EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2024 Measures No. 4) 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).

The *Health Insurance Regulations 2018* (HIR) provide the overarching policy framework supporting the provision of appropriate Medicare services. For the purposes of paragraph 10(2)(aa) of the Act, section 28 of the HIR prescribes items that have a Medicare benefit equal to 100 per cent of the fee in respect of the service.

Purpose

The purpose of the *Health Insurance Legislation Amendment (2024 Measures No. 4) Regulations 2024* (the Regulations) is to amend the DIST, GMST, PST and HIR from 1 November 2024. The Regulations will introduce and amend Medicare Benefits Schedule (MBS) items as agreed to in the 2023-24 Budget, 2023-24 Mid-Year Economic and Fiscal Outlook (MYEFO) and the 2024-25 Budget. Additionally, the Regulations will implement administrative and machinery changes to the GMST, PST and HIR. Further detail can be found in the Attachment.

Schedule 1 of the Regulations will implement the following changes to the DIST as announced in the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure:

- New positron emission tomography/computerised tomography for the evaluation of treatment response and recurrence for patients with rare and uncommon cancers;
- Amendment to magnetic resonance imaging (MRI) item 63476 to include use for the restaging and follow up of rectal cancer;
- One-off fee increases for non-PET nuclear medicine items in subgroup 1 of Group I4; and
- Schedule fee reduction for computed tomography items in Group I2 of the DIST.

Schedule 2 of the Regulations will make amendments to the GMST in line with changes announced in the 2024-25 Budget and in 2023-24 MYEFO. This includes:

- Administrative changes to remove references to incorrect items in various item descriptors and clauses;
- Amendment to item 22002 and related clauses to allow for intraoperative cell salvage (blood collection) and transfusion services;
- Consequential amendments to the GMST following the introduction of six new telehealth psychiatry items on 1 November 2024;
- Amendment to item 90300 to allow provision of the service in conjunction with intermediate or low surgical risk Transcatheter Aortic Valve Implantation (TAVI) services;
- Amendments to various radiation oncology services listed in Group T2 to address issues raised following implementation of new and amended radiation oncology items on 1 July 2024;
- Incorporation of item 31227 into the GMST;
- Minor amendments to 32135 and 32139 for the treatment of haemorrhoids;
- Amendment to item 45614 to allow the service to be provide out-of-hospital;
- Amendment to vertebroplasty item 35401 to allow additional appropriately trained clinicians to provide the service; and
- Miscellaneous administrative amendments to the GMST to align legislation with existing policy authority.

Schedule 3 of the Regulations will implement the following changes to the PST as announced in the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure:

- New item 66829 for N-Terminal-pro Brain Natriuretic Peptide (NT-proBNP) or BNP testing to aid in the diagnosis of patients with suspected heart failure in a non-hospital setting;
- Amendment to item 73343 for 17p deletion testing of chronic lymphocytic lymphoma patients to remove reference to test methodologies;
- Amendment to address typographical error in item 73410.
- Schedule fee increase for item 73420 for Rhesus D non-invasive prenatal testing (NIPT) of non-alloimmunised patients and amendment to item 73421 to allow for testing of patients with multiple birth pregnancies;
- Amendment to items 73424, 73434 and 73422 to clarify policy intent and specify the purposes of particular types of genetic testing for various neuromuscular conditions;

- Amendment to item 73429 for somatic gene testing to remove specification of a test methodology;
- Amendment to item 73441 for genetic testing for childhood hearing loss; and
- Amendment to item 73451 for reproductive carrier testing for cystic fibrosis, spinal muscular atrophy, and fragile X syndrome.

Schedule 4 of the Regulations will amend the HIR to make administrative changes following changes announced in the 2023-24 Budget and 2024-25 Budgets. This includes:

- Consequential amendments following the removal of collaborative arrangements for participating nurse practitioners and participating midwives; and
- Expansion of ultrasound services for nurse practitioners to assist with the prescription of MS2-Step.

