

## **EXPLANATORY STATEMENT**

### *Health Insurance Act 1973*

#### *Health Insurance Legislation Amendment (Hospital-Only Services and Other Measures) Regulations 2025*

The *Health Insurance Act 1973* (the Act) sets out the principles and definitions governing the Medicare Benefits Schedule (MBS). The Act provides for payments by way of medical benefits and for other purposes.

Subsection 133(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Part II of the Act provides for the payment of Medicare benefits for professional services rendered to eligible persons. Section 9 of the Act provides that Medicare benefits be calculated by reference to the fees for medical services set out in prescribed tables.

Subsection 4(1) of the Act provides that regulations may prescribe a table of general medical services which sets out items of general medical services, the fees applicable for each item, and rules for interpreting the table. The table made under this subsection is referred to as the General Medical Services Table. The most recent version of the regulations is the *Health Insurance (General Medical Services Table) Regulations 2021* (GMST).

Section 4A of the Act provides that regulations may prescribe a table of pathology services which set out items of pathology services, the fees applicable for each item, and rules for interpreting the table. The table made under this section is referred to as the Pathology Services Table. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020* (PST).

Section 4AA of the Act provides that regulations may prescribe a table of diagnostic imaging services which sets out items of diagnostic imaging services, the fees applicable for each item, and rules for interpreting the table. The table made under this section is referred to as the Diagnostic Imaging Services Table. The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* (DIST).

The *Health Insurance Regulations 2018* (HIR) provide the overarching policy framework supporting the provision of appropriate Medicare services:

- Paragraph 16A(1)(ab) of the Act provides a regulation making power to list the kinds of services which can be considered necessary by ‘treating practitioners’, who are participating nurse practitioners. Section 31 of the HIR prescribes the pathology services that may be requested by participating nurse practitioners and the simple basic pathology services in P9 which can be rendered by participating nurse practitioners subject to certain circumstances under subsection 16A(7A) of the Act.
- Subsection 16B(3E) of the Act provides a regulation making power to list the kinds of services which can be requested by participating nurse practitioners, which are defined in subsection 3(1). Section 44 of the HIR prescribes the diagnostic imaging services which can be requested by participating nurse practitioners.

## Purpose

The purpose of the *Health Insurance Legislation Amendment (Hospital-Only Services and Other Measures) Regulations 2025* (the Regulations) is to amend more than 800 MBS items to limit the services to being performed or provided in a hospital. This will align the MBS to contemporary clinical practice and ensure services are only rendered in the appropriate clinical location. This change was announced in the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure and as part of the 2024-25 MYEFO under the *An Effective and Clinically Appropriate Medicare Benefits Schedule* measure.

The Regulations will also implement recommendations of the Medical Services Advisory Committee (MSAC). Policy authority for these changes was given by the Minister of Health and Aged Care who has delegated authority from Expenditure Review Committee to approve new and amended MBS services following a positive recommendation from MSAC if under the \$20 million annual threshold. Changes include:

- Listing two new items (38376 for percutaneous technique, 38616 for surgical technique) for the insertion of an intravascular microaxial ventricular assist device into the left ventricle only, by arteriotomy. This change was recommended by MSAC to support a small and high-risk population of patients who are experiencing deteriorating cardiogenic shock who have not been stabilised despite pharmacotherapy or as an adjunct to Veno-Arterial Extra-corporeal Oxygenation. A new item will also be listed for the surgical removal of the device (38619) and two items will be amended (13851 and 13854) to clarify the services exclude intravascular microaxial ventricular assist device inserted into the right ventricle and must be performed or provided in a hospital.
- Listing a new item (22032) for perioperative continuous nerve blockade using catheter technique. This change was recommended by MSAC for the management of moderate to severe post-operative pain, acknowledging that it will provide a small but clinically important improvement in pain relief compared to current options (such as single nerve block or systemic opioids).
- Amending genetic testing items 73296 and 73297 for patients at greater risk of BRCA-related ovarian, fallopian tube, primary peritoneal, or breast cancer due to family history, to remove references to specific genes and instead refer to 'one or more other relevant genes'. This change was recommended by MSAC to future proof both items from further gene list changes, to avoid unnecessary treatment delay for patients, and to allow clinicians to choose the most appropriate genes to test.
- Allowing nurse practitioner to request plain abdominal x-ray diagnostic imaging services (item 58903). These changes align with the intent of MSAC executive support for expanding nurse practitioner requesting rights.

