EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2021 Measures No. 1) Regulations 2021

Subsection 133(1) of the *Health Insurance Act 1973* (Act) provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

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

Subsection 4(1) of the Act provides that regulations may prescribe a table of general medical services which sets out items of general medical services, the fees applicable for each item, and rules for interpreting the table. The table made under this subsection is referred to as the general medical services table (GMST). The most recent version of the regulations is the *Health Insurance (General Medical Services Table) Regulations (No. 2) 2020.* This regulation will be remade from 1 July 2021 and will be titled the *Health Insurance (General Medical Services Table) Regulations 2021*.

Subsection 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 subsection is referred to as the diagnostic imaging services table (DIST). The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020.*

Subsection 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 subsection is referred to as the pathology services table (PST). The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020*.

Purpose

The purpose of the *Health Insurance Legislation Amendment (2021 Measures No. 1) Regulations 2021* (the Regulations) is to amend the GMST, DIST and PST from 1 July 2021.

The Regulations will make changes to cardiac services and make minor administrative changes to reflect Government policy. The Regulations will also index diagnostic imaging services and two items for the management of bulk-billing pathology services.

Indexation

Part 1 of the Regulations will implement Government policy by increasing the schedule fee by 0.9 per cent for most diagnostic imaging services in the diagnostic

imaging services table (DIST), and for the management of bulk-billing pathology services in the pathology services table (PST). This means that patients will receive a higher Medicare benefit for these services from 1 July 2021.

In the 2017-18 Budget under the *Guaranteeing Medicare - Medicare Benefits Schedule - indexation* measure, the Government announced the re-commencement of indexation of Medicare benefits for computed tomography, mammography, fluoroscopy and interventional radiology diagnostic imaging services, and indexation of Medicare benefits for the management of bulk-billed services.

In the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure, the Government announced that it would expand indexation to ultrasound and x-ray diagnostic imaging services from 1 July 2020.

Changes for cardiac services
Part 2 and Part 3 of the Regulations will implement changes to cardiac services in the DIST and the GMST.

Part 2 of the Regulations will make minor amendments to existing cardiac services to align co-claiming restrictions with other cardiac services and to reflect the policy intent of the services, and to better align with clinical guidelines.

Part 3 of the Regulations will implement the second phase of cardiac changes which were recommended by the clinician-led Medicare Benefits Schedule (MBS) Review Taskforce (the MBS Review Taskforce) and agreed by Government in the 2020-21 Budget under the *Guaranteeing Medicare – Medicare Benefits Schedule (MBS) reviews – cardiac services* measure.

The first phase of cardiac changes were implemented on 1 August 2020. The changes included promoting high-value use of electrocardiogram (ECG), echocardiogram, ambulatory ECG, ECG stress testing, myocardial perfusion studies and stress echocardiogram. On 15 September 2020, one new ambulatory electrocardiogram monitoring item was introduced following technological advancements in this area, and five new myocardial perfusion study items were added to ensure timely access to cardiac diagnostic services in rural and remote areas.

The second phase of changes will build on the first phase by making a range of amendments to cardiac surgical services to define co-claiming restrictions, consolidate similar surgical procedures, incentivise advanced techniques, introduce items that represent a complete medical service, remove procedures that no longer represent best practice and align with clinical guidelines.

Other amendments
Part 3A makes amendments to the GMST to correct a handful of items relating to orthopaedic services.

Part 4 makes minor amendments to diagnostic imaging items in the DIST. These changes are administrative and housekeeping in nature.

Consultation

Consultation was undertaken on the cardiac changes that were recommended by MBS Review Taskforce, and announced in the 2020-21 Budget under the *Guaranteeing Medicare – Medicare Benefits Schedule (MBS) reviews – cardiac services* measure.

The MBS Review is conducted by expert committees and working groups focusing on specific areas of the MBS. The Cardiac Services Clinical Committee (CSCC) report on changes to cardiac services was released for public comment and further consideration was taken based on stakeholder feedback. The CSCC report was then presented to the MBS Review Taskforce for finalisation and endorsement of the recommendations, before being presented to Government.

The Department has also undertaken consultation with key stakeholders on the cardiac changes, including with the Cardiac Society of Australia and New Zealand, the Australian Medical Association, the Rural Doctors Association of Australia, the Royal Australian College of General Practice, the Australian and New Zealand Society of Cardiac and Thoracic Surgeons, the Australian Private Hospitals Association, as well as individual practitioners.

No consultation was undertaken on the indexation of the diagnostic imaging and bulk-billing pathology services, as this change continues business-as-usual implementation of the Government's policy on Medicare indexation, which is expected by stakeholders to be applied on 1 July of each year. The complete list of all indexed schedule fees will be distributed to stakeholders through the Medicare Benefits Schedule xml data file.

Details of the Regulations are set out in the Attachment.

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

Section 1 to 3 (and anything in this instrument not covered elsewhere) of the Regulations will commence the day after the instrument is registered. Schedule 1, Parts 1 and 4 will commence on 1 July 2021. Schedule 1, Parts 2, 3 and 3A will commence immediately after the commencement of the *Health Insurance (General Medical Services Table) Regulations 2021*.

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

ATTACHMENT

Details of the *Health Insurance Legislation Amendment (2021 Measures No. 1) Regulations 2021*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2021 Measures No. 1) Regulations 2021.*

Section 2 – Commencement

This section provides for Sections 1 to 3 (and anything in this instrument not covered elsewhere) of the Regulations to commence immediately after the instrument is registered, for Schedule 1, Parts 1 and 4 to commence on 1 July 2021, and for Schedule 1, Parts 2, 3 and 3A to commence immediately after the commencement of the *Health Insurance (General Medical Services Table) Regulations 2021.*

Section 3 – Authority

This section provides that the Regulations are made under the *Health Insurance Act 1973*.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

Part 1 – Indexation

Part 1 continues the Government's indexation measure by applying a clause in the diagnostic imaging services table to index the schedule fee for all diagnostic imaging services (DIST), except nuclear medicine imaging and MRI services, and by applying a clause in the pathology services table (PST) to index the schedule fee for the management of bulk-billing pathology services.

Items 1 to 4 inserts a note before the tables in the DIST which list diagnostic imaging services in Groups I1 (Ultrasound), I2 (Computed tomography – examination), I3 (Diagnostic radiology) and I6 (Management of bulk-billed services) to state that the fees for items in these groups are indexed on 1 July 2021 as per clause 2.7.1.

Item 5 inserts a new Division 2.7 and a new clause 2.7.1 at the end of Part 2 of Schedule 1 of the DIST to apply indexation to diagnostic imaging services. Clause 2.7.1 provides that on 1 July 2021, the fees for each item in Groups I1, I2, I3 and I6 are to be indexed by 0.9 per cent. The amount mentioned in subclauses 2.3.3(2) and 2.3.3(3), which is in relation to an increased fee for certain diagnostic imaging services carried out in residential aged care facilities, are also to be indexed by 0.9 per

cent. The indexed amount is to be rounded up or down to the nearest 5 cents (rounding down if the amount is an exact multiple 2.5 cents).

Item 6 inserts a new note before the table in the PST which lists the two items 74990 and 74991 in Group P12 (Management of bulk-billed services) to state that the fees for items in this group are indexed on 1 July 2021 as per clause 2.14.1.

