EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2022 Measures No. 3) Regulations 2022

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

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

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

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

Section 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).

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 provides items that have a Medicare benefit equal to 100% of the fee in respect of the service.

Purpose

The purpose of the *Health Insurance Legislation Amendment (2022 Measures No. 3) Regulations 2022* (the Regulations) is to amend the GMST, the DIST, the PST and the HIR from 1 November 2022.

Changes to Medical Services
Schedule 1 of the Regulations will amend the GMST to make changes to medical services.

Parts 1 to 10 of Schedule 1 of the Regulations will implement the following changes to the GMST as announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure:

- amend eight cardiothoracic surgery items to ensure procedures align with best practice;
- introduce a new item for remote programming of a neurostimulator for deep brain stimulation for Parkinson's disease, essential tremor and dystonia;
- amends six varicose vein services to allow appropriate co-claiming with other venography items;
- introduce two new items for remote monitoring of cardiac internal loop recorders;
- changes to paediatric surgery services;
- introduce a new item for remote reprogramming of a neurostimulator for the management of chronic neuropathic pain;
- amend oculoplastic surgery item 45617 to remove the requirement for visual field testing;
- changes to melanoma excision services;
- amend orthopaedic services to address service gaps and patient safety in response to the MBS Taskforce Review (the Taskforce) recommendations;
- changes to acupuncture services; and
- introduce a new item for cryoablation of renal cell carcinoma.

Part 10 of Schedule 1 of the Regulations will also make amendments to the GMST that are minor and machinery in nature.

Changes to Diagnostic Imaging Services
Schedule 2 of the Regulations will amend the DIST to make changes to diagnostic imaging services.

Part 1 of Schedule 2 of the Regulations will amend obstetric magnetic resonance imaging (MRI) item 63454, introduce a new MRI item (63549) for patients with a multiple pregnancy where fetal abnormality is suspected and introduce a new pelvic MRI item (63563) for the investigation of conditions affecting fertility, including endometriosis. The new pelvic MRI item for the investigation of conditions affecting fertility was announced in the 2022-23 Budget under the *Women's Health Package* measure. The other changes in Part 1 of Schedule 2 of the Regulations were announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure as part of the changes to obstetric and gynaecological diagnostic imaging services.

Parts 2, 4 of Schedule 2 of the Regulations will implement the following changes to the DIST as announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure:

- changes to obstetric and gynaecological diagnostic imaging services;

- a new positron emission tomography (PET) item for initial staging for patients diagnosed with rare and uncommon cancers;
- amending breast magnetic resonance imaging (MRI) item 63464 for patients at high risk of developing breast cancer, raising the age limit from 50 to 60 years of age; and
- amending MRI item 63545 to expand indications from colorectal cancer to include all cancer types that have potentially spread to the liver.

Part 3 of Schedule 2 of the Regulations will remove the requirement for the equipment used for MRI services in regional, remote and rural areas to have a Deed of Undertaking with the Commonwealth to be Medicare eligible. This change was announced in the 2022-23 Budget under the *Guaranteeing Medicare – Supporting patient access to Magnetic Resonance Imaging* measure.

Changes to Pathology Services
Schedule 3 of the Regulations will amend the PST to make changes to pathology services.

Part 1 of Schedule 3 of the Regulations will introduce new genetic testing items for the diagnosis of neuromuscular disorders. These new items were announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure.

Part 2 of Schedule 3 of the Regulations will implement amendments to the National Cervical Screening Program (NCSP) items and other administrative and consequential amendments. Part 2 of Schedule 3 of the Regulations will also amend genetic testing item 73410, which commenced on 1 July 2022, to clarify that patients with beta-thalassaemia can also access genetic testing for the diagnosis of alpha-thalassaemia under item 73410.

Changes to the HIR
Schedule 4 of the Regulations will amend the HIR to make changes to the policy framework supporting the provision of appropriate Medicare services, including administrative amendments to subsection 28(1) to allow specified items to attract a Medicare benefit of 100% and updating references to dental specialities.

Amendments commencing 1 July 2022
On 1 July 2022, the *Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022* (July 2022 MBS Regulations) will apply indexation to the GMST. However, item 195 and clause 2.30.1 of the GMST were not included in these changes in the July 2022 MBS Regulations. Schedule 5 of the Regulations will amend table item 9 in clause 2.1.1 and clause 2.30.1 of the GMST to apply indexation to the fees specified in these clauses, following their omission from the July 2022 MBS Regulations. These changes will commence retrospectively on 1 July 2022.