Consultation

A number of medical professional organisations were consulted regarding the Regulations as part of the MBS Review Taskforce and the MSAC process. These organisations include the Australian Diagnostic Imaging Association, Australian Medical Association, Australian Pathology, Australian Society of Medical Imaging and Radiation Therapy, Cancer Council Australia, General Practice and Primary Care Clinical Committee, Public Pathology Australia, Royal Australian College of Physicians, Royal College of Surgeons, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Royal Australian College of General Practitioners and the Royal College of Pathologists Australasia, 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 administrative 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*.

The Regulations will commence on 1 November 2024.

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

ATTACHMENT

Details of the *Health Insurance Legislation Amendment (2024 Measures No. 4) Regulations 2024*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2024 Measures No. 4) Regulations 2024* (the Regulations).

Section 2 – Commencement

This section provides for the Regulations to commence on 1 November 2024.

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 – Diagnostic imaging services

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

Item 1 introduces new positron emission tomography/computerised tomography (PET/CT) item 61614 for the evaluation of treatment response and recurrence for patients with rare and uncommon cancers. The new service was recommended by the Medical Services Advisory Committee (MSAC) at its March 2023 meeting in which the MSAC acknowledged the clinical need for testing and monitoring of patients with rare and uncommon cancers.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the new item was undertaken with the:

- Australian Diagnostic Imaging Association (ADIA);
- Royal Australian and New Zealand College of Radiologists (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 (AANMS);
- Australian and New Zealand Society of Nuclear Medicine (ANZSNM);
- Rural Alliance in Nuclear Scintigraphy (RAINS);
- NeuroEndocrine Cancer Australia;
- Myeloma Australia;
- Medical Oncology Group of Australia (MOGA);
- Clinical Oncology Society of Australia (COSA);

- 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 (ANZCHOG);
- Genetic Alliance Australia;
- Cancer Council Australia;
- Rare Cancers Australia;
- Syndromes Without a Name;
- Genetic Support Network Victoria;
- Australian and New Zealand Society of Nephrology;
- Australian Society of Medical Imaging and Radiation Therapy (ASMIRT);
- Kidney Health Australia;
- Consumers Health Forum of Australia;
- Tuberous Sclerosis Australia;
- Urological Society of Australia and New Zealand;
- Australian Genomic Cancer Medicine Centre (AGCMC); and
- Human Genetics Society of Australia and Rare Voices Australia.

Item 2 amends pelvic magnetic resonance imaging (MRI) item 63476 to allow for MRI scans of the pelvis for restaging and follow-up of rectal cancer, which are not currently allowed for under the item. Currently, item 63476 only provides patients with access to MRI scans of the pelvis for initial staging of rectal cancer.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS) measure*.
Consultation on the amendment was undertaken with the:

- RANZCR;
- ADIA;
- Abdominal Radiology Group of Australia and New Zealand;
- Colorectal Surgical Society of Australia and New Zealand (CSSANZ);
- ANZCHOG;
- Australian College of Rural and Remote Medicine;
- AGCMC;
- AMA;
- ASMIRT;
- Cancer Council Australia;
- COSA;
- Consumer Health Forum;
- Endocrine Society of Australia;
- Garvan Institute of Medical Research;
- Gastroenterological Society of Australia (GESA);
- General Surgeons Australia;
- MOGA;
- Private Cancer Physicians of Australia;
- RACP;
- RACS;
- RACGP; and

- Bowel Cancer Australia.

Item 3 reduces the schedule fee for computed tomography (CT) services by 2% from 1 November 2024. The fee reduction will apply to all items in Group I2 of the DIST.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. No consultation was undertaken regarding the schedule fee reduction for CT services, as the change forms part of a broader measure to reinvest in other areas of diagnostic imaging and is intended to manage expenditure growth of CT while supporting patients to access more appropriate imaging modalities.

Item 4 provides a one-off schedule fee increase of 3.5% to non-positron emission tomography (PET) nuclear medicine imaging items in the DIST from 1 November 2024. The schedule fee increase will apply to all items in Subgroup 1 of Group I4 of the DIST.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the schedule fee increases for non-PET nuclear medicine services was undertaken with the AANMS, ANZSNM, RAINS and RANZCR.