Item 7 inserts a new Division 2.14 and a new clause 2.14.1 at the end of the Part 2 of Schedule 1 of the PST to apply indexation to the management of bulk-billed services listed in Group P12. Clause 2.14.1 provides that on 1 July 2021, the fees for each item in Group P12 are to be indexed by 0.9 per cent. The indexed amount is to be rounded up or down to the nearest 5 cents (rounding down if the amount is an exact multiple 2.5 cents).

Part 2 – Administrative changes to cardiac items

Part 2 makes administrative amendments to cardiac items in the DIST and the general medical services table (GMST) which were introduced as part of phase 1 of cardiac changes announced in the 2018-19 Mid-Year Economic and Fiscal Outlook (MYEFO) under the *Guaranteeing Medicare – strengthening primary care* measure.

Items 8 to 33 of the Regulations make changes to cardiac items in the DIST, and items 34 to 39 of the Regulations make changes to cardiac items in the GMST.

Items 8 and 9 amends the item descriptor of cardiac item 55118 to clarify that the service can also be provided for a three-dimensional real time transoesophageal examination (as well as two-dimensional), and that the recording is only to be done by digital medium (and not by video tape). This is an administrative change to align item 55118 with other cardiac items in the DIST and to better align with clinical guidelines and contemporary practice.

Item 10 repeals and replaces the item descriptor of cardiac item 55130 to clarify that this service can also be provided for a three-dimensional real time transoesophageal examination (as well as two-dimensional examination), that the recording is only to be done by digital medium (and not by video tape), and that the service cannot be provided in association with a service to which an item in Subgroup 3 applies. This is an administrative change to align item 55130 with other cardiac items in the DIST and to better align with clinical guidelines and contemporary practice.

Item 11 repeals and replaces the item descriptor of cardiac item 55135 to clarify that this service can also be provided for an intra-operative three-dimensional real time transoesophageal examination (as well as a two-dimensional examination), that the recording is only to be done by digital medium (and not by video tape), and that the service cannot be provided in association with a service to which an item in Subgroup 3 applies.

The updated descriptor also provides that this service can only be provided if a service under the new valve surgery items 38477, 38484, 38499, 38516 or 38517 is provided on the same day. This change reflects the service provided under item 55135, including the assessment of cardiac function and valve competence, before and after

valve surgical procedures (where imaging is not already included in a complete service). This is an administrative change to align item 55135 with other cardiac items in the DIST and to better align with clinical guidelines and contemporary practice.

Item 12 amends the item descriptor of echocardiogram item 55137 to remove the restriction that the service cannot be provided in association with a service to an item in subgroup 7. This change will ensure that if a mother and fetus require independent (of each other) an echocardiographic investigation, that the two services can be claimed on the same day.

Item 13 amends the item descriptor of item 55143, which is for a repeat pharmacological or exercise stress echocardiography, to clarify that this service can also be performed if the patient has had a prior service under this item. This change will ensure that a service provided under this item can be provided on an ongoing basis, noting that it can only be provided once in a 12 month period. This service can continue to also be provided if a patient has had a service provided under echocardiography items 55141, 55145 or 55146 in the previous 24 months.

Item 14 amends the item descriptor of cardiac item 57360, which is for computed tomography (CT) of the coronary arteries, to provide that this service is to be performed if the patient is not known to have coronary artery disease, and is at low risk to intermediate risk of an acute coronary event which includes no significant cardiac biomarker elevation and no electrocardiogram changes indicating acute ischaemia. This change supports the role of CT of the coronary arteries in excluding coronary disease in those patients where significant coronary artery disease is suspected but has not been identified by first-line investigations.

A service under item 57360 can only be provided once in a 5 year period.

Item 15 repeals item 59903, as this item is obsolete, and also items 55912 and 59925 as a result of the restructure to coronary angiography items to simplify claiming processes for providers.

Items 16 to 18 amends Clause 2.3.9 and items 60918 and 60927 to remove references to items 59903, 59912 and 59925 as these items will be repealed (refer to item 15 of the Regulations).

Item 19 repeals clause 2.4.1D of the DIST which provides a co-claiming restriction for patients who are 17 years old or older and the provision of myocardial perfusion study (MPS) items 61321, 61324, 61325, 61329, 61345, 61357, 61394, 61398, 61406 or 61414. The item descriptors of these items have been amended in the Regulations to specify the relevant co-claiming restrictions for these patients.

Item 20 amends the item descriptor of MPS item 61321 to apply the current co-claiming restriction with mirrored nuclear medicine items 61332, 61380 and 61422. The substitute nuclear medicine items are a substitute service, including for MPS cardiac items, in circumstances when there is a disruption in the supply of certain radiopharmaceuticals. This is an administrative change which will ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The following mirrored nuclear medicine items are listed in the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019:*

- Nuclear medicine item 61311 mirrors cardiac items 61324 and 61357
- Nuclear medicine item 61332 mirrors cardiac items 61329 and 61345
- Nuclear medicine item 61365 mirrors cardiac item 61349
- Nuclear medicine item 61377 mirrors cardiac items 61394 and 61414
- Nuclear medicine item 61380 mirrors cardiac items 61398 and 61406
- Nuclear medicine item 61418 mirrors cardiac item 61410
- Nuclear medicine item 61422 mirrors cardiac item 61321

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service under this item, if they have had a service provided under this item (61321) or under items 61325, 61329, 61332, 61345, 61380, 61398, 61406 or 61422 in the previous 24 months.

Item 21 amends the item descriptor of MPS item 61324 to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61377, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service under this item, if they have had a service provided under this item (61324) or under items 61311, 61329, 61332, 61345, 61357, 61377, 61380, 61394, 61398, 61406 or 61414 in the previous 24 months.

Item 22 amends the item descriptor of MPS item 61325 to apply the current co-claiming restriction with mirrored nuclear medicine items 61332, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service under this item, if they have had a service provided under items 61321, 61329, 61332, 61345, 61380, 61398, 61406 or 61422 in 24 months.

The updated item descriptor also specifies that this service cannot be provided more than twice in 24 months if the patient is 17 years old or older. This requirement is currently listed in clause 2.4.1D of the DIST, which will be removed (refer to item 19 in the Regulations).

Item 23 amends the item descriptor of MPS item 61329 to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61377, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service provided under this item (61329), or under items 61311, 61321,

61324, 61325, 61332, 61345, 61357, 61380, 61394, 61398, 61406, 61414 or 61422 in the previous 24 months.

Item 24 amends the item descriptor of MPS item 61345 to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61377, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service provided under this item, if they have had a service provided under this item (61345) or under items 61311, 61321, 61324, 61325, 61329, 61332, 61357, 61377, 61380, 61394, 61398, 61406, 61414 or 61422 in the previous 24 months.

Items 25 and 26 amends the item descriptor of MPS item 61349 to apply the current co-claiming restriction with mirrored nuclear medicine items 61365 and 61418. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The amended item descriptor also clarifies that the patient has had to have a service performed under item 61311, 61324, 61329, 61332, 61337, 61345, 61357, 61365, 61380, 61394, 61398, 61406, 61410, 61414 or 61418 in the previous 24 months, and has subsequently undergone a revascularisation procedure.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service provided under this item, if they have had a service provided under this item (61349) or under items 61365, 61410 or 61418 in the previous 12 months.

