

## **EXPLANATORY STATEMENT**

### *Health Insurance Act 1973*

#### *Health Insurance Legislation Amendment (2024 Measures No. 2) Regulations 2024*

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.

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).

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).

### **Purpose**

The purpose of the *Health Insurance Legislation Amendment (2024 Measures No. 2) Regulations 2024* (the Regulations) is to amend the DIST, GMST and PST from 1 July 2024. The Regulations will apply annual indexation to MBS schedule fees, introduce and amend MBS items, as agreed to in the 2023-24 Budget and Mid-Year Economic and Fiscal Outlook (MYEFO), and implement other administrative and machinery changes.

Schedule 1 of the Regulations will implement annual fee indexation by increasing the schedule fee by 3.5 per cent for most general medical services in the GMST, diagnostic imaging services in the DIST, and specific items for the management of bulk-billing pathology services in the PST. This means that patients will receive a higher Medicare benefit for these services from 1 July 2024.

Part 1 of Schedule 2 of the Regulations will amend the DIST to:

- simplify the administrative arrangements for capital sensitivity provisions in the DIST;
- amend supervision requirements of diagnostic imaging nuclear medicine services to align supervision requirements with requirements for other diagnostic imaging modalities; and
- insert two new magnetic resonance imaging (MRI) services for annual surveillance to detect newly developed renal tumours, and ongoing assessment of changes over time to an existing renal tumour for patients with defined rare inherited conditions associated with an increased risk of renal tumours.

Part 2 of Schedule 2 of the Regulations will amend the GMST to:

- amend item 11300 for brain stem evoked response audiometry and items 11340, 11341 and 11343 for vestibular assessment to remove a co-claiming restriction;
- amend six colonoscopy items and endoscopic mucosal resection (EMR) item 32230 to clarify that the provision of a service under item 32230 includes a colonoscopy service described in items 32222, 32223, 32224, 32225, 32226 and 32228 to prevent inappropriate co-claiming;
- amend two items for non-invasive treatment for benign prostate hyperplasia (37204 and 37205) to correct typographical errors;
- insert two new items (41768 and 41769) for the insertion of bioabsorbable nasal implants;
- make minor administrative amendments to two orthopaedic items (49564 and 49565); and
- amend orthopaedic item 50654 to clarify anaesthesia requirements for the service.

Part 3 of Schedule 2 of the Regulations will amend the PST to:

- insert new item 66586 to provide pathology testing for quantifying BNP or NT-proBNP in patients with previously diagnosed pulmonary arterial hypertension;
- insert two new items (73313 and 73316) for the detection of measurable residual disease (MRD) in patients with acute lymphoblastic leukaemia (ALL) using quantitative molecular assay (qPCR);
- amend pathology item 73410 to include carrier testing of individuals with normal red cell indices if their reproductive partner has been diagnosed with a heterozygous 2-gene deletional alpha thalassemia; and
- amend items 73410, 73411, 73412 and 73413 to allow for testing of reproductive couples in either order.

### **Consultation**

A number of medical professional organisations were consulted on the 1 July 2024 changes as part of the Taskforce and MSAC process. These include the Australian Medical Association, Royal Australian and New Zealand College of Radiologists, Royal Australasian College of Surgeons and Royal Australasian College of Physicians, among others. Further consultation was also undertaken with Implementation Liaison Groups in the development of the changes. There was general support from stakeholders on the changes that will be implemented by the Regulations. Additional consultation information is outlined in the [Attachment](#).

Some of the amendments in the Regulations are minor and machinery in nature and did not require consultation to be undertaken.

Details of the Regulations are set out in the Attachment.

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

Sections 1 to 4 of the Regulations will commence the day after registration of this instrument, Schedule 1 of the Regulations will commence on 1 July 2024 and Schedule 2 of the Regulations will commence immediately after the commencement of Schedule 1.

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

## ATTACHMENT

### **Details of the *Health Insurance Legislation Amendment (2024 Measures No. 2) Regulations 2024***

#### Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2024 Measures No. 2) Regulations 2024* (the Regulations).

#### Section 2 – Commencement

This section provides for sections 1 to 4 of the Regulations to commence the day after registration of this instrument, Schedule 1 of the Regulations to commence on 1 July 2024 and Schedule 2 of the Regulations to commence immediately after the commencement of Schedule 1.