Schedule 2 – General medical services

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

Item 1 amends subparagraph 1.1.5(1)(b)(i) of the GMST to replace a reference to an existing item range, "735 to 758", with "735, 739, 743, 747, 750, 758". The existing item range listed in subparagraph 1.1.5(1)(b)(i) incorrectly includes items that are not for multidisciplinary case conference services and the updated subparagraph will specify for the purposes of items 735, 739, 743, 747, 750 and 758, ***multidisciplinary case conferencing team*** must include a medical practitioner, at least two other members and may also include a family member of the patient.

Consultation was not undertaken for this change as it is administrative and machinery in nature.

Item 2 inserts a new note at the end of clause 1.2.9 of Schedule 1 to specify that paragraph (h) of the clause does not apply to a service to which item 22002 applies. Paragraph 1.2.9(h) provides that an item in Schedule 1 of the GMST does not apply to a service described in the item if the service is rendered to a patient at the same time as, or in connection with, an injection of blood or a blood produce that is autologous. The new note is intended to remove the requisite for blood to be homologous for the purpose of blood injections under item 22002 (refer to **item 27** of Schedule 2 of the Regulations).

This change relates to changes announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the amendments was undertaken with the Australian Society of Anaesthetists.

Items 3 and 5 amends items 231, 232, 729 and 731 to remove references to items "735 to 758" and replace them with references to items "735, 739, 743, 747, 750 or 758". The existing item ranges listed in these items were intended to prevent claiming of 231, 232, 729 and 731 on the same occasion as a multidisciplinary case conference service, however, the item ranges include items that are not for multidisciplinary case conference services. Accordingly, these changes will update the item descriptors for items 231, 232, 729 and 731 to remove items that are not for multidisciplinary case conference services from the co-claiming restrictions. Consultation was not undertaken for these changes as they are administrative and machinery in nature.

Item 4 amends items 296, 297 and 299 to make consequential amendments following the introduction of six new telehealth psychiatry items. The new telehealth psychiatry items will be implemented through an amendment to the *Health Insurance (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021* on 1 November 2024. This change will add reference to new telehealth items 92478, 92479, 92480, 92481, 92482 and 92483 to the restriction specified in items 296, 297 and 299 to provide that a service to which item 296, 297 or 299 applies is not applicable if a service under any of the new telehealth items has been provided in the preceding 24 months.

The introduction of the telehealth psychiatry items was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on this change was undertaken with the Private Healthcare Australia (PHA) and Australian Health Service Alliance (AHSA) who had both raised concerns about the new items. Following consultation, the PHA and AHSA agreed to work with the Department during the 2-year implementation period to manage any concerns. Additionally, consultation was undertaken with the Australian Private Hospital Association (AHPA) and the Royal Australian and New Zealand College of Psychiatrists, who were both supportive of the new telehealth psychiatry items.

Item 6 makes administrative amendments to subclauses 2.22.1(3) and (4) to address a typographical error in the subclauses. The item replaces incorrect references to item "729" with references to item "792". Consultation was not undertaken for these changes as they are administrative and machinery in nature.

Item 7 amends item 90300 to allow cardiothoracic surgeons to provide standby surgical back up for non-cardiac surgeons undertaking transcatheter aortic valve implantation (TAVI) services described in items 38514 and 38522. This amendment will provide increased safety for patients if complications occur during intermediate or low surgical risk TAVI services. Minor amendments to items 38514 and 38522 will also be made through amendments to the *Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Determination 2018* to align the items with policy intent.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicate – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the amendments was undertaken with the Australian & New Zealand Society of Cardiac & Thoracic Surgeons and the Cardiac Society of Australia and New Zealand.

Item 8 to 25 of Schedule 2 of the Regulations make amendments to radiation oncology services listed in Group T2 to address issues raised following implementation of new and amended radiation oncology items on 1 July 2024.

