

## **EXPLANATORY STATEMENT**

### *Health Insurance Act 1973*

#### *Health Insurance Legislation Amendment (2018 Measures No. 1) Regulations 2018*

Subsection 133(1) of the *Health Insurance Act 1973* (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) and 4AA(1) of the Act provides that regulations may prescribe a table of medical and diagnostic imaging services which set out items of services, the fees applicable for each item, and rules for interpreting the tables. The *Health Insurance (General Medical Services Table) Regulations 2017* (GMST) and the *Health Insurance (Diagnostic Imaging Services Table) Regulations 2017* (DIST) currently prescribe such tables.

Section 23DZR of the Act sets out the primary information required for registration of diagnostic imaging premises or a base for mobile diagnostic imaging equipment. Subsection 23DZR(2) provides that regulations may prescribe types of diagnostic imaging equipment for the purpose of the section. The types of equipment are listed in regulation 20C of the *Health Insurance Regulations 1975* (HIR).

### **Purpose**

The purpose of the *Health Insurance Legislation Amendment (2018 Measures No. 1) Regulations 2018* (the Regulations) is to amend the GMST, DIST and the HIR from 1 May 2018. The Regulations make a number of changes to the Medicare Benefits Schedule (MBS) as recommended by the Medical Services Advisory Committee (MSAC) or the MSAC Executive. The changes were announced under the *Guaranteeing Medicare — Medicare Benefits Schedule — new and amended listings* measure in the 2017-18 Mid-Year Economic and Fiscal Outlook (MYEFO), and include:

#### **Amendments to the DIST**

- **New items for magnetic resonance imaging (MRI) of the cardiovascular system for the diagnosis of arrhythmogenic right ventricular cardiomyopathy**

This change lists new items for MRI of the cardiovascular system for the diagnosis of arrhythmogenic right ventricular cardiomyopathy.

Items 63395 and 63396 are for patients who have presented with symptoms or investigative findings consistent with arrhythmogenic right ventricular cardiomyopathy. Items 63397 and 63398 are for patients who are asymptomatic with a family history of confirmed arrhythmogenic right ventricular cardiomyopathy in a first degree blood relative. Two items are required for each patient group as the benefit varies based on the age of the equipment which performs the scan. See the attachment for more details about these requirements, known as capital sensitivity.

- **A new item for whole body positron emission tomography (PET) using <sup>68</sup>Gallium DOTA peptide for diagnosis of gastro-entero-pancreatic neuroendocrine tumour**

This change lists a new item 61647 for whole body PET using <sup>68</sup>Gallium DOTA peptide for the diagnosis of gastro-entero-pancreatic neuroendocrine tumour, or for the exclusion of additional disease sites in a patient with a surgically amendable gastro-entero-pancreatic neuroendocrine tumour.

- **New MRI items for detection of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)**

This change lists new items 63547 and 63548 for MRI of the breast to determine whether, in addition to a seroma type breast implant-associated anaplastic large cell lymphoma, lymphadenopathy and any solid tumours are present which require a biopsy. These services will also assist with surgical planning.

BIA-ALCL is a rare T-cell derived lymphoma within the non-Hodgkin lymphoma group which presents in two ways - the seroma type or the mass type. BIA-ALCL arises in the effusion or in the scar capsule surrounding a breast implant, and presents with unilateral swelling, pain or enlargement of an implanted breast.

Two items have been listed for this service as it subject to capital sensitivity. See the attachment for more details about these requirements.

#### Amendments to the GMST

- **A new ophthalmology item for the treatment of progressive corneal ectatic disease**

This change lists a new item 42652 for the treatment of progressive corneal ectatic disease. Corneal collagen cross-linking, uses UV light and (riboflavin) photosensitizer to strengthen chemical bonds in corneas weakened by disease. Corneal collagen cross-linking halts vision-threatening progressive change in corneal shape that can lead to extreme cases of myopia and astigmatism.

- **New items for the treatment of varicose veins caused by chronic venous insufficiency**

This change lists two new items 32528 and 32529 to treat varicose veins with chronic venous insufficiency (improper functioning of the vein valves) by injecting cyanoacrylate adhesive under ultrasound guidance. The service is a minimally invasive alternative procedure.