#### 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 – Indexation

Schedule 1 of the Regulations applies annual indexation of the schedule fees of Medicare Benefits Schedule (MBS) items from 1 July 2024. This will increase the benefit paid to patients for these services, which is calculated as a percentage of the fee per section 10 of the *Health Insurance Act 1973*. Indexation will be applied by 3.5 per cent, which is represented as 1.035 in the diagnostic imaging services table (clause 2.7.1), general medical services table (clause 1.3.1) and the pathology services table (clause 2.14.1).

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

**Items 1 and 2** apply indexation to imaging services in Groups I1 (ultrasound), I2 (computed tomography), I3 (diagnostic radiology), I5 (MRI) and I6 (bulk-billing incentive for unreferred services) of the diagnostic imaging services table. Nuclear medicine services in Group I4 will not be indexed.

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

**Items 3 to 23** applies indexation to all medical services in the general medical services table, other than the following items for services performed by medical practitioners other than a general practitioner which are not indexed:

- all items in Group A2 and A23; and
- items 90092, 90093, 90095, 90096 and 90098 in Group A35.

Previously, indexation of the fees for prescribed medical practitioner services (most items in Group A7, items 90183, 90188, 90202, 90212 and 90215 in Group A35 and items 90254, 90255, 90256, 90257, 90265, 90275 and 90277 in Group A36) was calculated by applying indexation to the equivalent general practitioner item and calculating 80 per cent of the indexed amount. These changes amend this methodology and apply indexation to the fees for the prescribed medical practitioner services in accordance with subclause 1.3.1(1) of the general medical services table.

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

**Items 24 and 25** apply indexation to the bulk-billing incentives for unreferral pathology services (Group P12) in the pathology services table. Indexation will not apply to any other pathology service.

#### Schedule 2 – Other amendments

##### Part 1 – Diagnostic imaging services table

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

**Items 1 to 14** of Schedule 2 of the Regulations will simplify the administrative arrangements for capital sensitivity provisions in the DIST. Capital sensitivity sets when a piece of diagnostic imaging equipment reaches the end of its life age and Medicare benefits are no longer payable for services performed on that equipment.

Under clauses 1.2.1 and 1.2.2 of the DIST, Medicare benefits are not payable for equipment that has exceeded its applicable life age. Clauses 1.2.8 and 1.2.10 of the DIST allow for the granting of exemptions where equipment is unable to be replaced or upgraded before the equipment reaches the end of its applicable life age.

The administrative amendments in **items 1 to 14** of Schedule 2 of the Regulations will provide support to diagnostic imaging practices and patients in response to continuing challenges in the global supply chain for diagnostic imaging equipment and will ensure affected practices continue to be able to provide Medicare eligible diagnostic imaging services to patients.

Consultation was undertaken regarding these changes with the following stakeholders, who were broadly supportive of the changes:

- Australian Diagnostic Imaging Association (ADIA);
- Australasian Society for Ultrasound in Medicine (ASUM);
- Rural Alliance in Nuclear Scintigraphy (RAINS);
- Royal Australian and New Zealand College of Radiologists (RANZCR);
- Diagnostic Imaging Manufacturers Association / GE Healthcare (DIMA/GE); and
- Australasian Association of Nuclear Medicine Specialists (AANMS).

**Item 1** amends paragraph 1.2.7(2)(c) of the DIST to provide that an application for an exemption to capital sensitivity under clause 1.2.8 must set out “the steps taken by the proprietor to replace the equipment (or upgrade the equipment, if it has not already been

upgraded)”. This new requirement is in addition to the current requirement that the proprietor must provide reasons why they are unable to replace or upgrade the equipment.

**Items 2 and 3** amend subclauses 1.2.8(3), (4) and (6) of the DIST to update the requirements that must be satisfied for an exemption to capital sensitivity to be granted under this clause.

Subclause 1.2.8(3) will be amended to:

- remove the current requirement that the Secretary must be satisfied that the proprietor will be able to replace the equipment before the end of the specified period; and
- amend the other current requirement to provide that the Secretary must be satisfied that the proprietor ‘is taking’ (rather than ‘has taken’) reasonable steps to replace the equipment before the end of the specified period.

This change simplifies the arrangements under this subclause and allows proprietors to establish that they are unable to replace their equipment owing to circumstances beyond their control.

