**EXPLANATORY STATEMENT**

*Health Insurance Act 1973*

*Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021*

Subsection 133(1) of the *Health Insurance Act 1973* (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 (GMST). The most recent version of the regulations is the *Health Insurance (General Medical Services Table) Regulations 2021.*

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 (DIST). The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020.*

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 (PST). The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020*.

**Purpose**

The purpose of the *Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021* (the Regulations) is to amend the GMST, DIST and PST from
1 November 2021. The Regulations will make changes to general medical services, pathology services and diagnostic imaging services to reflect Government policy.

***Changes to medical services***

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

Part 1 of Schedule 1 of the Regulations will introduce four new items 14216, 14217, 14219 and 14220 for repetitive transcranial magnetic stimulation (rTMS) therapy. This change was announced in the 2021-22 Budget under the *Primary Care* measure.

Parts 2 to 10 and Part 12 of Schedule 1 of the Regulations will implement the following changes as announced by Government in the 2021‑22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure:

* Introduce one new item 30311 for sentinel lymph node biopsy or biopsies to determine if the patient’s melanoma cells have spread to the sentinel lymph nodes.
* Amend three thoracic medicine items 11503, 11508 and 11512 to enable appropriately trained specialists to provide these services.
* Amend item 30210 to remove the age restriction that applies to this service.
* Introduce one new item 32230 for the removal of colorectal polyps to prevent colorectal cancer.
* Introduce one new item 35401 for the treatment of spinal fractures by vertebroplasty.
* Introduce three new items 45534, 45535 and 45589 for autologous fat grafting.
* Amend item 45558 to remove the restriction for pregnant patients.
* Introduce one new item 11607 for ambulatory blood pressure monitoring for the diagnosis of high blood pressure.
* Amend 12 items (32500 and 32507 to 32529) for varicose vein treatment services.
* Introduce one new item 13207 into the GMST for preimplantation embryo biopsy

Part 11 of Schedule 1 of the Regulations will introduce restrictions on the co-claiming of consultations with magnetic resonance imaging (MRI) services, announced in the 2021-22 Budget measure *Guaranteeing Medicare – Improving Diagnostic Imaging*.

Parts 13 to 17 of Schedule 1 of the Regulations will implement the following minor administrative amendments:

* Relocate item 41904 from subgroup 8 to subgroup 6 and replace with new item number 38428.
* Amend item 45632 to clarify the clinical intent of the service.
* Amend five spinal decompression items 51011, 51012, 51013, 51014 and 51015 to clarify the clinical intent of the services.
* Incorporate item 47491 which is currently listed in a determination under subsection 3C(1) of the Act.
* Amend a small number of cardiac and orthopaedic items to align with the policy intent of the services.

***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 ultrasound items 55065 and 55068 to remove an unintentional restriction. This change is consistent with the original policy intent of the services, announced by Government in the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure.

Part 2 of Schedule 2 of the Regulations will make the following changes to computed tomography services that were announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure:

* Amend one computed tomography colonography item 56553 to remove the restrictions of the service being performed 36 months before the scan.
* Amend computed tomography coronary angiography item 57360 to clarify policy intent.

This part of the Regulations will also remove item 57351, which is for computed tomography angiography, as this item is obsolete.

Part 3 of Schedule 2 of the Regulations will introduce one new item 61560 for proton emission tomography (PET) for the diagnosis of Alzheimer’s disease. This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

Part 4 of Schedule 2 of the Regulations will introduce a new clause in the DIST to provide co-claiming restrictions for MRI head and spine items. This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – improving diagnostic imaging* measure.

Part 4 of Schedule 2 of the Regulations will also amend one MRI item 63489 to retain only the MRI component, reduce the fee and clarify co-claiming requirements. This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

This part of the Regulations will also incorporate items 63541 and 63543 which are currently listed in the *Health Insurance (Section 3C Diagnostic Imaging Services—Multiparametric MRI of the prostate) Determination 2018*. Item 63541 will be amended to enable additional patient cohorts to access this service.

Part 5 of Schedule 2 of the Regulations will make minor technical changes to align the headings of provisions dealing with the multiple services rules for diagnostic imaging services. These changes are administrative in nature.

***Changes to pathology services***

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

Parts 1 to 3 of Schedule 3 of the Regulations will implement the following changes to pathology services announced by Government in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure:

* Introduce two new items 66522 and 65523 for faecal calprotectin testing.
* Introduce one new item 71175 for the detection of aquaporin-4 and myelin oligodendrocyte glycoprotein antibody (MOG) antibodies.
* Introduce one new item 73388 for new genome-wide microarray testing.
* Amend three genetic testing items 73361, 73362 and 73363 to clarify the requirements for targeted cascade testing of relatives.
* Introduce four new items 73384, 73385, 73386, 73387 for pre-implantation genetic testing.
* Introduce one item 73389 for genetic testing of conception.
* Introduce one item 73391 for genetic testing for people with multiple myeloma.

Part 3 of the Regulations will also amend item 73297 to align with the original policy intent of the item.

**Consultation**

The independent Medical Services Advisory Committee (MSAC), the MBS Review Taskforce and medical professional organisations were consulted on the 1 November 2021 changes.

The MBS Review is conducted by expert committees and working groups focusing on specific areas of the MBS. The clinical committee reports were released for public consultation to inform the final Taskforce reports and recommendations to Government.

