. The overarching objectives of the Principles include promoting the delivery of safe and reliable test results that are aimed at improving patient outcomes and reducing the risk to patients in the provision of pathology services.

Section 18 and the Schedule to the Principles specify the relevant standards that must be met by accredited pathology laboratories. These documents are developed and maintained by the National Pathology Accreditation Advisory Council (NPAAC) or endorsed by NPAAC as supplementary accreditation materials. The accreditation 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 assessments of pathology laboratories, in conjunction with the Royal College of Pathologists of Australasia.

The minimum best practice standards for supervision of pathology testing are set out in the 2018 Supervision Requirements. The 2018 Supervision Requirements replaced the *Requirements for the Supervision of Pathology Laboratories 2007* (2007 Supervision Requirements) as a relevant standard under the Principles on 1 August 2019, through the amendments made by Schedule 2 of the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment Instrument (No. 2) 2018*.

Initial transitional arrangements applying to some listed laboratories, and specialised category S laboratories that perform IVF testing, were included in the Principles through further amendments made by the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment Instrument (No. 1) 2019*. The intent of the initial transitional arrangements was to delay the application of the 2018 Supervision Requirements to the specified laboratories; but continue to apply all other relevant standards. The further transitional arrangements introduced by this instrument give effect to that intent for a further period of seven months and also include additional listed laboratories in the further transitional arrangements.

This instrument also makes minor amendments to section 17 of the Principles (unrelated to the further transitional arrangements) to align the criteria for Category GX and Category S laboratory accreditation with the 2018 Supervision Requirements by removing the requirement that the full-time direction and control of the designated person be ‘onsite’.

The pathology accreditation framework is aimed at assuring the quality of Australian pathology services. Copies of pathology accreditation materials listed in the Schedule to the Principles 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.

Consultation

NPAAC, as the ministerially-appointed expert pathology committee, has been consulted on the proposed further transitional arrangements for the specified laboratories.

The Department of Health (the Department) has liaised with the affected pathology stakeholders, including the IVF Directors Group, Australian Pathology that represent IVF laboratories and with laboratories that were identified as having issues with meeting the 2018 Supervision Requirements. The stakeholders were supportive of the option of a further transitional arrangements.

In addition, the Department has also liaised with Services Australia, who have administrative responsibilities for laboratory accreditation, regarding the laboratories appropriate to be included as listed laboratories in the further transitional arrangements.

The Department has also consulted with NATA, as the current pathology independent accreditation assessment body, to ensure it is informed of the proposed further transitional arrangements and expectations for the specified laboratories.

This instrument commences on 1 January 2021.

This instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Details of this instrument are set out in the Attachment.

ATTACHMENT

Details of the *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment (Transitional Arrangements) Principles 2020*

1. Name of legislative instrument

Section 1 provides that the title of this instrument is the *Health Insurance (Accredited Pathology Laboratories-Approval) Amendment (Transitional Arrangements) Principles 2020.*

2. Commencement

This section provides that the whole of this instrument commences on 1 January 2021.

3. Authority

Section 3 provides that this 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.

Schedule 1 –Amendments

Schedule 1 amends the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* (the Principles) to provide further transitional arrangements applying to Category S specialised pathology laboratories that perform In Vitro Fertilisation (IVF) testing related to the diagnosis and treatment of fertility services, and a number of other listed laboratories. Schedule 1 also makes minor amendments to section 17 of the Principles to align the criteria for Category GX and Category S accreditation with the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)* (the 2018 Supervision Requirements) by removing the requirement that the full-time direction and control of the designated person be 'onsite'.

Item 1

Item 1 amends subsection 17(1)(table item 1, column headed "Criteria", paragraph (a)) of the Principles to remove the word 'onsite' from the criteria description of a Category GX laboratory, to be consistent with the description in the 2018 Supervision Requirements.

Item 2

Item 2 amends subsection 17(1) (table item 5, column headed "Criteria", subparagraph (a)(i)) of the Principles to omit the word 'onsite' from the criteria description of a Category S laboratory, to be consistent with the description in the 2018 Supervision Requirements.

Items 3

Item 3 provides for a new Division Heading for the transitional arrangements relating to the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment Instrument (No. 2) 2018* as there are now two transitional arrangements in the Principles (section 19 and new section 20 inserted by item 5).

Item 4

Item 4 replaces the heading for the initial transitional arrangements under section 19 to 'Initial transitional arrangements (between 1 August 2019 and 31 December 2020)' as there are now two transitional arrangements in the Principles (section 19 and new section 20 inserted by item 5).

Item 5

Item 5 inserts new section 20, which sets out further transitional arrangements applying between 1 January 2021 and 31 July 2020.

New subsection 20(2) applies the Principles to the premises and applications covered by the further transitional arrangements as if the amendments made by Schedule 2 to the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment Instrument (No. 2) 2018* had not been made.