The Regulations will also implement minor and machinery changes, including:

- Incorporating items 69421 and 69422, which are currently made under a legislative instrument made under section 3C of the Act, into the PST.
- Making an editorial change to item 73297 to clarify the eligible patient cohort and the policy intent of the item.
- Amending section 31 of the HIR to clarify that all simple basic pathology services in P9 which can be rendered by participating nurse practitioners are conditional on the practitioner considering the clinical necessity of the test.

## Consultation

The Department of Health and Aged Care consulted with key stakeholders and offered an opportunity for them to provide input on the changes to hospital-only services. These stakeholders included the: Australian Medical Association, Australian and New Zealand Association of Oral and Maxillofacial Surgeons, Australian Society of Plastic Surgeons, Royal Australasian College of Surgeons, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Australasian College for Emergency Medicine, Australian and New Zealand College of Anaesthetists and Australasian College for Emergency Medicine.

The MSAC recommended changes were subject to public consultation which is consistent with the usual MSAC application and assessment process. Any individual, organisation, consumer, carer or health professionals can make a submission on an application that is out for consultation. There was also general consultation with peak bodies who represented the clinicians who render the MSAC-recommended changes, with peak bodies being supportive of the recommendations.

No consultation was undertaken with respect to machinery changes as these are minor and administrative in nature.

Details of the Regulations are set out in the Attachment.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations will commence on 1 March 2025.

Authority: Subsection 133(1) of the  
*Health Insurance Act 1973*

## ATTACHMENT

### **Details of the *Health Insurance Legislation Amendment (Hospital-Only Services and Other Measures) Regulations 2025***

#### Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (Hospital-Only Services and Other Measures) Regulations 2025* (the Regulations).

#### Section 2 – Commencement

This section provides for the Regulations to commence on 1 March 2025.

#### Section 3 – Authority

This section provides that the Regulations are made under the *Health Insurance Act 1973*.

#### Section 4 – Schedules

This section 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 – Hospital-only services

Schedule 1 of the Regulations is split into 5 parts to cover the following amendments:

- Part 1 of the Schedule amends GMST items to which “(H)” is to be added after the last word in the item descriptor.
- Part 2 of the Schedule amends GMST items to which “(H)” is to be added on a new line of the item descriptor.
- Part 3 of the Schedule amends GMST items to which “(H)” is to be added before an existing anaesthesia flag in the item.
- Part 4 of the Schedule amends other GMST items to which the “(H)” flag is required.
- Part 5 of the Schedule amends the DIST to define the “(H)” flag in clause 1.2.15 of Schedule 1 and amend DIST items to which the “(H)” flag is required.

### ***Health Insurance (General Medical Services Table) Regulations 2021***

**Item 1** adds the “(H)” flag to the end of the descriptor (column 2) of 278 relevant items as specified by the amending table. This will limit these services to being rendered in hospital only, per clause 1.1.7 of the GMST.

**Items 3 to 10** add the “(H)” flag to the specified part of the descriptor for 9 items (20560, 20745, 20790, 22012, 22014, 22025, 22065, 25205 and 51318). This will limit these services to being rendered in hospital only, per clause 1.1.7 of the GMST.

**Item 11** adds the “(H)” flag immediately before the appearance of the “(Anaes.)” flag at the end of the descriptor (column 2) of 495 relevant items, as specified by the amending table.

This will limit these services to being rendered in hospital only, per clause 1.1.7 of the GMST.

**Items 12 and 13** make an editorial change to the descriptor of item 16527. **Item 12** removes the “(Anaes.)” flag which was not specified in the correct part of the descriptor. **Item 13** inserts “(Anaes.)” at the end of the descriptor to make the editorial correction to the location where the anaesthesia flag should apply.