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

As part of the MSAC process, consultation was undertaken with key stakeholders, clinical experts and providers on the introduction of the new item 32230 for endoscopic mucosal resection (EMR), the new item 30311 for sentinel lymph node biopsy or biopsies, the new item 35401 for vertebroplasty, the new item 11607 for ambulatory blood pressure monitoring, the three new items 45534, 45535 and 45589 for autologous fat grafting, and the four new items 14216, 14217, 14219 and 14220 for rTMS.

The Medical Services Advisory Committee (MSAC) Executive, members of the MBS Review Taskforce Vascular Clinical Committee and the Vascular Working Group, which reported to the MBS Review Taskforce, were consulted on the changes to varicose vein items 32500 and 32507 to 32529.

The Royal Australian and New Zealand College of Radiologists and the Australian Diagnostic Imaging Association were consulted on the MRI co-claiming restrictions.

The Dermatology and Skin Services Advisory Group was consulted on the changes to item 30210.

The Plastic Surgery Continuous Improvement Committee was consulted on changes to item 45558.

Clinical experts were consulted on the changes to the spinal decompression items 51011, 51012, 51013, 51014 and 51015, following a 12 month post-implementation review of the spinal surgery services.

Key professional groups, including the Australian Medical Association, the Thoracic Society of Australia and New Zealand, and Australian and New Zealand College of Anaesthetists were consulted on the changes to thoracic medicine items 11503, 11508 and 11512.

The Australian Pathology, Public Pathology Australia, and the Royal College of Pathologists of Australasia were consulted on the changes to pathology services.

Targeted consultation was undertaken on the orthopaedic administrative changes to ensure the changes reflect the policy intent of recommendations of the MBS Review Taskforce, announced in Budget 2020-21 and Budget 2021-22 under the *Guaranteeing Medicare - Medicare Benefits Schedule review* and *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measures respectively.

Details of the Regulationsare 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 2021.

 Authority: Subsection 133(1) of the

 *Health Insurance Act 1973*

**ATTACHMENT**

**Details of the *Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021***

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021.*

Section 2 – Commencement

This section provides for the Regulations to commence on 1 November 2021.

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

***Changes to medical services in the general medical service table***

**Part 1 – Repetitive transcranial magnetic stimulation**

Part 1 makes changes to the general medical services table (GMST) to introduce four new items (14216, 14217, 14219 and 14220) for repetitive transcranial magnetic stimulation (rTMS) therapy for the treatment of medication resistant major depressive disorder.

Training requirements for providers using these items will be developed in consultation with the Royal Australian and New Zealand College of Psychiatrists.

These changes were recommended by the independent Medical Services Advisory Committee (MSAC) and were announced in the 2021-22 Budget under the *Primary Care* measure.

**Item 1** inserts items 14217 and 14220 into clause 1.2.11 of the GMST, to provide that these services can be provided by a person on behalf of the medical practitioner, if the service is rendered in accordance with accepted medical practice.

**Item 2** inserts new clause 5.2.6A, which applies a restriction to new rTMS items 14217 and 14220, to provide that a service under these items cannot be provided to a patient as maintenance therapy for the prevention of further relapse of the patient’s depression.

**Items 3 and 4** inserts four new rTMS items 14216, 14217, 14219 and 14220. The new items would provide rTMS services for eligible adult patients (18 years old or older), who have not previously received a rTMS service in the public or private setting, and who have trialled at least two different classes of antidepressant medicines but have not responded to this course of treatment.

Item 14216 is for a professional attendance provided by a psychiatrist to provide a treatment mapping service for rTMS treatment for patients who are at least 18 years old, and diagnosed with a medication resistant major depressive episode.

Item 14217 is for rTMS treatment of up to 35 services provided by or on behalf of a psychiatrist, if the patient has been assessed by a psychiatrist under item 14216.

Item 14219 is for a professional attendance by a psychiatrist to provide an assessment and treatment mapping for rTMS treatment services for patients with a medication resistant major depressive episode who have met a number of conditions.

Item 14220 is for rTMS treatment of up to 15 services provided by or on behalf of a psychiatrist, if the patient has received a service under item 14217 (which was not provided in the previous four months) and under 14219. Up to 15 retreatment services are allowed under this item.

**Part 2 – Sentinel lymph node biopsy**

Part 2 makes changes to the GMST to introduce one new item 30311 for sentinel lymph node biopsy or biopsies for intermediate thickness melanoma.

This change was recommended by MSAC, and announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 5 to 7** amends clause 5.10.4 of the GMST to include new item 30311 (refer to **item 8** of Schedule 1 in the Regulations) and correct a typographical error in the spelling of lymphotropic. A service described under this clause applies only if pre‑operative lymphoscintigraphy is used because the patient is allergic to lymphotropic dye.

**Item 8** inserts new item 30311 for a sentinel lymph node biopsy or biopsies for intermediate thickness melanoma. Patients with malignant cutaneous melanoma primary legion greater than 1mm in depth (or at least 0.8mm depth in the presence of ulceration) will be able to receive a service under the new item.

**Part 3 – Thoracic medicine**

Part 3 makes changes to the GMST to amend items 11503, 11508 and 11512, which are for diagnostic respiratory function tests, to enable appropriately trained specialists or consultant physicians to provide these services. Patients, particularly in rural and remote areas, will have better access to these diagnostic tests to ensure they are able to be treated for a range of diseases.