Subclause 1.2.8(4) will be amended to increase the specified period relevant to subclause 1.2.8(3) from three months to six months. This change is intended to reduce the number of applications for exemptions in response to the continuing challenges in the global supply chain for diagnostic imaging equipment.

The change to subclause 1.2.8(6) is a minor administrative amendment to clarify that a further extension under clause 1.2.10 could also apply (refer to **items 7 to 12** of Schedule 2 of the Regulations).

**Items 4 to 6** amend subclause (2) and paragraphs (3)(c) and (4)(a) of clause 1.2.9 of the DIST. Clause 1.2.9 provides the requirements for applications to extend an exemption to capital sensitivity. The changes to subclause 1.2.9(2) and paragraph 1.2.9(4)(a) are minor administrative amendments to reference that a further extension under clause 1.2.10 could also apply (refer to **items 7 to 12** of Schedule 2 of the Regulations).

Paragraph 1.2.9(3)(c) will be amended to provide that an application for an extension to an exemption to capital sensitivity under clause 1.2.10 must set out “the steps taken by the proprietor to replace the equipment (or upgrade the equipment, if it has not already been upgraded)”. This new requirement is in addition to the current requirement that the proprietor must provide reasons why they are unable to replace or upgrade the equipment.

**Items 7 to 12** amend subclause (1), paragraphs (2)(a) and (2)(b) and subclauses (3), (4) and (6) of clause 1.2.10 of the DIST. Clause 1.2.10 provides the requirements for extensions of exemptions to capital sensitivity. The changes to subclauses 1.2.10(1), (4) and (6), paragraphs 1.2.10(2)(a) and (b) are minor administrative amendments to clarify that a further extension under clause 1.2.10 could also apply.

Subclause 1.2.10(3) will be amended to:

- remove the current requirement that to grant an extension or further extension of an exemption to capital sensitivity, the Secretary must be satisfied that the proprietor will be able to replace the equipment before the end of the specified period; and

- amend the other current requirement to provide that the Secretary must be satisfied that the proprietor ‘is taking’ (rather than ‘has taken’) reasonable steps to replace the equipment before the end of the specified period.

This change simplifies the arrangements under this subclause and allows proprietors to establish that they are unable to replace their equipment owing to circumstances beyond their control.

**Item 13** makes a minor administrative amendment to paragraph 1.2.11(1)(b) of the DIST to clarify that a decision under clause 1.2.10 to refuse to extend the exemption period of an exemption in respect of diagnostic imaging equipment also includes a decision to refuse to further extend the exemption period.

**Item 14** repeals clause 1.2.14 of the DIST, which provides the delegation of the Secretary’s power under Subdivision B of Part 1 of Schedule 1 of the DIST. This clause will be removed as the delegation of the Secretary’s power under the specified subdivision is contained in the relevant instrument of delegation and the clause is redundant.

**Items 15 to 18** of Schedule 2 of the Regulations amend supervision requirements of diagnostic imaging nuclear medicine services to align with requirements for other diagnostic imaging modalities such as magnetic resonance imaging (MRI) and computed tomography (CT). These changes were agreed to by Government as part of the 2023-24 Budget under the *Strengthening Medicare* measure.

Consultation was undertaken regarding the changes to supervision requirements with professional organisations. The professional organisations consulted include:

- AANMS;
- ADIA;
- RANZCR; and
- RAINS.

**Item 15** repeals and substitutes clause 2.4.1 of the DIST to clarify the supervision requirements for nuclear medicine services not involving PET. This change simplifies the wording for supervision requirements described in clause 2.4.1 by introducing the term ***nuclear medicine credentialled specialist***, which will be defined in clause 3.1 and maintains the existing credentialling requirements for the performance or supervision of nuclear medicine services (refer to **item 22** of Schedule 2 of the Regulations). These changes are administrative in nature and are intended to support and ensure consistency with the changes to supervision requirements for PET services (refer to **item 16** of Schedule 2 of the Regulations).

**Item 16** repeals and substitutes clause 2.4.3 of the DIST to update the supervision requirements for PET nuclear medicine services to require personal supervision. This change aligns the supervision requirements for PET services with the supervision requirements for MRI and CT services and will ensure continued support for patients without compromising on safety and quality of care. The wording of the supervision requirements described in the revised clause 2.4.3 will also be simplified by introducing the term ***PET credentialled specialist***, which will be defined in clause 3.1 and maintains the existing credentialling requirements for the performance or supervision of PET services (refer to **item 22** of Schedule 2 of the Regulations).