The amendments to radiation oncology services align the services with original policy intent, as announced in the 2023-24 Mid-Year Economic and Fiscal Outlook under the *An Effective and Clinically Appropriate Medicare* measure. Consultation on these amendments was undertaken with RANZCR, Australasian College of Physical Scientists and Engineers in Medicine, ASMIRT, Radiation Therapy Advisory Group, AMA, Cancer Voices NSW, GenesisCare, ICON and an independent adviser.

Item 8 repeals clause 5.3.1 which specifies a derived fee for item 15954. Repealing clause 5.3.1 will support the removal of the derived fee for item 15954 from 1 November 2024 (refer to **item 23** of Schedule 2 of the Regulations).

Item 9 amends megavoltage planning items 15906 and 15908 to remove language restricting use of the item for treatment using specific technology, specifically, multi-leaf collimation. Since initial implementation of items 15906 and 15908 on 1 July 2024, the Department has received clinical advice confirming it is sometimes appropriate to undertake radiation therapy planning under item 15906 or 15908 without multi-leaf collimation. This information was included in the item descriptors on 1 July 2024 as guidance and was not intended to restrict use to only services where this specific technology. Accordingly, these changes are intended to align items 15906 and 15908 with the original policy intention of the services.

Items 10, 12, 14, 16 and 18 will update four megavoltage treatment items (15938, 15940, 15492 and 15944) and three replanning items (15912, 15916 and 15922) to remove specific references to the corresponding planning items (15910, 15914, 15918 and 15920). The references were included in the descriptors as a clinical guide and should be removed to align the items with original policy intention.

Since implementation of these items on 1 July 2024, the Department has been made aware that the specific reference to the corresponding planning item in each of the treatment and replanning items inadvertently restricts claiming of the items where patients may require access to treatment and replanning items for lower-level doses than specified in an initial planning item. To address this issue, these changes insert “at a level that is equivalent to or higher than that” into the treatment and replanning items to specify that Medicare benefits are payable for patients claiming treatment and replanning items at a different dosage level than that specified in their initial planning item.

Items 11, 13, 15, 17, 19, 20 and 21 will update megavoltage treatment items 15930, 15932, 15934, 15936, 15940, 15942, 15944, 15946 and 15948 to remove claiming frequency restrictions from the item descriptors. The restrictions as introduced on 1 July 2024 have inadvertently prevented practitioners from providing multiple treatments to the same tumour site on the same day where it is clinically relevant to do so. This change will align the items with original policy intention.

Item 22 removes a co-claiming restriction from item 15952 with 15954 in line with amendments to item 15954 (refer to **item 23** of Schedule 2 of the Regulations).

Item 23 updates the schedule fee of item 15954 to remove a derived fee and replace it with a flat fee of $22.00. The removal of the derived fee addresses concerns that the derived fee as currently specified in clause 5.3.1 of Schedule 1 of the GMST does not align with the initial policy intention of the service and may be confusing for providers.

Additionally, this change amends the item descriptor of item 15954 to clarify that the item is applicable for each additional anatomical site following delivery to one anatomical site treated under item 15952.

Item 24 amends item 15960 for brachytherapy treatment to the surface of the body to include the construction of surface moulds. Pre-implementation review of the item descriptor for item 15960 identified that the construction of surface moulds was inadvertently omitted from the item at initial time of implementation. This change removes "to treat intracavitary, intraoral or intranasal site," from the item descriptor to align the service with original policy intention.

Item 25 amends brachytherapy planning and replanning items to remove the restriction "Applicable once per course of treatment". This restriction as introduced on 1 July 2024 inadvertently restricts clinically appropriate planning and replanning services.

Item 26 inserts new clause 5.9.4A into Schedule 1 of the GMST to specify that paragraph 1.2.9(h) of the GMST does not apply in relation to a service to which item 22002 applies (refer to **item 27** of Schedule 2 of the Regulations).

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the amendments was undertaken with the Australian Society of Anaesthetists.