This change was recommended by the MBS Review Taskforce and announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Items 9 to 11** amends items 11503, 11508 and 11512 to enable appropriately trained specialists or consultant physicians to provide these services, not only consultant respiratory physicians, as is currently the case.

**Part 4 – Dermatology**

Part 4 makes changes to the GMST to amend 30210 to remove the age restriction for the service, which will increase access to patients of any age who have a clinical need for the service.

This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 12** amends item 30210, which is for multiple injections of glucocorticoid preparations into keloid scars and other skin lesions, to remove the age restriction of patients less than 16 years of age.

**Part 5 – Endoscopic mucosal resection**

Part 5 makes changes to the GMST to introduce one new item 32230 for an endoscopic mucosal resection. This service will provide patients with a safe, effective and cost effective service when compared with the surgical resection of colorectal polyps, which is already provided for under the Medicare Benefits Schedule (MBS).

This change was recommended by MSAC and announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 13** inserts new item 32230, which is for the removal of very large (≤ 25mm) sessile colorectal polyps by an endoscopic mucosal resection. A service under item 32230 is to be provided as an in-hospital service only, and must be performed in association with a service under items 32222, 32223, 32224, 32225, 32226 or 32228.

**Part 6 – Vertebroplasty**

Part 6 makes changes to the GMST to introduce one new item 35401 for vertebroplasty, which is for the injection of acrylic cement into a bone of the spine to treat a break (fracture) where the bone was already weakened due to osteoporosis, and where the break has resulted in pain and limited mobility affecting quality of life.

This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 14** inserts new item 35401 for vertebroplasty, which is to be performed by an interventional radiologist, and provided as an in-hospital service only. A service under this item is applicable only once for the same fracture, but is applicable for a new fracture for the same vertebra or vertebrae.

**Item 15** amends clause 7.1.1 of the GMST to remove vertebroplasty from the definition of a *non‑medicare service*. This is an administrative change as a vertebroplasty service will be able to be provided under the MBS under new item 35401.

**Part 7 – Autologous fat grafting**

Part 7 makes changes to the GMST to introduce three new items (45534, 45535 and 45589) for autologous fat grafting (AFG).

These changes were recommended by MSAC and were announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 16** inserts new items 45534 and 45535, which are for the provision of surgical treatment by AFG to patients requiring breast reconstruction and the correction of developmental breast disorders. New item 45534 is for a unilateral service, and new item 45535 is for a bilateral service. New items 45534 and 45535 may be performed up to four times, and are to be provided as an in-hospital service only.

**Item 17** inserts new item 45589, which is for the treatment of burn scars and facial defects due to craniofacial abnormalities using AFG. A service under item 45589 is to be provided as an in-hospital service only.

**Part 8 – Breast ptosis**

Part 8 makes changes to the GMST to amend item 45558, which is for the surgical correction of bilateral breast ptosis by mastopexy, to remove the restriction for patients that have been pregnant. This change will provide access to the patient populations at greatest need of the service, including individuals who have undergone significant weight loss.

This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 18** amends item 45558 to remove the restriction that for a patient who has been pregnant, the surgical correction can only be performed between one and seven years after the completion of the most recent pregnancy of the patient.

**Part 9 – Ambulatory blood pressure monitoring**

Part 9 makes changes to the GMST to introduce one new item 11607 for ambulatory blood pressure monitoring for the diagnosis of high blood pressure.

This change was recommended by MSAC and announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 19** amends clause 1.2.11(1) of the GMST, which lists services that may be provided by persons other than medical practitioners (if the service is rendered in accordance with accepted medical practice), to include new ambulatory blood pressure monitoring item 11607 (refer to **item 20** of Schedule 1 in the Regulations).

**Item 20** inserts new item 11607 for ambulatory blood pressure monitoring for the diagnosis of high blood pressure. Under new item 11607, practitioners will be able to more accurately diagnose high blood pressure in patients by continuously monitoring their blood pressure over 24 hours via a wearable portable measuring device. The new item includes analysis of the data observed, generation of a report and development of a treatment plan.

**Part 10 – Varicose vein treatment**

Part 10 makes changes to the GMST to amend 12 varicose vein items (32500 and 32507 to 32529) for varicose vein services to align the items with contemporary clinical practice, ensure appropriate patient access and prevent their use for cosmetic purposes. The amendments will also restrict the inappropriate and unsafe use of venography, fluoroscopy and angiography services with some varicose vein items.

These changes were informed by the Vascular Clinical Committee and subsequently recommended by the MBS Review Taskforce and MSAC. These changes were announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 21** amends varicose vein item 32500, which is for multiple injections of sclerosant using continuous compression techniques, to remove the restriction for a varicosity measurement of 2.5mm or greater in diameter, include that a proximal reflux of greater than 0.5 seconds must be excluded, and clarify the treatment is not to be performed for cosmetic purposes. A service under item 32500 may not be performed in association with a service under items 35200, 59970 to 60078, 60500 to 60509 and 61109.

**Item 22** amends the item descriptors of eleven varicose vein items (32507 to 32529).

Varicose vein item 32507, which is for sub-fascial surgical exploration of one or more incompetent perforating veins of one leg, will be amended to provide the item is for the sub-fasical ligation of one or more incompetent perforating veins in one leg. A service under item 32507 may not be performed in association with any other varicose vein operation on the same leg or with a service to which items 35200, 60072, 60075 or 60078 applies to the same leg, and must be performed as an in-hospital service. The amendments to item 32507 also provide that the procedure must be performed by open surgical technique, not including endoscopic ligation.

