EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories – Approval) Amendment Instrument (No. 2) 2019

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 provided for under 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 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 purpose of the *Health Insurance (Accredited Pathology Laboratories-Approval) Amendment Principle 2019 (No. 2)* (the Amending Principles) is to amend Schedule 1 of the Principles to incorporate the following revised and new accreditation standards:

- *Requirements for Transfusion Laboratory Practice (Fourth Edition 2019)*
- *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019)*
- *Requirements for Validation of Self-Collected Vaginal Swabs for use in the National Cervical Screening Program (First Edition 2019)*

These documents are as a result of the ongoing refinement of 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 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 Transfusion Laboratory Practice (Fourth Edition 2019) outlines minimum best practice standards for laboratories providing pre-transfusion and antenatal and post-natal immunohaematology testing and issuing of blood and blood products. They are also for use in patient testing where it is conducted by the Australian Red Cross Blood Service.

The document has been revised with a risk based approach to safeguard patients undergoing transfusion or immunohaematology testing, for the standards to reflect contemporary practice and to address patient testing in a donor testing setting.

Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019) outlines minimum best practice standards for using Human Papillomavirus (HPV) nucleic acid testing (NAT) as the primary screening method for cervical cancer screening with reflex liquid based cytology in cases positive for oncogenic HPV types. The Requirements document also provides guidance for the additional steps laboratories must take when using HPV NAT alone as a primary screening test in a population that includes both vaccinated and unvaccinated women.

The National Pathology Accreditation Advisory Council made a commitment to undertake a short review of quality measures set out in the previous Requirements document applying to HPV NAT, in particular the utility of the 2000 specimen quality measure that was intended to monitor broad assay issues once further national HPV data was available. From the review the 2000 specimen quality measure was considered not to be functioning as intended and is no longer a requirement. However, all other quality measures in the Requirements remain and provide a sufficiently rigorous quality framework for the performance of this testing.

Requirements for Validation of Self-Collected Vaginal Swabs for use in the National Cervical Screening Program (First Edition 2019) outlines the minimum best practice standards that an Applicant laboratory must meet in order to offer testing of self-collected vaginal swabs for Human Papillomavirus (HPV) as part of the National Cervical Screening Program as an in-house in vitro diagnostic medical device.

The accreditation requirements were developed in response to the self collection policy that is part of the renewed National Cervical Screening Program that is aimed at improving participation in screening by providing an alternative screening process for aysymptomatic individuals who are under-screened or never screened and who have declined conventional screening by healthcare professionals. Currently in the absence of any commercially supplied HPV tests that have been approved for primary population screening and have been validated for self collection, pathology laboratories using these in house in vitro diagnostic tests must validate the use of the test assays.

This accreditation standard will only be applicable for those laboratories that wish to perform self collect HPV testing for the National Cervical Screening Program. There are currently two pathology laboratories that have been accredited by the pathology independent assessment body for the performance of this testing in accordance with the Therapeutic Goods Administration's regulatory requirements.

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.

The above three standards documents are incorporated and applied by the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* on the day the amendments to Schedule 1 to this instrument commence. The Principles instrument will require amendment for any subsequent changes or replacement to the above standards documents to be applied and reflected in the Principles instrument.

CONSULTATIONS

As part of the accreditation standards development process, a public consultation process on the draft Requirements was undertaken. Stakeholders consulted on the revised document included all pathology laboratories, state and territory health departments, peak pathology and scientific organisations and consumers. There was overall support for the revised and new documents and the final versions take into consideration comments received from the public consultation process.

All NPAAC documents are available free of charge from the NPAAC website – www.health.gov.au/npaac.

The Amending Principles replace references to the *Requirements for Transfusion Laboratory Practice (Third Edition 2017)* and the *Requirements for Laboratories Reporting Testing for the National Cervical Screening Program (First Edition 2017)* and includes a reference to the new *Requirements for Validation of Self-Collected Vaginal Swabs for use in the National Cervical Screening Program (First Edition 2019)***.** The Amendment Instrument commences on the day after the day the Amending Instrument is registered on the Federal Register of Legislation.

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 Instrument (No. 2) 2019*

1. Name of legislative instrument

Section 1 provides that the title of the legislative instrument is the *Health Insurance (Accredited Pathology Laboratories-Approval) Amendment Instrument (No. 2) 2019* (the Amendment Instrument).

2. Commencement

Subsection 2(1) provides for commencement dates 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 day after the instrument is registered in the Federal Register of Legislation.

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 the day after registration of the instrument.

Schedule 1 – Amendments commencing on the day after registration

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

Item 1

Item 1 repeals the standard listed in Item 14 of the Table and substitutes it with a new standard in relation to laboratories reporting tests for the national screening program titled "*Requirements for Laboratories Reporting Testing for the National Cervical Screening Program (Second Edition 2019)".*

Item 2

Item 2 repeals the standard listed in Item 16 of the Table and substitutes it with a new standard in relation to transfusion laboratory practice titled "*Requirements for Transfusion Laboratory Practice (Fourth Edition 2019)"*

Item 3

Item 3 amends Schedule 1 to the current Principles by adding a new item 22 to the list of standards in the Table. The new standard is titled "*Requirements for Validation of Self-Collected Vaginal Swabs for use in the National Cervical Screening Program (First Edition 2019).*

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 Instrument (No.2) 2019

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 determines 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* ('Pathology Principles 2017').

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 currently recognised independent assessment body that conducts the accreditation assessment of pathology laboratories, in conjunction with the Royal College of Pathologists of Australasia.

This Legislative Instrument makes amendments to the Principles to incorporate one new pathology accreditation standard and two revised versions of NPAAC accreditation standards currently listed in Schedule 1 of the Principles, namely the -

a) *Requirements for Transfusion Laboratory Practice (Fourth Edition 2019)*

b) *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019)*

c) *Requirements for Validation of Self-Collected Vaginal Swabs for use in the National Cervical Screening Program (First Edition 2019)*

These documents set out minimum acceptable standards for good laboratory practice based on current best practice.

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.

This Legislative Instrument does not make any substantive changes to the law.

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.

The Legislative Instrument will maintain rights to access quality, safe, clinically relevant and cost effective Medicare eligible pathology services and does not engage any of the applicable rights or freedoms.

The revision or development of NPAAC 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. The revised and new accreditation standards do not impose any new requirements on pathology laboratories seeking approval to provide Medicare eligible pathology services. The revised and new accreditation materials are aligned with international best practice however, there may be some minimal costs for some laboratories associated with meeting these Requirements. The standards do not impose any obligations on individuals. The standards promote the right to health as they are aimed at ensuring pathology laboratories providing Medicare-eligible pathology services provide safe and high quality services.

This would not have an 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.

Conclusion

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

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