Consultation
MSAC, the Taskforce and medical professional organisations were consulted on 1 November 2022 changes. There was general support from stakeholders on the changes 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*.

The whole of the Regulations excluding Schedule 5 will commence on 1 November 2022 and Schedule 5 will commence retrospectively on 1 July 2022.

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

ATTACHMENT

Details of the *Health Insurance Legislation Amendment (2022 Measures No. 3) Regulations 2022*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2022 Measures No. 3) Regulations 2022.*

Section 2 – Commencement

This section provides for the whole of the Regulations excluding Schedule 5 to commence on 1 November 2022 and Schedule 5 of the Regulations to commence on 1 July 2022.

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 – General medical services

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

Part 1—Cardiothoracic items

Part 1 of Schedule 1 of the Regulations amends eight cardiothoracic surgery items to ensure these procedures align with best practice. The Australian and New Zealand Society of Cardiac and Thoracic Surgeons requested the changes, which were supported by the Medical Services Advisory Committee (MSAC) Executive.

Item 1 amends cardiothoracic surgery item 38510 to ensure that vessel harvesting (other than harvesting of left internal mammary artery and vein graft material or harvesting of left internal mammary artery or harvesting of vein graft material) may be performed by any medical practitioner for the purposes of of coronary artery bypass surgery. The amendment clarifies that the medical practitioner performing the service under item 38510 does not need to be the same practitioner performing the associated coronary artery bypass surgery.

Items 2 to 9 amend seven items (38513, 38516, 38517, 38555, 38556, 38557 and 38572) for cardiac valve replacement, aortic arch repair, anastomosis creation during coronary artery bypass and appropriate alignment of peripheral arterial cannulation services with aortic procedures.

The change to item 38556 remove the co-claiming restriction between services under item 38603 and services under this item.

The change to item 38572 restrict co-claiming of services under item 38603 with services under this item.

The changes will allow practitioners to provide services under the amended items for advanced procedures that improve clinical outcomes and rectify incongruencies in Medicare benefits for services undertaken on the aortic arch and major heart valves. These changes include amendments to the schedule fees for items 38516, 38517, 38555, 38556 and 38557.

The changes will further incentivise advanced practice and rectify minor unintended consequences following implementation of the MBS Review Taskforce (the Taskforce) recommendations for cardiothoracic surgery on 1 July 2021.

Part 2—Deep brain stimulation

Item 10 introduces a new item (40863) for remote programming of a neurostimulator for deep brain stimulation for Parkinson's disease, essential tremor and dystonia. The new item will provide patients with greater access to services for programming a neurostimulator by removing the need for patients to attend in person when clinically appropriate. It also offers this treatment modality to patients in regional, rural, and remote locations.

This new item was supported by MSAC Executive at their September 2021 meeting. The Movement Disorder Society of Australia and New Zealand (MDSANZ), the Australian and New Zealand Association of Neurologists, the Neurosurgical Society of Australasia, the Neuromodulation Society of Australia and New Zealand, the Australian and New Zealand Society of Neuroradiology, the Royal Australasian College of Surgeons and the Royal Australasian College of Physicians were consulted on this change. These stakeholders largely support this new item.

Part 3—Varicose veins

Items 11 to 16 amend items 32520, 32522, 32523, 32526, 32528 and 32529 for the treatment of varicose veins to enable co-claiming with appropriate venography items. The amendments will ensure that patients receive Medicare benefits for venography services when required during varicose vein interventions.

This change was supported by the MSAC Executive at its meeting on 28 January 2022. Consultation was undertaken with the Australian and New Zealand Society for Vascular Surgery, Private Healthcare Australia (PHA), the Australian Medical Association (AMA), the Australian Private Hospital Association, Ramsay Health Care, Members Health Fund Alliance, Day Hospitals Australia, HAMBS, Australian Health Service Alliance, Consumers Health Forum of Australia, the Royal Australasian College of Surgeons, the Royal Australian and New Zealand College of Radiologists (RANZCR), and the Australian Diagnostic Imaging Association.

Part 4—Cardiac implantable loop recorder devices

Item 17 introduces two new remote items (11736 and 11737) for implanted loop recorders (ILR) monitoring of electrical activity of the heart, continuously storing information as electrocardiograms and recording abnormal activity such as arrhythmias. The new items will provide patients with greater access to ILR monitoring by removing the need for patients to attend in person when clinically appropriate. This change will offer greater access to this treatment modality for patients in regional, rural and remote locations.

