EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2023 Measures No. 3) Regulations 2023

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 prescribes items that have a Medicare benefit equal to 100 per cent of the fee in respect of the service.

Purpose

The purpose of the *Health Insurance Legislation Amendment (2023 Measures No. 3) Regulations 2023* (the Regulations) is to amend the GMST, the DIST, the PST and the HIR from 1 November 2023.

Schedule 1 of the Regulations will amend the fees for ten items in the GMST from the day after registration, to correct the fees for the items which were not indexed as part of the *Health Insurance Legislation Amendment (2023 Measures No. 1) Regulations 2023* (the July 23 Regulations). Schedule 1 of the Regulations will rectify this error.

Schedule 2 of the Regulations will implement an additional fee indexation by increasing the stated fee by 0.5 per cent from 1 November 2023 for most general medical services in the GMST, diagnostic imaging services in the DIST, and specific items for the management of bulk-billing pathology services in the PST. This amendment aligns with the Government announcement of 9 May 2023, as part of the 2023-24 Budget, which included changes to the indexation methodology applying to Government programs, including the Medicare benefits schedule (MBS), to better align with changes in economic conditions. This means that patients will receive a higher Medicare benefit for these services from 1 November 2023.

Schedule 3 of the Regulations will amend the DIST to make changes to the supervision requirements of musculoskeletal (MSK) ultrasound services and make minor administrative amendments to remove references to ceased items. Further, Schedule 3 of the Regulations will increase the fee for existing adrenal study item 61485 in line with the recent increased cost of purchasing the radiopharmaceutical. The amendments to the supervision requirements for MSK ultrasound services and item 61485 were announced under the *A Modern and Clinically Appropriate Medicare Benefits Schedule* measure in 2023-24 Budget.

Part 1 of Schedule 4 of the Regulations will include changes to the GMST which were announced under the *A Modern and Clinically Appropriate Medicare Benefits*Schedule measure in 2023-24 Budget, the Guaranteeing Medicare – Medicare

Benefits Schedule new and amended listings measure under 2021-22 Mid-Year

Economic and Fiscal Outlook, the Guaranteeing Medicare – Updating the Medicare

Benefits Schedule measure under 2021-22 Budget, the Guaranteeing Medicare –

Medicare Benefits Schedule (MBS) Review measure under 2022-23 Budget or are administrative and minor in nature. The changes include:

- The amendment of six level B general practitioner items to introduce a minimum service duration for the items in response to the recommendations from the MBS Review Taskforce (the Taskforce);
- Amending six otolaryngology, head and neck surgery services implemented on 1 March 2023 in response to further recommendations from the sector and implementation liaison group following implementation;
- Minor amendments to seven plastic and reconstructive service items to better align with contemporary clinical practice and further consequential amendments;
- Administrative amendments to items 38477, 11729 and 11730 to correct typographical errors in the items; and
- Administratively update the subgroup name for subgroup 16 of Group T8 in line with the sector's requests for the subgroup's name to reflect amendments to the items contained in the subgroup on 1 July 2021.

Part 2 of Schedule 4 of the Regulations will amend the GMST to amend seven bulk-billing incentive items and introduce 13 new bulk-billing incentive items to further incentivise practitioners to bulk-bill certain eligible Australians. These

changes were announced under the *Strengthening Medicare* measure in the 2023-24 Budget.

Part 3 of Schedule 4 of the Regulations will amend the GMST to introduce items which provide MBS services to patients requiring a consultation of 60 minutes or more (also known as level E consultation items), and consequential amendments to existing 45 minutes or more consultation items (also known as level D consultation items) to include a maximum attendance time for services provided under these items. These changes were announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget.

Part 4 of Schedule 4 of the Regulations will amend the GMST to introduce five new items for the insertion, replacement or removal of a leadless permanent pacemaker where the patient and procedure meets certain criteria. These new items were announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget.

Schedule 5 of the Regulations will incorporate all groups and subgroups, except subgroup 10 of Group A7, of the *Health Insurance (Section 3C General Medical Services – Other Medical Practitioner) Determination 2018* into the GMST. This change is considered administrative and machinery in nature.

Schedule 6 of the Regulations will amend the PST to introduce new items and amend existing pathology testing services. These changes were announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget and will:

- Amend and increase the fee for item 73418 for genetic testing for cardiac arrhythmias;
- Introduce five new items for genetic testing for childhood hearing loss;
- Introduce four new items for gene panel testing for haematological malignancies;
- Introduce one new item for the quantification of N-terminal pro B-type natriuretic peptide (NT-proBNP) or B-type natriuretic peptide (BNP) in patients with systemic sclerosis;
- Amend four items and introduce one new item to better align prostate specific antigen testing with the Prostate Cancer Foundation of Australia guidelines;
- Introduce two new items for reproductive carrier testing for cystic fibrosis, spinal muscular atrophy and fragile X syndrome;
- Introduce three new items for targeted carrier testing for severe monogenic conditions:
- Introduce two new items for the detection of measurable residual disease in acute lymphoblastic leukaemia;
- Introduce one new item for EndoPredict prognostic gene expression profile testing for breast cancer tissue;
- Introduce seven new items for the diagnosis of mitochondrial disease in patients who are suspected of having either acute or chronic diseases, and the cascade testing of their biological relatives; and

• Amend two items to expand the eligible patient population which can access pathology testing for breast, ovarian, fallopian tube or primary peritoneal cancer testing services.

Schedule 7 of the Regulations will amend subsection 28(1) of the HIR to specify 18 new attendance items for consultation lasting 60 minutes or more (including Telehealth consultations) and nine new telehealth consultation items for consultations lasting at least 30 and 45 minutes which are being listed in the *Health Insurance* (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021 on 1 November 2023. This change will allow the specified items to attract a Medicare benefit equal to 100 per cent of the schedule fee.

Consultation

As part of the Taskforce, Strengthening Medicare Taskforce and the Medical Services Advisory Committee (MSAC), a number of medical professional organisations were consulted on 1 November 2023 changes. Further consultation was also undertaken with Implementation Liaison Groups in the development of the changes. There was general support from stakeholders on the changes implemented by the Regulations. Additional consultation information is outlined in the <u>Attachment</u>.

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

Details of the Regulations are set out in the Attachment.

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

Sections 1 to 4 and Schedule 1 of the Regulations will commence the day after registration of this instrument, Schedule 2 commences on 1 November 2023 and Schedules 3 to 7 of the Regulations commence immediately after the commencement of Schedule 2.

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

ATTACHMENT

Details of the Health Insurance Legislation Amendment (2023 Measures No. 3) Regulations 2023

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2023 Measures No. 3) Regulations 2023.*

Section 2 – Commencement

This section provides for sections 1 to 4 and Schedule 1 of the Regulations to commence the day after registration of this instrument, Schedule 2 to commences on 1 November 2023 and Schedules 3 to 7 of the Regulations to commence immediately after the commencement of Schedule 2.

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.

<u>Schedule 1 – Amendments commencing day after registration</u>

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

Schedule 1 of the Regulations will amend the GMST the day after registration of the Regulations.

Items 1 to 10 amend the fees for items 32026, 32028, 32117, 32231, 32232, 32233, 32234, 32235, 32236 and 32237 to correct the fees for the items which were not indexed as part of the *Health Insurance Legislation Amendment (2023 Measures No. 1) Regulations 2023* (the July 23 Regulations). This amendment is considered administrative in nature.

Schedule 2 – Indexation

On 1 July 2023, annual fee indexation of 3.6 per cent was applied to most services under the Medicare Benefits Schedule (MBS). On 9 May 2023, as part of the 2023-24 Budget, the Government annuanced changes to the indexation methodology applying to Government programs, including the MBS, to better align with changes in economic conditions.

Schedule 2 of the Regulations will apply additional indexation of the schedule fees of MBS items from 1 November 2023. This will increase the benefit paid to patients for these services, which is calculated as a percentage of the fee per section 10 of the *Health Insurance Act 1973*. Indexation will be applied by 0.5 per cent, which is represented as 1.005 in the diagnostic imaging services table (clause 2.7.1), general medical services table (clause 1.3.1) and the pathology services table (clause 2.14.1).

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

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

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

Items 3 to 24 apply indexation to all medical services in the general medical services table, other than the following items for services performed by prescribed medical practitioners, indexation has been manually applied or items which are not indexed:

- all items in Group A2, A23 and T10;
- all items in Group A7 (other than items 193, 197 and 199);
- items 90092, 90093, 90095, 90096, 90098, 90183, 90188, 90202 and 90212 in Group A35; and
- items 90254, 90255, 90256, 90257, 90265, 90275 and 90277 in Group A36.

Items 13 and 14 also amend clause 2.30.1 of the GMST, which prescribes the fee in relation to the first patient during each attendance at a residential aged care facility.

Item 13 inserts a reference to new items 90098 and 90054 (refer to **Part 3** of Schedule 4 of the Regulations) and prescribed medical practitioner items 90183, 90188, 90292 or 90121 (refer to **Schedule 5** of the Regulations) into subclause 2.30.1(1), which is the fee relating to attendances at a residential aged care facility performed by a GP. The prescribed fee will be indexed to \$60.55.

Item 14 inserts a reference to new items 90098, 90183, 90188, 90202, 90212 and 90215 (refer to **Part 3** of Schedule 4 of the Regulations) into subclause 2.30.1(1), which is the fee relating to attendances at a residential aged care facility performed by a medical practitioner. The prescribed fee will be indexed to \$43.95.

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

Items 25 and 26 apply indexation to the bulk-billing incentives for unreferred pathology services (Group P12) in the pathology services table. Indexation will not apply to any other pathology service.

Schedule 3 – Diagnostic imaging Services

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

Item 1 amends subclause 1.2.18(3), which prescribes the application of the bulk-billing incentive items, to replace a reference to item 63549 with items 61466 and 61485. The practical application of this amendment is that from 1 November 2023, services under items 61466 and 61485 will be exempt from meeting the requirements of bulk-billing as outlined in clause 1.2.18, whereas item 63549 will no longer be exempt from meeting the requirements of bulk-billing as outlined in clause 1.2.18.

Item 2 repeals clause 2.1.7, which outlines the requirements of personal attendance for musculoskeletal (MSK) ultrasound services, of the DIST. This change will allow supervision requirements for MSK ultrasound services listed on the MBS to default to clauses 2.1.2 or 1.2.16 which also detail supervision requirements for ultrasound services, where appropriate. This change was announced under the 2023-24 Budget measure *A Modern and Clinically Relevant Medicare Benefits Schedule*.

The Department of Health and Aged Care (the department) consulted on the changes to MSK ultrasound supervision requirements with the Australasian Society of Ultrasound in Medicine (ASUM), the Australasian Sonographers Association, the Australian Diagnostic Imaging Association (ADIA), the Australian Society of Medical Imaging and Radiation Therapy (ASMIRT), and the Royal Australian and New Zealand College of Radiologists (RANZCR). Stakeholders were supportive of this change.

Item 3 amends item 56219 to remove an incorrect reference to item number 59275 from the item description. Item 59275 does not exist on the MBS and as such this change is considered minor and administrative in nature.

Item 4 amends subclause 2.4.2(1) to update the reference to the applicable items under which this clause applies. Under this change, 'items 61523 to 61647' will be updated to read 'items in Subgroup 2 of Group I4' to clarify the groups to which clause 2.4.2 applies. This change is considered administrative and minor in nature.

Items 5 to 27 amend the item descriptors for 12 items to remove references to ceased item numbers from the item descriptions. The ceased items, and the items they are referenced within, are detailed below:

- items 61332, 61380 and 61422, contained within the item descriptor for items 61321 and 61325;
- items 61311, 61332, 61377, 61380 and 61422, contained within the item descriptor for items 61324, 61329, 61345, 61357, 61394, 61398, 61406 and 61414; and
- items 61311, 61332, 61337, 61365, 61380 and 61418, contained within the item descriptor for items 61349 and 61410.

These changes are considered minor and administrative in nature.