The intent of this provision is that the *Requirements for the Supervision of Pathology Laboratories* (2007 Edition) (2007 Supervision Requirements) will apply to the covered premises until 31 July 2021. Sections 17 and 18 of the Principles will also apply to the covered premises as they were in effect prior to 1 August 2019, consistently with the 2007 Supervision Requirements. This means that in exercising the power of approval (or variation or revocation of approval) of the covered premises as accredited pathology laboratories under section 23DN of the Act, the Minister must consider if he or she is satisfied with a high level of confidence that the pathology services to be rendered at the premises will meet the 2007 Supervision Requirements, rather than the 2018 Supervision Requirements (see sections 11, 15 and 16 of the Principles).

The further transitional arrangements only apply to the premises specified in new subsection 20(2) and as defined in subsection 20(1). Those premises are:

- Category S IVF premises for which the approval was still covered by the initial transitional arrangement immediately before 1 January 2021 ('section 19 category S IVF premises');
- the listed premises in subsection 19(1) for which the approval was still covered by the initial transitional arrangement immediately before 1 January 2021 ('section 19 listed premises'); and
- the premises listed in subsection 20(1) for which the approval was in effect immediately before 1 January 2021 ('section 20 listed premises').

The further transitional arrangement only applies to applications for re-approval specified in new subsection 20(4). The intent of this provision is to allow premises covered by the further transitional arrangement, and for which an application for re-approval is made between

1 January 2021 and 1 June 2021, to elect to apply the further transitional arrangements to the re-approval. For the further transitional arrangements to apply, the re-approval must be for the same kind of pathology services and the same category of accreditation.

Premises can elect to end coverage of the further transitional arrangements and become approved against the 2018 Supervision Requirements at any time leading up to 1 January 2021, by seeking re-approval under section 23DN of the Act during the transition period.

On 1 August 2021, all premises approved as accredited pathology laboratories (or seeking approval) will need to be compliant with the 2018 Supervision Requirements, otherwise the Minister of Health could refuse, vary or revoke their approval under section 23DN of the Act.

New section 21 provides for automatic repeal of the transitional arrangements when they cease to have effect on 1 August 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 (Transitional Arrangement) Principles 2020

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

The Minister for Health determines the principles to be applied in exercising his or her powers under section 23DN of the *Health Insurance Act 1973* (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).

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 relevant standards that must be met as part of the accreditation assessment for each category of laboratory and the 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 Services Australia, while the National Association of Testing Authorities (NATA) is currently the independent assessment body that conducts the accreditation assessment of pathology laboratories, in conjunction with the Royal College of Pathologists of Australasia.

The *Health Insurance (Accredited Pathology Laboratories – Approval) Amendment (Transitional Arrangements) Principles 2020* (this Legislative Instrument) amends the Principles to include further transitional arrangements for the listed laboratories, and specialised S category laboratories that perform In-vitro Fertilisation (IVF) testing related to the diagnosis and treatment of fertility issues, to meet the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)* (the 2018 Supervision Requirements). The further transitional arrangements for these specific laboratories are to ensure they can continue operations in the interim of making arrangements to meet the 2018 Supervision Requirements by the end of the transitional arrangements.

The *Requirements for the Supervision of Pathology Laboratories 2007 Edition* (2007 Supervision Requirements) will continue to remain as an applicable accreditation supervision standard for the laboratories covered by the further transitional arrangements until 1 August 2021, when it is expected that these laboratories will meet the 2018 Supervision Requirements. It should be noted that these laboratories are able to elect to seek approval to the 2018 Supervision Requirements during the further transitional arrangements if they are in a position to meet the accreditation standard earlier than 1 August 2021.

This Legislative Instrument also makes minor amendments to section 17 of the Principles (unrelated to the further transitional arrangements) to align the criteria for Category GX and Category S accreditation with the 2018 Supervision Requirements by removing the requirement that the full-time direction and control of the designated person be 'onsite'.

The pathology supervision standard is one standard amongst a suite of accreditation materials set out as relevant standards in the Principles. 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

The International Covenant on Economic, Social and Cultural Rights recognises that individuals have the right to the enjoyment of the highest attainable standard of health, including a right to a system of health protection.

This Legislative Instrument will maintain rights to access quality, safe, clinically relevant and cost effective Medicare eligible pathology services.

Although a majority of accredited pathology laboratories will be assessed to the 2018 Supervision Requirements, specialised Category S IVF testing laboratories and a small number of other listed laboratories, will be allowed to be assessed and comply with the 2007 Supervision Requirements until 1 August 2021. This has no effect on the Australian public's access to Commonwealth subsidised pathology services nor impact on people's right to quality health services and social security.

This Legislative Instrument promotes the right to health as the accreditation standards are aimed at ensuring pathology laboratories providing Medicare-eligible pathology services deliver high quality services.

Conclusion

This Legislative Instrument is compatible with human rights as it maintains existing arrangements and the protection of human rights.

Michael Ryan
Assistant Secretary (A/g)
Diagnostic Imaging and Pathology Branch
Medical Benefits Division