This change was supported by the MSAC Executive. Cardiac Society of Australia and New Zealand (CSANZ) and the Australian and New Zealand Society of Cardiac and Thoracic Surgeons were consulted on this change and are largely supportive.

Part 5—Paediatric surgery services

Part 5 of Schedule 1 of the Regulations implements the Taskforce's recommendations for paediatric surgery. The Department of Health conducted a consultation process with relevant paediatric professional groups, including the AMA and Royal Australasian College of Surgeons to further inform the implementation of the Taskforce's recommended changes for paediatric surgery and to mitigate any unintended consequences or barriers for patients. Only minor changes were made following this process, with all groups supporting these recommendations progressing to implementation.

Item 18 introduces two new items for circumcision revision procedures, one for minor surgical repair following a complication (30661) and one for complex surgical repair following a complication (30662). Item 30661 must be performed in conjunction with a service to which an item in Group T7 or T10 applies and cannot be co-claimed with item 45206. Item 30662 cannot be co-claimed with item 37819, 37822, 45200, 45201, 45202, 45203 or 45206. The new items must be required to be performed in-hospital.

Item 19 amends item 43882 for repair of a cloacal exstrophy (a rare birth defect) to specify that this service can only be performed in hospital because of its complexity. The change will improve safety and health outcomes by ensuring patients receive services that align with current best practice guidelines.

Items 20 and 21 amend item 44108 for the repair of inguinal hernias in children younger than 12 months of age to reflect the complexity of this procedure and more accurately define the service. These amendments include increasing the schedule fee for item 44108 to $638.35. The changes will improve safety and health outcomes by ensuring patients receive services that align with current best practice guidelines.

Items 22 to 24 amend item 44111 for repair of an obstructed or strangulated hernia to reflect the complexity of this procedure and more accurately define this service, and to specify that this service can only be performed in hospital because of its complexity. These amendments include increasing the schedule fee for item 44111 to $716.45. The changes will improve safety and health outcomes by ensuring patients receive services that align with current best practice guidelines.

Items 25 and 26 amends item 44114 for the repair of inguinal hernias in children younger than 12 months of age to reflect the complexity of this procedure and more accurately define the service. These amendments include increasing the schedule fee for item 44114 to $716.45. The changes will improve safety and health outcomes by ensuring patients receive services that align with current best practice guidelines.

Part 6—Chronic neuropathic pain

Item 27 introduce a new item 39141 for remote reprogramming of a neurostimulator for the management of chronic neuropathic pain. The amendment will provide patients with access to a remote service for the adjustment of their neurostimulator if this is considered clinically appropriate by the treating practitioner.

The MSAC Executive Committee supported the listing of this remote service item at its meeting on 24 September 2021. Consultation has been undertaken regarding this item with the Australian and New Zealand College of Anaesthetists, AMA, Royal Australasian College of Surgeons, and the Neuro-modulation Society of Australia and New Zealand.

Part 7—Oculoplastic surgery

Item 28 amends item 45617 to remove the reference to visual field testing and requirement that a visual field defect must be confirmed by an optometrist or ophthalmologist. The amendment will ensure item 45617 does not unintentionally exclude patients requiring appropriate treatment in response to advice from practitioners that visual field testing does not consistently distinguish between patients who do and do not qualify for the service.

This change to item 45617 was proposed by the Continuous Improvement Committee for Plastic and Reconstructive Surgery, which was established following the disbanding of the Medicare Claims Review Panel (MCRP).

Part 8—Melanoma services

Part 8 of Schedule 1 of the Regulations implements amendments to melanoma excision services. These changes to melanoma services have been developed by the Department of Health in collaboration with the Dermatology and Skin Services Advisory Group (DASAG), containing representatives from the AMA, Australasian College of Dermatologists (ACD) and Australian Society of Plastic Surgeons (ASPS). The AMA, ACD and ASPS support the changes to melanoma excision services.

Items 29 to 37 amends items 31371, 31372, 31373, 31374, 31375 and 31376 to ensure clarity regarding appropriate claiming for melanoma excision services.

Item 38 introduces seven new items for the surgical excision and repair of clinically suspected melanoma. These new items are for clinically suspected melanoma services in the first instance, pending histological confirmation of malignancy.