Item 28 amends the schedule fee for adrenal study item 61485 from \$999.20 to \$3,364.00. The purpose of this fee increase is to cover the cost of the radiopharmaceutical administered as a part of the service, which has become significantly more expensive over time. The amendment was recommended by the

Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) at recommendation 21 in the Final Report on the MBS Items for Nuclear Medicine, and will ensure that these services continue to be accessible and affordable for patients. This fee amendment was announced under the *A Modern and Clinically Appropriate Medicare Benefits Schedule* in 2023-24 Budget.

Schedule 4 – General medical services

Part 1 – General Amendments

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

Items 1 to 6 amend GMST clauses 1.2.3, 1.2.5, 1.2.6, 1.2.7 and 1.2.8 to include references to new Level E consultation items (refer to Part 3 of Schedule 4 of the Regulations) and items which are being incorporated into the GMST from the *Health Insurance (Section 3C General Medical Services – Other Medical Practitioner)*Determination 2018 (the OMP Determination). These changes are considered minor and administrative in nature.

Item 7 amends clause 1.2.11 of the GMST to allow services under items 11340, 11341 and 11343 to be provided by persons other than medical practitioners. These consequential amendments are required in order to implement in line with the recommendations from the Taskforce and are considered to be included in the announcement of changes to otolaryngology, head and neck surgery items announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medicare Benefits Schedule (MBS) Review* measure.

The Otolaryngology Head and Neck Surgery Implementation Liaison Group (the OHNSILG) was established to provide advice on the implementation of the Taskforce's recommendations. The OHNSILG included representatives from the Australian Medical Association (AMA), Australasian Society of Otolaryngology, Head and Neck Surgery, Laryngology Society of Australia, Audiology Australia, Independent Audiologists Australia and Private Healthcare Australia. The OHNSILG were supportive of this amendment.

Item 8 amends general practitioner consultation items 23 and 24 to insert a minimum service time to which the items apply. Under these changes, items 23 and 24 will apply to a consultation service lasting at least six minutes and less than 20 minutes. This change was recommended by the clinician led MBS Review Taskforce through the General Practice and Primary Care Clinical Committee report and was announced in the May 2023-24 Budget under the *A Modern and Clinically Appropriate Medicare Benefits Schedule* measure.

Item 9 inserts a new subgroup name for subgroup 1 of Group A2. Under this change, the subgroup name of "Other medical practitioner attendances" will apply to items 52 to 65. This change is considered minor and administrative in nature.

Item 10 corrects a typographical error in item 946, where an "a" was omitted following the words "member of". This change is considered minor and administrative in nature.

- Item 11 amends domiciliary medication management review (DMMR) item 900 to clarify that the item may not be claimed if a service under item 245 had been rendered to the same patient in the previous 12 months, except if there has been a significant change in the patient's condition or medication regimen requiring a new DMMR. This amendment is considered consequential and administrative in nature and has occurred as a result of the incorporation of the OMP Determination into the GMST.
- Item 12 amends residential medication management review (RMMR) item 903 to clarify that the item may not be claimed if a service under item 249 has been rendered to the same patient in the previous 12 months, unless there has been a significant change in the resident's medical condition or medication management plan requiring a new RMMR. This amendment is considered consequential and administrative in nature and has occurred as a result of the incorporation of the OMP Determination into the GMST.
- **Item 13** inserts a new subgroup name for subgroup 1 of Group A21. Under this change, the subgroup name of "Consultations" will apply to items 5001 to 5036. This change is considered minor and administrative in nature.
- **Item 14** inserts a new subgroup name for subgroup 2 of Group A21. Under this change, the subgroup name of "Prolonged professional attendances to which no other Group applies" will apply to items 5039 to 5044. This change is considered minor and administrative in nature.
- **Item 15** amends general practitioner consultation items 5020, 5023 and 5028 to insert a minimum service time to which the items apply. Under these changes, items 5020, 5023 and 5028 will apply to a consultation service lasting at least six minutes and less than 20 minutes. This change was recommended by the clinician led MBS Review Taskforce through the General Practice and Primary Care Clinical Committee report, and was announced in the May 2023-24 Budget under the *A Modern and Clinically Appropriate Medicare Benefits Schedule* measure.
- **Item 16** amends the item descriptor for item 11332 to correct a spelling error in the item description. Under this change, the error of 'cochlear' will be amended to read 'cochlear'. This change is considered minor and administrative in nature.
- **Item 17** amends the item descriptor for items 11729 and 11730 to remove referces to ceased item numbers 61311, 61332, 61365, 61377, 61380 and 61418 from the item descriptions. These changes are considered minor and administrative in nature.
- **Item 18** amends the item descriptor for item 38477 to remove a typographical error where the words 'to which' appear twice in the co-claiming restriction at paragraph (b). This change is considered minor and administrative in nature.
- **Item 19** amends the item descriptor for item 41603 to specify that the procedure may be claimed alongside an item for the administration of anaesthetic. This change is in line with the recommendations from the Taskforce and is considered to be included in the announcement of changes to otolaryngology, head and neck surgery items announced in the 2022-23 Budget under the *Guaranteeing Medicare Medicare Benefits Schedule (MBS) Review* measure.

The OHNSILG was supportive of this amendment.

Items 20 and 21 amends the item descriptor for items 41671 and 41693 to specify that the service may claim an assistance item. These amendments are required in line with the intention of the recommendations from the Taskforce and are considered to be included in the announcement of changes to otolaryngology, head and neck surgery items announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medicare Benefits Schedule (MBS) Review* measure.

The OHNSILG was supportive of this amendment.

Item 22 to 23 amend items 41740, 41743 and 41870 to clarify that the items are not applicable when the same item has been performed on the same side. These amendments are in line with the intention of the recommendations from the Taskforce more completely and are considered to be included in the announcement of changes to otolaryngology, head and neck surgery items announced in the 2022-23 Budget under the *Guaranteeing Medicare – Medicare Benefits Schedule (MBS) Review* measure.

The OHNSILG was supportive of this amendment.

Item 24 amends item 45571 to include references to items 46080, 46082, 46084, 46086, 46088 and 46090 in the list of services to which the item is to apply. This change is in line with align with the original intent of the plastic and reconstructive surgery service amendments recommended by the Taskforce. This amendment falls within the Government's announcement under the *Guaranteeing Medicare* — *Medicare Benefits Schedule new and amended listings* measure in 2021-22 Mid-Year Economic and Fiscal Outlook (MYEFO) and the *Guaranteeing Medicare* — *Updating the Medicare Benefits Schedule* measure in 2021-22 Budget.

The Department of Health and Aged Care consulted with the Australian Society of Plastic Surgeons, who were supportive of the change.

Item 25 amends the item descriptor for items 45794 and 45797 to remove a reference to ceased item 41604. This change is considered minor and administrative in nature.

Item 26 amends the item description for item 46108 to specify that the service excludes aftercare. This change is required to align with the original intent of the changes to plastic and reconstructive services recommended by the Taskforce more closely. This amendment falls within the Government's announcement under the *Guaranteeing Medicare – Medicare Benefits Schedule new and amended listings* measure in 2021-22 MYEFO and the *Guaranteeing Medicare – Updating the Medicare Benefits Schedule* measure in 2021-22 Budget.

As part of the Implementation Liaison Group formed under the Taskforce Report for Plastic and Reconstructive Surgery Items 2019, extensive consultations were undertaken with peak bodies, who were supportive of the Taskforce's recommendation for item 46108 to exclude aftercare.

Item 27 amends the item description for item 46116 to state that the service applies to an area covering more than 10 per cent but less than 20 per cent of total body surface.

This change is required to align with the original intent of the changes to plastic and reconstructive services recommended by the Taskforce more closely. This amendment falls within the Government's announcement under the *Guaranteeing Medicare* – *Medicare Benefits Schedule new and amended listings* measure in 2021-22 MYEFO and the *Guaranteeing Medicare* – *Updating the Medicare Benefits Schedule* measure in 2021-22 Budget.

As part of the Implementation Liaison Group formed under the Taskforce Report for Plastic and Reconstructive Surgery Items 2019, extensive consultations were undertaken with peak bodies, who were supportive of the Taskforce's recommendation regarding the total body surface area covered under item 46116.

Item 28 amends the item descriptor for items 46120 and 46122 to clarify that the items are not intended to be used for services related to contracture release. This change is required to align with the original intent of the changes to plastic and reconstructive services recommended by the Taskforce more closely. This amendment falls within the Government's announcement under the *Guaranteeing Medicare – Medicare Benefits Schedule new and amended listings* measure in 2021-22 MYEFO and the *Guaranteeing Medicare – Updating the Medicare Benefits Schedule* measure in 2021-22 Budget.

As part of the Implementation Liaison Group formed under the Taskforce Report for Plastic and Reconstructive Surgery Items 2019, extensive consultation was undertaken with peak bodies, who were supportive of the Taskforce's recommendation for items 46120 and 46122 to not include contracture release.

Item 29 amends general practitioner consultation at a residential aged care facility item 90035 to insert a minimum service time to which the item applies. Under these changes, item 90035 will apply to a consultation service lasting at least six minutes and less than 20 minutes. This change was recommended by the clinician led MBS Review Taskforce through the General Practice and Primary Care Clinical Committee report, and was announced in 2023-24 Budget under the *A Modern and Clinically Appropriate Medicare Benefits Schedule* measure.

Item 30 amends the subgroup heading for subgroup 16 of Group T8 to read 'Tissue Ablation'. This amendment is made in response to the sector's requests to remove the specification of the ablation method in line with the amendments to the items made on 1 July 2021. This change is considered minor and administrative in nature.

<u>Part 2 – Bulk-billing incentive</u>

Part 2 of Schedule 4 of the Regulations make changes which were announced by the Governments as part of 2023-24 Budget under the *Strengthening Medicare* measure. As part of the announcement, seven GMST bulk-billing incentive (BBI) items will be amended and 13 new BBI items will be inserted into the GMST. The amendments to the existing items and introduction of new items will incentivise practitioners to bulk-bill eligible Australians.

The new BBI items support the recommendation of the Strengthening Medicare Taskforce to increase more affordable care, assisting Australians on low incomes to access primary care at no or low cost.

Item 31 inserts three new definitions into clause 3.2.1 of the GMST which defines terms relating to the BBI items. Under this amendment, 'general practice support service' means a service to which an item specified in subclause 3.2.2A(2) applies, 'MyMedicare program' means the registration program by that name administered by the department, and 'MyMedicare service' means a service to which an item specified in subclause 3.2.2B(2) applies that is provided to a person, if the person is enrolled in the MyMedicare program and the service is provided at the practice at the which the person is so enrolled.

Item 32 inserts two new clauses, clause 3.2.2A and 3.2.2B, which prescribe what items apply to the new BBI service items.

Clause 3.2.2A prescribes services to which new BBI items 75870, 75871, 75872, 75873, 75874, 75875 and 75876 apply. Paragraph 3.2.2A(1) prescribes that where items 75870, 75871, 75872, 75873, 75874, 75875 or 75876 apply to a medical service, the fee for that item as well as the fee for the item prescribed in subclause 3.2.2A(2) applies.

Subclause 3.2.2A(2) prescribes which items may be co-claimed alongside the new BBI items 75870, 75871, 75872, 75873, 75874, 75875 and 75876.

Clause 3.2.2B prescribes services to which new BBI items 75880, 75881, 75882, 75883, 75884 and 75885 apply. Paragraph 3.2.2B(1) prescribes that where items 75880, 75881, 75882, 75883, 75884 or 75885 apply to a medical service, the fee for that item as well as the fee for the item prescribed in subclause 3.2.2B(2) applies.

Subclause 3.2.2B(2) prescribes which items may be co-claimed alongside the new BBI items 75880, 75881, 75882, 75883, 75884 and 75885.

Item 33 inserts a new subgroup into Group M1, which groups the existing BBI items into the subgroup. Under this change, items 10990 to 75858 will be contained within subgroup 1 titled "Management of general bulk-billed services".

Item 34 repeals and replaces the item descriptor for item 10990 to clarify the co-claiming restriction which will apply to the 13 new BBI items. Under this change, item 10990 will not apply when the item is claimed with another item to which Group M1 applies, a general practice support service or a MyMedicare service. This change is considered consequential in nature.