Item 27 amends the item descriptor of MPS item 61357 to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61377, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient who is 17 years or older, they cannot have a service provided under this item, if they have had a service provided under this item (61357) or under items 61311, 61324, 61329, 61332, 61345, 61377, 61380, 61394, 61398, 61406 or 61414 in the previous 24 months.

Item 28 amends the item descriptor of MPS item 61394 to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61377, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service provided under this item, if they have had a service provided

under this item (61394) or under items 61311, 61324, 61329, 61332, 61345, 61357, 61377, 61380, 61398, 61406 or 61414 in the previous 24 months.

Item 29 amends the item descriptor of MPS item 61398 to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61377, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service provided under this item, if they have had a service provided under this item (61398) or under items 61311, 61321, 61324, 61325, 61329, 61332, 61345, 61357, 61377, 61380, 61394, 61406, 61414 or 61422 in the previous 24 months.

Item 30 amends the item descriptor of MPS item 61406 to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61377, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service provided under this item, if they have had a service provided under this item (61406) or under items 61311, 61321, 61324, 61325, 61329, 61332, 61345, 61357, 61377, 61380, 61394, 61398, 61414 or 61422 in the previous 24 months.

Items 31 and 32 amends the item descriptor of MPS item 61410 to apply the current co-claiming restriction with mirrored nuclear medicine item 61365 and 61418. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine item, as clinically appropriate.

The amended item descriptor also clarifies that the patient has had to have had a service provided under items 61311, 61324, 61329, 61332, 61345, 61349, 61357, 61365, 61377, 61380, 61394, 61398, 61406, 61414 or 61418 in the previous 24 months, and has subsequently undergone a revascularisation procedure.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service provided under this item, if they have had a service provided under items 61349, 61365 or 61418 in the previous 12 months.

Item 33 amends the item descriptor of MPS item 61414 to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61377, 61380 and 61422. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

The updated item descriptor also provides that if a patient is 17 years or older, they cannot have a service provided under this item, if they have had a service provided

under this item (61414) or under items 61311, 61324, 61329, 61332, 61345, 61357, 61377, 61380, 61398 or 61406 in the previous 24 months.

Item 34 amends clause 1.2.13 of the GMST to clarify that the clause applies to a medical practitioner in addition to specialists or consultant physicians. Clause 1.2.13 provides a co-claiming restriction for attendances on the same day as electrocardiogram services, to which items 11716, 11717, 11723, 11729 or 11735 apply, are performed.

Item 35 repeals and replaces clause 4.1.3A to include items 11716, 11717 and 17735 in addition to items 11704, 11705 and 11723. Clause 4.1.3A outlines requirements for the provision of a report for these items. This includes that the report must be in writing and must be prepared by a specialist or consultant physician. The report must include an interpretation of the trace, comments on the significance of the trace findings, and if appropriate, a copy of the trace and any measurements taken or automatically generated.

Item 36 amends the heading of clause 4.1.3B 'Restriction on items 11704, 11705 and 11723—services to include formal reports' to remove the words 'services to include' in the heading. This is an editorial change and does not change the intent of the clause.

Items 37 and 38 amends the item descriptor of electrocardiogram items 11729 and 11730 respectively in the GMST to apply the current co-claiming restriction with mirrored nuclear medicine items 61311, 61332, 61365, 61377, 61380 and 61418. As outlined under item 20 of the Regulations, this is an administrative change to ensure that the co-claiming restrictions will apply to the mirrored nuclear medicine items, as clinically appropriate.

Item 39 repeals and replaces item 38286, which is for the removal of an implantable ECG loop recorder. The amendment removes the requirement that the service must be provided in a hospital setting as improvements in device technology now enable the ECG loop recorder to be removed subcutaneously, which does not require the patient to be admitted to hospital. The schedule fee is also amended to reflect the shorter procedure time for this service.

Part 3 – Cardiac services

Part 3 makes changes to the DIST and the GMST to implement the second phase of cardiac changes which were recommended by the MBS Review Taskforce and announced in the 2020-21 Budget under the *Guaranteeing Medicare – Medicare Benefits Schedule (MBS) reviews – cardiac services* measure.

Items 40 to 42 of the Regulations make changes to cardiac items in the DIST, and items 43 to 95 of the Regulations make changes to cardiac items in the GMST.

Items 40 amends subclause 2.2.1(1) of the DIST to clarify new computed tomography (CT) coronary angiography item 57364 is to be excluded from this clause. This clause provides that a CT service is to be performed under the supervision of a specialist in diagnostic radiology who is available to monitor and influence the conduct and

diagnostic quality of the examination; and if necessary, to attend on the patient personally. The service is to be reported by a specialist in diagnostic radiology.

Item 41 amends subclause 2.2.1(2) of the DIST to insert new item 57364 to provide that the service is to be performed under the supervision of a specialist or consultant physician who is recognised by the Conjoint Committee for the Recognition of Training in CT Coronary Angiography, and is available to monitor and influence the conduct and diagnostic quality of the examination and if necessary, can attend to the patient personally. The service is to be reported by a specialist or consultant physician who is recognised by the Conjoint Committee for the Recognition of Training in CT Coronary Angiography.

Item 42 inserts new item 57364 for CT of the coronary arteries requested by a specialist or consultant physician for patients who require investigation of non-coronary artery related indications including newly diagnosed left ventricular systolic dysfunction, patients who are undergoing non-coronary cardiac surgery, or as an alternative treatment to selective coronary angiography.

Item 43 amends clause 1.2.11 of the GMST to remove items 11715 and 11718 as these items will be repealed (refer to item 45 in the Regulations).

Item 44 inserts new item 90300, which is for a professional attendance by a cardiothoracic surgeon to provide surgical backup for a provider (who is not a cardiothoracic surgeon) that is conducting extraction of chronically implanted transvenous pacing or defibrillator lead or leads which have been in place for more than six months and require removal. The cardiothoracic surgeon must be present for the full duration of lead extraction and be able to immediately scrub and perform a thoracotomy if major complications occur.

This service is to be provided in association with a service under item 38358.

Item 45 repeals items 11715 and 11718 as these items are obsolete.

Item 46 amends the item descriptor of item 11720, which is for implanted pacemaker testing following the detection of abnormality by remote monitoring, to remove the restriction against item 11718 as this item is obsolete and will be repealed (refer to item 45 in the Regulations).

Item 47 amends the item descriptor of item 11721, which is for implanted pacemaker testing of atrioventricular sequential, to provide that the service cannot be provided with a service under item 11704 (in addition to items 11719, 11720, 11725 and 11726), and to remove this restriction against item 11718 as this item is obsolete and will be repealed (refer to item 45 in the Regulations).

Item 48 amends the item descriptor of item 11727, which is for implanted defibrillator testing involving electrocardiography, to remove the restriction against item 11718 as this item is obsolete and will be repealed (refer to item 45 in the Regulations).

Item 49 repeals and replaces item 13400 to provide that the service can only be performed in a hospital setting to ensure best practice care, as performing outside a hospital could compromise patient safety.

Item 50 amends subclause 5.10.17(2) to remove reference to items which will be repealed.

Item 51 inserts new clauses 5.10.17A, 5.10.17B, 5.10.17C and 5.10.17D after clause 5.10.17 in the GMST.

Clause 5.10.17A provides patient eligibility and timing requirements for new cardiac items 38244, 38247, 38307, 38308, 38310, 38316, 38317 and 38319.