Item 27 amends item 22002 to remove the word "homologous" from the descriptor to remove a requisite for blood to be homologous for the purpose of blood injections under the item. This change will allow for intraoperative cell salvage and transfusion services to be available under the item. This change is supported by changes as listed in **item 2 and 26.**

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the amendments was undertaken with the Australian Society of Anaesthetists.

Item 28 inserts item 31227 of the *Health Insurance (Section 3C General Medical Services – Removal of Single Tumour, Lipoma or Cyst) Determination 2023* (the Removal of Tumour, Lipoma or Cyst Determination) into the GMST. Item 31227 for the removal of a single tumour, lipoma or cyst was introduced on 1 July 2023 as part of the implementation of the Government's response to recommendations from the MBS Review Taskforce relating to plastic and reconstructive surgery. The Removal of Tumour, Lipoma or Cyst Determination will be repealed immediately following the commencement of this change.

No consultation was undertaken regarding the change to incorporate item 31227 into the GMST as the amendment is administrative and machinery in nature.

Items 29 and 30 will make minor amendments to items 32135 and 32139 for the treatment of haemorrhoids. Item 32135 will be amended to clarify that topical energy therapies are non-operative treatment for haemorrhoids, which can be provided under the item. Topical energy therapies are already being provided under item 32135 and the purpose of the amendment is to provide certainty about use of the item.

Item 32139 will be amended to expand its use for the operative treatment of all degrees of symptomatic haemorrhoids, not just third and fourth-degree haemorrhoids. This amendment will address a gap in services that arose following changes made on 1 July 2022 to simplify items available for the treatment of haemorrhoids. These changes were based on recommendations from the MBS Review Taskforce, informed by its Colorectal Surgery Clinical Committee. Following these changes, the Department was informed of concerns that there was no longer an item available for the operative treatment of first and second-degree haemorrhoids, previously provided under item 32138, which was deleted on 1 July 2022. The amendment to item 32139 will address this gap and ensure patients with first and second-degree haemorrhoids who require operative treatment will have access to services under the MBS.

These changes were announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the amendments was undertaken with key stakeholders including representatives from CSSANZ, RACS, GESA, private hospitals, and private health insurers.

Item 31 amends item 35401 to allow appropriately trained clinicians to provide the service described in the item. This change allows a specialist or consultant physician practicing in one of the following specialities to provide services under item 25401, if they have undertaken appropriate training for the vertebroplasty procedure:

- diagnostic radiology;
- neurosurgery;
- neurology;
- orthopaedic surgery.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the change was undertaken with the RANZCR, Australian and New Zealand Society of Neuroradiology, Australian and New Zealand Association of Neurologists, Spine Society of Australia/the Australian Orthopaedic Association and the Neurosurgical Society of Australasia.

Item 32 amends item 45614 to allow the services under the item to be provided in out-of-hospital settings. Following 1 March 2022 amendments to item 45614 to make the item an in-hospital only service, the Department was made aware that the items is predominantly provided by ophthalmology outside of a hospital setting. The Department was informed that it may be necessary to perform some of these procedures outside of the hospital setting in a well-equipped procedure room without compromising patient safety. The amendment will remove the "(H)" hospital marker from the descriptor of item 45614.

The change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the amendment was undertaken with the Royal Australian and New Zealand College of Ophthalmologists and the Continuous Improvement Committee for Plastic and Reconstructive Surgery.

Item 33 amends clause 7.1.1 of the GMST to repeal the definition of "***amount under clause 5.3.1"*** as the definition will no longer be relevant following removal of clause 5.3.1 on 1

November 2024 (refer to **item 60**), and repeal of the definitions of ***completes the minimum requirements for a cycle of care of a patient with established diabetes mellitus***" and "***completes the minimum requirements of the Asthma Cycle of Care***" as they are definitions for the purposes of clauses that no longer exist in the GMST.

No consultation was undertaken on these changes as they will be administrative and machinery in nature.