Varicose vein item 32508, which is for the complete dissection at the sapheno-femoral or sapheno-popliteal junction of one leg, will be amended to update the item descriptor to refer to the great or small saphenous vein, as opposed to the long or short saphenous vein.

Varicose vein item 32511, which is for which is for the complete dissection at the sapheno-femoral and sapheno-popliteal junction of one leg, will be amended to refer to the great or small saphenous vein, as opposed to the long or short saphenous vein.

Varicose vein item 32514, which is for ligation of the long or short saphenous vein on the same leg, will be amended to refer to the great or small saphenous vein, as opposed to the long or short saphenous vein.

Varicose vein item 32517, which is for which is for ligation of the long and short saphenous vein on the same leg, will be amended to refer to the great and small saphenous vein, as opposed to the long or short saphenous vein.

Varicose vein item 32520, which is for the abolition of venous reflux by occlusion of a primary or recurrent great (long) or small (short) saphenous vein of one leg using a laser probe introduced by an endovenous catheter, (not including radiofrequency diathermy, radiofrequency ablation or cyanoacrylate embolisation) , will be amended to provide that the service does not include cyanoacrylate adhesive instead of cyanoacrylate embolisation, and to provide that the service cannot be performed in association with items 32500 to 32507, 35200, 59970 to 60078, 60500 to 60509 and 61109. The item will also be amended to update the item descriptor to refer to the great or small saphenous vein only, as opposed to the great (long) or small (short) saphenous vein.

Varicose vein item 32522, which is for the abolition of venous reflux by occlusion of a primary and recurrent great (long) and small (short) saphenous vein of one leg using a laser probe introduced by an endovenous catheter (not including radiofrequency diathermy, radiofrequency ablation or cyanoacrylate embolisation), will be amended to provide that the service does not include cyanoacrylate adhesive instead of cyanoacrylate embolisation, and to provide that the service cannot be performed in association with items 32500 to 32507, 35200, 59970 to 60078, 60500 to 60509 and 61109. The item will also be amended to update the item descriptor to refer to the great or small saphenous vein only, as opposed to the great (long) or small (short) saphenous vein.

Varicose vein item 32523, which is for the abolition of venous reflux by occlusion of a primary and recurrent great (long) or small (short) saphenous vein of one leg using a radiofrequency catheter introduced by an endovenous catheter (not including endovenous laser therapy or cyanoacrylate embolisation), will be amended to provide that the service does not include cyanoacrylate adhesive instead of cyanoacrylate embolisation, and to provide that the service cannot be performed in association with items 32500 to 32507, 35200, 59970 to 60078, 60500 to 60509 and 61109. The item will also be amended to update the item descriptor to refer to the great or small saphenous vein only, as opposed to the great (long) or small (short) saphenous vein.

Varicose vein item 32526, which is for the abolition of venous reflux by occlusion of a primary and recurrent great (long) and small (short) saphenous vein of one leg using a radiofrequency catheter introduced by an endovenous catheter (not including endovenous laser therapy or cyanoacrylate embolisation), will be amended to provide that the service does not include cyanoacrylate adhesive instead of cyanoacrylate embolisation, and to provide that the service cannot be performed in association with items 32500 to 32507, 35200, 59970 to 60078, 60500 to 60509 and 61109. The item will also be amended to update the item descriptor to refer to the great or small saphenous vein only, as opposed to the great (long) or small (short) saphenous vein.

Varicose vein item 32528, which is for the abolition of venous reflux by occlusion of a primary or recurrent great (long) or small (short) saphenous vein of one leg using cyanoacrylate adhesive (not including radio frequency diathermy, radiofrequency ablation or endovenous laser therapy), will be amended to provide that the service cannot be performed in association with items 32500 to 32507, 35200, 59970 to 60078, 60500 to 60509 and 61109. The item will also be amended to update the item descriptor to refer to the great or small saphenous vein only, as opposed to the great (long) or small (short) saphenous vein.

Varicose vein item 32529, which is for the abolition of venous reflux by occlusion of a primary or recurrent great (long) and small (short) saphenous vein of one leg using cyanoacrylate adhesive (not including radio frequency diathermy, radiofrequency ablation or endovenous laser therapy), will be amended to provide that the service cannot be performed in association with items 32500 to 32507, 35200, 59970 to 60078, 60500 to 60509 and 61109. The item will also be amended to update the item descriptor to refer to the great or small saphenous vein only, as opposed to the great (long) or small (short) saphenous vein.

Items 32507 to 32529 are also amended to provide that services under these items are to be provided in a patient who has significant signs or symptoms (including one or more of the following) attributable to venous reflux:

i. ache; or

ii. pain; or

iii. tightness; or

iv. skin irritation; or

v. heaviness; or

vi. muscle cramps; or

vii. limb swelling; or

viii. discolouration; or

ix. discomfort; or

x. any other sign or symptom attributable to venous dysfunction.

**Part 11 – Co-claiming restrictions**

Part 11 makes changes to the GMST to introduce a new restriction to prevent co-claiming attendance items in association with a magnetic resonance imaging (MRI) item (that is, an item listed in Group I5 of the diagnostic imaging services table (DIST)). This change will clarify appropriate claiming arrangements for consultations rendered in association with MRI services.