Item 35 repeals and replaces the item descriptor for item 10991 to clarify the co-claiming restriction which will apply to the 13 new BBI items. Under this change, item 10991 will not apply when the item is claimed with another item to which Group M1 applies, a general practice support service or a MyMedicare service. This change is considered consequential in nature.

Item 36 repeals and replaces paragraphs (a) and (b) of item 10992 to remove references to items covered under 75872 and insert a reference to 5260. This change is considered consequential in nature.

Item 37 repeals and replaces the item descriptor for item 75855 to clarify the co-claiming restriction which will apply to the 13 new BBI items. Under this change, item 75855 will not apply when the item is claimed with another item to which Group M1 applies, a general practice support service or a MyMedicare service. This change is considered consequential in nature.

Item 38 repeals and replaces the item descriptor for item 75856 to clarify the co-claiming restriction which will apply to the 13 new BBI items. Under this change, item 75856 will not apply when the item is claimed with another item to which Group M1 applies, a general practice support service or a MyMedicare service. This change is considered consequential in nature.

Item 39 repeals and replaces the item descriptor for item 75857 to clarify the co-claiming restriction which will apply to the 13 new BBI items. Under this change, item 75857 will not apply when the item is claimed with another item to which Group M1 applies, a general practice support service or a MyMedicare service. This change is considered consequential in nature.

Item 40 repeals and replaces the item descriptor for item 75858 to clarify the co-claiming restriction which will apply to the 13 new BBI items. Under this change, item 75858 will not apply when the item is claimed with another item to which Group M1 applies, a general practice support service or a MyMedicare service. This change is considered consequential in nature.

Item 41 inserts two new subgroups, and their respective items, into Group M1 of the GMST. Subgroup 2 is titled 'General support service', containing seven new BBI items, and subgroup 3 is titled 'Patients enrolled in MyMedicare', containing six new BBI items.

New item 75870 is for professional attendances provided by a general practitioner (GP), medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2A(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations). The new item must be claimed in association with a general practice support service provided to a patient who is under the age of 16 or a concessional beneficiary and is not an admitted patient of a hospital.

New item 75871 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2A(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 2 area. The new item must be claimed in association with a general practice support service provided to a patient who is under the age of 16 or a concessional beneficiary and is not an admitted patient of a hospital.

New item 75872 is for an unreferred professional attendance provided by or on behalf of a GP, medical practitioner or a prescribed medical practitioner to which item 763, 766, 769, 776, 788, 789, 2198, 2200, 5023, 5028, 5043, 5049, 5063, 5067, 5076,

5077, 5223, 5227, 5228, 5261, 5263, 5265, 5267 or 5262 applies. The new item must be provided to a patient who is under the age of 16 or a concessional beneficiary and is not an admitted patient of a hospital.

New item 75873 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2A(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 3 or 4 area. The new item must be claimed in association with a general practice support service provided to a patient who is under the age of 16 or a concessional beneficiary and is not an admitted patient of a hospital.

New item 75874 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2A(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 5 area. The new item must be claimed in association with a general practice support service provided to a patient who is under the age of 16 or a concessional beneficiary and is not an admitted patient of a hospital.

New item 75875 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2A(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 6 area. The new item must be claimed in association with a general practice support service provided to a patient who is under the age of 16 or a concessional beneficiary and is not an admitted patient of a hospital.

New item 75876 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2A(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 7 area. The new item must be claimed in association with a general practice support service provided to a patient who is under the age of 16 or a concessional beneficiary and is not an admitted patient of a hospital.

New item 75880 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2B(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations). The new item must be claimed in association with a MyMedicare service provided to a patient who is under the age of 16 or a concessional beneficiary, enrolled in the MyMedicare program at the general practice through which the attendance service is provided and is not an admitted patient of a hospital.

New item 75881 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2B(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 2 area. The new item must be claimed in association with a MyMedicare service provided to a patient who is under the age of 16 or a concessional beneficiary, enrolled in the MyMedicare program at the general practice through which the attendance service is provided and is not an admitted patient of a hospital.

New item 75882 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2B(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 3 or 4 area. The new item must be claimed in association with a MyMedicare service provided to a patient who is under the age of 16 or a concessional beneficiary, enrolled in the MyMedicare program at the general practice through which the attendance service is provided and is not an admitted patient of a hospital.

New item 75883 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2B(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 5 area. The new item must be claimed in association with a MyMedicare service provided to a patient who is under the age of 16 or a concessional beneficiary, enrolled in the MyMedicare program at the general practice through which the attendance service is provided and is not an admitted patient of a hospital.

New item 75884 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2B(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 6 area. The new item must be claimed in association with a MyMedicare service provided to a patient who is under the age of 16 or a concessional beneficiary, enrolled in the MyMedicare program at the general practice through which the attendance service is provided and is not an admitted patient of a hospital.

New item 75885 is for professional attendances provided by a GP, medical practitioner or a prescribed medical practitioner for items which are also specified in new subclause 3.2.2B(2) (refer to **item 32** of Part 2 of Schedule 4 of the Regulations) performed in a Modified Monash 7 area. The new item must be claimed in association with a MyMedicare service provided to a patient who is under the age of 16 or a concessional beneficiary, enrolled in the MyMedicare program at the general practice through which the attendance service is provided and is not an admitted patient of a hospital.

Part 3 – Consultations lasting 60 minutes or more

Part 3 of Schedule 4 of the Regulations make changes which were announced by the Government as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget. As part of the announcement, 18 new items for consultations lasting 60 minutes or more (Level E attendance items) in general practice settings. Further, the existing items which provide for consultations lasting more than 45 minutes (Level D attendance items) will be amended to provide a maximum service time where this is consistent with the drafting of the other time tiers of the same type.

15 new level E items will be added to the GMST as a part of the Regulations, and three more items will be added to the OMP Determination. The insertion of new

Level E attendance items 301 and 303 for prescribed medical practitioners is contained within Schedule 5 of the Regulations.

The introduction of a longer general attendance consultation was a recommendation of the Strengthening Medicare Taskforce and the MBS Review Taskforce.

Item 42 inserts two new items into Group A1 of the GMST.

New Level E item 123 is for professional attendances by a GP lasting at least 60 minutes. The schedule fee for new item 123 is \$191.20.

New Level E item 124 is for professional attendances by a general practitioner, other than attendances at consulting rooms or a residential aged care facility or a service which is listed in the GMST. The fee for this item depends on the amount of patients seen (refer to the table at **item 7** of Schedule 2 of the Regulations).

Item 43 amends Level D attendance item 57 to prescribe the maximum time for a service provided under this item applies. Under this change, item 57 will apply to a service lasting more than 45 minutes but not more than 60 minutes.

Item 44 inserts new Level E item 151 into subgroup 1 of Group A2 of the GMST. New item 151 is for professional attendances at consulting rooms lasting more than 60 minutes (other than a service to which any other item applies) provided by a medical practitioner who is not a GP or a Group A1 disqualified GP. The schedule fee for new item 151 is \$98.40.

Item 45 amends Level D attendance item 65 to prescribe the maximum time for a service provided under this item applies. Under this change, item 65 will apply to a service lasting more than 45 minutes but not more than 60 minutes.

Item 46 inserts new Level E item 165 into subgroup 1 of Group A2 of the GMST. New item 165 is for professional attendances, other than attendances consulting rooms or a residential aged care facility or a service provided by a medical practitioner who is not a GP or a Group A1 disqualified GP which is listed in the GMST. The fee for this item depends on the amount of patients seen (refer to the table at **item 7** of Schedule 2 of the Regulations).

Item 47 inserts a reference to new Level E item 5071 into subclause 2.24.1(1), which prescribes the restrictions on items in Group A22 relating to the timing for the services. Under this change, new item 5071 will only apply to a professional service that is provided on a public holiday, on a Sunday, during prescribed hours on a Saturday, or before 8am or after 8 pm on a day other than those mentioned above.

Item 48 inserts a reference to new Level E item 5071 into subclause 2.24.1(2), which prescribes the restrictions on items in Group A22 relating to the timing for the services. Under this change, new item 5071 will only apply to a professional service that is provided in an after-hours period.

Item 49 inserts new items 5071, 5076 and 5077 into Group A22 of the GMST.

New Level E item 5071 is for after-hours professional attendances by a GP lasting at least 60 minutes. The schedule fee for new item 5071 is \$220.25.

New Level E item 5076 is for after-hours professional attendances by a GP, other than attendances at consulting rooms, a hospital or a residential aged care facility or o which another service which is listed in the GMST applies. The fee for this item depends on the amount of patients seen (refer to the table at **item 7** of Schedule 2 of the Regulations).

New Level E item 5077 is for an after-hours professional attendance by a GP in a residential aged care facility. The fee for this item depends on the amount of patients seen (refer to the table at **item 7** of Schedule 2 of the Regulations).

Item 50 inserts a reference to new Level E item 5209 into subclause 2.25.1(1), which prescribes the restrictions on items in Group A23 relating to the timing for the services. Under this change, new item 5209 will only apply to a professional service that is provided on a public holiday, on a Sunday, during prescribed hours on a Saturday, or before 8am or after 8 pm on a day other than those mentioned above.

Item 51 amends Level D attendance item 5208 to prescribe the maximum time for a service provided under this item applies. Under this change, item 5208 will apply to a service lasting more than 45 minutes but not more than 60 minutes.

Item 52 inserts new Level E item 5209 into Group A23 of the GMST. New item 5209 is for a professional attendance lasting more than 60 minutes by a medical practitioner who is not a GP. The schedule fee for this item is \$122.40.

Item 53 amends Level D attendance item 5228 to prescribe the maximum time for a service provided under this item applies. Under this change, item 5228 will apply to a service lasting more than 45 minutes but not more than 60 minutes.

Item 54 inserts new Level E item 5261 into Group A23 of the GMST. New item 5261 is for a professional attendance lasting more than 60 minutes by a medical practitioner who is not a GP. The fee for this item depends on the amount of patients seen (refer to the table at **item 7** of Schedule 2 of the Regulations).

Item 55 amends Level D attendance item 5267 to prescribe the maximum time for a service provided under this item applies. Under this change, item 5267 will apply to a service lasting more than 45 minutes but not more than 60 minutes.

Item 56 inserts new Level E item 5262 into Group A23 of the GMST. New item 5261 is for professional attendances by a medical practitioner (other than a GP) in a residential aged care facility or at consulting rooms situated within such a complex. The fee for this item depends on the amount of patients seen (refer to the table at **item 7** of Schedule 2 of the Regulations).

Item 57 inserts new Level E item 90054 into Group A35 of the GMST. New item 90054 is for professional attendances by a GP for patients in a residential aged care facility at least 60 minutes. The schedule fee for item 90054 is \$191.20.

Item 58 amends Level D attendance item 90096 to prescribe the maximum time for a service provided under this item applies. Under this change, item 90096 will apply to a service lasting more than 45 minutes but not more than 60 minutes.

Item 59 inserts new Level E items 90098 and 90215, and amends Level D consultation item 90212 to prescribe a maximum service time for a service provided under this item applies. Items 90183, 90188, 90202 and 90212 have been incorporated from the OMP Determination (refer to **Schedule 5** of the Regulations).

New Level E item 90098 is for professional attendances by a medical practitioner (other than a GP) in a residential aged care facility or at consulting rooms situated within such a complex lasting at least 60 minutes. The schedule fee for item 90098 is \$88.20.

Level D attendance item 90212 will be amended to prescribe the maximum time for which the service is to apply. Under this change, item 90212 will apply to a service lasting more than 45 minutes but not more than 60 minutes.

New Level E item 90215 is for professional attendances by a prescribed medical practitioner at a residential aged care facility (other than a professional attendance at a self-contained unit) or at consulting rooms situated within such a complex lasting at least 60 minutes. The schedule fee for item 90215 is \$152.95.