A service under these items applies if the service has not been provided to the patient in the previous 3 months, unless the patient experiences a new acute coronary syndrome or angina in that period or requires staging of the initial percutaneous coronary intervention procedure under items 38316, 38317 or 38319, and one of the following indications apply to the patient:

a) the patient has an acute coronary syndrome evidenced by any of the following:
    i. ST segment elevation;
    ii. new left bundle branch block;
    iii. troponin elevation above the local upper reference limit;
    iv. new resting wall motion abnormality or perfusion defect;
    v. cardiogenic shock;
    vi. resuscitated cardiac arrest;
    vii. ventricular fibrillation;
    viii. sustained ventricular tachycardia; or
b) the patient has unstable angina or angina equivalent with a crescendo pattern, rest pain or other high-risk clinical features, such as hypotension, dizziness, pallor, diaphoresis or syncope occurring at a low threshold; or
c) the patient has either of the following detected on computed tomography coronary angiography:
    i. significant left main coronary artery disease with greater than 50 per cent stenosis or a cross-sectional area less than $6mm^2$
    ii. severe proximal left anterior descending coronary artery disease

Clause 5.10.17B provides patient eligibility requirements for new cardiac items 38248 and 38249.

A service under these items applies if the patient is recommended for coronary angiography as a result of a heart team conference, or has one of the following indications:

a) the patient has limiting angina or angina equivalent despite an adequate trial of optimal medical therapy; or
b) the patient has high risk features, including at least one of the following:
    i. myocardial ischaemia demonstrated on functional imaging;
    ii. ST segment elevation, sustained ST depression, hypotension or a Duke treadmill score of minus 11 or less, demonstrated by stress electrocardiogram testing; ;

iii. computed tomography coronary angiography evidence of one or more coronary arteries with stenosis of 70 per cent or more; or
iv. left ventricular dysfunction or segmental wall motion abnormality at rest.

A heart team conference must be conducted by a team of specialists or consultant physicians practising in the speciality of cardiology or cardiothoracic surgery, and must include each of the following:

i. an interventional cardiologist;
ii. a non-interventional cardiologist;
iii. a specialist or consultant physician.

The team must assess the patient's risk and technical suitability to receive the service and make a recommendation about whether or not the patient is suitable for invasive coronary angiography

A record of the conference must be created and include the following:

i. the particulars of the assessment of the patient during the conference;
ii. the recommendations made as a result of the conference;
iii. the names of the members of the team making the recommendations.

Clause 5.10.17C provides patient eligibility requirements for new cardiac items 38311, 38313, 38314, 38320, 38322 and 38323.

A service under these items applies if the patient is recommended for coronary angiography as a result of a heart team conference, or:

(a) if the patient has any of the following indications:
    i. limiting angina or angina equivalent despite an adequate trial of optimal medical therapy;
    ii. myocardial ischaemia demonstrated on functional imaging;
    iii. high risk features such as ST segment elevation, sustained ST depression, hypotension or a Duke treadmill score of minus 11 or less, demonstrated by stress electrocardiogram testing; and
(b) if the patient has either of the following in the vascular territory treated:
    i. a stenosis of 70 per cent or more;
    ii. a fractional flow reserve of 0.80 or less, or non-hyperaemic pressure ratios distal to the lesions of 0.89 or less

A service under items 38314 and 38323 is to be provided if either the patient does not have diabetes mellitus and the multi-vessel coronary artery disease of the patient meets the criteria outlined in subclause 5.10.17C(3), or despite a recommendation that surgery is preferable, the patient has expressed a preference for catheter-based intervention.

Subclause 5.10.17C(3) provides the criteria for the multi-vessel coronary artery disease which includes that it does not involve stenosis of more than 50 per cent in the left main coronary artery, bifurcation lesions involving side branches with a diameter of more than 2.75 mm, chronic vessel occlusions for more than three months, severely angulated or calcified lesions or a SYNTAX score of more than 23.

Subclause 5.10.17C(4) provides the requirements for a heart team conference, relating to procedural items for coronary artery disease. The conference must be conducted by a team of specialists or consultant physicians practising in the speciality of cardiology or cardiothoracic surgery, and must include each of the following:

i. an interventional cardiologist;
ii. a specialist or consultant physician;
iii. for items 38314 and 38323 – a cardiothoracic surgeon;
iv. for items 38311, 38313, 38320 and 38322 – a cardiothoracic surgeon or a non-interventional cardiologist.

The team must assess the patient's risk and technical suitability to receive the service and make a recommendation about whether or not the patient is suitable for percutaneous coronary intervention.

A record of the conference must be created and include the following:

i. the particulars of the assessment of the patient during the conference;
ii. the recommendations made as a result of the conference;
iii. the names of the members of the team making the recommendations.

Clause 5.10.17D provides that a report or clinical note is to be created for a service under items 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38320, 38322, 38323, 38316, 38317 and 38319. The report or clinical note must include documentation that demonstrates how the item applies to the service, including how the patient is eligible for the service.

Item 52 repeals and replaces items 38200 to 38206 to insert amendments to the descriptors of these items.

Item 38200 is amended to provide that the service cannot be performed in association with a selective coronary angiography service under items 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38254 or 38368. This change will provide access to right heart catheterisation in the non-coronary setting outside of coronary angiography.

Item 38203 is amended to provide that the service cannot be performed in association with a selective coronary angiography service under items 38200, 38206, 38244, 38247, 38248, 38249, 38251, 38252 or 38254. This change will provide access to left heart catheterisation in the non-coronary setting outside of coronary angiography.

Item 38206 is amended to provide that the service cannot be performed in association with a selective coronary angiography service under items 38200, 38203, 38244, 38247, 38248, 38249, 38251, 38252 or 38254. This change will provide access to right heart catheterisation with left catheterisation in the non-coronary setting outside of coronary angiography.

Item 53 repeals and replaces items 38212 to 38246 to insert amended items 38212, 38213 and 38241, insert new items 38244, 38247, 38248, 38249, 38251, 38252 and 38254, and to repeal items 38215, 38218, 38220, 38222, 38225, 38228, 38231, 38234, 38237, 38240, 38243 and 38246 as these items have been restructured into new procedural items for coronary artery disease (refer to item 57 in the Regulations).

Item 38212, which is for a cardiac electrophysiological study, is amended to clarify that the service must involve four or more catheters, and to remove that the study can be for an electrophysiological service during defibrillator implantation or testing, as this service will be provided under item 38213.

Item 38213, which is for a cardiac electrophysiological study, is amended to provide that the service is to be performed during the insertion of an implantable defibrillator, or for defibrillation threshold testing at a different time to implantation. Previously, a study under this service was for follow up testing of an implanted defibrillator.

Item 38241, which is for the use of coronary pressure wire during selective coronary angiography, is amended to provide that it is to measure fractional flow reserve, non-hyperaemic pressure ratios or coronary flow reserve in intermediate coronary artery or graft lesions to determine if revascularisation is required via angioplasty, stenting or angioplasty with stenting. This item is used where previous functional imaging has either not been performed, or the results are inconclusive or do not apply to the vessel being interrogated. The amended item descriptor also amends the stenosis of graft lesions from 30 - 70 per cent to 50 - 70 per cent.

New item 38244, which is for selective coronary angiography, is for the placement of one or more catheters and injection of opaque material into the native coronary arteries. A service under this item cannot be performed in association with a service under items 38200, 38203, 38206 38247, 38248, 38249, 38251 or 38252. Clause 5.10.17A provides the patient and eligibility requirements for a service under this item (refer to item 51 in the Regulations).