This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – Improving Diagnostic Imaging* measure.

**Item 23** amends clause 1.2.3 to apply a co-claiming restriction against attendances by a practitioner in association with a service under an item in Group I5 of the DIST. This exemption will not apply if the providing practitioner considers the attendance is necessary for the management or treatment of the patient.

**Part 12 – Preimplantation embryo biopsy**

Part 12 makes changes to the GMST to introduce one new item 13207 for the biopsy of an embryo.

This change is part of genetic testing items which were announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 24** inserts new item 13207 for the biopsy of an embryo for the purposes of providing a sample for preimplantation genetic testing. The new item 13207 is part of a suite of genetic testing items which will be introduced in the Pathology Services Table (refer to **item 9** of Schedule 3 of the Regulations)

**Part 13 – Bronchoscopy with dilatation of tracheal stricture**

Part 13 amends the GMST to relocate item 41904, which is for a bronchoscopy with dilation of the tracheal stricture, from *Subgroup 8 – Ear, nose and throat* into *Subgroup 6 – Cardio-thoracic of Group T8.* This change is administrative in nature, and will enable consistent listing arrangements for similar services for diagnostic and therapeutic procedures of the lung, trachea and bronchus. It does not change the nature of the service or patient access.

**Item 25** inserts new item 38428, which is the new item number for item 41904. Item 38428 will be listed in *Subgroup 6 – Cardio thoracic* of Group T8.

**Item 26** repeals item 41904, which will become item 38247 (refer to **item 25** of Schedule 1 of the Regulations).

**Part 14 – Partial rhinoplasty**

Part 14 amends the GMST to amend item 45632, which is for partial rhinoplasty, to clarify the clinical intent of the service. This change is administrative in nature and clarifies the intent of the service.

**Item 27** amends the item descriptor for item 45632 to specify that the item is for the correction of one or both lateral cartilages, one or both alar cartilages, or one or both lateral cartilages and alar cartilages.

**Part 15 – Spinal decompression**

Part 15 amends the GMST to amend spinal decompression items 51011 to 51015 to clarify the intent for these services. These changes are administrative in nature and will not alter provider or patient populations.

**Item 28** amends the item descriptor of spinal decompression items 51011 to 51015 to clarify that the services are to be provided for direct spinal decompression or a posterior spinal release, and not in instances where spinal decompression occurs as an indirect result of the procedure performed.

**Part 16 – Anterior and posterior pelvic ring disruption**

Part 16 amends the GMST to incorporate item 47491, which is listed in the *Health Insurance (Section 3C General Medical Services – Anterior and Posterior Pelvic Ring Disruption) Determination 2021*. This change is administrative in nature.

**Item 29** lists item 47491, which is for combined anterior and posterior pelvic ring disruption, after item 47490 in the GMST.

**Part 17 – Additional amendments**

Part 17 amends the GMST to make minor changes to cardiac, general surgery and orthopaedic items to align with the policy intent of the services.

**Item 30** amends the item descriptor of item 35638 to provide that this service can be provided with a service under intraperitoneal or retroperitoneal procedure item 30724, instead of item 30393. This change is administrative in nature as item 30393 ceased on 1 July 2021.

**Items 31 and 32** corrects the item descriptor for item 38212 by removing the requirement for the use of four or more catheters for all indications, instead applying the restriction to the first indication only. This change is administrative in nature.

**Items 33** **to 45** makes minor amendments to the item descriptors of orthopaedic and cardio-thoracic items to align the items with the policy intent of the service. These changes are considered minor and administrative in nature, and include removing references to repealed items and correction of typographical errors and specifying services must be assisted (where applicable).

Schedule 2 – Diagnostic imaging services

***Changes to diagnostic imaging services in the diagnostic imaging services table***

**Part 1 – Ultrasound**

Part 1 amends the DIST to amend ultrasound items 55065 and 55068 to remove an unintentional restriction.

**Item 1** amends items 55065 and 55068, which are for an ultrasound of the pelvis, to allow the service to be rendered in association with gynaecological items 55736 and 55739. This change will provide eligible patients access to a service under items 55065 or 55068, and items 55736 and 55739 when rendered on same occasion.

The change aligns with the original intent of the recommendations of the MBS Review Taskforce when introducing restrictions on the claiming of items 550685 or 55068 with pregnancy related services introduced on 1 May 2020. These restrictions were announced in the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure.

**Part 2 – Computed tomography (examination)**

Part 2 amends the DIST to amend computed tomography services. These changes were announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure, or are administrative in nature.

**Item 2** amends computed tomography colonography item 56553, which is for colorectal neoplasia, by removing the current claiming restriction of one scan in 36 months. This change will allow high risk category patients to be able to access diagnostic scans as frequently as recommended, and aligns with the National Health and Medical Research Council (NHMRC) clinical guidelines.

**Item 3** repeals item 57351 as this item is obsolete. This is a consequential change arising from changes announced in the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure.

**Item 4** inserts new clause 2.2.5A into the DIST, which provides patient eligibility requirements for a service under cardiac item 57360, to specify the target patient cohort for a service under this item. Item 57360 is for computed tomography of the coronary arteries.