- **New items for diagnosis of atrial fibrillation in patients with embolic stroke of undetermined source using implantable loop recorder**

This change lists two new items 11728 and 38288 for the detection and investigation of atrial fibrillation in patients with embolic stroke of undetermined source. Item 38288 is for the insertion of the implantable loop recorder used to detect atrial fibrillation, and item 11728 is for the investigation of the recorded data as well as checking and re-programming the device.

- **Amendment of gastrostomy items to prevent clinically inappropriate claiming**

This change amends existing gastrostomy items 30481, 30482 and 30483 (for patients who require long term enteral feeding/nutrient support) to prevent the items from being claimed in association with the insertion of experimental weight loss surgical devices.

- **Minor machinery amendments to the GMST**

The Regulations also make a minor machinery amendment to the GMST from 1 May 2018. This change amends existing item 15565 to remove references to the use of a dosimetric phantom. A dosimetric phantom refers to a block of tissue equivalent material which is used to measure absorbed radiation dose, usually using thermoluminescent devices. The Royal Australian and New Zealand College of Radiologists have advised the department that this requirement is outdated and does not reflect current methodology for performing dosimetry checks. This is due to developments in the area of the methodology of dosimetric checks, for example the use of methods involving dedicated software, electronic portal imaging devices or 3D dosimetry phantom.

### Amendments to the HIR

- **Amendment to regulation 20C of the HIR to insert reference to new positron emission tomography (PET) item 61647**

This change inserts new PET item 61647 (listed above) into the table in regulation 20C of the HIR. This prescribes that this new service is to be performed on nuclear medicine imaging equipment for PET.

### **Consultation**

As part of the MSAC process, consultation was undertaken with professional bodies, consumer groups, the public and clinical experts for proposals put forward for consideration by the Committee.

MSAC reviews new or existing medical services or technology, and the circumstances under which public funding should be supported through listing on the MBS. This includes the listing of new items, or amendments to existing items on the MBS.

Additional consultation was undertaken by the Department of Health with the following stakeholders:

- the Royal Australian and New Zealand College of Radiologists;
- the Australian Society of Ophthalmologists;
- the Royal Australian and New Zealand College of Ophthalmologists;
- the Royal Australian College of Surgeons; and
- the Cardiac Society of Australia and New Zealand.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions which need to be met before the power to make the Regulations may be exercised.

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

The Regulations commence on 1 May 2018.

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

## ATTACHMENT

**Details of the *Health Insurance Legislation Amendment (2018 Measures No. 1) Regulations 2018***Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2018 Measures No. 1) Regulations 2018*.

Section 2 – Commencement

This section provides that the Regulations commence on 1 May 2018.

Section 3 – Authority

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

Section 4 – Schedule(s)

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 – Amendments***Health Insurance (Diagnostic Imaging Services Table) Regulations 2017*****Items 1 - Subclause 2.4.2(1) of Schedule 1**

This item inserts new item 61647 (see item 3) into subclause 2.4.2(1). Subclause 2.4.2(1) prescribes the specified nuclear medicine items must:

- be requested by a specialist or consultant physician in writing; and
- be performed in a comprehensive facility using eligible equipment; and
- be performed by, or under the supervision of, a medical practitioner in clause 2.4.3.

**Item 2 - Schedule 1 (item 61369)**

This item makes a minor editorial amendment by repealing and substituting item 61369 with a slightly restructured item descriptor. This is to make the requirements of the item clearer but does not change the current intention or requirements of the item.

**Item 3 - Schedule 1 (after item 61646)**

This item inserts new PET item 61647 after item 61646. This new item is for:

- diagnosis of gastro-entero-pancreatic neuroendocrine tumour; or
- for the exclusion of additional disease sites in a patient with a surgically amendable gastro-entero-pancreatic neuroendocrine tumour.

**Item 4 – Schedule 1 (item 61671)**

This item makes a minor editorial amendment by repealing and substituting item 61671 with a slightly restructured item descriptor. This is to make the requirements of the item clearer but does not change the current intention or requirements of the item.