New item 38247, which is for selective coronary and graft angiography, is for the placement of one of more catheters and injection of opaque material into the native coronary arteries and free coronary grafts attached to the aorta, and/or into the direct internal mammary artery grafts. A service under this item cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38248, 38249, 38251 or 38252.

This service is for the management of a patient who has an acute coronary syndrome, or has unstable angina or angina equivalent with a crescendo pattern, rest pain or other high-risk clinical features, or who has significant left main coronary artery disease or severe proximal left anterior descending coronary artery disease. Clause 5.10.17A provides the patient and eligibility requirements for a service under this item (refer to item 51 in the Regulations).

New item 38248, which is for selective coronary angiography, is for the placement of catheters and injection of opaque material into the native coronary arteries. A service under this item cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38249, 38251 or 38252.

This services is for the management of a patient with clinically stable indications, demonstrated by suspected or known coronary artery disease who has limiting angina or angina equivalent or high risk features, or where a heart team conference has recommended the coronary angiography. Clause 5.10.17B provides the patient and

eligibility requirements for a service under this item (refer to item 51 in the Regulations).

New item 38249, which is for selective coronary and graft angiography, is for the placement of catheters and injection of opaque material into the native coronary arteries and free coronary grafts attached to the aorta and/or into direct internal mammary artery grafts. A service under this item cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38251 or 38252.

This service is for the management of a patient with clinically stable indications, demonstrated by suspected or known coronary artery disease who has limiting angina or angina equivalent, has high risk features, or where a heart team conference has recommended the coronary angiography. Clause 5.10.17B provides the patient and eligibility requirements for a service under this item (refer to item 51 in the Regulations).

New item 38251, which is for selective coronary angiography, is for the placement of catheters and injection of opaque material into the native coronary arteries. The service is for the management of a symptomatic patient with valvular or other non-coronary structural heart disease for a pre-operative assessment to plan non-coronary cardiac surgery, or for the evaluation of valvular heart disease or other non-coronary structural heart disease. A service under this item cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249 or 38252.

New item 38252, which is for selective coronary and graft angiography, is for the placement of one or more catheters and injection of opaque material into the native coronary arteries and free coronary grafts attached to the aorta. A service under this item cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249 or 38251.

The service is for the management of a symptomatic patient with valvular or other non-coronary structural heart disease for a pre-operative assessment to plan non-coronary cardiac surgery, or for the evaluation of valvular heart disease or other non-coronary structural heart disease.

New item 38254 is for right heart catheterisation. This service is be provided in association with a selective coronary angiography service under items 38244, 38247, 38248, 38249, 38251 or 38252, and is to include any of the following:

i. a fluoroscopy;
ii. oximetry;
iii. dye dilution curves;
iv. cardiac output measurement;
v. shunt detection; or
vi. an exercise stress test.

Item 54 repeals and replaces item 38272, which is for an atrial sepal defect closure, to provide that the service is also for a patent foramen ovale closure, including right and

or left heart catheterisation, for congenital heart disease in a patient with documented evidence of right heart overload or paradoxical embolism.

The amended item descriptor also provides that a service under this item cannot be provided in association with heart catheterisation services under items 38200, 38203, 38206 or 38254.

Item 55 repeals and replaces item 38274, which is for a transcatheter closure of a ventricular septal defect with cardiac catheterisation, to provide that the service is to exclude imaging, as this would be routinely provided by a different provider.

Item 56 repeals and replaces item 38285, which is to insert an ECG loop recorder for the diagnosis of a primary disorder, to remove the requirement that the service must be provided in a hospital as improvements in technology now enable the ECG loop recorder to be inserted subcutaneously, which does not always require the patient to be admitted to hospital.

The amended item descriptor provides that the insertion is to be performed by a specialist or consultant physician.

Item 57 repeals items 38300 to 38318 to inserts 12 new items for percutaneous coronary intervention (items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 and 38323), to insert amended item 38309, and to repeal items 38300, 38303, 38306, 38312, 38315 and 38318.

<u>New items</u>
The restructure of the new items will introduce single items as a complete medical service based on inclusion criteria and the number of vascular territories treated. The inclusion criteria of these items will align with the inclusion criteria of the selective coronary angiography items to allow appropriate progression to intervention when clinically required.

Clause 5.10.17A provides the patient and eligibility requirements for a service under items 38307, 38308, 38310, 38316, 38317 and 38319 (refer to item 51 in the Regulations).

Clause 5.10.17C provides the patient and eligibility requirements for a service under items 38311, 38313, 38314, 38320, 38322 and 38323 (refer to item 51 in the Regulations).

New item 38307 is for performing percutaneous coronary intervention in the setting of acute coronary syndrome. This item includes selective coronary angiography (and all associated imaging, catheter and contrast) and either or both percutaneous angioplasty or transluminal insertion of one or more stents in a single coronary vascular territory, if selective coronary angiography has not been completed in the previous three months. The service excludes associated after-care.

A service under new item 38307 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323.

New item 38308 is for performing percutaneous coronary intervention in the setting of acute coronary syndrome. This item includes selective coronary angiography (and all associated imaging, catheter and contrast) and either or both percutaneous angioplasty or transluminal insertion of one or more stents in two coronary vascular territories, if selective coronary angiography has not been completed in the previous three months. The service excludes associated after-care.

A service under new item 38308 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323.

New item 38310 is for performing percutaneous coronary intervention in the setting of acute coronary syndrome. This item includes selective coronary angiography (including all associated imaging, catheter and contrast) and either or both percutaneous angioplasty or transluminal insertion of one or more stents in three coronary vascular territories, if selective coronary angiography has not been completed in the previous three months. The service excludes associated after-care.

A service under new item 38310 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323.

New item 38311 is for performing percutaneous coronary intervention in the setting of the patient with stable indications. This item includes selective coronary angiography (including all associated imaging, catheter and contrast) and either or both percutaneous angioplasty or transluminal insertion of one or more stents in a single coronary vascular territory, if selective coronary angiography has not been completed in the previous three months. This service can only be provided to patients with triple vessel disease and excludes after-care.

A service under new item 38311 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323.

New item 38313 is for performing percutaneous coronary intervention in the setting of the patient with stable indications. This item includes selective coronary angiography (including all associated imaging, catheter and contrast) and either or both percutaneous angioplasty or transluminal insertion of one or more stents in any two coronary vascular territories, if selective coronary angiography has not been completed in the previous three months. The service can only be provided to patients with triple vessel disease and excludes after-care.

A service under new item 38313 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38314, 38316, 38317, 38319, 38320, 38322 or 38323.

New item 38314 is for performing percutaneous coronary intervention in the setting of the patient with stable indications. This service includes selective coronary angiography (including all associated imaging, catheter and contrast) and either or both percutaneous angioplasty or transluminal insertion of one or more stents in all

three coronary vascular territories, if selective coronary angiography has not been completed in the previous three months. The service can only be provided to patients with triple vessel disease and excludes after-care.

A service under new item 38314 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38316, 38317, 38319, 38320, 38322 or 38323.

New item 38316 is for performing percutaneous coronary intervention in the setting of acute coronary syndrome. This item includes any associated coronary angiography and includes either or both percutaneous angioplasty or transluminal insertion of one or more stents in a single coronary vascular territory, if invasive coronary angiography has been completed in the previous three months. The service excludes after-care.