New clause 2.2.5A clarifies that this service cannot be provided more than once in a five year period if the patient has had a service under this item or item 57364, and there was no obstructive coronary artery disease detected as part of the first service. This restriction does not apply if the patient meets the eligibility criteria for selective coronary and graft angiography items 38244, 38247, 38248 or 38249. The eligibility criteria for items 38244, 38247, 38248 and 38249 are set out in clauses 5.10.17A and 5.10.17B of the GMST. This change reflects the policy intent of the item 57360 as recommended by the MBS Review Taskforce.

**Item 5** amends computed tomography item 57360 to remove the requirement that the patient is known to have coronary artery disease. This change reflects the policy intent of the item 57360 as recommended by the MBS Review Taskforce.

**Part 3 – Nuclear medicine imaging**

Part 3 amends the DIST to make changes to introduce one new item 61560 for proton emission tomography (PET) for the diagnosis of Alzheimer’s disease. This change was announced in the 2021-22 Budget under the Guaranteeing *Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 6**inserts new PET item 61560 for the diagnosis of Alzheimer’s disease in patients. The new item will allow patients with suspected Alzheimer Disease to access more effective diagnostic imaging where diagnosis through clinical evaluation is equivocal.

A service under new item 61560 must be provided by credentialled nuclear medicine specialists, may only be claimed once per year with a maximum of three services per patient’s lifetime, and cannot be claimed if single photon emission tomography (SPET) item 61402 has been claimed for the diagnosis or management of Alzheimer’s disease in the previous 12 months.

**Part 4 – Magnetic resonance imaging**

Part 4 amends the DIST to amend magnetic resonance imaging (MRI) services.

**Item 7** repeals and replaces clause 2.5.8, which is in relation to multiple services provided on one day, to restructure the clause layout and better clarify when it is appropriate to claim certain multiple MRI scans.

The requirements in the existing subclause 2.5.8(2) and 2.5.8(3) have been moved to new clause 2.5.8B. The requirements in the current subclause 2.5.8(1) remain in the replaced clause 2.5.8. There is no change to the effect of the requirements as a result of this restriction.

Item 7 also introduces a new clause 2.5.8A. Subclause 2.5.8A(1) prevents the claiming of more than one item for a MRI scan of the head at the same attendance. It provides for the item with the highest schedule fee to be claimed.

Subclause 2.5.8(2) prevents the claiming of more than one item for a MRI scan of the spine at the same attendance and provides for the item with the highest schedule fee to be claimed.

Subclause 2.5.8(3) clarifies that if there are two or more items that have the equal highest schedule fees, only one of those items is taken to apply for the purposes of subclause 2.5.8A(1) and (2).

**Item 8** amends clause 2.5.9 to include item 63541, which is for a multiparametric MRI scan of the prostate for the detection of cancer. Clause 2.5.9 provides a claiming frequency restriction on certain MRI and magnetic resonance angiography (MRA) items. Under this change, item 63541 may only be claimed once every 12 months.

**Item 9** inserts clauses 2.5.9A and 2.5.9B, which provide for the circumstances for suspecting prostate cancer for item 63541 and a timing and purpose for item 63453 respectively. Items 63541 and 63543 will be incorporated into the DIST. These items are currently listed in the *Health Insurance (Section 3C Diagnostic Imaging Services—Multiparametric MRI of the prostate) Determination 2018.*

Under Clause 2.5.9A, in order to meet the criteria for suspecting prostate cancer for a service under 63541, a patient must have had at least two prostate specific antigen (PSA) tests performed, with an interval between the first test of at least one month but not more than three months. Subsections (2) to (6) specify further requirements, dependant on the patient’s age and increased risk due to family history,

Clause 2.5.9B provides restrictions for a service under item 63453. A service under item 63543 is applicable for a patient diagnosed with prostate cancer if it is the first service provided after the date of diagnosis (the first service), or provided 12 months after the first service (the second service), or provided three years after the second service. A service under item 63543 cannot be provided for treatment planning or for monitoring after treatment of prostate cancer.

**Item 10** amends MRI item 63489 to retain only the MRI component.

The fee for item 63489 currently includes a component for a breast biopsy procedure and ultrasound scan. The biopsy procedure and the ultrasound scan cannot also be claimed with item 63489.

The amendment disaggregates item 63489 such that it only applies to the MRI scan component, and the biopsy and ultrasound scan can now be co-claimed with the scan. The fee for a service under item 63489 has been reduced to reflect the MRI scan element only.

**Item 11** incorporates items 64351 and 63543 into the DIST.

Item 63541 has been amended to enable patients who are at very high risk of prostate cancer due to family history, and who have a high repeat PSA result of over 5.5 ug/L, to access this service. This change will expand patient access for mpMRI scans of the prostate, particularly for patients who are at high risk of having or developing prostate cancer. This eligibility requirement is now set out in clause 2.5.9A rather than the item descriptor.

There are no changes to item 63543.

**Item 12** inserts a definition for PSA, which is defined as prostate specific antigen, into clause 3.1 of the DIST.

**Part 5 – Technical amendments**

Part 5 makes minor technical changes, which are administrative in nature and have been made for consistency purposes.

**Items 13 to 17** amends the headings of clause 1.2.21 and 2.1.17 and moves clause 1.2.20 to the vascular ultrasound section, which becomes clause 2.1.2A. The clauses prescribe a reduction to fees for multiple services on the same day.