**Item 17** amends clause 2.4.4 of the DIST to align a reference to clause 2.4.2 with the changes to the structure of clause 2.4.2 (refer to **item 16** of Schedule 2 of the Regulations). This change is consequential in nature.

**Item 18** amends paragraph 2.4.5(1)(a) of the DIST to replace a reference to the credentialing requirements currently specified in clause 2.4.3 with the term “PET credentialled specialist” to align with the changes to clause 2.4.3 (refer to **item 16** of Schedule 2 of the Regulations).

**Item 19** inserts two new magnetic resonance imaging (MRI) services, allowing for annual surveillance to detect newly developed renal tumours, and ongoing assessment of changes over time to an existing renal tumour for patients with defined rare inherited conditions associated with an increased risk of renal tumours. These new services will facilitate the early detection and associated treatment, of renal tumours in eligible patients with a rare inherited condition.

The items provide that the service must be requested by a specialist or consultant physician. Services under the new items must also be performed by a specialist in diagnostic radiology who is a participant in the RANZCR Quality and Accreditation Program and who meets all the usual requirements under the DIST.

The Department consulted broadly with the following organisations and feedback received was supportive of the new services:

- ADIA;
- RANZCR;
- Royal Australian College of General Practitioners (RACGP);
- Australian Medical Association (AMA);
- Royal College of Pathologists of Australasia (RCPA);
- Australasian Association of Nuclear Medicine Specialists;
- Australian and New Zealand Society of Nuclear Medicine;
- RAINS;
- Genetic Undiagnosed and Rare Disease Network;
- NeuroEndocrine Cancer Australia;
- Myeloma Australia;
- Medical Oncology Group of Australia (MOGA);
- Clinical Oncology Society of Australia;
- Royal Australasian College of Physicians (RACP);
- Royal Australasian College of Surgeons (RACS);
- Genetic and Rare Diseases Network;
- Australian and New Zealand Children's Haematology/Oncology Group;
- Genetic Alliance Australia;
- Cancer Council Australia;
- Rare Cancers Australia (RCA);
- Rare Voices Australia;
- Syndromes Without a Name;
- Genetic Support Network Victoria;
- Australian and New Zealand Society of Nephrology;
- Australian Society of Medical Imaging and Radiation;

- Kidney Health Australia;
- Consumer Health Forum;
- Tuberos Sclerosis Australia;
- Urological Society of Australia and New Zealand;
- Australian Genomic Cancer Medicine Centre; and
- Human Genetics Society of Australia.

These new items were announced in the 2023-24 MYEFO under the *An Effective and Clinically Appropriate Medicare* measure.

**Items 20 to 22** amend clause 3.1 of the DIST to:

- insert two new terms and remove an obsolete term in accordance with the changes to supervision requirements of diagnostic imaging nuclear medicine services (refer to **items 15 to 18** of Schedule 2 of the Regulations); and
- amend the term *exemption period* to reference a further extension of the exemption period where applicable.

The new term *nuclear medicine credentialled specialist* maintains the credentialling requirements for the performance or supervision of nuclear medicine currently specified in clause 2.4.1.

The new term *PET credentialled specialist* maintains and consolidates the credentialling requirements for the performance or supervision of PET services currently specified in clause 2.4.3 and the definition of *credentialled specialist* in clause 3.1. Accordingly, the term *credentialled specialist* will be removed from clause 3.1.

**Item 23** inserts new Division 2 into Part 4 of Schedule 1 of the DIST, which provides transitional provisions relating to the changes to capital sensitivity requirements and supervision requirements for PET services.

New clause 4.3 inserts a definition for the term *amending instrument* for the purposes of the new Division. The term *amending instrument* means the Regulations.

New clause 4.4 provides that:

- (a) The amendments to clauses 1.2.8, 1.2.9, 1.2.10, 1.2.11 and 1.2.14 of the DIST (refer to **items 2 to 4** and **6 to 14** of Schedule 2 of the Regulations) apply to any decision made by the Secretary on or after 1 July 2024, regardless of when the application for an exemption to capital sensitivity or for an extension or further extension to an exemption was made.
- (b) The amendments to clauses 1.2.7 and 1.2.9 of the DIST (refer to **items 1 and 5** of Schedule 2 of the Regulations) only apply to applications for an exemption to capital sensitivity or for an extension or further extension to an exemption made on or after 1 July 2024.