**Item 5 - Subclause 2.5.1(1) of Schedule 1**

This item makes a minor editorial amendment by replacing the item numbers listed in this subclause with the subgroups they are contained within. This change is to make it easier to read and understand but does not change the current requirements.

This change also applies new MRI items for cardiac (63395, 63396, 63397 and 63398) and breast (63547 and 63548) to this subclause. Subclause 2.5.1(1) prescribes the MRI or magnetic resonance angiography (MRA) services that can be performed if:

- requested by a specialist or consultant physician in accordance with clause 2.5.2; and
- performed in a permissible circumstance in accordance with clause 2.5.3; and
- performed using eligible equipment mentioned in clause 2.5.5.

**Item 6 - Subclause 2.5.1(2) of Schedule 1**

This item makes a minor editorial amendment by replacing some of the item numbers listed in this subclause with the subgroups they are contained within. This change is to make it easier to read and understand but does not change the current requirements.

This change also applies new MRI items for cardiac (63395, 63396, 63397 and 63398) and breast (63547 and 63548) to this subclause. Subclause 2.5.1(2) prescribes the MRI services that can be performed if:

- requested by a specialist or consultant physician in accordance with clause 2.5.2; and
- performed in a permissible circumstance in accordance with clause 2.5.3; and
- performed using partial eligible equipment mentioned in clause 2.5.6.

**Item 7 - Subclause 2.5.1(3) of Schedule 1**

This item makes a minor editorial amendment by replacing the item numbers listed in this subclause with the subgroups they are contained within. This change is to make it easier to read and understand but does not change the current requirements.

**Item 8 - Subclause 2.5.1(4) of Schedule 1**

This item makes a minor editorial amendment by replacing the item numbers listed in this subclause with the subgroups they are contained within. This change is to make it easier to read and understand but does not change the current requirements.

**Item 9 - Clause 2.5.4 of Schedule 1**

This item repeals clause 2.5.4 and substitutes with a new table to define what an ‘eligible provider’ is for the supervision and reporting of the new cardiac MRI items 63395 to 63398. For these items, eligible providers will be a radiologist or a consultant physician who is recognised by the by the Conjoint Committee for Certification in Cardiac MRI.

The Conjoint Committee for Certification in Cardiac MRI has been formed by the Cardiac Society of Australia and New Zealand and the Royal Australian and New Zealand College of Radiologists.

There is no change to what an ‘eligible provider’ is for the existing MRI or MRA services.

**Item 10 - Clause 2.5.9 of Schedule 1**

This item repeals clause 2.5.9 and substitutes it with a new clause to include new MRI item items for cardiac (63395, 63396, 63397 and 63398) and breast (63547 and 63548). This

clause prescribes the maximum number of services which can be provided in the same time period. No changes have been made to the application of existing items covered by this clause.

**Item 11 - Schedule 1 (at the end of Subgroup 14 of Group I5)**

This item inserts four new items into subgroup 14 of group I5 (magnetic resonance imaging). These items are for the provision of MRI of the cardiovascular system for assessment of myocardial structure and function.

Items 63395 (K) and 63396 (NK) are for patients who have presented with symptoms or investigative findings consistent with arrhythmogenic right ventricular cardiomyopathy. Items 63397 (K) and 63398 (NK) are for patients who are asymptomatic with a family history of confirmed arrhythmogenic right ventricular cardiomyopathy in a first degree blood relative.

An (NK) item applies to a service that is performed on:

(a) diagnostic imaging equipment:

(i) that has not been upgraded; and

(ii) the age of which exceeds the new effective life age for the equipment;

or

(b) diagnostic imaging equipment:

(i) that has been upgraded; and

(ii) the age of which exceeds the maximum extended life age for the equipment.

A (K) item does not apply to a service to which an (NK) item applies. These requirements are known as capital sensitivity, and are prescribed in Division 1.2 of the DIST.