Schedule 3 – Pathology services

***Changes to pathology services in the pathology services table***

**Part 1 – Group P2: Chemical**

Part 1 makes changes to the pathology services table (PST) to introduce two new items (66522 and 66523) for faecal calprotectin (FC) testing. These changes were recommended by MSAC and announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 1** inserts new items 66522 and 66523 for FC testing to diagnosis inflammatory bowel disease (IDB). A service under these items will be available to patients who are less than 50 years of age presenting with gastrointestinal symptoms suggestive of inflammatory or functional bowel disease with more than six weeks duration. This change will reduce the number of patients for which a colonoscopy is required to diagnose IBD. Item 66522 provides for an initial FC test to be performed to diagnosis IBD in symptomatic patients.

Item 66523 provides for a second FC test to be performed to diagnosis IDB in symptomatic patients, where the results of an initial test under item 66522 were inconclusive. A service under item 66523 must be requested by a specialist gastroenterologist where the request indicates that an endoscopic examination is not initially required, and there are no relevant clinical alarms present. Clinical alarms are a terms of art which is understood by the profession in relation to this service.

**Part 2 – Group P4: Immunology**

Part 2 makes changes to the PST to introduce one new item (71175) for the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) or myelin oligodendrocyte glycoprotein antibody0related demyelination (MARD). This change was recommended by MSAC and announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

**Item 2** inserts new item 71175 for the diagnosis of NMOSD or MARD by the detection of aquaporin-4 (AQP4) and myelin oligodendrocyte glycoprotein antibody (MOG) antibodies. A service under this item cannot be used for monitoring purposes, and may not be claimed more than four times in 12 months.

**Part 3 – Group P7: Genetics**

Part 3 amends the PST to make changes to genetic pathology services. These changes were announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure, or are administrative in nature.

**Item 3** inserts two new clauses 2.7.1A and 2.7.1B which provides a restriction in relation to claiming two pathology genetic services.

Clause 2.7.1A provides that if item 73287 is performed in conjunction with item 73388, only the service under item 73388 can be claimed.

Clause 2.7.1B provides that if item 73290 is performed in conjunction with item 73391, only the service under item 73391 can be claimed.

**Item 4** inserts new clause 2.7.3A which provides patient eligibility requirements for new preimplantation genetic testing items 73384 and 73387 (refer to **item 9** of Schedule 3 in the regulations). A service under these items can only be provided if the patient or the patient’s reproductive partner has previously had a consultation with a specialist or consultant physician practising as a clinical geneticist which included a discussion about the disorder, and there is no curative treatment for the disorder and there is severe limitation of quality of life despite contemporary management of the disorder. At least one of the following must apply to the patient or the reproductive partner:

1. has an identified gene variant which places the patient at a risk of having a pregnancy affected by a Mendelian or mitochondrial disorder; or
2. is at risk of an autosomal dominant disorder which places the patient at a risk of having a child who develops the autosomal dominant disorder; or
3. has a chromosome re‑arrangement or copy number variant which places the patient at a risk of having a pregnancy affected by a chromosome disorder.

**Item 5** amends item 73297, which is for the characterisation of specific germline variations, to align with the original policy intent of the service which is that testing under this service is required for at least one of the genes listed in the item descriptor (at least one of BRCA1 or BRCA2, or STK11 or PTEN or CDH1 or PALB2 or TP53). The amended item descriptor also provides a claiming restriction against item 73302 and removes the claiming restriction against itself (item 73297). These changes are administrative in nature.

**Items 6 to 8** amends items 73361, 73362 and 73363, which are for the genetic testing of childhood syndromes, to clarify the requirements for targeted cascade testing of relatives under the items. This change will assist in confirming the presence of a spontaneous gene variant that is the cause of the affected child’s condition.

**Item 9** inserts four new items 73384, 73385, 73386 and 73387 for preimplantation genetic testing (PGT) for specific genetic or chromosomal abnormalities, one new item 73388 for genome-wide microarray (GWMA) testing for pregnancies, one new item 73389 for an analysis of products of conception, and one new item 73391 for GWMA testing for people with multiple myeloma.

Items 73384, 73385, 73386 and 73387 for preimplantation genetic testing

The new suite of PGT items includes a test to identify pathogenic variants in reproductive couples (item 73384), and to further identify the genetic variants in the biopsied embryo or embryos (items 73385, 73386 and 73387).

Item 73384 may be claimed once in a patient episode for disorder (of a kind mentioned in clause 2.7.3A). This includes it the patient has the disorder, or if the patient has gene variant(s) associated with a disorder that was previously identified.

Items 73385, 73386 and 73387 may be claimed once per embryo produced during a single Assisted Reproductive Treatment cycle.

Clause 2.7.3A provides patient eligibility requirements for the four new PGT items (refer to **item 4** of Schedule 3 in the Regulations).

Item 73388 for genome-wide microarray testing for pregnancies

New item 73388 is for GWMA testing for pregnancies with major fetal structural abnormalities. This service will provide for the investigation of a pregnancy where there are major fetal structural abnormalities, which can often result from pathological gene variants, detected by ultrasound.

Item 73389 for analysis at conception

New item 73389 is for the analysis of products of conception from a patient with suspected hydatidiform moles for the characterisation of ploidy status. This item will assist doctors in providing patients with targeted treatment and advice regarding when patients can safely become pregnant again, and is applicable once per pregnancy.

Item 73391 for genome-wide microarray testing

New item 73391 is for GWMA testing for people with multiple myeloma. Item 73391 will allow for the diagnosis and monitoring of multiple myeloma, as a complementary service to fluorescence in-situ hybridisation (FISH) testing currently provided under item 73290.