New items 31377 and 31378 are for surgical excision of clinically suspected melanoma from the nose, eyelid, eyebrow, lip, ear, digit or genitalia, or from a contiguous area.

New items 31379 and 31380 are for surgical excision of clinically suspected melanoma from the face, neck, scalp, nipple-areola complex, distal lower limb (distal to, and including, the knee) or distal upper limb (distal to, and including, the ulnar styloid).

New items 31381, 31382 and 31383 are for surgical excision of clinically suspected melanoma from a part of the body not covered by item 31377, 31378, 31379 or 31380.

Part 9—Orthopaedic services

Part 9 of Schedule 1 of the Regulations amends orthopaedic services in subgroup 15 of Group T8 in response to recommendations from the Final Medicare Benefits Schedule Review Taskforce Report from the Orthopaedic Clinical Committee 2019 (MBS Review Orthopaedics Report) and feedback from the orthopaedic sector as part of the early post implementation review of changes to the orthopaedic surgery items that took effect on 1 July 2021.

Item 39 introduce two new generic orthopaedic items (47790 and 47791) to address potential service gaps following changes made to orthopaedic services on 1 July 2021, and one new item (47792) for stabilisation of the scapula-thoracic joint or the acromio-clavicular joint. Services under item 47792 include procedures used in the treatment of winged scapula, which were previously available under generic joint stabilisation items 50106 or 50109, prior to 1 July 2021. The changes will ensure patients receive benefits for the listed services.

Item 40 amends item 47967 to allow the service to be used for the restoration of elbow function. The change will allow patients to access MBS services for restoration of elbow function by major muscle tendon transfer.

Item 41 amends item 49212 to allow patients to access MBS services for arthrotomy of the wrist in the absence of infection.

Item 42 amends items 49215 and 49236 to allow for wrist ligament or capsule reconstruction to be performed via open or arthroscopic approach and to allow stabilisation of the soft tissue of the distal radioulnar joint to be performed via open or arthroscopic approach respectively. The amendment will ensure patients have access to services that reflect contemporary clinical practice.

Item 43 amends item 49734 to allow patients to access MBS services for arthrotomy of the hindfoot, midfoot or metatarsophalangeal joint in the absence of infection.

Part 10—Miscellaneous amendments

Item 44 makes a minor consequential amendment to subclause 1.2.6(1) to remove a reference to item 173 (refer to **item 47** in Part 10 of Schedule 1 for item 173).

Item 45 amend subclauses 1.2.6(1) and 1.2.7(1) to insert Repetitive Transcranial Magnetic Stimulation (rTMS) items 14216 and 14219. Clauses 1.2.6 and 1.2.7 provide requirements for personal attendances by medical practitioners. This change is administrative in nature and will ensure clauses 1.2.6 and 1.2.7 clearly apply to rTMS items 14216 and 14219.

Item 46 repeals and replaces clause 2.10.1 to provide a restriction on treatment time for acupuncture items 193 to 199. The amendments to items 193, 195, 197 and 199 (refer to **items 48 to 55** in Part 10 of Schedule 1 of the Regulations) make the current clause 2.10.1, which provides the meaning of qualified medical acupuncturist, redundant. The new clause 2.10.1 clarifies that treatment time for the specified services only includes the time between application and removal of the acupuncture stimuli if the medical practitioner personally attends the patient during that time to provide another consultation service. The change will prevent inappropriate claiming of longer duration items where a medical practitioner is not physically present with the patient and implements the Government's response to recommendations from the Taskforce regarding acupuncture services.

Item 47 repeals acupuncture item 173, which does not require the clinician to be appropriately credentialled to provide acupunctures services. The change implements the Government's response to recommendations from the Taskforce regarding acupuncture services.

Items 48 to 55 amend acupuncture items 193, 195, 197 and 199 to allow all appropriately credentialled medical practitioners, in addition to general practitioners, to provide acupuncture services. The change implements the Government's response to recommendations from the Taskforce regarding acupuncture services.

Item 56 makes a minor amendment to item 11614 to remove a reference to repealed item 55229. Item 55229 ceased on 30 April 2020 when the Diagnostic Imaging Services Table (DIST) was remade in the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 1) 2020*. This change is administrative in nature.