Part 4 – Leadless permanent pacemaker services

Part 4 of Schedule 4 of the Regulations will introduce four new items for the insertion, replacement or removal of a leadless permanent pacemaker (LPM) for the treatment of patients with bradyarrhythmia, including cardiac electrophysiological services where transvenous pacemaker is inappropriate due to an inaccessible upper extremity venous system, increased risk of infection or history of venous thrombosis. MBS item 90300 will also be amended to include the new LPM service under a professional attendance of a cardiothoracic surgeon to provide immediate surgical backup.

These changes were considered under Medical Services Advisory Committee (MSAC) application number 1672 at the July 2022 MSAC meeting, and subsequently announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget. The department has consulted with the Cardiac Society of Australia and New Zealand (CSANZ) and the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) were consulted on the changes and they are supportive of the changes.

Item 60 inserts four new items (items 38372, 38373, 38374 and 38375) into subgroup 6 of Group T8 of the GMST.

New item 38372 is for the insertion of LPM devices for the treatment of bradycardia, including cardiac electrophysiological services. New item 38372 may not be claimed in association with a service to which item 38350 applies and may only be performed in a hospital setting. The schedule fee for this item is \$830.30.

New item 38373 is for the percutaneous retrieval and replacement of LPM devices, if the service is performed by an appropriately trained specialist or consultant physician in a facility where cardiothoracic surgery is available and a thoracotomy can be performed immediately and without transfer (if the device has been insitu for more than 4 weeks). If the device is being percutaneously removed or replaced after 4 weeks by an interventional cardiologist, a cardiothoracic surgeon must be in attendance. New item 38373 may not be claimed in association with a service to which item 38350 applies and may only be performed in a hospital setting. The schedule fee for this item is \$830.30.

New item 38374 is for the percutaneous retrieval of LPM devices, if the service is performed by an appropriately trained specialist or consultant physician in a facility where cardiothoracic surgery is available and a thoracotomy can be performed immediately and without transfer (if the device has been insitu for more than 4 weeks). If the device is being percutaneously removed or replaced after 4 weeks by an interventional cardiologist, a cardiothoracic surgeon must be in attendance. If the service is performed by an appropriately trained specialist or consultant physician in a facility where cardiothoracic surgery is available and a thoracotomy can be performed immediately and without transfer, or a cardiothoracic surgeon is in attendance where the service is performed by an interventional cardiologist. New item 38374 may only be performed in a hospital setting. The schedule fee for this item is \$830.30.

New item 38375 is for the open surgical explanation of a LPM device performed in a hospital setting. The schedule fee for this item is \$3,107.15.

Item 61 amends professional attendance item 90300 to allow the service claimed by a cardiothoracic surgeon in the event they are providing immediate medical assistance to a service under items 38373 or 38374 applies.

Schedule 5 – Prescribed medical practitioner services

Schedule 5 of the Regulations incorporate all parts, except subgroup 10 of Group A7, of the *Health Insurance (Section 3C General Medical Services – Other Medical Practitioner) Determination 2018* (the OMP Determination) into the GMST. The changes made to the items and provisions contained in the OMP Determination (the incorporated items) are administrative in nature and are not intended to change the arrangements for patients receiving services under the incorporated items.

No consultation occurred on this incorporation, as these amendments are considered machinery in nature and administrative.

Item 1 amends subparagraph 1.1.5(1)(b)(i), which sets out which multidisciplinary case conference team items are required to have at least two other members in addition to the lead medical practitioner, to include incorporated items 235, 236, 237, 238, 239, 240, 964, 969, 971, 972, 973, 975 and 986 to this definition. This amendment provides the requirements were previously in subclause 1.6.1(12) of the OMP Determination.

Item 2 incorporates clause 1.1.1 of the OMP Determination into the GMST as a new clause 2.1.2. Clause 2.1.2 outlines the fees for items which have derived fees, this

being the set fees for item is dependent on how many patients the prescribed medical practitioner has attended.

If a practitioner attends not more than 6 patients in a single attendance, the amount mentioned in column 3 of the table under clause 2.1.2 for the item, divided by the number of patients attended, applies. If a practitioner attends more than 7 patients in a single attendance, the amount mentioned in column 4 of the table under clause 2.1.2 for the item applies. The fee specified in column 3 or 4 applies in addition to the fee for the relevant item listed in column 2.

Item 3 inserts two notes into the GMST to provide guidance regarding:

- the location in the GMST of restrictions, limitations and other requirements relating to the incorporated items; and
- where certain expressions within the incorporated items are defined in the GMST.

Item 4 inserts new clause 2.10.1A, which prescribes the application of items 214 to 220. New clause 2.10.1A relates to requirements which were covered by clause 1.3.1 of the OMP Determination. Incorporated items 214 to 220 are equivalent to general practitioner items 160 to 164, and as such have the same claiming restrictions and requirements applying to them.

New clause 2.10.1A prescribes that items 214 to 220 apply only to a service provided in the course of a personal attendance by one or more prescribed medical practitioners on a single patient on a single occasion and if the professional attendance is provided by one or more prescribed medical practitioners concurrently, each prescribed medical practitioner may claim an attendance fee. However, if the personal attendance is not continuous, the occasion on which the service is provided is taken to be the total time of the attendance

The addition of new clause 2.10.1A represents the continuation of existing claiming arrangements.

Item 5 amends the note contained within clause 2.10.2 which specifies which items of Group A7 are indexed in accordance with clause 1.3.1. The revised note explains that the fees in items 193, 197 and 199 of Group A7 are indexed in accordance with clause 1.3.1.

Item 6 inserts the items incorporated from the OMP Determination at the end of the table contained within Group A7 (excluding subgroup 10 of Group A7 and A35 items) and adds the new prescribed medical practitioner consultation items lasting 60 minutes or more (items 301 and 303).

Incorporated items previously listed in subgroup 2 of Group A7 of the OMP Determination are equivalent to the general practitioner items contained within Group A1 of the GMST, however they are for prescribed medical practitioners (refer to **item 102** of Schedule 5 of the Regulations). Subgroup 2 items are only available at a location in an eligible area, which is a Modified Monash 2 to 7 area (refer to **item 95** of Schedule 5 of the Regulations).

New item 301 is for prescribed medical practitioner attendances at consulting rooms lasting 60 minutes or more other than attendances consulting rooms or a residential aged care facility or a service to which any other item applies. The fee for this item is \$152.95.

New item 303 is for prescribed medical practitioner attendances lasting 60 minutes or more other than attendances at a residential aged care facility or a service to which any other item applies. The fee for this item depends on the amount of patients seen (refer to the table at **item 2** of Schedule 5 of the Regulations).

The incorporated and new items will sit in new subgroup 2, titled "Prescribed medical practitioner attendance to which no other item applies", within Group A7 of the GMST.

Incorporated items previously listed in subgroup 3 of Group A7 of the OMP Determination are equivalent items of GMST items contained within Group A5, however they are for prescribed medical practitioners (refer to **item 102** of Schedule 5 of the Regulations). Subgroup 3 items must adhere to the requirements set out in new clause 2.10.1A (refer to **item 4** of Schedule 5 of the Regulations) in order for the items to be eligible to be claimed. The incorporated items will sit in new subgroup 3, titled "Prescribed medical practitioner prolonged attendances to which no other item applies", within Group A7 of the GMST. Incorporated items 214 to 220 are intended for use where a patient is considered to be in a critical condition and in imminent danger of death.

Incorporated items previously listed in subgroup 4 of Group A7 of the OMP Determination are equivalent items of GMST items contained within Group A6, however they are for prescribed medical practitioners (refer to **item 102** of Schedule 5 of the Regulations). The incorporated items will sit in new subgroup 4, titled "Prescribed medical practitioner group therapy", within Group A7 of the GMST. Incorporated items 221 to 223 are for attendances by prescribed medical practitioners to family group therapy where a formal intervention a specific therapeutic outcome is undertaken.

Incorporated items previously listed in subgroup 5 of Group A7 of the OMP Determination are equivalent items of GMST items contained within Group A14, however they are for prescribed medical practitioners (refer to **item 102** of Schedule 5 of the Regulations). The incorporated items will sit in new subgroup 5, titled "Prescribed medical practitioner health assessments", within Group A7 of the GMST. Incorporated items 224 to 228 are for a prescribed medical practitioner to undertake a health assessment on a patient.

Incorporated items previously listed in subgroup 6 of Group A7 of the OMP Determination are equivalent items of GMST items contained within Group A15, however they are for prescribed medical practitioners (refer to **item 102** of Schedule 5 of the Regulations). The incorporated items will sit in new subgroup 6, titled "Prescribed medical practitioner management plans, team care arrangements and multidisciplinary care plans and case conferences", within Group A7 of the GMST. Incorporated items 229 to 986 are for prescribed medical practitioner attendances to

develop team care plans or arrangement and attend case conferences which discuss the management of a patient.

Incorporated items previously listed in subgroup 7 of Group A7 of the OMP Determination are equivalent items of GMST items contained within Group A17, however they are for prescribed medical practitioners (refer to **item 102** of Schedule 5 of the Regulations). The incorporated items will sit in new subgroup 7, titled "Prescribed medical practitioner domiciliary and residential medication management review", within Group A7 of the GMST. Incorporated items 245 to 249 are for the management of a patients DMMR or RMMR for the optimisation of the patient's medication regimen by a prescribed medical practitioner and the patient's preferred community pharmacy or accredited pharmacist.

Incorporated items previously listed in subgroup 9 of Group A7 of the OMP Determination are equivalent items of GMST items contained within Group A20, however they are for prescribed medical practitioners (refer to **item 102** of Schedule 5 of the Regulations). The incorporated items will sit in new subgroup 9, titled "Prescribed medical practitioner mental health care", within Group A7 of the GMST. Incorporated items 272 to 315 are for attendances by prescribed medical practitioners to undertake early intervention, assessment and management of patients with mental health issues.

The incorporated item previously listed in subgroup 11 of Group A of the OMP Determination is an equivalent item of GMST item 4001 contained within Group A27, however it is for prescribed medical practitioners (refer to **item 102** of Schedule 5 of the Regulations). The incorporated item will sit in new subgroup 11, titled "Prescribed medical practitioner pregnancy support counselling", within Group A7 of the GMST. Incorporated item 792 is for the attendance of a prescribed medical practitioner to provide non-directive pregnancy support counselling lasting at least 20 minutes to a person who is currently pregnant or was pregnant in the last 12 months preceding the provision of the first service to which item 792, or item 4001, 81000, 81005, 81010, 92136, 92137, 92138, 92139, 93026 or 93029, applies in relation to that pregnancy.

Item 7 amends the heading for Division 2.15 to include a reference to subgroup 5 of Group A7 and insert a note. Under this amendment, Division 2.15 will be titled "Group A14 and Subgroup 5 of Group A7: Health assessments" and will include a note regarding the location of specified items into Division 2.10.

Item 8 repeals and replaces clause 2.15.1 of the GMST, which prescribes the restrictions on items in Group A14, to amend the heading of the clause to include a reference to Subgroup 5 of Group A7 and incorporates a restriction relating to incorporated items 224 to 227. Under this amendment, items 224 to 227 apply to a service provided in the course of a personal attendance by a single prescribed medical practitioner on a single patient. This restriction was contained within clause 1.5.1 of the OMP Determination.

Item 9 amends subclause 2.15.2(1) of the GMST to include a reference to incorporated items 224 to 227, a specification which was previously under subclause 1.5.1(2) of the OMP Determination. Under this change, clause 2.15.2, which

prescribes the types of health assessments, will include references to incorporated items 224, 225, 226 and 227.

Items 10 to 12 amend clause 2.15.3 of the GMST, for the application of health assessment item 715, to include a reference to incorporated prescribed medical practitioner item 228 and insert a reference to "prescribed medical practitioner" where appropriate. This was previously prescribed in subclause 1.5.1(3) of the OMP Determination.

Items 13 and 14 amend clause 2.15.5 of the GMST, which prescribes what a 45 year old Health Assessment must include, to refer to a "prescribed medical practitioner" (refer to **item 13** of Schedule 5 of the Regulations) and substitute general practitioner with medical practitioner (refer to **item 14** of Schedule 5 of the Regulations) to cover both general practitioners and prescribed medical practitioners. This was previously prescribed in subclause 1.5.1(4) of the OMP Determination.