A service under new item 38316 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38317, 38319, 38320, 38322 or 38323.

New item 38317 is for performing percutaneous coronary intervention in the setting of acute coronary syndrome. This item includes any associated coronary angiography and includes either or both, percutaneous angioplasty or transluminal insertion of one or more stents in two coronary vascular territories, if selective coronary angiography has been completed in the previous 3 months. The service excludes after-care.

A service under new item 38317 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38319, 38320, 38322 or 38323.

New item 38319 is for performing percutaneous coronary intervention in the setting of acute coronary syndrome. This item includes any associated coronary angiography and includes either or both, percutaneous angioplasty or transluminal insertion of one or more stents in three coronary vascular territories, if invasive coronary angiography has been completed in the previous 3 months. The service excludes after-care.

A service under new item 38319 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38320, 38322 or 38323.

New item 38320 is for performing percutaneous coronary intervention in the setting of the patient with stable indications. This item includes any associated coronary angiography and includes either or both, percutaneous angioplasty or transluminal insertion of one or more stents in a single coronary vascular territory, if selective coronary angiography has been completed in the previous three months. The service can only be provided to patients with triple vessel disease and excludes after-care.

A service under new item 38320 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38322 or 38323.

New item 38322 is for performing percutaneous coronary intervention in the setting of the patient with stable indications. This item includes any associated coronary angiography and includes either or both, percutaneous angioplasty or transluminal insertion of one or more stents in two coronary vascular territories, if selective coronary angiography has been completed in the previous 3 months. The service can only be provided to patients with triple vessel disease, and excludes after-care.

A service under new item 38322 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320 or 38323.

New item 38323 is for performing percutaneous coronary intervention in the setting of the patient with stable indications. This item includes any associated coronary angiography and includes either or both, percutaneous angioplasty or transluminal insertion of one or more stents in three coronary vascular territories, if selective coronary angiography has been completed in the previous 3 months. The service can only be provided to patients with triple vessel disease, and excludes after-care.

A service under new item 38323 cannot be performed in association with a service under items 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320 or 38322.

Amended item

Item 38309, which is for the percutaneous transluminal rotational atherectomy of one coronary artery, has been amended to provide that this service will now be for one or more coronary arteries where the target stenosis within at least one coronary artery is heavily calcified and balloon angioplasty (with or without stenting), where it is not feasible without rotational atherectomy.

This change will consolidate the initial service provided under item 38309 and services provided under items 38312, 38315 and 38318 which will be repealed into a single item for rotational atherectomy.

To simply this service, this item can only be provided in association with a percutaneous coronary intervention items (38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323) and claimed once on each occasion the service is performed.

Item 58 repeals and replaces item 38358, which is for the extraction of one or more chronically implanted transvenous pacing or defibrillator leads if the leads been in place for more than six months and requires removal by percutaneous method, to provide the service is performed by an appropriately trained provider.

The amended item descriptor addresses when the service is performed by an interventional cardiologist, a cardiothoracic surgeon is to be attend the service during the extraction should major complications occur (requiring open surgery). A service under this item, which is the primary procedural item, will attract 70 per cent of the previous fee of this item.

Item 59 repeals items 38365 to 38393 to amend items 38365 and 38368, and to repeal items 38371, 38384, 38387, 38390 and 38393. These items have been repealed to clarify inclusion criteria and allow for the provision of a complete medical service under items 38365, 38368 and new item 38471 (refer to item 61 in the Regulations).

Item 38365, which is for the insertion, removal or replacement of a permanent cardiac synchronisation device, is amended to provide that the service is not to include a cardiac synchronisation device that is capable of defibrillation.

The amended item descriptor provides that the service is to be performed on a patient who has chronic heart failure aligning with clinical guidelines, and is not be performed in association with item 38212. This service has also been amended to be provided in association with an assistance item due to the complexity of the procedure.

Item 38368, which is for the insertion, removal or replacement of a permanent transvenous left ventricular electrode through the coronary sinus, is amended to provide that the service is for a patient who has chronic heart failure aligning with clinical guidelines. This service has also amended to include assist due to the complexity of the procedure. A service under this item cannot be performed in association with a service under items 35200, 38200 or 3212.

Item 60 inserts new item 38467, which is for the insertion, removal or replacement of a permanent myocardial electrode by open surgical approach. A service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

Item 61 repeals items 38470 to 38483 to insert new items 38471, 38472, 38474 and 38484, to amend item 38477, and to repeal items 38470, 38473, 38475, 38478, 38480, 38481 and 38483. These items have been repealed to remove obsolete items and to allow for the provision of a complete medical service under items 38467, 38516 and 38517.

Amended item

Item 38477, which is for a valve annuloplasty with insertion of ring, is amended to provide that the service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38516, 38517, 38806 or 45503.

New items

New item 38471 is for the insertion of an implantable defibrillator including the insertion of patches for the insertion of one or more transvenous endocardial leads in a patient. The patient must have at least a history of haemodynamically significant ventricular arrhythmias in the presence of structural heart disease, documented high-risk genetic cardiac disease, ischaemic heart disease or chronic heart failure aligning with clinical guidelines. This service consolidates items 38384 and 38390 which will be repealed, and it cannot be performed in association with a service under item 38212.

New item 38472 is for the insertion, replacement or removal of an implantable defibrillator generator for a patient who has at least a history of haemodynamically

significant ventricular arrhythmias in the presence of structural heart disease, documented high-risk genetic cardiac disease, ischaemic heart disease, or chronic heart failure aligning with clinical guidelines. This service consolidates items 38387 and 38393 which will be repealed, and it cannot be performed in association with a service under item 38212.

New item 38474 is for the repair, augmentation or replacement of the branch pulmonary arteries, with cardiopulmonary bypass for patients with congenital heart disease. This is a complex surgery which is not well described under existing items. A service under item 38474 cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

New item 38484 is for aortic or pulmonary valve replacement with bioprosthesis or mechanical prosthesis. It is for a complete medical service according to valve location, and cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

Item 62 repeals items 38488 to 38490 to insert amended item 38490, and to repeal items 38488 and 38489. These items have been replaced by new items 38484 and 38499 to allow for the provision of complete medical services under the new items.

Item 38490, which is for the reconstruction and re-implantation of sub-valvular structures, is amended to provide that the service can only be provided in association with a service under new item 38499, which is for mitral or tricuspid valve replacement.

Item 63 repeals items 38496 to 38518 to insert new items 38499, 38502, 38510, 38511, 38513, 38516, 38517 and 38519, to amend items 38508, 38509, 35812, 38515 and 38518, and to repeal items 38496, 38497, 38498, 38500, 38501, 38503, 38504, 38505, 38506 and 38507. These items are being repealed as part of the restructure of coronary artery bypass graft surgery items to allow for the provision of a complete medical service.

<u>New items</u>
New item 38499 has been created following the restructure of the surgical valve replacement items to provide a complete medical service according to valve location. This item is for mitral or tricuspid valve replacement with bioprosthesis or mechanical prosthesis, and includes retrograde cardioplegia (if performed). A service provided under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

New item 38502 is for a coronary artery bypass including cardiopulmonary bypass, which is to include the harvesting of the left internal mammary artery or the harvesting of vein graft material or both. The service can include retrograde cardioplegia and vein graft(s), and cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

New item 38510 is for artery harvesting (other than of the left internal mammary), for coronary artery bypass where more than one arterial graft is required. It can only be performed in association with a service under item 38502.