Item 57 repeals Division 2.9 of Part 2 of Schedule 1, which contains consultation items used for calculating the Practice Incentives Program Asthma, Cervical Screening and Diabetes incentive payments that ceased on 31 July 2019. Medical practitioners working in general practice will continue to be able to render time tiered consultation services under the relevant items in Groups A1, A2 and A7 (subgroup 2 and 10), A22 and A23; and for urgent attendances under the items in Group A11.

Item 58 introduces a new item for cryoablation of renal cell carcinoma (36530). The change will support providers of urologist specialist services to treat patients with biopsy confirmed renal cell carcinoma less than or equal to 4 cm, not suitable for partial nephrectomy (PN), using cryoablation.

MSAC recommended this new item in response to application 1597 at their meeting on 26-27 November 2020. Consultation was undertaken with the Royal Australasian College of Surgeons, Australia and New Zealand Society of Nephrology, RANZCR, Urological Society of Australia and New Zealand and Kidney Health Australia and

the feedback received was supportive of MBS listing of cryoablation for the proposed patient cohort population.

Item 59 makes a minor amendment to item 38417 to fix a typographical error, replacing "I5" with "15".

Item 60 makes a minor amendment to subclause 5.10.7(2) to remove a reference to repealed items 60010, 60073, 60076 and 60079. Item 60010, 60073, 60076 and 60079 ceased on 30 April 2020 when the DIST was remade in the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 1) 2020*. This change is administrative in nature.

Item 61 makes a minor amendment to item 35412 to remove a reference to repealed items 60010, 60073, 60076 and 60079. Item 60010, 60076 and 60079 ceased on 30 April 2020 when the DIST was remade in the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 1) 2020*. This change is administrative in nature.

Item 62 amends gynaecology items 35657, 35673 and 35726 to clarify the co-claiming restrictions for these services to ensure these items align with the Taskforce's recommendations, following the implementation of the implemented the Government's response to recommendations from the Taskforce regarding gynaecology services by the *Health Insurance Legislation Amendment (2021 Measures No. 4) Regulations 2021* on 1 March 2022.

Item 63 removes a reference to item 73073 (refer to **item 5** in Part 2 of Schedule 3 of the Regulations) from the definition of ***cervical screening service*** in clause 7.1.1.

Item 64 repeals the definition of ***qualified medical acupuncturist*** in clause 7.1.1, which the amendments to items 193, 195, 197 and 199 (refer to **items 48 to 55** in Part 10 of Schedule 1 of the Regulations) makes redundant.

Schedule 2 – Diagnostic imaging services

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

Part 1—Pelvic MRI

Item 1 amends clause 2.5.7 to include new item 63563 (refer to **item 2** in Part 1 of Schedule 2 of the Regulations) in the meaning of ***scan*** for the purposes of magnetic resonance imaging (MRI) services.

Items 2 to 4 amend obstetric MRI item 63454 to expand the eligible patient cohort to include all patients with suspected fetal abnormalities and ensure consistent language used with this item and new mirror MRI item 63549 for multiple pregnancies (refer to **item 5** in Part 1 of Schedule 2 of the Regulations).

Item 5 introduces a new obstetric MRI item (63549) for patients with a multiple pregnancy where fetal abnormality is suspected and a new pelvic MRI item (63563) for conditions that affect fertility.

New item 63549 mirrors existing obstetric MRI item (63454) for singleton pregnancies, with a higher schedule fee. The new item will benefit patients who require this investigation, with the higher fee helping to reduce the financial pressure of pregnancy for patients and their families. This new item was recommended by MSAC at its Executive meetings in August and October 2021. A number of organisations have been consulted and RANZCR, the Australasian Sonographers Association (ASA) and Australasian Society for Ultrasound in Medicine (ASUM) are supportive of the change.

New item 63563 was recommended by the Diagnostic Imaging Clinical Committee (DICC) of the Taskforce. The change will provide patients experiencing infertility with access to services for MRI of the pelvis. Pelvic MRI is the preferred imaging modality for investigating congenital abnormalities of the uterus (Mullerian duct anomalies), for identifying rectal involvement of endometriosis and for identifying the cause of recurrent implantation failure through in vitro fertilisation (IVF).

Item 6 amends clause 3.1 to include new item 63563 (refer to **item 2** in Part 1 of Schedule 2 of the Regulations) in the definition of ***scan***. Clause 3.1 provides that ***scan*** has the meaning given by 2.5.7.