Items 15 to 19 amend clauses 2.15.6, 2.15.8, 2.15.9, 2.15.10, 2.15.11, 2.15.12 and 2.15.13 to insert references to "a prescribed medical practitioner" where appropriate. This was previously prescribed in 1.5.1(4) of the OMP Determination.

Items 20 to 25 amend clause 2.15.14 of the GMST, which details the restrictions on health assessments for Group A14, to include a reference to Subgroup 5 of Group A7 and insert references to "a prescribed medical practitioner" where appropriate. This amendment provides the requirements which were in subclause 1.5.1(4) of the OMP Determination.

Item 26 amends the heading of Division 2.16 to include a reference to Subgroup 6 of Group A7, and to include a note. Under this amendment, division 2.16 will be titled "Group A15 and Subgroup 6 of Group A7: GP management plans, team care arrangements and multidisciplinary care plans and case conferences" and include a note advising that items in subgroup 6 of Group A7 are set out in Division 2.10.

Item 27 amends the heading for clause 2.16.1 of the GMST, which details the restrictions on items 729 to 866, to include a reference to prescribed medical practitioner items 229 to 240.

Item 28 amends subclause 2.16.1(1), which details the restrictions on services by certain medical practitioners, to reference incorporated items 229 to 240. This amendment provides the requirements which were in subclauses 1.6.2(1) and (2) of the OMP Determination.

Item 29 amends the heading of Subdivision B of Division 2.16 to include a reference to Subgroup 6 of Group A7. Under this amendment, subdivision B of Division 2.16 will be titled "Subgroup 1 of Group A15 and Subgroup 6 of Group A7".

Items 30 and 31 amend clause 2.16.2 of the GMST to insert a definition for "associated medical practitioner" which is a term used in incorporated prescribed medical practitioner item 233. Under this amendment, an associated medical practitioner means a medical practitioner who, if not engaged in the same general practice as the prescribed medical practitioner mentioned in the item, performs the

service described in the item at the request of the patient (or the patient's guardian). This amendment provides the requirements which were in subclause 1.6.1(5) of the OMP Determination.

Item 32 amends clause 2.16.3 of the GMST, which prescribes the meaning of "contribute to a multidisciplinary care plan" to include a reference to incorporated items 231 and 232. This amendment provides the requirements which were set out in subclause 1.6.1(4) of the OMP Determination.

Items 33 and 34 amend subclause 2.16.4(1) to insert a reference to incorporated item 230 and to clarify which items relate to which practitioner types in the definition for "coordinate the development of team care arrangements". Under the amendments, subclause 2.16.4(1) clarifies that item 723 is performed by a GP and item 230 is performed by a prescribed medical practitioner. This was previously prescribed in 1.6.1(2) of the OMP Determination.

Items 35 and 36 amend subclause 2.16.5(1) to insert a reference to incorporated item 233 and to clarify which items relate to which practitioner types in the definition for "coordinating a review of team care arrangements". Under the amendments, subclause 2.16.5(1) clarifies that item 732 is performed by a GP and item 233 is performed by a prescribed medical practitioner. This was previously prescribed in 1.6.1(6) of the OMP Determination.

Items 37 to 39 amend subclause 2.16.6(1) to insert a reference to incorporated item 231 and 232, to clarify which items relate to which practitioner types in the definition for "multidisciplinary care plan" and insert a reference to prescribed medical practitioner, where required. Under the amendments, subclause 2.16.6(1) clarifies that items 729 and 731 are performed by GPs and items 231 and 232 are performed by prescribed medical practitioners. This was previously prescribed in 1.6.1(3) of the OMP Determination.

Items 40 and 41 amend clause 2.16.7 to insert a reference to incorporated item 229 and to clarify which items relate to which practitioner types in the definition for "preparation of a GP management plan". Under the amendments, clause 2.16.7 clarifies that item 721 is performed by a GP and item 229 is performed by a prescribed medical practitioner. This was previously prescribed in 1.6.1(1) of the OMP Determination

Items 42 and 43 amend clause 2.16.8 to insert a reference to incorporated item 223 and to clarify which items relate to which practitioner types in the definition for "reviewing a GP management plan". Under the amendments, clause 2.16.8 clarifies that item 732 is performed by a GP and item 223 is performed by a prescribed medical practitioner. This was previously prescribed in 1.6.1(7) of the OMP Determination.

Items 44 to 50 amend clause 2.16.9 of the GMST, which prescribes patient eligibility for items 721, 723, 729, 731 and 732, to insert references to incorporated prescribed medical practitioner items 229, 230, 231, 232 and 233, and insert references to "a prescribed medical practitioner" where appropriate. This was previously prescribed in 1.6.2(5) of the OMP Determination.

- **Item 51** repeals and replaces clause 2.16.10 of the GMST, which prescribes the restrictions on items 721, 723 and 732, to include references to incorporated items 229, 230 and 231, and include new subparagraph 2.16.10(2). New subparagraph 2.16.10(2) provides the requirements for services performed under items 229, 230 and 231, which were contained in subclause 1.6.2(3) of the OMP Determination. Items 229, 230 and 231 are equivalent items of GMST items 721, 723 and 732, and as such have the same claiming restrictions and requirements applying to them.
- **Item 52** repeals and replaces clause 2.16.11 to include references to incorporated items 229, 230 and 233 and include references to the new Level E consultation items (refer to **Part 3** of Schedule 4 of the Regulations for the addition of new Level E consultation items). This clause prescribes restrictions on the items billed with items 721, 723 and 732 for the same patient on the same day. This was previously prescribed in subclause 1.6.2(4) of the OMP Determination.
- Item 53 inserts new clause 2.16.12A into the GMST, which prescribes the conditions which relate to timing of services for items 229, 230, 231 and 232 if exceptional circumstances do not apply. Under new clause 2.16.12A, "exceptional circumstances", for a patient, means there has been a significant change in the patient's clinical condition or care circumstances that necessitates the performance of the service for the patient. New clause 2.16.12A provides the requirements set out in a tabulated format, with column 1 being the item to which the circumstances apply and column 2 being the circumstances, which were previously prescribed in clause 1.6.3 of the OMP Determination.
- **Item 54** amends clause 2.16.14 of the GMST, which prescribes the meaning of "multidisciplinary discharge case conference", to include references to incorporated prescribed medical practitioner items 235, 236, 237, 238, 239 and 240 into the applicable items for the definition. This was previously prescribed in subclause 1.6.1(8) of the OMP Determination.
- **Item 55** amends clause 2.16.15 of the GMST, which prescribes the meaning of "organise and coordinate, to include reference to incorporated prescribed medical practitioner items 235, 236, 237, 969, 971 and 972 into the applicable items for the definition. This was previously prescribed in subclause 1.6.1(9) of the OMP Determination.
- **Item 56** amends 2.16.16 of the GMST, which prescribes the meaning of "participate", to include references to incorporated prescribed medical practitioner items 238, 239, 240, 973, 975 and 986 into the applicable items for the definition. This was previously prescribed in subclause 1.6.1(10) of the OMP Determination.
- Items 57 and 58 repeals and replaces the heading of clause 2.16.19A of the GMST to include references to incorporated prescribed medical practitioner items 969, 971, 972, 973, 975 and 986. Clause 2.16.19A prescribes the eligibility requirements for items 930 to 964. These requirements the patient needs to meet are that the patient has been referred for items within the subgroups stated in subparagraph 2.16.19A(a)(i) to (v) and the patient has a current eating disorder treatment and management plan, to

access the services named in clause 2.16.19A. This amendment provides the requirements which were in clause 1.6.4 of the OMP Determination.

Item 59 amends the heading for Division 2.17 to include a reference to "Subgroup 7 of A7" and insert a note. Under this amendment, Division 2.17 will be titled "Group A17 and Subgroup 7 of Group A7: Domiciliary and residential medication management reviews" and will include a note regarding the location of specified items into Division 2.10.

Item 60 amends clause 2.17.1 of the GMST, which prescribes what is meant by "living in a community setting", to insert a reference to incorporated item 245. This was previously prescribed in 1.7.1(1) of the OMP Determination.

Items 61 and 62 amend subclause 2.17.2(1) to insert a reference to incorporated item 249 and to clarify which items relate to which practitioner types in the definition for "residential medication management review". Under the amendments, subclause 2.17.2(1) clarifies that item 903 is performed by a GP and item 249 is performed by a prescribed medical practitioner. This was previously prescribed in 1.7.1(2) of the OMP Determination.

Item 63 amends subclauses 2.17.2(2) and (3) to replace "general" practitioner with "medical" practitioner. Subclauses 2.17.2(2) and (3) set out the requirements of a medical practitioner involvement as part of a residential medication management review.

Item 64 amends paragraph 2.17.2(4)(c) to replace "general" practitioner with "medical" practitioner. Paragraph 2.17.2(4)(c) provides that a post-review discussion is not required if the pharmacist and medical practitioner agree that issues arising out of the residential medication management review should be considered in a case conference.

Item 65 repeals and replaces clause 2.17.3 to insert new subclause 2.17.3(2) which references incorporated items 245 and 249. Subclause 2.17.3(2) provides that items 245 and 249 apply only to a service provided in the course of personal attendance by a single general practitioner on a single patient. Items 245 and 249 are equivalent services of GMST items 900 and 903, and as such have the same claiming restrictions and requirements applying to them. This was previously prescribed in 1.7.2(1) of the OMP Determination.

Item 66 amends the heading of Division 2.20 to include a reference to "Subgroup 9 of Group A7" and insert a note. Under this amendment, Division 2.20 will be titled "Group A20 and Subgroup 9 of Group A7: Mental health care" and include a note regarding the location of specified items into Division 2.10.

Item 67 inserts new clause 2.20.2A into the GMST, which prescribes the derived fees for incorporated prescribed medical practitioner items 285, 287, 311 and 315. Clause 2.20.2A provides the fees for these items which were in clause 1.9.2 of the OMP Determination.

Item 68 to 70 amend subclauses 2.20.3(1) and (2) to include a reference to "a prescribed medical practitioner" into the definition of "preparation of a GP mental health treatment plan" and "referral and treatment options". This was previously prescribed in 1.9.1(1)(b) of the OMP Determination.

Item 71 amends clause 2.20.4 to amend the definition of "review of a GP mental health treatment plan", to include a reference to "a prescribed medical practitioner".

Item 72 repeals and replaces the definition contained within clause 2.20.5 for "associated general practitioner" to insert a reference to "medical practitioner" and add new subclause 2.20.5(2) purposes of incorporated prescribed medical practitioner item 277. For the purposes of item 277, "associated medical practitioner" means a medical practitioner who, if not engaged in the same general practice as the prescribed medical practitioner mentioned in the item, performs the service described in the item at the request of the patient or the patient's guardian. Incorporated medical practitioner item 277 previously prescribed the definition for "associated medical practitioner" in subclause 1.9.1(d) of the OMP Determination.

Item 73 amends the heading for clause 2.20.6 to include a reference to "Subgroup 9 of Group A7". Under this amendment, clause 2.20.6 will be titled "Restrictions on items in Subgroup 1 of Group A20 and Subgroup 9 of Group A7 (GP mental health treatment plans)".

Item 74 amends subclause 2.20.6(1) of the GMST, which prescribes that items 2700, 2701, 2712, 2713, 2715 and 2717 apply only to a patient with a mental disorder. This amendment will include references to incorporated items 272, 276, 277, 279, 281 and 282 in clause 2.20.6(1). This amendment provides the requirements which were in subparagraph 1.9.3(1)(a) of the OMP Determination.

Item 75 amends subclause 2.20.6(2) to include references to incorporated items 272, 276, 277, 281 and 282. This amendment provides the requirements which were in subparagraph 1.9.3(1)(b) of the OMP Determination.

Item 76 amends paragraph 2.20.6(2)(c) to clarify that services performed under incorporated items 272, 276, 277, 281 and 282 are to be performed by a single prescribed medical practitioner on a single patient. This was previously prescribed in subparagraph 1.9.3(1)(b) of the OMP Determination.