**Items 14 and 15** make an editorial change to the descriptor of item 16528 to remove the “(Anaes.)” flag which was not currently specified in the correct part of the descriptor and to limit the service to being rendered in hospital only. **Item 14** removes the “(Anaes.)” flag which was not specified in the correct part of the descriptor. **Item 15** inserts “(H) (Anaes.)” at the end of the descriptor to make the editorial correction to the location where the anaesthesia flag should apply and to add the “(H)” flag to limit the service to being rendered in hospital only.

**Item 16** makes an editorial change to item 42504 to correct the location where the “(Anaes.)” flag should apply and to add the “(H)” flag to limit the service to being rendered in hospital only.

### ***Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020***

**Items 17 and 18** amend clause 1.2.15 of the of the DIST to clarify the use of the “(H)” flag in relation to the DIST. **Item 17** amends the heading of clause 1.2.15 to reflect the nature of the amendments to the clause. **Item 18** adds new subclause 1.2.15(3) to prescribe that an item in this Schedule including the symbol “(H)” applies only to a service performed or provided in a hospital.

**Item 19** omits and substitutes parts of the descriptor of item 55130 in the DIST to add the “(H)” flag to immediately before the appearance of the “(Anaes.)” flag. This will limit this service to being rendered in hospital only, per subclause 1.2.15(3) of the DIST.

**Item 20** omits and substitutes parts of the descriptor of item 55135 in the DIST to add the “(H)” flag to immediately before the appearance of the “(Anaes.)” flag. This will limit this service to being rendered in hospital only, per subclause 1.2.15(3) of the DIST.

**Item 21** adds the “(H)” flag to items 66072, 66075 and 60078 in the DIST immediately after the “(NR)” flag. This will limit these services to being rendered in hospital only, per subclause 1.2.15(3) of the DIST.

**Item 22** omits and substitutes parts of the descriptor of item 63499 in the DIST to add the “(H)” flag to the end of the descriptor. This will limit this service to being rendered in hospital only, per subclause 1.2.15(3) of the DIST.

**Item 23** will add the meaning of “(H)” to the dictionary of the DIST.

**Item 24** adds the “(H)” flag immediately after the appearance of the “(R)” flag at the end of the descriptor (column 2) of 30 relevant items, as specified by the amending table. This will limit these services to being rendered in hospital only, per subclause 1.2.15(3) of the DIST.

## Schedule 2 – Other amendments

### ***Health Insurance (General Medical Services Table) Regulations 2021***

**Item 1** amends item 13851 of the GMST for the implantation of a ventricular assist device, or for complications arising from implantation or management of the device, on the first day a patient is admitted to an intensive care unit. **Item 1** amends this service to clarify it excludes intravascular microaxial ventricular assist device inserted into the right ventricle and to apply the “(H)” symbol to limit the service to being rendered in hospital only, per clause 1.1.7 of the GMST.

**Item 2** amends item 13854 in the GMST for the management of a ventricular assist device, including for complications arising from implantation of the device, when a patient is in an intensive care unit (excluding the day of admission to intensive care). **Item 2** amends this service to clarify it excludes intravascular microaxial ventricular assist device inserted into the right ventricle and to apply the “(H)” symbol to limit the service to being rendered in hospital only, per clause 1.1.7 of the GMST.

**Item 3** makes a consequential amendment to subclause 5.10.17(2) of the GMST which has applications to items 38817, 38818 and the range of items from 38485 to 38766 unless they are explicitly carved out from that subclause. Services which are subject to that clause must be performed using open exposure or minimally invasive surgery which excludes percutaneous and transcatheter techniques unless otherwise stated in the item. **Item 3** will exclude the new surgical removal service of a left sided intravascular microaxial ventricular assist device (38619), which is being listed by **item 6** of Schedule 2 of the Regulations.