Part 2—Obstetric and gynaecological services

Part 2 of Schedule 2 of the Regulations implements changes to obstetric and gynaecology services recommended by MSAC at its Executive meetings in August and October 2021. A number of organisations have been consulted and RANZCR, The Australasian Sonographers Association (ASA) and Australasian Society for Ultrasound in Medicine (ASUM) are supportive of the changes.

Items 7 and 8 amend clause 2.1.4, which provides limitations for obstetric and gynaecological ultrasound services. The changes will provide that subsection (1), which prevents claiming of the specified items more than three times per pregnancy, does not apply to item 55758, and that subsection (2), which prevents claiming of the specified items more than once per pregnancy, applies to items 55742 and 55743.

Items 9 and 10 amend clause 2.1.5, which provides requirements for referrals and clinical notes in relation to obstetric and gynaecological ultrasound services. The changes insert new ultrasound items 55740, 55742 and 55757 (refer to **item 46** in Part 2 of Schedule 2 of the Regulations) in subclause 2.1.5(1) and new ultrasound items 55741, 55743 and 55758 (refer to **item 46** in Part 2 of Schedule 2 of the Regulations) in subclause 2.1.5(3).

Items 11 to 45 amend 14 existing obstetric ultrasound items to prevent inappropriate co-claiming with new obstetric ultrasound items (refer to **item 46** in Part 2 of Schedule 2 of the Regulations) and ensure consistent language in obstetric ultrasound items.

Item 46 introduces six ultrasound items (55740, 55741, 55742, 55743, 55757 and 55758) for:

- monitoring pregnancies at risk of premature delivery;

- examining the morphology (size, shape and other characteristics) of foetuses in multiple pregnancies;
- measuring the nuchal translucency of foetuses of multiple pregnancies to determine the risk of chromosomal abnormalities; and
- monitoring pregnancies with suspected fetal abnormalities.

The change will help improve the health outcomes of pregnant women and the successful birth of their babies at term.

Items 47 to 78 amend eight existing obstetric ultrasound items to prevent inappropriate co-claiming with new obstetric ultrasound items (refer to **item 48** in Part 2 of Schedule 2 of the Regulations) and ensure consistent language in obstetric ultrasound items.

Item 79 amends clause 2.5.9 to remove a claiming limitation for item 63454 of once per pregnancy (refer to **items 2 to 4** in Part 1 of Schedule 2 of the Regulations).

Part 3—Magnetic resonance imaging and magnetic resonance angiography services

Items 80 to 85 amend the DIST to remove the requirement for the equipment used for MRI services in regional, remote and rural areas to have a Deed of Undertaking with the Commonwealth to be Medicare eligible. The change will increase competition and provide additional patient access and choice, assist in reducing out-pocket expenses for patients and reduce red tape for MRI service providers through no longer having to manage Deeds of Undertaking.

Item 86 introduces the definition of ***Modified Monash 1 area***. Modified Monash 1 area will be defined as an area that is not a Modified Monash 2 to 7 area.

Part 4—Miscellaneous amendments

Item 87 amends subclause 1.2.18(3) to insert item 63549. The change will provide that the bulk-billing incentive under clause 1.2.18 does not apply to item 63549.

Item 88 introduces a new item (61612) for positron emission tomography (PET) for initial staging for patients diagnosed with rare and uncommon cancers who are considered suitable for active therapy. The change will enable PET to be used in relation to all fluorodeoxyglucose F-18 (FDG) avid tumours, regardless of the origin or site of the cancer and will lead to improved outcomes for patients with rare and uncommon cancers by assisting with better staging for the management of the cancer.

Item 61612 can only be claimed once per cancer diagnosis. The service must be provided by nuclear medicine specialists who meet the eligibility requirements of the DIST.

The RANZCR, Australian Diagnostic Imaging Association (ADIA), Australian and New Zealand Society of Nuclear Medicine (ANZSNM) and Medical Oncology Group of Australia (MOGA) have been consulted and are supportive of the changes.

Item 89 amends breast MRI item 63464 to expand the patient cohort from patients younger than 50 years of age to patients younger than 60 years of age. This change will ensure patients at high risk of breast cancer continue to have access to breast MRI services up to the age of 60 and was recommended by the Taskforce and supported by MSAC at its November 2021 meeting.

A number of organisations have been consulted and RANZCR, ADIA, Breast Surgeons of Australia & New Zealand, and MOGA are supportive of the change.

Items 90 and 91 make a minor administrative amendment, moving clause 2.5.12 to Subdivision D of Division 2.5, which contains the items to which the clause applies. The change renames the clause 2.1.13A.