Item 77 makes a consequential amendment to the heading for subclause 2.20.6(3) to clarify that the items for which the timing of certain services is to apply to are items 2700, 2701, 2715 and 2717. Under this amendment, subclause 2.20.6(3) will be titled "Timing of certain services—items 2700, 2701, 2715 and 2717".

Item 78 inserts new subclauses 2.20.6(8A), (8B), (8C), (8D) and (8E) which prescribes the rules around the billing and timing for the co-claiming of services rendered under incorporated prescribed medical practitioner items 272, 276, 277, 279, 281 and 282. These amendments are incorporations of the restrictions and requirements detailed across clauses 1.9.3(2), (3), (4), (5) and (6) of the OMP Determination for items 272, 276, 277, 279, 281 and 282.

- **Item 79** inserts new clause 2.20.7A, which details the restrictions on items in Subgroup 9 of Group A7. This amendment incorporates clause 1.9.4 and clause 1.9.5 which were part of the OMP Determination.
- **Item 80** amends the heading for Division 2.22 to include a reference to "Subgroup 11 of Group A7" and inserts a note. Under this amendment, division 2.22 will be titled "Group A27 and Subgroup 11 of Group A7: Pregnancy support counselling" and include a note regarding the location of specified items into Division 2.10.
- **Item 81** amends the heading of clause 2.22.1 of the GMST, which prescribes the restrictions on item 4001, to include a reference to incorporated prescribed medical practitioner item 792. Under this amendment, clause 2.22.1 will be titled "Restrictions on items 4001 and 792".
- Item 82 inserts subclause 2.22.1(1A) to clarify in which circumstances incorporated item 792 applies. Under this change, a service to which item 792 applies must not be provided by a prescribed medical practitioner who has a direct pecuniary interest in a health service that has as its primary purpose the provision of services for pregnancy termination. This amendment provides the requirements which were in subclause 1.11.1(1) of the OMP Determination.
- **Items 83 to 86** makes an administrative amendment to subclauses 2.22.1(2) and 2.22.1(3) to insert references to incorporated item 792 and amends the definitions contained within subclause 2.22.1(3). Under this amendment, the definition of "non-directive pregnancy support counselling" will clarify which practitioner types perform services under 4001 and 729.
- **Item 87** amends subclause 2.22.1(4) to insert a reference to incorporated item 729 into the subclause. Subclause 2.22.1(4) will be amended to state that a service to which item 4001 or 729 applies may be used to address any pregnancy-related issue.
- **Items 88 to 90** make administrative amendments by repealing the notes contained within clause 2.31.5 and item 11607. These notes provided the location (the OMP Determination) for items 285, 286 and 287 which is no longer required as these items will now be contained within the GMST.
- **Item 91** amends dictionary clause 7.1.1 to insert references to where the definitions for "amount under clause 2.1.2", "amount under clause 2.20.2A" and "associated medical practitioner" can be found.
- **Items 92 to 94** amend dictionary clause 7.1.1 to amend the definitions for "contribute to a multidisciplinary care plan", "coordinating a review of team care arrangements" and "coordinating the development of team care arrangements" to insert references to incorporated items which were previously in the OMP Determination.
- **Item 95** amends dictionary clause 7.1.1 to insert a definition for "eligible area". This term is used within various items being incorporated from the OMP Determination.

Items 96 to 101 amend dictionary clause 7.1.1 to amend references to incorporated items which were previously contained in the OMP Determination in the following definitions:

- "living in a community setting";
- "multidisciplinary care plan";
- "multidisciplinary discharge case conference";
- "organise and coordinate";
- "participate"; and
- "preparing a GP management plan".

Item 102 amends dictionary clause 7.1.1 to insert a definition for "prescribed medical practitioner". Under this definition, a prescribed medical practitioner is a medical practitioner who is not a general practitioner, specialist or consultant physician and who meets one of the conditions prescribed in paragraph (b) of the same definition. This definition mirrors the definition for "medical practitioner" which was in section 4 of the OMP Determination. This amendment maintains the cohort of medical practitioners who may provide services under the incorporated items.

Items 103 and 104 amend dictionary clause 7.1.1 to amend the definitions for "residential medication management review" and "reviewing a GP management plan" to insert references to items which were in the OMP Determination.

Item 105 amends dictionary clause 7.1.1 to insert a definition for "Telehealth and Telephone Determination". This term was used in items in the incorporated OMP Determination.

Schedule 6 – Pathology services

Part 1 – Genetic testing – general

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

Item 1 clarifies the co-claiming restriction for services provided under HbA1c items 66551, 73812 and 73826 within the PST. Under this change, clause 1.2.13 of the PST will be updated to apply the claiming restrictions which were previously contained within the *Health Insurance (Section 3C Pathology Services – HbA1c Point of Care Testing) Determination 2021* (the HbA1c Determination).

Clause 1.2.13 provides that items 73812, 66551 and 73826 do not apply to services provided to a patient who has already been provided, in the last 12 months, four other services to which items 73812 apply. This amendment clarifies the existing claiming restrictions against the HbA1c items listed on the MBS.

Item 2 inserts item 73343 from the *Health Insurance (Section 3C Pathology –17p chromosomal deletion testing) Determination 2023* (the 17p Determination), which is for the detection of 17p chromosomal deletions in patients with chronic lymphocytic leukaemia or small lymphocytic lymphoma, into Group P7 of the PST. The 17p Determination will be repealed following the insertion of item 73343 into the PST. This change is considered minor and machinery in nature.

Item 3 inserts 21 new items into Group P7 of the PST. These new items were announced as part of the 2023-24 Budget measure *A Modern and Clinically Relevant Medicare Benefits Schedule*.

Five new pathology items (items 73440, 73441, 73442, 73443 and 73444) have been listed on the MBS for genetic testing to diagnose a genetic cause of hearing loss in children. This testing is more effective than the current standard of care for affected children (GJB2/GJB6 gene sequencing) and may allow these children to avoid further investigations such as magnetic resonance imaging (MRI).

These changes were recommended by MSAC at its November 2022 meeting under MSAC Application 1680. As a part of this process, consultation was undertaken with Australian Genomics, Australasian Newborn Hearing Screening Committee (ANHSC), Australian Pathology (AP), Aurora School, Centre for Genetics Education NSW Health, Deafness Foundation (DF), Genetic Undiagnosed and Rare Disease (GUARD) Collaborative Australia, the Human Genetics Society of Australasia (HGSA) including its Ethics and Social Issues Committee, Neurodevelopmental and Behavioural Paediatric Society of Australasia (NBPSA), Public Pathology Australia (PPA), the Royal College of Pathologists of Australasia (RCPA) and UsherKids Australia, who were supportive of the changes.

New item 73440 is for genetic testing of genes known to be causative or likely causative of childhood hearing loss. The service must be requested by a specialist or consultant physician for a patient who has congenital or childhood onset hearing loss that presented before the patient was 18 years of age and is permanent moderate, severe, or profound (>40 dB in the worst ear over 3 frequencies) and classified as sensorineural, auditory neuropathy or mixed. Item 73440 may not be claimed in association with a service under new item 73441 and is applicable once per lifetime. The schedule fee for this item is \$1,200.00.

New item 73441 is for genetic testing of genes known to be causative or likely causative of childhood hearing loss. The service must be requested by a specialist or consultant physician for a patient who has congenital or childhood onset hearing loss that presented before the patient was 18 years of age and is permanent moderate, severe, or profound (>40 dB in the worst ear over 3 frequencies) and classified as sensorineural, auditory neuropathy or mixed. The genetic testing for this item must be performed using a sample from the patient and a sample from each of the parent's biological patients. Item 73441 may not be claimed in association with a service under new item 73440 and is applicable once per lifetime. The schedule fee for this item is \$2,100.00.

New item 73442 is for the re-analysis of whole exome or genome data obtained under a service to which item 73440 or 73441 applies, for characterisation of previously unreported germline gene variants for childhood hearing loss. The service must be requested by a specialist or consultant physician, and performed at least 24 months after a service to which items 73440 or 73441 applies has been provided to the patient or a service to which this item applies is performed for the patient. This item is applicable twice per lifetime and has a schedule fee of \$500.00.

New item 73443 is for the characterisation of one or more familial germline gene variants known to be causative or likely causative of childhood hearing loss in a person. The person being tested must have a biological relation to a patient with a germline gene variant known to be causative or likely causative of hearing loss confirmed by laboratory findings, and the result of a previous proband test is made available to the laboratory undertaking the characterisation. The schedule fee for item 73343 is \$400.00.

New item 73444 is for the characterisation of all germline variants in one or more genes known to cause hearing loss, for the reproductive partner of a patient with a causative recessive pathogenic or likely pathogenic variant for hearing loss identified in the same gene. The service must be requested by a specialist or consultant physician, the characterisation is for the reproductive partner of the patient and the patient has a pathogenic or likely pathogenic recessive germline gene variant known to cause hearing loss confirmed by laboratory findings and the result of the patient's previous test is made available to the laboratory undertaking the characterisation. The schedule fee for this item is \$1,200.00.

Four new pathology items (items 73445, 73446, 73447 and 73448) have been listed on the MBS to test for genetic variants in patients suspected of having either a myeloid or lymphoid haematological malignancy through next generation sequencing (NGS). The NGS panel results will be used by clinicians for diagnosis and to inform prognosis and optimal treatment pathways for patients. NGS panel testing may also help patients avoid alternative invasive and expensive medical testing, such as bone marrow biopsy and testing. As the NGS panels have the capability to test for a broader range of malignancies and gene variants than existing single-gene tests currently listed on the MBS, it is expected that clinicians will increasingly order NGS panel testing instead of the existing items which test for lymphoid haematological malignancies.

The new items were recommended by MSAC at its November 2022 meeting under MSAC application 1684. As a part of this process, consultation was undertaken with 45 different organisations. The feedback received was generally supportive of the changes.

New item 73445 is for the characterisation of a variant or variants in a panel of at least 25 genes using DNA and RNA, requested by a specialist or consultant physician, to determine the diagnosis, prognosis and/or management of a patient presenting with a clinically suspected haematological malignancy of myeloid origin. This item is applicable once per diagnostic episode, at diagnosis, disease progression or relapse, and has a schedule fee of \$1,100.00.

New item 73446 is for the characterisation of a variant or variants in a panel of at least 25 genes using DNA and RNA for patients presenting with a clinically suspected haematological malignancy of lymphoid origin. The item must be requested by a specialist or consultant physician, is applicable once per diagnostic episode, at diagnosis, disease progression or relapse, and has a schedule fee of \$1,100.00.

New item 73447 is for the characterisation of a variant or variants in a panel of at least 25 genes using DNA for patients presenting with clinically suspected

haematological malignancy of myeloid origin. The item must be requested by a specialist or consultant physician, is applicable once per diagnostic episode, at diagnosis, disease progression or relapse, and has a schedule fee of \$927.90.

New item 73448 is for the characterisation of a variant or variants in a panel of at least 25 genes using DNA for patients presenting with a clinically suspected haematological malignancy of lymphoid origin. The item must be requested by a specialist or consultant physician, is applicable once per diagnostic episode, at diagnosis, disease progression or relapse, and has a schedule fee of \$927.90.

Two new items have been listed on the MBS (items 73451 and 73452) for genetic testing to determine carrier status of cystic fibrosis (CF), spinal muscular atrophy (SMA) and fragile X syndrome (FXS) in patients who are planning pregnancy or who are already pregnant, and their reproductive partners. The main benefit of this testing is that it will support improved reproductive decision making for those who test positive, including decisions about how to plan a pregnancy, or what to do if a prospective parent is already pregnant.

These new items were recommended by MSAC at its July 2020 meeting under MSAC application 1573. As a part of this process, consultation was undertaken with eight organisations. The organisations consulted were Cystic Fibrosis Community Care Ltd (CFCC), Fragile X Alliance Clinic, Fragile X Association of Australia (FXAA), Genetic, Undiagnosed and Rare Disease (GUARD) Collaborative, Mackenzie's Mission Research Team/Victorian Clinical Genetics Services Reproductive Screening Team, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Royal College of Pathologists of Australasia (RCPA) and Spinal Muscular Atrophy (SMA) Australia, who were supportive of the changes.