**Item 4** introduces new item 38376 to the GMST for the percutaneous insertion of an intravascular microaxial ventricular assist device, into the left ventricle only, by arteriotomy. This service will be available to a small and high-risk population of patients who:

- has deteriorating cardiogenic shock which has not stabilised despite optimal medical therapy (pharmacotherapy); or
- has deteriorating cardiogenic shock which has not stabilised despite optimal medical therapy (pharmacotherapy), is on veno-arterial extracorporeal membrane oxygenation (VA-ECMO) as an intervention, but due to the effects of VA-ECMO requires unloading of the left ventricle.

The fee for this item includes all intraoperative imaging and an associated imaging service in the DIST is not to be claimed with this service.

**Item 5** introduces new item 38616 to the GMST for the surgical insertion of an intravascular microaxial ventricular assist device, into the left ventricle only, by arteriotomy. Apart from the technique, this item will have the same patient cohort as item 38375. The fee for this item includes all intraoperative imaging and an associated imaging service in the DIST is not to be claimed with this service.

**Item 6** introduces new item 38619 to the GMST for the surgical removal of a left sided intravascular microaxial ventricular assist device.

**Item 7** amends the descriptor of item 38621 for an independent procedure for the removal of left or right ventricular assist device. The amendment will include a co-claim limitation with the new surgical removal service of a left sided intravascular microaxial ventricular assist device (38619), which is being listed by **item 6** of Schedule 2 of the Regulations.

**Item 8** introduces a new item 22032 for perioperative continuous nerve blockade using catheter technique to the GMST. Continuous peripheral nerve blockade involves the insertion of a catheter (a thin, flexible tube) next to the target nerve, which is then used to deliver a continuous flow of pain medication to the affected nerve.

### ***Health Insurance (Pathology Services Table) Regulations 2020***

**Item 9** inserts items 69421 and 69422 into the PST as part of minor and machinery change. Items 69421 and 69422 for testing of respiratory pathogens were introduced to the MBS on 1 July 2024 and were prescribed in the *Health Insurance (Section 3C Pathology Services – Respiratory Pathogen Testing) Determination 2024* (the Respiratory Pathogen Testing Determination). The Respiratory Pathogen Testing Determination will be repealed immediately following the commencement of this change. There is no change to the clinical intent of these items under this change. A single Medicare benefit is payable for the testing of 4 pathogens regardless how many specimens are being tested.

**Item 10** amends the descriptor of item 73296 in the PST for characterisation of germline gene variants in genes associated with breast, ovarian, fallopian tube or primary peritoneal cancer to replace the specified genes listed under subparagraph (a)(ii) with “one or more other relevant genes” respectively.

Item 73296 is available to patients with a cancer diagnosis and a family or clinical history which indicates they have a greater than 10% risk of having a pathogenic or likely pathogenic gene associated with breast, ovarian, fallopian tube or primary peritoneal cancer.

**Items 11 and 12** amend the descriptor of item 73297 in the PST which is for characterisation of germline gene variants in genes associated with breast, ovarian, fallopian tube or primary peritoneal cancer, which may include the following genes:

- BRCA1 or BRCA2, per subparagraph (a)(i);
- STK11, PTEN, CDH1, PALB2 and TP53, per subparagraph (a)(ii).

**Item 11** amends the specified genes in subparagraph (a)(ii) to replace the specified genes with “one or more other relevant genes” respectively.

**Item 12** omits “; or”, and replaces it with “; and” in subparagraph (b)(i) to fix a typographical error and align with the intended clinical intent of the item. This will make it clear the patient cohort is:

- patients who have a biological relative who has had a pathogenic or likely pathogenic gene variant identified in one or more of the genes mentioned in paragraph (a); and
- the patient has not previously had genetic testing under items 73295, 73296 or 73302.

### ***Health Insurance Regulations 2018***

**Item 13** amends section 31 of the HIR to omit “73828” (wherever occurring) and substitute “73825”. This change clarifies that participating nurse practitioners must consider the clinical necessity for all simple basic pathology services in P9 which they can render.

**Item 14** amends section 44 of the HIR to add item “58903” to enable participating nurse practitioners to request an x-ray for suspected acute abdomen or bowel obstruction.

