#### EXPLANATORY STATEMENT

#### Health Insurance Act 1973

Health Insurance (Pathologist-determinable Services) Amendment Determination 2021

Section 16A of the *Health Insurance Act 1973* (the Act) specifies that certain requirements have to be met for the payment of Medicare benefits in relation to pathology services, including the requirement for a pathology service to be requested (subsection 16A(3)). Pathologist-determinable services allow Medicare benefits to be paid for pathology services which are requested and performed by an approved pathology practitioner for their own patients, or for certain tests which are not requested, but are performed on the basis of information learned from an originally requested service.

Section 4BA of the Act provides that the Minister for Health may determine by legislative instrument, that a particular pathology service, or pathology services included in a class of pathology services, are pathologist-determinable services after consultation with Royal College of Pathologists of Australasia.

This instrument relies on subsection 33(3) of the *Acts Interpretation Act 1901* (AIA). Subsection 33(3) of the AIA 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 (Pathologist-determinable Services) Amendment Determination 2021* (the Amendment Determination) is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* (Principal Determination) to include a reference to item 73389 and amend how item 72860 may be rendered as a pathologist determinable service to better reflect clinical practice.

Item 73389 is for the analysis of products of conception from a patient with suspected hydatidiform mole for the characterisation of ploidy status and was introduced by the *Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021* on 1 November 2021. A hydatidiform mole is a benign or malignant growth that can occur during pregnancy, and often results in miscarriage. Genetic testing on a piece of tissue from a hydatidiform mole can help doctors provide women with targeted treatment and advice.

By including item 73389 in the Principal Determination, a service under item 73389 can be rendered by a pathologist, without a request, on the basis of information learned from the original requested service.

Item 73389 was announced in the 2021-22 Budget under the *Guaranteeing Medicare* – *changes to the Medicare Benefits Schedule* measure.

The Amendment Determination also makes changes to subparagraph 5(d)(iii) of the Principal Determination to better reflect how item 72860 is rendered by a pathologist in clinical practice. Subparagraph 5(d)(iii) prescribes that if a pathologist determines they are unable to perform the service under the original requested service located in P7 they may perform a service under 72860 where clinically appropriate.

This provision is amended to expand the eligible provider group identified in the subparagraph to include an approved pathology practitioner at the accredited pathology laboratory, where the initial service was rendered. The change better reflects clinical practice as it is unlikely that the pathologist who rendered the initial service will determine that archival tissue retrieval is necessary as the tissue sample is likely to be years old.

#### Consultation

Section 4BA of the Act requires that the Royal College of Pathologists of Australasia (RCPA) is consulted on pathology services being made pathologist-determinable services. The RCPA was consulted on the inclusion of item 73389 and the amendment to subparagraph 5(d)(iii) in the Amendment Determination and supported the changes.

Details of the Determination are set out in the Attachment.

The Determination commences on 1 November 2021.

The Determination is a legislative instrument for the purposes of the *Legislation Act* 2003.

Authority: Section 4BA of the

Health Insurance Act 1973

# Details of the Health Insurance (Pathologist-determinable Services) Amendment Determination 2021

# Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Pathologist-determinable Services) Amendment Determination 2021.* 

# Section 2 – Commencement

Section 2 provides that the Determination commences on 1 November 2021.

# Section 3 – Authority

Section 3 provides that the Determination is made under subsection 4BA of the *Health Insurance Act 1973*.

# Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to this Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Determination has effect according to its terms.

#### Schedule 1 – Amendments

Health Insurance (Pathologist-determinable Services) Determination 2015

**Item 1** amends the table under subparagraph 5(b)(iii) to insert item 73389, which is for the analysis of products of conception from a patient with suspected hydatidiform mole for the characterisation of ploidy status, in column 1 of row 1 of the table.

**Item 2** repeals and replaces subparagraph 5(d)(iii) to expand the eligible provider group identified in the subsection to include an approved pathology practitioner at the accredited pathology laboratory, where the initial service was rendered. This change will update the subsection to better reflect clinical practice.

# **Statement of Compatibility with Human Rights**

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Health Insurance (Pathologist-determinable Services) Amendment Determination 2021

This 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 Determination**

The purpose of the *Health Insurance (Pathologist-determinable Services) Amendment Determination* 2021 (the Amendment Determination) is to amend the *Health Insurance (Pathologist-determinable Services) Determination* 2015 (Principal Determination) to include a reference to item 73389 and amend how item 72860 may be rendered as a pathologist determinable service to better reflect clinical practice.

Item 73389 is for the analysis of products of conception from a patient with suspected hydatidiform mole for the characterisation of ploidy status and was introduced by the *Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021* on 1 November 2021. A hydatidiform mole is a benign or malignant growth that can occur during pregnancy, and often results in miscarriage. Genetic testing on a piece of tissue from a hydatidiform mole can help doctors provide women with targeted treatment and advice.

By including item 73389 in the Principal Determination, a service under item 73389 can be rendered by a pathologist, without a request, on the basis of information learned from the original requested service.

Item 73389 was announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

The Amendment Determination also makes changes to subparagraph 5(d)(iii) of the Principal Determination to better reflect how item 72860 is rendered by a pathologist in clinical practice. Subparagraph 5(d)(iii) prescribes that if a pathologist determines they are unable to perform the service under the original requested service located in P7 they may perform a service under 72860 where clinically appropriate.

This provision is amended to expand the eligible provider group identified in the subparagraph to include an approved pathology practitioner at the accredited pathology laboratory, where the initial service was rendered. The change better reflects clinical practice as it is unlikely that the pathologist who rendered the initial service will determine that archival tissue retrieval is necessary as the tissue sample is likely to be years old.

# **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.

# The right of equality and non-discrimination

The rights of equality and non-discrimination are contained in articles 2, 16 and 26 of the International Covenant on Civil and Political Rights (ICCPR). Article 26 of the ICCPR requires that all persons are equal before the law, are entitled without any discrimination to the equal protection of the law and in this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

# **Analysis**

This instrument maintains the right to health and the right to social security by ensuring access to publicly subsidised health services which are clinically effective, safe and cost-effective.

### Conclusion

This instrument is compatible with human rights as it maintains the right to health and the right to social security.

Travis Haslam
Acting First Assistant Secretary
Medical Benefits Division
Health Resourcing Group
Department of Health