Schedule 3 – Pathology Services

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

Item 1 inserts new item 66829 for brain natriuretic peptide (BNP) or N-Terminal-pro brain natriuretic peptide (NT-pro-BNP) laboratory testing for the diagnosis of patients with suspected but uncertain heart failure in non-hospital settings into the PST. Diagnosis of heart failure can be difficult as symptoms of heart failure are non-specific, and patients are often suffering from co-morbidities. Patients presenting in non-hospital settings with symptoms of heart failure are usually sent to have an echocardiogram test to diagnose the condition.

New item 66829 will allow for BNP or NT-pro-BNP testing to be performed as part of an initial check by a treating medical practitioner. The new item will allow for BNP or NT-pro-BNP testing to be used as a triage to avoid unnecessary echocardiograms and their associated wait times and out-of-pocket costs.

This change was announced as part of the 2024-24 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the new item was undertaken with Lung Foundation Australia, National Heart Foundation of Australia, RACGP, RCPA, RACP, Australian Commission on Safety and Quality in Health Care and Cardiovascular Health Mission.

Item 2 amends item 73343 to remove specification of test methodology to allow for broader use of the item. The amendment will allow patients with chronic lymphocytic leukaemia or small lymphocytic lymphoma to receive testing for 17p chromosomal deletion under the MBS using methodologies not limited to just fluorescence in situ hybridisation (FISH) or genome wide micro-array (GWMA). The amendment responds to advice provided by the sector that Next Generation Sequencing (NGS) is increasingly replacing FISH as a testing methodology.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the amendment was undertaken with Public Pathology Australia (PPA), RCPA and Australian Pathology (AP).

Item 3 amends item 73410 to address a typographical error in the item descriptor and update the word "thalassemia" in subparagraph (c)(i) to reflect the English-Australian spelling of the word, "thalassaemia". No consultation was undertaken on this change as it is administrative in nature.

Items 4 and 5 amend item 73420 to increase the schedule fee to $150.40 to address concerns that services under the item are not commercially viable. Additionally, the amendment

updates the item descriptor to specify requirements for services provided under item 73420. The amendment to item 73420 will allow for Rhesus D (RhD) non-invasive prenatal testing (NIPT) of non-alloimmunised patients.

These changes were announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the amendments were undertaken with RCPA, Australian and New Zealand Society of Blood Transfusion (ANZSBT), PPA and AP.

Item 6 amends item 73421 to expand the eligible patient cohort who can access services listed under the item. The amendment will allow alloimmunised patients with non-singleton pregnancies to be eligible for testing under this item, where currently the item is restricted to alloimmunised patients with singleton pregnancies.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on this amendment was undertaken with RCPA, ANZSBT, PPA and AP.

Items 7, 8 and 10 amend items 73422, 73424 and 73434 to clarify the policy intention of the items and make consequential changes to gene testing services as described in the items.

On 1 November 2022, new items for genetic testing of neuromuscular conditions (NMDs) were introduced for patient's suspected of having NMDs, biological relatives of affected individuals for the purpose of identifying the causative variant or variants and reproductive partners of patients who have been diagnosed with an inherited genetic variant linked to an NMD. However, there are some NMDs caused be specific types of genetic variants that gene panel testing cannot detect. To address this issue, MSAC supported a proposal to introduce two new items (73434 and 73435) for single gene tests (SGTs) for certain NMDs that cannot be detected by a gene panel test from 1 July 2023. Additionally, MSAC was supportive of describing the variant as "detectable" (rather than "detected") by NGS methods.

These changes were announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. No consultation was undertaken for these amendments, as the changes are intended to align items 73422, 73424 and 73434 with existing policy intent, and make consequential changes to clarify the service requirements described in the items.

Item 9 amends pathology item 73429 for somatic gene testing to remove specification of a test methodology to align the item with the original policy intention. The item will be amended so that it no longer requires providers to perform the test in a "single" gene panel, given the test often requires multiple gene panels. The amendment will align item 73429 with other pathology items specified in the PST, which allow a provider to determine the most appropriate test methodology required for the service.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the original introduction of the service was undertaken with AP, PPA, Telethon Kids Institute, Cancer Australia, the Industry Genomics Network Alliance, the Neurosurgical Society of Australasia and Cooperative Trials Group for Neuro-Oncology. Consultation on the amendment to item 73429 was undertaken with the RCPA, PPA and AP.