New item 73451 is for the testing of a patient who is either pregnant, or planning pregnancy, to identify their carrier status relating to CF, SMA and/or FXS. This item is applicable once per condition per lifetime and has a schedule fee of \$400.00.

New item 73452 is for the testing of the reproductive partner of a patient who is a carrier of CF, SMA and/or FXS identified by testing under item 73451. This item is applicable once per condition per lifetime and has a schedule fee of \$400.00.

The intent of item 73451 is to test a patient who is pregnant, or planning pregnancy, to identify carrier status and the intent of item 73452 is to test the reproductive partner. The pregnant (or planning to be pregnant) patient should be tested first under item 73451 prior to testing the reproductive partner under MBS item 73452, to ensure an informative test result is obtained for FXS. MBS item 73452 supports carrier testing for CF and SMA, as FXS is inherited in an X-linked dominant fashion, therefore it is not clinically relevant to test reproductive partners for FXS once the carrier status of the pregnant (or planning pregnancy) patient is known.

Three new pathology items (items 73453, 73454 and 73455) have been listed on the MBS for reproductive carrier testing for specific genetic variants that cause nine severe conditions commonly found in the Ashkenazi Jewish population. Testing will be available to individuals of reproductive age and who identify as being of Ashkenazi Jewish decent, reproductive partners of Ashkenazi Jewish people

(including those who are not of Ashkenazi Jewish descent) and for fetal testing. The listing of these items will enable eligible patients to make informed reproductive choices.

People with Ashkenazi Jewish ancestry have a one in five chance (20 per cent) of being a genetic carrier for at least one of the nine conditions. The changes will allow equitable access to carrier testing for a high-risk group. Currently, carrier testing in the Ashkenazi Jewish population is undertaken on a user-pays basis or through small-scale programs funded by private organisations.

The change was recommended by MSAC at its July 2022 meeting under MSAC application 1671. As a part of this process, consultation was undertaken with seven organisations and one individual. The organisations consulted were Victorian Clinical Genetics Service, PPA, Australian Genomics Health Alliance, AP, Human Genetics Society of Australasia, RACGP and SMA Australia, who were generally supportive of the changes.

New item 73453 is for the characterisation of germline pathogenic or likely pathogenic gene variants in a patient of reproductive age, who is of Ashkenazi Jewish descent, for the purpose of determining the patients carrier status for Bloom syndrome, Canavan disease, CF, Familial dysautonomia, Fanconi anaemia type C, FXS, Gaucher disease, Glycogen storage disease type I, Mucolipidosis type IV, Niemann Pick disease type A 7, SMA, and Tay Sachs disease. This item is applicable once per lifetime and has a schedule fee of \$425.00.

New item 73454 is for whole gene sequencing of a gene or genes described in item 73453 in a person who is a reproductive partner of an individual who is affected by, or a genetic carrier of, one or more conditions described in item 73453 (other than CF, SMA or FXS) to determine the couples combined reproductive risk of the conditions. Item 73454 is available for patients who are ineligible to receive (and has not previously received) a service under item 73453 and the patient has not accessed this item previously with the reproductive partner. This item is applicable once per couple per lifetime and has a schedule fee of \$1,200.00.

New item 73455 is for the testing of a pregnant patient, if at least one prospective parent is known to be affected by, or is a genetic carrier of, one or more conditions described in item 73453, for the purpose of determining whether a familial variant or variants are present in the fetus. Testing under item 73455 must be requested by a specialist or consultant physician if there is at least a 25 per cent risk of the fetus inheriting a condition described in item 73453. The schedule fee for this item is \$1,600.00.

Seven new items (items 73456, 73457, 73458, 73459, 73460, 73461 and 73462) have been added to the MBS for the diagnosis of mitochondrial disease in patients who are suspected of having either acute or chronic diseases, and the cascade testing of their biological relatives. The new services will be performed through virtual panel based whole genome sequencing or whole exome sequencing after mitochondrial DNA sequencing.

Listing these services on the MBS also informs the risk of disease in relatives and support informed reproductive decision-making. Providing a Medicare benefit for this testing will support equitable access to targeted therapies and identify when mitochondrial donation may be appropriate.

In November 2022, MSAC supported the creation of new MBS items for genetic testing for mitochondrial disease under MSAC application 1675. As a part of this process, consultation was undertaken with ten organisations. The organisations consulted were Australian Genomics (AG), AP, Childhood Dementia Initiative (CDI), GUARD Collaborative Australia (GUARD), Human Genetics Society of Australasia (HGSA), Murdoch Children's Research Institute (MCRI) Mito Foundation (Mito), PPA, The Royal College of Pathologists of Australasia (RCPA), and Rare Voices Australia (RVA, who were supportive of the changes.

New item 73456 is for characterisation by whole genome sequencing, or by either or both whole exome sequencing and mitochondrial DNA sequencing, of germline variants present in nuclear DNA and in mitochondrial DNA of a patient with a strong suspicion of a mitochondrial disease. The service must be requested by a specialist or consultant physician and meet the requirements as set out in the item of meeting one or more clinical features indicative of mitochondrial disease as set out in the item descriptor. This service does not apply to a service associated with a service to which item 73457, 73358 or 73359 applies, is applicable once per lifetime and has a schedule fee of \$2,100.00.

New item 73457 is for genomic characterisation of germline variants present in nuclear DNA and in mitochondrial DNA of a patient who is strongly suspected of living with mitochondrial disease performed using a sample from the patient and a sample from each of the patient's biological parents. The service must be requested by a specialist or consultant physician and meet the requirements as set out in the item of meeting one or more clinical features indicative of mitochondrial disease as set out in the item descriptor. This service does not apply to a service associated with a service to which item 73456, 73358 or 73359 applies, is applicable once per lifetime and has a schedule fee of \$3,300.00.

New item 73458 is for the re-analysis of whole genome or whole exome or mitochondrial DNA data obtained in performing a service to which item 73456 or 73457 applies, for characterisation of previously unreported germline variants related to the clinical phenotype. Item 73458 must be requested by a specialist or consultant physician for a patient who is strongly suspected of having a monogenetic mitochondrial disease and the re-analysis is performed at least 24 months after the service to which item 73456 or 73457 applies or a service to which this item applies. This item is applicable twice per lifetime and has a schedule fee of \$500.00.

New item 73459 is for testing for diagnostic purposes of a pregnant patient, for detection in the fetus of a gene variant or variants indicative of mitochondrial disease which is also present in the parents or a biological sibling of the fetus. Item 73459 must be requested by a specialist or consultant physician if the causative variant or variants for the condition of the fetus' first degree relative have been confirmed by laboratory findings and the service is not associated with a service to which item 73462, 73361, 73362 or 73363 applies. The schedule fee for this item is \$1,600.00.

New item 73460 is for the characterisation of mitochondrial DNA deletion or variant for diagnostic purposes in a patient suspected to have mitochondrial disease where the item is requested by the specialist or consultant physician managing the patient's treatment. The request must meet the requirements as set out in the item of meeting one or more clinical features indicative of mitochondrial disease as set out in the item descriptor. Item 73460 must be performed following a service to which items 73292, 73456, 73457, 73358 or 73359 applies for the same patient if the results were non informative, is applicable three times per lifetime and has a schedule fee of \$450.00.

New item 73461 is for whole gene testing of a person who is the reproductive partner of a patient who has a pathogenic or likely pathogenic germline recessive gene variant for mitochondrial disease, if the patient's germline recessive gene variant is confirmed by laboratory findings and the testing is requested by a specialist or consultant physician. The schedule fee for this item is \$1,200.00.

New item 73462 is for the testing of a person for the detection of a single gene variant if the person has a biological relative with a known pathogenic or likely pathogenic mitochondrial disease variant confirmed by laboratory findings. Item 73462 must be requested by a specialist or consultant physician and not be a service associated with a service to which item 73361, 73362 or 73363 applies. The schedule fee for this item is \$400.00.

Part 2 – Genetic testing for cardiac arrhythmias

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

Part 2 of Schedule 6 of the Regulations implements changes to item 73418 which was announced under the 2023-24 Budget measure *A Modern and Clinically Relevant Medicare Benefits Schedule*.

These changes were recommended by the MSAC Executive at its December 2022 meeting. As a part of this process, consultation was undertaken with one organisation, the RCPA, who did not oppose to the amendments, however they noted item 73418 is unlikely to be used in clinical practice.

Item 4 amends genetic testing item 73418 to amend the claiming restrictions for services provided under this item. Under this change, item 73418 will apply once per gene per lifetime in alignment with item 73394.

Item 5 amends the schedule fee for genetic testing item 73418 from \$400.00 to \$1,200. This means patients will have access to a higher benefit for services rendered under item 73418 from 1 November 2023.

Part 3 – NT-proBNP or BNP testing in patients with systemic sclerosis

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

Part 3 of Schedule 6 of the Regulations lists new pathology item 66585 for the quantification of N-terminal pro B-type natriuretic peptide (NT-proBNP) or B-type

natriuretic peptide (BNP) in patients with systemic sclerosis. The purpose of the test is to assess the risk of pulmonary arterial hypertension so that appropriate treatment can be provided. This testing may also reduce the number of transthoracic echocardiograms and other tests patients would otherwise be required to undergo, saving patients money and time.

This change was recommended by MSAC at its July 2022 meeting under MSAC application 1689 and was announced under the 2023-24 Budget measure *A Modern and Clinically Relevant Medicare Benefits Schedule*.

As a part of these processes, consultation was undertaken with the Australian Scleroderma Interest Group (ASIG), Scleroderma Australia, Thoracic Society of Australia and New Zealand (TSANZ), Australian Rheumatology Association (ARA), PPA, the RCPA and Lung Foundation Australia (LFA), who were supportive of the amendments.

Item 6 inserts new item 66585 into Group P2 of the PST. Item 66585 is for the quantification of laboratory-based NT proBNP or BNP testing in a patient with systemic sclerosis (scleroderma) to assess risk of pulmonary arterial hypertension. This item applies a maximum of two tests over a 12 month period and has a schedule fee of \$58.50.

<u>Part 4 – Prostate specific antigen testing</u>

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

Part 4 of Schedule 6 of the Regulations makes changes to the PST to amend prostate specific antigen testing items 66655, 66656, 66659 and 66660 and insert new item 66654 for testing patients with a first degree relative diagnosed with prostate cancer as a 'high risk' patient. These amendments will align PSA services on the MBS with the Prostate Cancer Foundation of Australia (PCFA) guidelines (the Guidelines) on PSA Testing.

In August 2022, MSAC supported the proposed amendments to prostate specific antigen testing listed on the MBS to align with the requirements as laid out in the Guidelines and was announced under the 2023-24 Budget measure *A Modern and Clinically Relevant Medicare Benefits Schedule*. As a part of these processes, consultation was undertaken the AP, PPA and the RCPA, who were supportive of the amendments.

Item 7 inserts new PSA testing item 66654 into Group P2 of the PST. Item 66654 is for the quantitation of PSA in the monitoring of patients at a high risk of prostate cancer. For any particular patient, this item applies once every 11 months. The schedule fee for this item is \$20.15.

Item 8 amends existing PSA testing item 66655 to amend the timing restriction which applies to the item. Under this change, item 66655 will apply once in 23 months.

Item 9 amends the item descriptor for item 66656 to clarify the patient population eligible for services under this item. Under this change, item 66656 will apply to

patients with a previously diagnosed prostatic disease, including prostate cancer, prostatitis or a premalignant condition such as atypical small acinar proliferation.