Item 73391 is applicable once per lifetime and will provide patients with faster access to more accurate results compared to a service under existing item 73290.

**Item 10** inserts a definition for treatment cycle into clause 3.1 of the PST. Under this definition, treatment cycle has the same meaning as in the GMST.

**Statement of Compatibility with Human Rights**

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

***Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021***

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 (2021 Measures No. 2) Regulations 2021* (the Regulations) is to amend the GMST, DIST and PST from
1 November 2021. The Regulations will make changes to general medical services, pathology services and diagnostic imaging services to implement Government policy.

***Changes to medical services***

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

Part 1 of Schedule 1 of the Regulations will introduce four new items 14216, 14217, 14219 and 14220 for repetitive transcranial magnetic stimulation (rTMS) therapy. This change was announced in the 2021-22 Budget under the *Primary Care* measure.

Parts 2 to 10 and Part 12 of Schedule 1 of the Regulations will implement the following changes to general medical services announced by Government in the 2021‑22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure:

* Introduce one new item 30311 for sentinel lymph node biopsy or biopsies to determine if the patient’s melanoma cells have spread to the sentinel lymph nodes.
* Amend three thoracic medicine items 11503, 11508 and 11512 to enable appropriately trained specialists to provide these services.
* Amend item 30210 to remove the age restriction that applies to this service.
* Introduce one new item 32230 for the removal of colorectal polyps to prevent colorectal cancer.
* Introduce one new item 35401 for the treatment of spinal fractures by vertebroplasty.
* Introduce three new items 45534, 45535 and 45589 for autologous fat grafting.
* Amend item 45558 to remove the restriction for pregnant patients.
* Introduce one new item 11607 for ambulatory blood pressure monitoring for the diagnosis of high blood pressure.
* Amend 12 items (32500, and 32507 to 32529) for varicose vein treatment services.
* Introduce one new item 13207 into the GMST for preimplantation embryo biopsy

Part 11 of Schedule 1 of the Regulations will introduce restrictions on the co-claiming of consultations with magnetic resonance imaging (MRI) services, announced in the 2021-22 Budget measure *Guaranteeing Medicare – Magnetic Resonance Imaging*.

Parts 13 to 17 of Schedule 1 of the Regulations will implement the following minor administrative amendments:

* Relocate item 41904 from subgroup 8 to subgroup 6 and replace with new item number 38424.
* Amend item 45632 to clarify the clinical intent of the service.
* Amend five spinal decompression items 51011, 51012, 51013, 51014 and 51015 to clarify the clinical intent of the services.
* Incorporate item 47491 which is currently listed in a determination under subsection 3C(1) of the *Health Insurance Act 1973* (the Act).
* Amend a handful of orthopaedic items to align with the policy intent of the service.

***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 ultrasound items 55065 and 55068 to remove an unintentional restriction. This change resulted an announcement in the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure.

Part 2 of Schedule 2 of the Regulations will make the following changes to computed tomography services that were announced in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure:

* Amend one computed tomography colonography item 56553 to remove the restrictions of the service being performed 36 months before the scan.
* Amend computed tomography item 57360 to clarify policy intent.

This part of the Regulations will also remove item 57351, which is for computed tomography angiography, as this item is obsolete.

Part 3 of Schedule 2 of the Regulations will introduce one new item 61560 for proton emission tomography (PET) for the diagnosis of Alzheimer’s disease. This change was announced in the 2021-22 Budget under *the Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

Part 4 of Schedule 2 of the Regulations will introduce a new clause in the DIST to provide co-claiming restrictions for MRI head and spine items. This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – Improving Diagnostic Imaging* measure.

Part 4 of Schedule 2 of the Regulations will also amend one MRI item 63489 to retain only the MRI component, reduce the fee and clarify co-claiming requirements. This change was announced in the 2021-22 Budget under the *Guaranteeing Medicare – Magnetic Resonance Imaging* measure.

This part of the Regulations will also incorporate items 63541 and 63543 which are currently listed in the *Health Insurance (Section 3C Diagnostic Imaging Services—Multiparametric MRI of the prostate) Determination 2018*. Item 63541 will be amended to enable additional patients’ cohorts to access this service.

Part 5 of Schedule 2 of the Regulations will make minor technical changes to align the headings of provisions dealing with the multiple services rules for diagnostic imaging services. These changes are administrative in nature.

***Changes to pathology services***

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

Parts 1 to 3 of Schedule 3 of the Regulations will implement the following changes to pathology services announced by Government in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure:

* Introduce two new items 66522 and 65523 for faecal calprotectin testing.
* Introduce one new item 71175 for the detection of aquaporin-4 and myelin oligodendrocyte glycoprotein antibody (MOG) antibodies.
* Introduce one new item 73388 for new genome-wide microarray testing.
* Amend three genetic testing items 73361, 73362 and 73363 to clarify the requirements for targeted cascade testing of relatives.
* Introduce four new items 73384, 73385, 73386, 73387 for pre-implantation genetic testing.
* Introduce one item 73389 for genetic testing of conception.
* Introduce one item 73391 for genetic testing for people with multiple myeloma.

This part of the Regulations will also amend item 73297 to align with the original policy intent of the item.

**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 or advance rights to health and social security by ensuring access to publicly subsidised general medical services are clinically and cost-effective.

**Conclusion**

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

**Greg Hunt**

**Minister for Health and Aged Care**