Item 92 amends liver MRI item 63545 to expand indications from colorectal cancer to include all cancer types that have potentially spread to the liver. The change, which was recommended by the Taskforce and supported by MSAC at its November 2021 meeting, will help guide appropriate treatment for patients with any oncological condition with suspected or proven liver cancer. RANZCR, MOGA and the Garvan Institute of Medical Research have been consulted and are supportive of the changes.

Schedule 3 – Pathology Services

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

Part 1—Neuromuscular disorders

Item 1 introduces seven new pathology items (73422 to 73428) for genetic testing for the diagnosis of neuromuscular disorders (NMDs). The new items are available for patients who are suspected of having NMDs, biological relatives of affected individuals, including fetuses, for the purpose of identifying any close family members who might also be affected, reproductive partners of patients who have been diagnosed with an inherited genetic variant for a NMD, and data reanalysis to support re-testing where new genetic variants of significance are identified. The changes were recommended by MSAC at its July 2021 meeting. Currently, neuromuscular disorders are diagnosed by imaging studies, muscle and/or nerve biopsies, and nerve conduction studies. The introduction of these genetic testing items will provide patients with access to safer and more effective testing than the tests used currently.

Part 2—Miscellaneous amendments

Items 2, 3 and 5 amend National Cervical Screening Program (NCSP) items 73072 and 73074 to align with the *National Cervical Screen Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding* (the Guidelines), following changes to items 73072 and 73074, commencing on 1 July 2022, to expand patient access to self-collected cervical screening tests under the NCSP. The changes will contribute to increasing participation rates under the NCSP and will assist the NCSP to achieve its objective of reducing morbidity and mortality from cervical cancer. MSAC supported these amendments to NCSP items, including removal of item 73073 following integration of suggested amendments to 73072 and 73074.

Item 4 repeals NCSP item 73073 to avoid duplication of services with 73072, following the amendments in the Regulations (refer to **items 2** and **3** in Part 2 of Schedule 3 of the Regulations).

Item 6 amends item 73410 to clarify that patients with beta-thalassaemia can also access genetic testing for the diagnosis of alpha-thalassaemia under item 73410. The previous wording used in the item descriptor for this service would exclude this group of patients. This issue was raised to the MSAC Executive, who considered that it would be inequitable to exclude patients with beta-thalassaemia from testing for alpha-thalassaemia, and advised that they should be included in line with standard clinical practice. The change is consistent with the policy intent of the item.

Item 7 amends items 75862, 75863 and 75864 to replace references to "Commonwealth concession card holder" with "concessional beneficiary" to align with updated terminology in the *National Health Insurance Act 1953*. The change is administrative in nature.

Item 8 makes consequential amendments to the listed clauses and items following the repeal of item 73073 (refer to **item 4** in Part 2 of Schedule 3 of the Regulations).

Schedule 4 – Other amendments

Health Insurance Regulations 2018 **(HIR)**

Items 1 and 2 amend subsection 28(1) of the HIR to prescribe items 941, 942, 2733 and 2735 to enable the benefit to be calculated as 100% of the schedule fee for these GP items. This change aligns these items with existing policy regarding the benefit for GP services and is administrative in nature as the benefit amount the patient receives will remain unchanged.

Item 3 amends subclause 28(2) to remove a reference to clause 1.2.19 of the DIST, which was repealed by *Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022* on 1 July 2022. The change is administrative in nature.

Items 4 to 11 amend subsections 39(5) and (6) to align dental specialties referenced in the HIR with those recognised under the Australian Health Practitioner Regulation Agency (AHPRA). The change also provides additional requesting rights for diagnostic imaging services to two dental specialties (Oral Surgery and Special Needs Dentistry) to align with their scope of practice and assist in the treatment of their patients.

The Australian Dental Association (ADA) and the Australian and New Zealand Association of Oral Surgeons (ANZAOS) have been consulted and are supportive of the changes.

Schedule 5 – Amendments commencing 1 July 2022

Items 1 and 2 amend table item 9 in clause 2.1.1 to apply indexation to the schedule fees for item 195. The change will address an omission in the *Health Insurance*

Legislation Amendment (2022 Measures No. 1) Regulations 2022 and will commence retrospectively on 1 July 2022.

Items 3 and 4 amend subclauses 2.30.1(1) and (2) to apply indexation to the flag fall amounts for the first patient attended at a residential aged care facility for:

- a general practitioner service to which item 90020, 90035, 90043 or 90051; and
- another medical practitioner service to which item 90092, 90093, 90095 or 90096.

