

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing) Determination 2024*

Subsection 3C(1) of the *Health Insurance Act 1973* (the Act) provides that the Minister may, by legislative instrument, determine that a health service not specified in an item in the pathology services table (the PST) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the PST.

The PST is set out in the regulations made under subsection 4A of the Act. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020*.

#### **Purpose**

From 1 July 2024, the *Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing) Determination 2024* (the Determination) introduces new permanent pathology items 69421 and 69422 to the Medicare Benefits Schedule (MBS). The new items will allow for nucleic acid testing for respiratory pathogens, which may include COVID-19, in patients with suspected respiratory infection.

The purpose of the Determination is to introduce upfront testing of multiple respiratory pathogens under the MBS to reduce the number of tests a patient requires to reach a diagnosis. The new items will allow for more efficient and effective patient management, including allowing access to appropriate Pharmaceutical Benefits Schedule (PBS) treatments and reducing inappropriate antibiotic prescribing.

The new items will replace temporary pathology items 69511, 69512, 69513, 69514 and 69515 listed in the *Health Insurance (Section 3C Pathology Services – COVID-19) Determination 2020* which is due to cease on 30 June 2024.

The new items were supported by the Medical Services Advisory Committee (MSAC) at its July 2023 meeting under Application 1747.

#### **Consultation**

The Department of Health and Aged Care consulted with the Royal College of Pathologists of Australasia, Australian Pathology and Public Pathology Australia in relation to the new items listed in the Determination.

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

The Determination commences on 1 July 2024.

Details of the Determination are set out in the [Attachment](#).

**Authority:** Subsection 3C(1) of the  
*Health Insurance Act 1973*

## ***Details of the Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing) Determination 2024***

### Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing) Determination 2024* (the Determination).

### Section 2 – Commencement

Section 2 provides for the Determination to commence on 1 July 2024.

### Section 3 – Authority

Section 3 provides that the Determination is made under subsection 3C(1) of the *Health Insurance Act 1973* (the Act).

### Section 4 – Definitions

Section 4 defines terms used in the Determination.

### Section 5 – Treatment of relevant services

Section 5 provides that a clinically relevant service in Schedule 1 provided in accordance with the Determination shall be treated, for relevant provisions of the *Health Insurance Act 1973* and *National Health Act 1953*, and regulations made under those Acts, as if it were both a professional service and a pathology service and as if it were an item specified in Group P3 of the pathology services table (the PST) for the service.

### Section 6 – Application of provisions of the pathology services table

Section 6 specifies general provisions of the PST that apply as if the items in Schedule 1 of the Determination were specified in the PST.

Subsection 6(1) provides that clause 1.2.1 of the PST shall have effect as if the items in Schedule 1 of the Determination were specified in that clause. Clause 1.2.1 of the PST provides that where a service is described in more than one item, the item that describes the service in the most specific terms applies. Clause 1.2.1 also provides that if an item is expressed to include a service that is described in another item, the other item does not apply to the service in addition to the first-mentioned item, whether or not the services in the two items are requested separately.

Subsection 6(2) provides that clause 1.2.2 of the PST shall have effect as if the items in Schedule 1 of the Determination were specified in that clause. Clause 1.2.2 of the PST provides that two or more pathology services that are rendered for a patient following two or more requests are taken to have been rendered following a single request if the services are listed in the same item, and, if the patient's need for the services was determined on the same day even if the services are rendered by an approved pathology practitioner on more than one day.

Subsection 6(3) provides that clause 1.2.9 of the PST shall have effect as if the items in Schedule 1 of the Determination were specified in subclause (1) of that clause. Subclause 1.2.9(1) of the PST provides that clause 1.2.8 of the PST applies to items specified in the subclause. Clause 1.2.8 of the PST provides that where a medical practitioner (other than a specialist or consultant physician), participating midwife or participating nurse practitioner requests a set of pathology services to which clause 1.2.9 applies, the pathology services in the set are to be treated as individual pathology services.

Subsection 6(4) provides that clause 1.2.10 of the PST shall have effect as if the items in Schedule 1 of the Determination were specified in that clause. Clause 1.2.10 of the PST provides that where there is a requirement contained in the description of a pathology service, the requirement is satisfied if:

- for a requirement for information, the information is included in the request for service or was supplied in writing on an earlier occasion to the practitioner that rendered the services; and
- for a requirement for laboratory results, the results are included in the request for service, or are obtained from another laboratory test performed in the same patient episode, or the results are included in results from an earlier laboratory test.

Subsection 6(5) provides that clause 1.2.11 of the PST shall have effect as if the items in Schedule 1 of the Determination were specified in that clause. Clause 1.2.11 of the PST provides that an item specified in the clause does not apply to a service described in the item if the service is rendered to a patient at the same time as, or in connection with, an injection of blood or a blood produce that is autologous.

Subsection 6(6) provides that clause 1.2.12 of the PST shall have effect as if the items in Schedule 1 of the Determination were specified in that clause. Clause 1.2.12 provides that an item specified in the clause does not apply to a service described in the item if the service is rendered to a patient at the same time as, or in connection with, the harvesting, storage, in vitro processing, or injection of non-haematopoietic stem cells.

Subsection 6(7) provides that clause 1.3.2 of the PST shall have effect as if the items in Schedule 1 of the Determination were specified in subclause (2) of that clause. Subclause 1.3.2(2) of the PST provides requirements for Group P3 services rendered as part of a patient episode.

### Schedule 1 – Pathology services

Schedule 1 specifies the services and associated fees for new permanent pathology items 69421 and 69422.

The new items form a two-item multi-pathogen testing ladder – with separate items for testing of 4 respiratory pathogens and testing of 5 or more respiratory pathogens – to replace the previous temporary COVID-19 testing items. The new items ensure that permanent pathology testing services are available for patients with suspected respiratory infection following the cessation of the previous temporary COVID-19 pathology items, and that pathology testing services cover a broader range of respiratory pathogens.

## Statement of Compatibility with Human Rights

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

*Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing)  
Determination 2024*

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

From 1 July 2024, the *Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing) Determination 2024* (the Determination) introduces new permanent pathology items 69421 and 69422 to the Medicare Benefits Schedule (MBS). The new items will allow for nucleic acid testing for respiratory pathogens, which may include COVID-19, in patients with suspected respiratory infection.

The purpose of the Determination is to introduce upfront testing of multiple respiratory pathogens under the MBS to reduce the number of tests a patient requires to reach a diagnosis. The new items will allow for more efficient and effective patient management, including allowing access to appropriate Pharmaceutical Benefits Schedule (PBS) treatments and reducing inappropriate antibiotic prescribing.

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### 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, social security and equality and non-discrimination by ensuring patients with suspected respiratory infection have access to permanent pathology services for testing of multiple respiratory pathogens. Multi-pathogen testing maintains clinical best practice by providing clinically effective and cost-effective pathology services, reducing the number of tests a patient may require to reach a diagnosis, and allowing for more effective and efficient patient management.

#### **Conclusion**

This instrument is compatible with human rights as it maintains the right to health, the right to social security and the right of equality and non-discrimination.

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