**Item 12 - Schedule 1 (at the end of Subgroup 19 of Group I5)**

This item inserts two new breast MRI items 63547 (K) and 63548 (NK) at the end of subgroup 19 of group I5. These items would be to determine whether, in addition to a seroma type breast implant-associated anaplastic large cell lymphoma, lymphadenopathy and any solid tumours are present which require a biopsy. They will also assist with surgical planning. These items are also subject to capital sensitivity (see above information about capital sensitivity).

**Item 13 – Clause 3.1 of Schedule 1 (definition of scan)**

This item makes a minor editorial amendment to the definition of ‘scan’ so that the item numbers in the definition match those listed in clause 2.5.7.

***Health Insurance (General Medical Services Table) Regulations 2017***

**Item 14 - Subclause 1.2.5(1) of Schedule 1**

This item inserts new implanted loop recording item 11728 (see item 15) into subclause 1.2.5(1). This subclause specifies the service must be provided with the medical practitioner in personal attendance and may be performed in a hospital by a practitioner exercising their right to private practice.

**Item 15 - Schedule 1 (at the end of Subgroup 6 of Group D1)**

This item inserts new item 11728 at the end of subgroup 6 in group D1 (Miscellaneous diagnostic procedures and investigations). Item 11728 is for the investigation of the recorded data as well as checking and re-programming the device.

**Item 16 - Schedule 1 (item 15565, column headed “Description”, subparagraphs (b)(iii) and (iv))**

This item repeals the requirement of the use of a dosimetric phantom to align the item with modern clinical practice.

**Item 17 - Schedule 1 (items 30481 to 30483)**

This item repeals and substitutes items 30481, 30482 and 30483 to restrict the items from being claimed in association with the insertion of experimental weight loss surgical devices.

**Item 18 - Schedule 1 (items 32520 to 32526)**

This item makes a consequential amendment to existing items 32520, 32522, 32523 and 32526 to restrict them from being used for cyanoacrylate embolization. This item also inserts two new items (32528 and 32529) to treat varicose veins with chronic venous insufficiency (improper functioning of the vein valves) by injecting cyanoacrylate adhesive under ultrasound guidance.

**Item 19 - Schedule 1 (item 34103, column headed “Description”)**

This item makes a consequential amendment to item 34103 to restrict new items 32528 and 32529 from being claimed at the same time as the service provided by item 34103.

**Item 20 - Schedule 1 (after item 38287)**

This item inserts new item 38288 after item 38287. This new item is for the insertion of the implantable loop recorder used to detect atrial fibrillation. Paragraph (b) of the item descriptor does not prevent additional matters being considered in the diagnosis.

**Item 21 - Schedule 1 (after item 42651)**

This item inserts new item 42652 after item 42651. This new item is for the provision of treatment for progressive corneal ectatic disease.

***Health Insurance Regulations 1975*****Item 22 - Subregulation 20C(1) (table item 12, column 2)**

This item would make a consequential amendment to table item 12, column 2 of 20C(1) (primary information - types of diagnostic imaging equipment) by inserting reference to new PET item 61647.

**Item 23 - Subregulation 20C(1) (table items 13 and 14, column 3)**

This item would make a consequential amendment to table items 13 and 14, column 3 of 20C(1) (primary information - types of diagnostic imaging equipment) by inserting reference to new PET item 61647.



## Statement of Compatibility with Human Rights

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

*Health Insurance Legislation Amendment (2018 Measures No. 1) Regulations 2018*

This Disallowable 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 Disallowable Legislative Instrument

The purpose of the *Health Insurance Legislation Amendment (2018 Measures No. 1) Regulations 2018* (the Regulations) is to amend the GMST, DIST and the HIR from 1 May 2018. The Regulations make a number of changes to the Medicare Benefits Schedule (MBS) as recommended by the Medical Services Advisory Committee (MSAC) or the MSAC Executive. The changes were announced under the *Guaranteeing Medicare — Medicare Benefits Schedule — new and amended listings* measure in the 2017-18 Mid-Year Economic and Fiscal Outlook.

### 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.

### Analysis

The Regulations will maintain or advance rights to health and social security by ensuring access to publicly subsidised health services which are clinically effective and cost-effective.

### **Conclusion**

This Disallowable Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

**Greg Hunt**

**Minister for Health**