Item 11 amends item 73441 to remove the requirement for patients to have bilateral hearing loss to access testing under this item to align the service with the original policy intention. The qualifier of "bilateral" will be removed from the item descriptor to allow patients with either unilateral or bilateral moderate, severe, or profound congenital or childhood onset hearing loss to access services under item 73441. The amendment ensures that all eligible patients can access this service under the MBS.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the original introduction of the service was undertaken with:

- Australian Genomics;
- Australasian Newborn Hearing Screening Committee;
- AP;
- Aurora School;
- Centre for Genetics Education NSW Health;
- Deafness Foundation;
- Genetic Undiagnosed and Rare Disease (GUARD) Collaborative Australia;
- Human Genetics Society of Australasia (including its Ethics and Social Issues Committee);
- Neurodevelopmental and Behavioural Paediatric Society of Australasia;
- PPA;
- RCPA; and
- UsherKids Australia.

Consultation on the amendment to item 73441 was undertaken with the RCPA, PPA and AP.

Item 12 amends item 73451 to align the item descriptor with the original policy intention. On 1 November 2023, two new pathology items (item 73451 and 73452) were introduced for genetic testing to determine carrier status of cystic fibrosis, spinal muscular atrophy and fragile X syndrome in people who are planning pregnancy or who are already pregnant and their reproductive partners.

The amendment will add a co-claiming restriction to item 73451 to prevent services under the item from being provided in addition to services described in other similar items, i.e. items 73300, 73305 and 73345 to 73350, to avoid duplicative testing.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the original introduction of the service was undertaken with Cystic Fibrosis Community Care Ltd, Fragile X Alliance Clinic, Fragile X Association of Australia, GUARD Collaborative Australia, Mackenzie's Mission Research Team/Victorian Clinical Genetics Services Reproductive Screening Team, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), RCPA and Spinal Muscular Atrophy (SMA) Australia. Consultation on the amendment to item 73451 was undertaken with the RCPA, PPA and AP.

Schedule 4 – Health Insurance Regulations 2018

Health Insurance Regulations 2018 **(HIR)**

Items 1 to 3 will make consequential changes to the HIR following the removal of the requirements for participating nurse practitioners and participating midwives to have collaborative arrangements in place with a medical practitioner to provide MBS eligible services. The change to the Act was implemented through the *Health Legislation Amendment (Removal of Requirement for a Collaborative Arrangement) Act 2024* and allowed for eligible midwives and nurse practitioners to prescribe Pharmaceutical Benefits Scheme (PBS) medicines and provide certain services under the MBS.

The removal of collaborative arrangements for participating nurse practitioners and participating midwives was announced as part of the 2023-24 Budget under the *Strengthening Medicare* measure. Peak stakeholders including the AMA, Australian College of Nurse Practitioners, Australian College of Midwives and RACGP were consulted through the Independent Review of Collaborative Arrangements and Nurse Practitioner Workforce Plan.

Items 1 and 2 remove the definitions of ***hospital-authorised medical practitioner*** and ***obstetric medical*** practitioner at section 4 of the HIR as they will no longer be relevant following the removal of collaborative arrangements for participating nurse practitioners and participating midwives.

Item 3 will remove Divisions 1 and 2 of Part 2 of the HIR following the removal of collaborative arrangement requirements for participating nurse practitioners and participating midwives. Divisions 1 and 2 of Part 2 of the HIR currently specify the requirements for participating nurse practitioners and midwives who have collaborative arrangements in place, including provisions that specify the elements of a collaborative arrangement and the requirements for record keeping for participating midwives and nurse practitioners.

Item 4 amends the table of items at section 44 of the HIR to allow participating nurse practitioners to request ultrasound imaging services under items 55700, 55704 and 55065 listed in Group I1 of the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* (DIST). This change supports nurse practitioners' ability to prescribe the MS2-Step Medical Abortion Program in line with the Government's objective of affordable and accessible termination services.