## Statement of Compatibility with Human Rights

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

### ***Health Insurance Legislation Amendment (Hospital-Only Services and Other Measures) Regulations 2025***

This Regulation 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 Disallowable Legislative Instrument**

The *Health Insurance Act 1973* (the Act) sets out the principles and definitions governing the Medicare Benefits Schedule (MBS). The Act provides for payments by way of medical benefits and for other purposes.

Subsection 133(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Part II of the Act provides for the payment of Medicare benefits for professional services rendered to eligible persons. Section 9 of the Act provides that Medicare benefits be calculated by reference to the fees for medical services set out in prescribed tables.

Subsection 4(1) of the Act provides that regulations may prescribe a table of general medical services which sets out items of general medical services, the fees applicable for each item, and rules for interpreting the table. The table made under this subsection is referred to as the General Medical Services Table. The most recent version of the regulations is the *Health Insurance (General Medical Services Table) Regulations 2021* (GMST).

Section 4A of the Act provides that regulations may prescribe a table of pathology services which set out items of pathology services, the fees applicable for each item, and rules for interpreting the table. The table made under this section is referred to as the Pathology Services Table. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020* (PST).

Section 4AA of the Act provides that regulations may prescribe a table of diagnostic imaging services which sets out items of diagnostic imaging services, the fees applicable for each item, and rules for interpreting the table. The table made under this section is referred to as the Diagnostic Imaging Services Table. The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* (DIST).

#### **Purpose**

The purpose of the *Health Insurance Legislation Amendment (Hospital-Only Services and Other Measures) Regulations 2025* (the Regulations) is to amend more than 800 MBS items to limit the services to being performed or provided in a hospital. This will align the MBS to contemporary clinical practice and ensure services are only rendered in the appropriate clinical location. This change was announced in the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure and as part of the 2024-25 MYEFO under the *An Effective and Clinically Appropriate Medicare Benefits Schedule* measure.

The Regulations will also implement recommendations of the Medical Services Advisory Committee (MSAC). Policy authority for these changes was given by the Minister of Health

and Aged Care who has delegated authority from Expenditure Review Committee to approve new and amended MBS services following a positive recommendation from MSAC if under the \$20 million annual threshold. Changes include:

- Listing two new items (38376 for percutaneous technique, 38616 for surgical technique) for the insertion of an intravascular microaxial ventricular assist device into the left ventricle only, by arteriotomy. This change was recommended by MSAC to support a small and high-risk population of patients who are experiencing deteriorating cardiogenic shock who have not been stabilised despite pharmacotherapy or as an adjunct to Veno-Arterial Extra-corporeal Oxygenation. A new item will also be listed for the surgical removal of the device (38619) and two items will be amended (13851 and 13854) to clarify the services exclude intravascular microaxial ventricular assist device inserted into the right ventricle and must be performed or provided in a hospital.
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The Regulations will also implement minor and machinery changes, including:

- Incorporating items 69421 and 69422, which are currently made under a legislative instrument made under section 3C of the Act, into the PST.
- Making an editorial change to item 73297 to clarify the eligible patient cohort and the policy intent of the item.
- Amending section 31 of the HIR to clarify that all simple basic pathology services in P9 which can be rendered by participating nurse practitioners are conditional on the practitioner considering the clinical necessity of the test.

### **Human rights implications**

The Regulations engage 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

Schedule 1 of the Regulations will maintain the rights to health and social security by ensuring conditions on the location particular Medicare services can be rendered reflects contemporary and appropriate clinical practice. Schedule 2 of the Regulations advance the rights to health and social security by introducing new services which will be available as publicly subsidised medical services. The Regulations make no change to the right of equality and non-discrimination, as a Medicare-eligible person (as defined in the Act) continues to have access to all Medicare services based on clinical need consistent with a universal health insurance program.

### **Conclusion**

This instrument is compatible with human rights because it maintains existing arrangements and the protection of human rights.

**Mark Butler**

**Minister for Health and Aged Care**