New clause 4.5 provides that the changes to clause 2.4.5 of the DIST (refer to **item 18** of Schedule 2 of the Regulations) only apply to statutory declarations given on or after 1 July 2024.

## Part 2 – General medical services table

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

**Item 24** amends brain stem evoked assessment item 11300 to remove the co-claiming restriction with items 11340, 11341 and 11343 (refer to **item 25** of Schedule 2 of the Regulations). This change responds to the recommendation of members of the Otolaryngology Head and Neck Surgery Implementation Liaison Group, following the implementation of the Government's response to the MBS Review Taskforce recommendations relating to otolaryngology, head and neck surgery items on 1 March 2023. This change was announced in the 2023-24 MYEFO under the *An Effective and Clinically Appropriate Medicare* measure.

**Item 25** amends vestibular function assessment items 11340, 11341 and 11343 to remove the co-claiming restriction with item 11300 (refer to **item 24** of Schedule 2 of the Regulations). These changes respond to the recommendation of members of the Otolaryngology Head and Neck Surgery Implementation Liaison Group, following the implementation of the Government's response to the MBS Review Taskforce recommendations relating to otolaryngology, head and neck surgery items on 1 March 2023. These changes were announced in the 2023-24 MYEFO under the *An Effective and Clinically Appropriate Medicare* measure.

**Items 26 to 31** amend colonoscopy items 32222, 32223, 32224, 32225, 32226 and 32228 to prevent claiming of a service under one of these items on the same occasion as an endoscopic mucosal resection (EMR) service under item 32230. These co-claiming restrictions reflect the original policy intent that the fee and the service described in item 32230 is inclusive of the colonoscopy service (item 32222, 32223, 32224, 32225, 32226 and 32228).

Consultation was undertaken relating to these changes with peak bodies, including the Gastroenterological Society of Australia (GESA). These changes were announced in the 2023-24 MYEFO under the *An Effective and Clinically Appropriate Medicare* measure.

**Item 32** amends EMR item 32230 item to make a consequential amendment following the changes to colonoscopy items 32222, 32223, 32224, 32225, 32226 and 32228 (refer to **items 26 to 31** of Schedule 2 of the Regulations). In accordance with the changes to the colonoscopy items, it is intended that a service under item 32222, 32223, 32224, 32225, 32226 or 32228 cannot be claimed on the same occasion as a service to which item 32230 applies.

**Item 33** amends item 37204 to address a typographical error following amendments to this item on 1 March 2024. No consultation was undertaken relating to this change as it is administrative in nature.

**Item 34** amends item 37205 to address a typographical error following amendments to this item on 1 March 2024. No consultation was undertaken relating to this change as it is administrative in nature.

**Item 35** inserts two new items for the unilateral (item 41768) and bilateral (41769) insertion of a bioabsorbable implant to treat nasal airway obstruction that has occurred due to lateral wall insufficiency. The two new items were supported by the Medical Services Advisory Committee (MSAC) in March 2023 (refer MSAC Application 1719).

Following the MSAC application process, consultation was undertaken with peak bodies such as the RACS, AMA, Australian Society of Otolaryngology Head and Neck Surgery (ASOHNS) and Australian Society of Plastic Surgeons (ASPS). These new items were announced in the 2023-24 MYEFO under the *An Effective and Clinically Appropriate Medicare* measure.

**Item 36** amends patellofemoral joint of knee items 49564 and 49565 to address a minor typographical error, inserting “with” after “service associated”. No consultation was undertaken relating to these changes as they are administrative in nature.

**Item 37** amends orthopaedic item 50654 to clarify that this service must be performed under anaesthesia. Item 50654 was amended on 1 March 2024 and this requirement was inadvertently omitted. This change addresses this issue to prevent potential inappropriate claiming for routine paediatric hip examination and align the item with the original policy intention. Consultation was undertaken with peak bodies, including the Australian Orthopaedic Association (AOA), AMA and RACS, as part of the 1 March 2024 amendments to item 50654, which was announced in the 2023-24 Budget under *A Modern and Clinically Appropriate Medicare Benefits Schedule* measure.