New item 38511 is for coronary artery bypass with the aid of tissue stabilisers, and is to be performed without cardiopulmonary bypass. It can only be performed in in association with a service under item 38502.

New item 38513 is for creation of a graft to graft anastomosis, which requires micro-arterial or micro-venous anastomosis using microsurgical techniques. This item addresses the added procedural complexity of this harvesting approach and the relation of this technique for better patient outcomes. It can only be performed in association with a service under item 38502.

New item 38516 is for a simple valve repair, which is to include quadrangular resection, cleft closure, or alfieri. It can include annuloplasty and retrograde cardioplegia (if performed). This item consolidates the services provided under items 38475, 38478 and 38480 which will be repealed (refer to item 61 in the Regulations) to provide a complete medical service for a simple valve repair.

A service under this item includes retrograde cardioplegia, if performed, and is not to be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

New item 38517 is for a complex valve repair that can include annuloplasty and retrograde cardioplegia (if performed). The service is to include at least neochords, chordal transfer, patch augmentation, or multiple leaflets. This item provides a complete medical service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

New item 38519 is for the valve explant of a previous prosthesis that is performed during a valve replacement procedure under items 38484 or 38499. A service under this item must be performed in association with a service under item 38484 or 38499, and is not to be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Amended items

Item 38508, which is for the repair or reconstruction of a left ventricular aneurysm, has been amended to provide that the service includes plication, resection, and primary and patch repairs. This change consolidates a service under this item and two left ventricular aneurysm repair items 38506 and 38507 which will be repealed (refer to item 63 in the Regulations) into a single service. The amendment also provides that the service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

Items 38509, 38512, 38515 and 38518 have been amended to provide that a service under these items cannot be performed in association with a service under items

11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Item 64 repeals items 38550 to 38565 to insert new items 38554, 38555, 38557 and 38558, to amend items 38550, 38553 and 38556, and to repeal items 38559, 38562 and 38565. Items 38559, 38562 and 38565 have been restructured into new items 38555 and 38557 to allow for a complete medical service to be provided under these items.

New items

New item 38554 is for a valve sparing aortic root surgery with reimplantation of aortic valve and coronary arteries and with replacement of the ascending aorta. The item provides for cardiopulmonary bypass and retrograde cardioplegia when performed, and is not to be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

New item 38555 is for a simple replacement or repair of the aortic arch including deep hypothermic circulatory arrest, peripheral cannulation for cardiopulmonary bypass, and antegrade or retrograde cerebral perfusion (if performed).

It must be performed in association with a service under items 38550, 38553, 38554, 38556, 38568 or 38571. It cannot be performed in association with a service under item 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38603, 38806 or 45503.

New item 38557 is for a complex replacement or repair of the aortic arch involving debranching and re-implantation of head and neck vessels, deep hypothermic circulatory arrest, peripheral cannulation for cardiopulmonary bypass, and antegrade or retrograde cerebral perfusion (if performed).

New item 38558 is for aortic repair involving the augmentation of hypoplastic or interrupted aortic arch, including use of antegrade cerebral perfusion or deep hypothermic circulatory arrest, and associated myocardial preservation, and retrograde cardioplegia.

The service is for a patient who is a neonate, and cannot be performed in association with a service under item 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

Amended items

Item 38550, which is for the repair or replacement of the ascending thoracic aorta that does not involve valve replacement or repair or coronary artery implantation, is amended to provide that the service is to include cardiopulmonary bypass, and retrograde cardioplegia (if performed) as this is a complete medical service, where performed.

The cannulation of the coronary sinus, required for retrograde cardioplegia is incorporated into the fee for this item (which has also been indexed), as item 38588 will be repealed (refer to item 65 in the Regulations). The amended item descriptor also provides that a service under this item cannot be performed in association with a

service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Item 38553, which is for the repair or replacement of the ascending thoracic aorta without implantation of coronary arteries, is amended to provide that the service is to include cardiopulmonary bypass, and retrograde cardioplegia (if performed), as this is a complete medical service, where performed.

The cannulation of the coronary sinus, required for retrograde cardioplegia is incorporated into the fee for this item (which has also been indexed), as item 38588 will be repealed (refer to item 65 in the Regulations). The amended item descriptor also provides that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Item 38556, which is for the repair or replacement of the ascending thoracic aorta with implantation of coronary arteries, is amended to provide that the service is to include cardiopulmonary bypass, and retrograde cardioplegia (if performed) as this is a complete medical service, where performed.

The cannulation of the coronary sinus, required for retrograde cardioplegia is incorporated into the fee for this item (which has also been indexed), as item 38588 will be repealed (refer to item 65 in the Regulations). The amended item descriptor also provides that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Item 65 repeals items 38568 to 38588 to amend items 38568, 38571 and 38572, and to repeal items 38577 and 38588 as these items are not stand-alone procedures and have been consolidated into their associated items.

Items 38568 and 38571, which are for the repair or replacement of the ascending thoracic aorta, have been amended to provide that the services cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38603, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 38572, which is for the operative management of acute rupture, has been amended to provide that the service is to be performed in conjunction with procedures on the thoracic aorta under items 38550, 38553, 38554, 38555, 38556, 38557, 38558, 38568, 38571, 38706 or 38709.

The amended item descriptor also provides that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Item 66 repeals items 38603 to 38613 to amend items 38603, 38609 and 38612, and to repeal item 38613 as this item has been consolidated under item 38612.

Item 38603, which is for the peripheral cannulation for cardiopulmonary bypass excluding post-operative management, is amended to provide that the service cannot be provided where peripheral cannulation is used in preference over central cannulation for valve or coronary bypass procedures, or in association with a service under items 38555 or 38572 as these items already include circulatory support.

Item 38609, which is for the insertion of an intra-aortic balloon pump by arteriotomy, is amended to provide that the service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Item 38612, which is for the removal of an intra-aortic balloon pump with closure of artery by direct suture, is amended to provide that the service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Items 67 amends items 38615 and 38618 to provide that a service under these items cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38627, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Items 68 and 69 amends items 38621, 38624, and 38627 to provide that a service under these items cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38627, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 70 amends item 38637 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Item 71 repeals items 38640 to 38654 to amend items 38643 and 38653, and to repeal items 38640, 38647, 38650 and 38654 as these services have been consolidated under item 38764 (refer to item 93 in the Regulations).

Item 38643 is amended to clarify that the service is for a re-operation via thoracotomy or sternotomy which includes any divisions of adhesions, and to amend the time period to greater than 30 minutes. The amended item descriptor also provides that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure.

Item 38653, which is for open heart surgery, is amended to provide that the service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with this procedure. Cannulation of the coronary item 38588, which will be repealed (refer to item 65 in the Regulations), has been incorporated into the fee for this item.

Items 72 to 75 amends items 38656, 38670, 38673 and 38677 to provide that a service under these items cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 76 amends item 38680, which is for the partial thickness excision of a cardiac tumour arising from ventricular myocardium, to provide that the service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Items 77 amends items 38700 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim this item with these procedures.

Items 78 repeals and replaces item 38703 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim this item with these procedures.

Item 79 amends item 38706 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 80 repeals and replaces item 38709 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 81 repeals item 38712 as this item is obsolete.

