EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

Health Insurance Act 1973

Health Insurance (Pathologist-determinable Services) Amendment Determination (No. 2) 2020

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.

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 (Pathologist-determinable Services) Amendment Determination (No. 2) 2020* (the Amendment Determination) is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* (Principal Determination) to include a reference to:

- three pathology items for the detection of *Chlamydia trachomatis* (69316, 69317, and 69319);
- two pathology items for viral or microbial antigen/nucleic acid pathology tests where the service is referred to a laboratory that did not receive the original request (69497 and 69498);
- twenty new items for genetic testing of somatic markers for the diagnosis and classification of tumours (73364 to 73383); and
- one pathology item for archival tissue retrieval and review (72860).

The inclusion of these items in the Principal Determination will enable the services to be rendered by a pathologist, without a request, on the basis of information learned in an original requested service.

Three pathology items for the detection of *Chlamydia trachomatis* commenced on 1 May 2007 (69316, 69317, and 69319). Item 69316 is for the initial test for the detection of *Chlamydia trachomatis.* Items 69317 and 69319 are subsequent tests, where a viral or microbial antigen/nucleic acid pathology test under item 69494 is also performed at the same time. Enabling items 69316, 69317 and 69319 to be pathologist-determinable will ensure pathologists can test for *Chlamydia trachomatis,* if it is deemed necessary subject to the original test.

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Two pathology items for viral or microbial antigen/nucleic acid pathology tests where the service is referred to a laboratory that did not receive the original request, commenced on 1 May 2007 (69497 and 69498). Three other pathology items that provide this test are pathologist-determinable (items 69494, 69495 and 69496). Enabling items 69497 and 69498 to be pathologist-determinable will ensure that pathologists can also render these services if it is referred to a laboratory that did not receive the original request.

Twenty new items for the genetic testing of somatic markers for diagnosis and classification of tumours will be implemented by the *Health Insurance (Pathology Services Table) Regulations 2020* and will commence on 1 May 2020. These items will provide for the diagnosis and testing of a range of rare cancers including different lymphomas, T-cell prolymphocytic leukaemia, plasma cell myeloma, central nervous system neoplasms, sarcomas and various carcinomas. Enabling these items to be pathologist-determinable will ensure that pathologists can also render these genetic tests, if it is deemed necessary.

A new pathology item for the retrieval and review of archival tissue by a pathologist for the purpose of identifying appropriate sample(s) for further genetic testing commenced on 1 May 2019 (item 72860). Enabling item 72860 to be pathologist-determinable will allow a pathologist to render the service, without a requirement for the treating practitioner to specifically request item 72860. This will reduce administrative burden on the clinician.

Although pathology service item 72860 is not listed in the pathology services table made for the purposes of section 4A(1) of the Act, the *Health Insurance (Section 3C Pathology Services – Archival Tissue Retrieval) Determination 2019* deems it to be a pathology service specified in that table. The rendering of that service, subject to requirements being met, allows for Medicare benefits to be payable in relation to that service.

The Amendment Determination also removes reference to item 69485 consequent to it being replaced with two new items 69479 or 69480, which increase the Medicare benefit for the pathology service and which may be claimed as standalone pathology tests for COVID-19.

Item 69485 commenced on 13 March 2020 to provide a pathology service to test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is the virus that causes the disease known commonly as COVID-19. Item 69485 was provided in conjunction with other separate viral respiratory tests (provided under items 69494, 69495 or 69496) to determine if the patient had COVID-19 or another respiratory virus such as influenza. This item was replaced with items 69479 and 69480 and may be claimed as stand-alone tests. The removal of item 69485 in the Amendment Determination is a consequential change, as the pathologist will no longer be able to self-determine tests for other respiratory viruses when performing a COVID-19 test, if the treating practitioner did not also request a service under items 69494, 69495 or 69496.

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. RCPA was consulted on the inclusion of items 69316, 69317, 69319, 69497, 69498, 72860, 73364, 73365, 73366, 73367, 73368, 73369, 73370, 73371, 73372, 73373, 73374, 73375, 73376, 73377, 73378, 73379, 73380, 73381, 73382 and 73383 in this legislative instrument, and supported the inclusion of these items as pathologist-determinable items.

Details of the Determination are set out in the Attachment.

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The Determination commences on 1 May 2020.

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

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ATTACHMENT

Details of the *Health Insurance (Pathologist-determinable Services) Amendment Determination (No. 2) 2020*

Section 1 – Name

Section 1 provides for the instrument to be referred to as the *Health Insurance (Pathologist-determinable Services) Amendment Determination (No. 2) 2020.*

Section 2 – Commencement

Section 2 provides that the instrument commences on 1 May 2020.

Section 3 – Authority

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

Section 4 – Schedules

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

Schedule 1 – Amendment

Health Insurance (Pathologist-determinable Services) Determination 2015

Item 1 – Subsection 5(b)(iii) (table)
Item 1 repeals and replaces the table under subsection 5(b)(iii) to insert the twenty new items for genetic testing of somatic markers (73364, 73365, 73366, 73367, 73368, 73369, 73370, 73371, 73372, 73373, 73374, 73375, 73376, 73377, 73378, 73379, 73380, 73381, 73382 and 73383), in column 1 of row 1 of the table.

Item 2 – Paragraph 5(c)
Item 2 repeals and replaces paragraph 5(c) to insert items 69316, 69317, 69319, 69497 and 69498. This means that a pathology service provided under these items can be rendered as a pathologist-determinable service as a result of information learned from a service provided under items 69303, 69306, 69312, 69318, 69321 or 69345.

Item 2 also repeals subparagraph 5(c)(D), which referenced item 69485, as this is no longer required due to the item 69485 being replaced by items 69479 and 69480.

Item 3 – Section 5 (after paragraph 5(c))
Item 3 inserts a new paragraph which inserts archival tissue service item 72860, and specifies that a service provided under item 72860 can be rendered as a pathologist determinable service.

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An initial service, which is a pathology service mentioned in an item in Group P5 (other than item 72860), P6 or P7 of the pathology services table, is to be rendered on the patient. Following the initial service, the treating practitioner, must request a subsequent service under an item in Group P7 (subsequent P7 service). Following the request from the treating practitioner for the subsequent P7 service, the pathologist who rendered the initial service, must determine they are unable to perform the subsequent P7 service and consequently retrieves and reviews the archival tissue to select appropriate tissue sample for referral to a different accredited pathology laboratory for testing.

The subsequent P7 service and a service under item 72860 must be rendered in a different accredited pathology laboratory, by or on behalf of, an approved pathology practitioner who is a recognised pathologist.

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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 (No. 2) 2020

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 (No. 2) 2020* (the Amendment Determination) is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* (Principal Determination) to include a reference to:

- three pathology items for the detection of *Chlamydia trachomatis* (69316, 69317, and 69319);
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The inclusion of these items in the Principal Determination will enable the services to be rendered by a pathologist, without a request, on the basis of information learned in an original requested service.

The Amendment Determination also removes reference to item 69485 consequent to it being replaced with two new items 69479 or 69480, which increase the Medicare benefit for the pathology service and which may be claimed as standalone pathology tests for COVID-19. This is a consequential change, as the pathologist will no longer be able to self-determine tests for other respiratory viruses when performing a COVID-19 test, if the treating practitioner did not also request a service under items 69494, 69495 or 69496.

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

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 has a positive effect on the right to health and the right to social security.

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