### Part 3 – Pathology services table

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

**Item 38** inserts new item 66586, which will allow medical practitioners to quantify BNP or NT-proBNP in patients with previously diagnosed pulmonary arterial hypertension. The intention of this new item is to monitor disease progression in patients who have been diagnosed with pulmonary arterial hypertension.

Consultation was undertaken regarding the introduction of this item with the following stakeholders:

- Australian Pathology (AP);
- Public Pathology Australia (PPA);
- RCPA;
- Australian Scleroderma Interest Group;
- Scleroderma Australia;
- Thoracic Society of Australia and New Zealand;
- Australian Rheumatology Association; and
- Lung Foundation Australia.

This new item was announced in the 2023-24 MYEFO under the *An Effective and Clinically Appropriate Medicare* measure.

**Items 39 and 40** insert two new items for the detection of measurable residual disease (MRD) in patients with acute lymphoblastic leukaemia (ALL) using quantitative molecular assay (qPCR). The addition of two items for MRD testing using qPCR was recommended by MSAC at its 30-31 March 2023 meeting as part of MSAC Application 1703.

The Department approached the following organisations as part of its targeted consultation process:

- Australasian Leukaemia & Lymphoma Group (ALLG);

- Australasian Society of Genetic Counsellors (ASGC);
- Australian and New Zealand Children's Haematology Oncology Group (ANZCHOG);
- Australian Cancer Research Foundation (ACRF);
- Australian Commission on Safety and Quality in Health Care (ACSQHC);
- Australian Genomic Cancer Medicine Centre;
- AMA;
- AP;
- Australian Society for Biochemistry and Molecular Biology (ASBMB);
- Cancer Australia;
- Cancer Voices Australia;
- Centre for Genetics Education, NSW Health;
- Children's Cancer Institute;
- Department of Haematology, Children's Hospital at Westmead;
- Children's Medical Research Institute (CMRI);
- Clinical Oncological Society of Australia (COSA);
- Consumers Health Forum;
- Garvan Institute of Medical Research;
- Haematology Society of Australia and New Zealand (HSANZ);
- Human Genetics Society of Australasia (HGSA);
- Kids' Cancer Project;
- Blood Cancer Taskforce, Leukaemia Foundation;
- MOGA;
- National Association of Testing Authorities (NATA);
- National Pathology Accreditation Advisory Council (NPAAC);
- NSW Health Pathology;
- PathWest Laboratory Medicine WA;
- Peter MacCallum Cancer Foundation;
- Department of Haematology, Prince of Wales Hospital, Sydney;
- Private Cancer Physicians of Australia (PCPA);
- PPA;
- RCA;
- RACP – Adult Medicine;
- RACP – Paediatrics and Child Health Division;
- RACS;
- RACGP; and
- Royal College of Pathologists of Australasia Quality Assurance Programs.

The Department received responses from six organisations (AP, ANZCHOG, ALLG, HSANZ, Leukaemia Foundation and PathWest) and from one individual specialist. All responses were broadly supportive of the new items.

These new items were announced in the 2023-24 MYEFO under the *An Effective and Clinically Appropriate Medicare* measure.

**Item 39** inserts new item 73313 for the detection of MRD in patients with ALL using qPCR. Item 73313 will provide a Medicare benefit for the development and initial use of a patient-specific quantitative molecular assay.

Specialists and consultant physicians practising as a haematologist or an oncologist will be able to order this test on a bone marrow specimen (or a peripheral blood sample if bone marrow cannot be collected) from a patient diagnosed with ALL who is being treated with combination chemotherapy or after salvage therapy. The target population for this service is patients diagnosed with ALL who are being monitored for response to treatment or suspected ALL relapse.

**Item 40** inserts new item 73316 for the detection of MRD in patients with ALL using qPCR. Item 73316 will provide a Medicare benefit for MRD tests using a patient-specific quantitative molecular assay, which has previously been developed using item 73313.

Specialists and consultant physicians practising as a haematologist or an oncologist will be able to order this test on a bone marrow specimen (or a peripheral blood sample if bone marrow cannot be collected) from a patient diagnosed with ALL who is being treated with combination chemotherapy or after salvage therapy. The target population for this service is patients diagnosed with ALL who are being monitored for response to treatment or suspected ALL relapse.