Item 10 amends the item descriptor for item 66659 to clarify the patient population eligible for services under this item and amends the timing restriction which applies to the item. Under this change, item 66659 will apply to patients with a previously demonstrated PSA test result of more than 2.0 ug/L but less than or equal to 5.5 ug/L for patients with a family history of prostate cancer, more than 3.0 ug/L but less than or equal to 5.5 ug/L for patients who are at least 50 years of age but under 70 years of age, or more than 5.5 ug/L but less than or equal to 10.0 ug/L for patients who are at least 70 years of age. Item 66659 will also apply once every 11 months.

Item 11 amends the item descriptor for item 66660 to clarify the patient population eligible for services under this item and amends the timing restriction which applies to the item. Under this change, item 66660 will apply to patients with previously diagnosed prostatic disease where the current PSA level lies more than 2.0 ug/L but less than or equal to 5.5 ug/L for patients with a family history of prostate cancer, more than 3.0 ug/L but less than or equal to 5.5 ug/L for patients who are at least 50 years of age but under 70 years of age, or more than 5.5 ug/L but less than or equal to 10.0 ug/L for patients who are at least 70 years of age. Item 66660 will also apply once every 11 months.

<u>Part 5 – Detection of measurable residual disease in acute lymphoblastic leukaemia</u>

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

Part 5 of Schedule 6 of the Regulations makes changes to the PST to insert two new items for the detection of measurable residual disease (MRD) in patients with acute lymphoblastic leukaemia (ALL), using flow cytometry and next-generation sequencing (NGS) methods.

This change was recommended by MSAC at its July 2022 meeting under MSAC application 1707 and announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget. As a part of these processes, consultation was undertaken with PathWest laboratory medicine WA and AP, who were supportive of the amendments.

Item 12 inserts new MRD testing item 71202 into Group P4 of the PST. Item 71202 is for MRD testing by flow cytometry performed on bone marrow from a patient with ALL. Item 71202 must be requested by a specialist or consultant physician practising as a haematologist or oncologist and has a schedule fee of \$550.00.

Item 13 inserts new MRD testing item 73310 into Group P7 of the PST. Item 73310 is for MRD testing by NSG performed on bone marrow (a peripheral blood sample if bone marrow cannot be collected) from a patient with ALL. Item 73310 must be requested by a specialist or consultant physician practising as a haematologist or oncologist and has a schedule fee of \$1,550.00.

<u>Part 6 – Prognostic gene expression profile testing</u>

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

Part 6 of Schedule 6 of the Regulations introduces one new item for the EndoPredict brand gene expression profiling test. EndoPredict is a genetic test that looks at the expression levels of several genes that can be involved in breast cancer. EndoPredict then combines the test results with other clinical information using an algorithm to calculate a score which provides a patient's risk of getting breast cancer again (recurrent breast cancer).

In July 2022, MSAC supported MBS funding of EndoPredict for prognostic purposes only under MSAC application 1408.1. MSAC supported MBS funding of EndoPredict because it considered it to be comparatively safe, effective and good value for money when used as a prognostic test. As a part of this process, consultation was undertaken with Australian Genomics – AGHA (funded by NHRMC and MRFF, administered by Murdoch Children's Research institute), AMA, AP, Breast Cancer Network Australia, Cancer Australia , Cancer Action VIC, Clinical Oncology Society of Australia , Genetic Support Network of Victoria, Human Genetics Society of Australasia, Industry Genomics Network Alliance, Medical Oncology Group of Australia, NPAAC, Private Cancer Physicians of Australia, PPA, RCPA Quality Assurance Program, RCPA, Rare Cancers Australia, the Australian Genomic Cancer Medicine Centre (now known as OMICO), RACGP and the Royal Australasian College of Physicians, who were supportive of the amendments.

This new item was announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget.

Item 14 inserts new item 73306 into Group P7 of the PST. Item 73306 is for gene expression profiling testing using EndoPredict, for the purpose of profiling gene expression in formalin fixed, paraffin embedded primary breast cancer tissue from core needle biopsy or surgical tumour sample to estimate the risk of distant recurrence of breast cancer within 10 years. The item is applicable once per new primary breast cancer diagnosis for any particular patient and has a schedule fee of \$1,200.00.

Part 7 – Improved access for certain pathology testing

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

Part 7 of Schedule 6 of the Regulations amends two pathology items to expand the eligible patient population which can access these services. The amendments will ensure the original intent of the item is implemented by expanding the eligible patient population who may access the service by removing the requirement for a quantitative algorithm to be calculated.

MSAC considered and supported the amendments which were later announced under the 2023-24 Budget measure *A Modern and Clinically Relevant Medicare Benefits Schedule*. As a part of these processes, consultation was undertaken with the Human Genetics Society of Australia (HGSA) and the Clinical Oncology Society of Australia (COSA), both of whom were supportive of the amendments.

Item 15 amends item 73296 to expand the eligible patient population to include the testing of genes associated with breast, ovarian, fallopian tube or primary peritoneal cancer and remove the requirement for the use of a 'quantitative algorithm' to determine a patient's eligibility. The item will also be updated to specify item 73296 is applicable once per cancer diagnosis.

Item 16 amends item 73297 to expand the eligible patient population in alignment with the amendments to item 73296 (refer to **item 15** of Part 7 of Schedule 5 of the Regulations). Under these changes, item 73297 will also not apply to a patient who has previously received a service to which item 73295, 73296 or 73302 applies.

Schedule 7 – Medicare benefits

Health Insurance Regulations 2018 (HIR)

Schedule 7 of the Regulations will amend subsection 28(1) of the HIR to specify 18 new general practice items for consultation lasting 60 minutes or more (including Telehealth consultations) and nine new telehealth consultation items for consultations lasting at least 30 and 45 minutes which are being listed in the *Health Insurance* (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021 on 1 November 2023. This change will allow the specified items to attract a Medicare benefit equal to 100 per cent of the schedule fee.

This amendment was announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget. No consultation was undertaken for this amendment as the addition of the Level E consultation items and the level C and D telehealth consultation items to subsection 28(1) of the HIR is consistent with the Medicare benefits paid for the existing GP (and equivalent) consultation items.

Items 1 to 9 list the items 123, 124, 151, 165, 301, 303, 2197, 2198, 2200, 5071, 5076, 5077, 5209, 5261, 5262, 90054, 90098, 90215, 91920, 91923, 91926, 91900, 91903, 91906, 91910, 91913 and 91916 into subsection 28(1) of the HIR to allow them to attract a Medicare benefit equal to 100 per cent of the schedule fee.

Statement of Compatibility with Human Rights

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

Act 2011

Health Insurance Legislation Amendment (2023 Measures No. 3) Regulations 2023

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 (2023 Measures No. 3) Regulations 2023* (the Regulations) is to amend the GMST, the DIST, the PST and the HIR from 1 November 2023.

Schedule 1 of the Regulations will amend the fees for ten items in the GMST from the day after registration, to correct the fees for the items which were not indexed as part of the *Health Insurance Legislation Amendment (2023 Measures No. 1) Regulations* 2023 (the July 23 Regulations). Schedule 1 of the Regulations will rectify this error.

Schedule 2 of the Regulations will implement an additional fee indexation by increasing the stated fee by 0.5 per cent from 1 November 2023 for most general medical services in the GMST, diagnostic imaging services in the DIST, and specific items for the management of bulk-billing pathology services in the PST. This amendment aligns with the Government announcement of 9 May 2023, as part of the 2023-24 Budget, which included changes to the indexation methodology applying to Government programs, including the Medicare benefits schedule (MBS), to better align with changes in economic conditions. This means that patients will receive a higher Medicare benefit for these services from 1 November 2023.

Schedule 3 of the Regulations will amend the DIST to make changes to the supervision requirements of musculoskeletal (MSK) ultrasound services and make minor administrative amendments to remove references to ceased items. Further, Schedule 3 of the Regulations will increase the fee for existing adrenal study item 61485 in line with the recent increased cost of purchasing the radiopharmaceutical. The amendments to the supervision requirements for MSK ultrasound services and item 61485 were announced under the *A Modern and Clinically Appropriate Medicare Benefits Schedule* measure in 2023-24 Budget.

Part 1 of Schedule 4 of the Regulations will include changes to the GMST which were announced under the *A Modern and Clinically Appropriate Medicare Benefits Schedule* measure in 2023-24 Budget, the *Guaranteeing Medicare – Medicare Benefits Schedule new and amended listings* measure under 2021-22 Mid-Year Economic and Fiscal Outlook, the *Guaranteeing Medicare – Updating the Medicare Benefits Schedule* measure under 2021-22 Budget, the *Guaranteeing Medicare – Medicare Benefits Schedule (MBS) Review* measure under 2022-23 Budget or are administrative and minor in nature. The changes include:

- The amendment of six level B general practitioner items to introduce a minimum service duration for the items in response to the recommendations from the MBS Review Taskforce (the Taskforce);
- Amending six otolaryngology, head and neck surgery services implemented on 1 March 2023 in response to further recommendations from the sector and implementation liaison group following implementation;
- Minor amendments to seven plastic and reconstructive service items to better align with contemporary clinical practice and further consequential amendments;
- Administrative amendments to items 38477, 11729 and 11730 to correct typographical errors in the items; and
- Administratively update the subgroup name for subgroup 16 of Group T8 in line with the sector's requests for the subgroup's name to reflect amendments to the items contained in the subgroup on 1 July 2021.

Part 2 of Schedule 4 of the Regulations will amend the GMST to amend seven bulk-billing incentive items and introduce 13 new bulk-billing incentive items to further incentivise practitioners to bulk-bill certain eligible Australians. These changes were announced under the *Strengthening Medicare* measure in the 2023-24 Budget.

Part 3 of Schedule 4 of the Regulations will amend the GMST to introduce items which provide MBS services to patients requiring a consultation of 60 minutes or more (also known as level E consultation items), and consequential amendments to existing 45 minutes or more consultation items (also known as level D consultation items) to include a maximum attendance time for services provided under these items. These changes were announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget.

Part 4 of Schedule 4 of the Regulations will amend the GMST to introduce five new items for the insertion, replacement or removal of a leadless permanent pacemaker where the patient and procedure meets certain criteria. These new items were announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget.

Schedule 5 of the Regulations will incorporate all groups and subgroups, except subgroup 10 of Group A7, of the *Health Insurance (Section 3C General Medical Services – Other Medical Practitioner) Determination 2018* into the GMST. This change is considered administrative and machinery in nature.

Schedule 6 of the Regulations will amend the PST to introduce new items and amend existing pathology testing services. These changes were announced as part of the *A Modern and Clinically Relevant Medicare Benefits Schedule* measure under the 2023-24 Budget and will:

- Amend and increase the fee for item 73418 for genetic testing for cardiac arrhythmias;
- Introduce five new items for genetic testing for childhood hearing loss;
- Introduce four new items for gene panel testing for haematological malignancies;

- Introduce one new item for the quantification of N-terminal pro B-type natriuretic peptide (NT-proBNP) or B-type natriuretic peptide (BNP) in patients with systemic sclerosis;
- Amend four items and introduce one new item to better align prostate specific antigen testing with the Prostate Cancer Foundation of Australia guidelines;
- Introduce two new items for reproductive carrier testing for cystic fibrosis, spinal muscular atrophy and fragile X syndrome;
- Introduce three new items for targeted carrier testing for severe monogenic conditions;
- Introduce two new items for the detection of measurable residual disease in acute lymphoblastic leukaemia;
- Introduce one new item for EndoPredict prognostic gene expression profile testing for breast cancer tissue;
- Introduce seven new items for the diagnosis of mitochondrial disease in patients who are suspected of having either acute or chronic diseases, and the cascade testing of their biological relatives; and
- Amend two items to expand the eligible patient population which can access pathology testing for breast, ovarian, fallopian tube or primary peritoneal cancer testing services.

Schedule 7 of the Regulations will amend subsection 28(1) of the HIR to specify 18 new attendance items for consultation lasting 60 minutes or more (including Telehealth consultations) and nine new telehealth consultation items for consultations lasting at least 30 and 45 minutes which are being listed in the *Health Insurance* (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021 on 1 November 2023. This change will allow the specified items to attract a Medicare benefit equal to 100 per cent of the schedule fee.

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

Conclusion

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

Mark Butler

Minister for Health and Aged Care