Item 82 amends item 38715 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 83 repeals and replaces item 38718 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 84 amends item 38721 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 85 repeals and replaces item 38724 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707,

11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim this item with these procedures.

Item 86 repeals and replaces items 38727 and 38730.

Item 38727, which is for the anastomosis or repair of the intrathoracic vessels without cardiopulmonary bypass, is amended to provide that the service is to be performed as a primary procedure not as an integral component of another procedure.

The amended item descriptor also provides that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, and removes this co-claiming restriction with item 38712, as this item is obsolete and will be repealed (refer to item 81 in the Regulations).

Item 38730, which is for the anastomosis or repair of the intrathoracic vessels with cardiopulmonary bypass, is amended to provide that the service is to be performed a primary procedure not as an integral component of another procedure.

The amended item descriptor also provides that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38700, 38703, 38706, 38709, 38715, 38718, 38721 38724, 38806 or 45503 (this change aligns with item 38727).

Item 87 amends items 38733 and 38736 to provide that a service under these items cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 88 repeals and replaces item 38739 to provide that a service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim this item with these procedures.

Item 89 amends item 38742, which is for the closure by open exposure and direct suture or patch of an atrial septal defect, to provide that the service is to be performed on a patient with documented evidence of right heart overload or paradoxical embolism. A service under this item cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

Items 90 to 92 amend items 38745, 38748, 38751, 38754, 38757 and 38760 to provide that a service under these items cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503.

Item 93 repeals item 38763 and inserts new item 38764, which is for ventricular myectomy for the relief of ventricular obstruction. This item consolidates a service under this item and item 38650 which will be repealed (refer to item 71 in the Regulations) to provide a complete medical service.

A service under this item cannot be performed in association with a service under item 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 94 amends item 38766, which is for ventricular augmentation for congenital heart disease, to provide that the service cannot be performed in association with a service under items 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503, as it is not appropriate to claim these items with these procedures.

Item 95 inserts a definition for coronary vascular territory, for an item in Subgroup 6 of Group T8 (cardio-thoracic surgical operations), into the GMST. Under this definition, a coronary vascular territory means a vascular territory supplied by the left anterior descending artery, the circumflex artery, the right coronary artery, or one or more of the branches of these arteries, or one or more coronary bypass grafts.

Part 3A – Orthopaedics

Part 3A makes amendments to the GMST to correct a handful of items relating to orthopaedic services. On 1 July 2021, the GMST was repealed and remade to implement a number of Government policy changes. This included implementing the Government's response to the Taskforce recommendations on orthopaedic services to restructure the existing items to reflect contemporary practice, ensure services are clinically appropriate and improve quality of care and safety for patients.

The GMST required amendment to correct a handful of orthopaedic services to reflect the intent of the Government policy. The Regulations amend the GMST to specifically list the parts of the procedure included (if performed). This includes removal of bone, excision of surrounding osteophytes, synovectomy and/or joint release for items 48400, 48403, 48406 and 48409 (**item 95A**) and capsulotomy, debridement or release of ligament and/or debridement or release of tendon for item 50312 (**item 95B).** This change was recommended by the Taskforce per recommendation 2 of its report on orthopaedic services, which can be found at https://www1.health.gov.au/internet/main/publishing.nsf/Content/MBSReviewTaskforce.

Part 4 – Other amendments

Part 4 makes minor amendments to diagnostic imaging items in the DIST. These changes are administrative and housekeeping in nature.

Item 96 amends computed tomography (CT) item 57351 to provide a patient who has had a service under item 57357 (which is for a repeat CT angiography service) in the previous 12 months, is able to access item 57351. This is an administrative change and is in line with policy intent of the service.

Items 97 and 98 removes the current 12 month restriction on the claiming of item 63454 and restrict the claiming of this service to once per pregnancy. This changes recognises that there may be occasions when a woman has two pregnancies within a 12 month period and is in line with the original policy intent.

Items 99 and 100 moves item 63454 from *Subgroup 19 – Scan of body – for specified conditions* into *Subgroup 20 – Scan of pelvis and upper abdomen – for specified conditions* under *Group I5 – Magnetic resonance imaging*. Item 63454, which is for an MRI scan of the pelvis or abdomen for a patient who is pregnant, sits more appropriately under Subgroup 20 of Group I5.

The item descriptor of item 63454 is also amended to clarify that this service is for a patient who is pregnant. This is an administrative change and is in line with the policy intent of the service.

Statement of Compatibility with Human Rights

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

Health Insurance Legislation Amendment (2021 Measures No. 1) Regulations 2021

This Regulation is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Disallowable Legislative Instrument

The purpose of the *Health Insurance Legislation Amendment (2021 Measures No. 1) Regulations 2021* (the Regulations) is to amend the GMST, DIST and PST from 1 July 2021. The Regulations will make changes to cardiac services and make minor administrative changes to reflect Government policy. The Regulations will also index diagnostic imaging services and two items for the management of bulk-billing pathology services.

Indexation

Part 1 of the Regulations will implement Government policy by increasing the schedule fee by 0.9 per cent for some diagnostic imaging services in the diagnostic imaging services table (DIST), and for the management of bulk-billing pathology services in the pathology services table (PST). This means that patients will receive a higher Medicare benefit for these services from 1 July 2021.

In the 2017-18 Budget under the *Guaranteeing Medicare - Medicare Benefits Schedule - indexation* measure, the Government announced the re-commencement of indexation of Medicare benefits for computed tomography, mammography, fluoroscopy and interventional radiology diagnostic imaging services, and indexation of Medicare benefits for the management of bulk-billed services.

In the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure, the Government announced that it would expand indexation to ultrasound and x-ray diagnostic imaging services from 1 July 2020.

Changes for cardiac services

Part 2 and Part 3 of the Regulations will implement changes to cardiac services in the DIST and the general medical services table (GMST).

Part 2 of the Regulations will make minor amendments to existing cardiac services to align co-claiming restrictions with other cardiac services and to reflect the policy intent of the services, and to better align with clinical guidelines.

Part 3 of the Regulations will implement the second phase of cardiac changes which were recommended by the clinician-led MBS Review Taskforce (the MBS Review Taskforce) and agreed by Government in the 2020-21 Budget under the *Guaranteeing Medicare – Medicare Benefits Schedule (MBS) reviews – cardiac services* measure.

The first phase of cardiac changes were implemented on 1 August 2020. The changes included promoting high-value use of electrocardiogram (ECG), echocardiogram,

ambulatory ECG, ECG stress testing, myocardial perfusion studies and stress echocardiogram. On 15 September 2020, one new ambulatory electrocardiogram monitoring item was introduced following technological advancements in this area, and five new myocardial perfusion study items were added to ensure timely access to cardiac diagnostic services in rural and remote areas.

The second phase of changes will build on the first phase by making a range of amendments to cardiac surgical services to define co-claiming restrictions, consolidate similar surgical procedures, incentivise advanced techniques, introduce items that represent a complete medical service, remove procedures that no longer represent best practice and align with clinical guidelines.

Other amendments

Part 3A makes amendments to the GMST to correct a handful of items relating to orthopaedic services. Part 4 makes minor amendments to diagnostic imaging items in the DIST.

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.

Analysis

The Regulations maintain rights to health and social security by ensuring access to publicly subsidised general medical services, diagnostic imaging services and pathology services are clinically and cost-effective.

Conclusion

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

Greg Hunt

Minister for Health and Aged Care