**Item 41** amends pathology item 73410 to include carrier testing of individuals with normal red cell indices if their reproductive partner has been diagnosed with a heterozygous 2-gene deletional alpha thalassemia.

In addition, the term “of child-bearing potential with diagnosed alpha thalassaemia” will be replaced with “with alpha thalassaemia” to allow for reproductive testing in either order of reproductive partner.

Consultation was undertaken with the Royal College of Pathologists of Australasia, Public Pathology Australia and Australian Pathology regarding these changes, which were announced in the 2023-24 MYEFO under the *An Effective and Clinically Appropriate Medicare* measure.

**Item 42** amends pathology items 73411, 73412 and 73413, replacing the phrase “of child-bearing potential with diagnosed alpha thalassaemia” with the words “with alpha thalassaemia” to allow for reproductive testing in either order of reproductive partner. The changes align with a change to item 73410 to allow for reproductive testing in either order (refer to **item 41** of Schedule 2 of the Regulations). No consultation was undertaken regarding these changes as they are consequential in nature and intended to align with the changes to item 73410.

## Statement of Compatibility with Human Rights

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

### ***Health Insurance Legislation Amendment (2024 Measures No. 2) Regulations 2024***

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**

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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.

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The purpose of the *Health Insurance Legislation Amendment (2024 Measures No. 2) Regulations 2024* (the Regulations) is to amend the DIST, GMST and PST from 1 July 2024. The Regulations will apply annual indexation to MBS schedule fees, introduce and amend MBS items, as agreed to in the 2023-24 Budget and Mid-Year Economic and Fiscal Outlook (MYEFO), and implement other administrative and machinery changes.

Schedule 1 of the Regulations will implement annual fee indexation by increasing the schedule fee by 3.5 per cent for most general medical services in the GMST, diagnostic imaging services in the DIST, and specific items for the management of bulk-billing pathology services in the PST. This means that patients will receive a higher Medicare benefit for these services from 1 July 2024.

Part 1 of Schedule 2 of the Regulations will amend the DIST to:

- simplify the administrative arrangements for capital sensitivity provisions in the DIST;
- amend supervision requirements of diagnostic imaging nuclear medicine services to align supervision requirements with requirements for other diagnostic imaging modalities; and
- insert two new magnetic resonance imaging (MRI) services for annual surveillance to detect newly developed renal tumours, and ongoing assessment of changes over time to an existing renal tumour for patients with defined rare inherited conditions associated with an increased risk of renal tumours.

Part 2 of Schedule 2 of the Regulations will amend the GMST to:

- amend item 11300 for brain stem evoked response audiometry and items 11340, 11341 and 11343 for vestibular assessment to remove a co-claiming restriction;
- amend six colonoscopy items and endoscopic mucosal resection (EMR) item 32230 to clarify that the provision of a service under item 32230 includes a colonoscopy service described in items 32222, 32223, 32224, 32225, 32226 and 32228 to prevent inappropriate co-claiming;
- amend two items for non-invasive treatment for benign prostate hyperplasia (37204 and 37205) to correct typographical errors;
- insert two new items (41768 and 41769) for the insertion of bioabsorbable nasal implants;
- make minor administrative amendments to two orthopaedic items (49564 and 49565); and
- amendment to orthopaedic item 50654 to clarify anaesthesia requirements for the service.

Part 3 of Schedule 2 of the Regulations will amend the PST to:

- insert new item 66586 to provide pathology testing for quantifying BNP or NT-proBNP in patients with previously diagnosed pulmonary arterial hypertension;
- insert two new items (73313 and 73316) for the detection of measurable residual disease (MRD) in patients with acute lymphoblastic leukaemia (ALL) using quantitative molecular assay (qPCR);
- amend pathology item 73410 to include carrier testing of individuals with normal red cell indices if their reproductive partner has been diagnosed with a heterozygous 2-gene deletional alpha thalassemia; and
- amend items 73410, 73411, 73412 and 73413 to allow for testing of reproductive couples in either order.

### **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

The Regulations maintain the rights to health and social security and the right of equality and non-discrimination by ensuring access to publicly subsidised medical services that are clinically relevant and cost-effective as intended. The Regulations also advance the rights to health and social security and the right of equality and non-discrimination by introducing new services which will be available as publicly subsidised medical services.

### **Conclusion**

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

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