This change was announced as part of the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure. Consultation on the change was undertaken with the:

- Australian College of Nurse Practitioners;
- RANZCOG;
- RANZCR;
- RACGP;
- AMA;
- Consumers Health Forum of Australia; and
- Guild Insurance and Berkshire Hathaway Speciality Insurance.

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. 4) 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

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. 4) Regulations 2024* (the Regulations) is to amend the DIST, GMST, PST and HIR from 1 November 2024. The Regulations will introduce and amend Medicare Benefits Schedule (MBS) items as agreed to in the 2023-24 Budget, 2023-24 Mid-Year Economic and Fiscal Outlook (MYEFO) and the 2024-25 Budget. Additionally, the Regulations will implement administrative and machinery changes to the GMST, PST and HIR. Further detail can be found in the Attachment.

Schedule 1 of the Regulations will implement the following changes to the DIST as announced in the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure:

- New positron emission tomography/computerised tomography for the evaluation of treatment response and recurrence for patients with rare and uncommon cancers;
- Amendment to magnetic resonance imaging (MRI) item 63476 to include use for the restaging and follow up of rectal cancer;
- One-off fee increases for non-PET nuclear medicine items in subgroup 1 of Group I4; and
- Schedule fee reduction for computed tomography items in Group I2 of the DIST.

Schedule 2 of the Regulations will make amendments to the GMST in line with changes announced in the 2024-25 Budget and in 2023-24 MYEFO. This includes:

- Administrative changes to remove references to incorrect items in various item descriptors and clauses;
- Amendment to item 22002 and related clauses to allow for intraoperative cell salvage (blood collection) and transfusion services;
- Consequential amendments to the GMST following the introduction of six new telehealth psychiatry items on 1 November 2024;
- Amendment to item 90300 to allow provision of the service in conjunction with intermediate or low surgical risk Transcatheter Aortic Valve Implantation (TAVI) services;
- Amendments to various radiation oncology services listed in Group T2 to address issues raised following implementation of new and amended radiation oncology items on 1 July 2024;
- Incorporation of item 31227 into the GMST;
- Minor amendments to 32135 and 32139 for the treatment of haemorrhoids;
- Amendment to item 45614 to allow the service to be provide out-of-hospital;
- Amendment to vertebroplasty item 35401 to allow additional appropriately trained clinicians to provide the service; and
- Miscellaneous administrative amendments to the GMST to align legislation with existing policy authority.

Schedule 3 of the Regulations will implement the following changes to the PST as announced in the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule (MBS)* measure:

- New item 66829 for N-Terminal-pro Brain Natriuretic Peptide (NT-proBNP) or BNP testing to aid in the diagnosis of patients with suspected heart failure in a non-hospital setting;
- Amendment to item 73343 for 17p deletion testing of chronic lymphocytic lymphoma patients to remove reference to test methodologies;
- Amendment to address typographical error in item 73410.
- Schedule fee increase for item 73420 for Rhesus D non-invasive prenatal testing (NIPT) of non-alloimmunised patients and amendment to item 73421 to allow for testing of patients with multiple birth pregnancies;

- Amendment to items 73424, 73434 and 73422 to clarify policy intent and specify the purposes of particular types of genetic testing for various neuromuscular conditions;
- Amendment to item 73429 for somatic gene testing to remove specification of a test methodology;
- Amendment to item 73441 for genetic testing for childhood hearing loss; and
- Amendment to item 73451 for reproductive carrier testing for cystic fibrosis, spinal muscular atrophy, and fragile X syndrome.

Schedule 4 of the Regulations will amend the HIR to make administrative changes following changes announced in the 2023-24 Budget and 2024-25 Budgets. This includes:

- Consequential amendments following the removal of collaborative arrangements for participating nurse practitioners and participating midwives; and
- Expansion of ultrasound services for nurse practitioners to assist with the prescription of MS2-Step.

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.

Mark Butler

Minister for Health and Aged Care