The change will address an omission in the *Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022* and will commence on retrospectively on 1 July 2022.

Statement of Compatibility with Human Rights

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

Health Insurance Legislation Amendment (2022 Measures No. 3) Regulations 2022

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 purpose of the *Health Insurance Legislation Amendment (2022 Measures No. 3) Regulations 2022* (the Regulations) is to amend the GMST, the DIST, the PST and the HIR from 1 November 2022.

Changes to Medical Services

Schedule 1 of the Regulations will amend the GMST to make changes to medical services.

Parts 1 to 10 of Schedule 1 of the Regulations will implement the following changes to the GMST as announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure:

- amend eight cardiothoracic surgery items to ensure procedures align with best practice;
- introduce a new item for remote programming of a neurostimulator for deep brain stimulation for Parkinson's disease, essential tremor and dystonia;
- amends six varicose vein services to allow appropriate co-claiming with other venography items;
- introduce two new items for remote monitoring of cardiac internal loop recorders;
- changes to paediatric surgery services;
- introduce a new item for remote reprogramming of a neurostimulator for the management of chronic neuropathic pain;
- amend oculoplastic surgery item 45617 to remove the requirement for visual field testing;
- changes to melanoma excision services;
- amend orthopaedic services to address service gaps and patient safety in response to the MBS Taskforce Review (the Taskforce) recommendations;
- changes to acupuncture services; and
- introduce a new item for cryoablation of renal cell carcinoma.

Part 10 of Schedule 1 of the Regulations will also make amendments to the GMST that are minor and machinery in nature.

Changes to Diagnostic Imaging Services

Schedule 2 of the Regulations will amend the DIST to make changes to diagnostic imaging services.

Part 1 of Schedule 2 of the Regulations will introduce a new magnetic resonance imaging (MRI) item for the investigation of conditions affecting fertility, including endometriosis. This new pelvic MRI item was announced in the 2022-23 Budget under the *Women's Health Package* measure.

Parts 2, 4 of Schedule 2 of the Regulations will implement the following changes to the DIST as announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure:

- changes to obstetric and gynaecological diagnostic imaging services;
- a new positron emission tomography (PET) item for initial staging for patients diagnosed with rare and uncommon cancers;
- amending breast magnetic resonance imaging (MRI) item 63464 for patients at high risk of developing breast cancer, raising the age limit from 50 to 60 years of age; and
- amending MRI item 63545 to expand indications from colorectal cancer to include all cancer types that have potentially spread to the liver.

Part 3 of Schedule 2 of the Regulations will remove the requirement for the equipment used for MRI services in regional, remote and rural areas to have a Deed of Undertaking with the Commonwealth to be Medicare eligible. This change was announced in the 2022-23 Budget under the *Guaranteeing Medicare – Supporting patient access to Magnetic Resonance Imaging* measure.

Changes to Pathology Services

Schedule 3 of the Regulations will amend the PST to make changes to pathology services.

Part 1 of Schedule 3 of the Regulations will introduce new genetic testing items for the diagnosis of neuromuscular disorders. These new items were announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure. Part 1 of Schedule 3 of the Regulations will also amend genetic testing item 73410, which commenced on 1 July 2022, to clarify that patients with beta-thalassaemia can also access genetic testing for the diagnosis of alpha-thalassaemia under item 73410.

Part 2 of Schedule 3 of the Regulations will implement amendments to the National Cervical Screening Program (NCSP) items and other administrative and consequential amendments.

Changes to the HIR

Schedule 4 of the Regulations will amend the HIR to make changes to the policy framework supporting the provision of appropriate Medicare services, including administrative amendments to subsection 28(1) to allow specified items to attract a Medicare benefit of 100% and updating references to dental specialities.

Amendments commencing 1 July 2022

On 1 July 2022, the *Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022* (July 2022 MBS Regulations) will apply indexation to the GMST. However, clause 2.30.1 of the GMST was not included in the changes in the July 2022 MBS Regulations. Schedule 5 of the Regulations will amend clause 2.30.1 of

the GMST to apply indexation to the fees specified in this clause, following its omission from the July 2022 MBS Regulations. This change will commence retrospectively on 1 July 2022.

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 rights to health and social security by ensuring access to publicly subsidised medical services are clinically and cost-effective as intended.

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