

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022

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

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

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

Section 4AA of the Act provides that regulations may prescribe a table of diagnostic imaging services which sets out items of diagnostic imaging services, the fees applicable for each item, and rules for interpreting the table. The table made under this section is referred to as the diagnostic imaging services table (DIST). The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020*.

Section 4A of the Act provides that regulations may prescribe a table of pathology services which set out items of pathology services, the fees applicable for each item, and rules for interpreting the table. The table made under this section is referred to as the pathology services table (PST). The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020*.

Purpose

The purpose of the *Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022* (the Regulations) is to amend the general medical services table (GMST), diagnostic imaging services table (DIST) and pathology services table (PST) to:

- implement the Government's response to recommendations from the MBS Review Taskforce (the Taskforce) regarding colorectal surgery services and recommendations from the independent Medical Services Advisory Committee (MSAC) on pathology services and prostate-specific membrane antigen (PSMA) positron emission tomography (PET) services; and
- implement annual indexation of Medicare schedule fees by 1.6 per cent, which includes indexation of MRI diagnostic imaging services for the first time. Indexation will be applied to the schedule fees of GP and specialist attendances, diagnostic investigations, therapeutic and procedural items, and diagnostic imaging services (other than nuclear medicine). This reflects the

Government's policy regarding Medicare indexation and means that patients will receive an increased Medicare benefit for these services.

The Regulations also make minor administrative changes to four general medical service items.

Changes to Pathology Services

Parts 3 and 4 of the Regulations will implement the following changes to genetic testing and cervical screening services announced by Government in the 2021-22 Mid-Year Economic and Fiscal Outlook (MYEFO) measure *Guaranteeing Medicare – Medicare Benefits Schedule new and amended listings*:

- introduce four new items for genomic testing for heritable cardiomyopathies;
- introduce four new items for genetic testing for diagnosis of inheritable cardiac arrhythmia disorders;
- introduce two new items for Non-Invasive Prenatal Testing for fetal Rhesus D genotype;
- introduce six new items for genetic testing for heritable kidney disease other than Alport syndrome;
- introduce four new items for genetic testing for alpha thalassaemia;
- amend item 73325 to allow the service to be delivered to patients with primary myelofibrosis and introduce four new items for testing for myeloproliferative neoplasms; and
- amend cervical screening items 73071 and 73073 to expand access to self-collected cervical screening tests.

Part 3 will also amend pre-implantation genetic testing items 73385, 73386 and 73387 to clarify the policy intent of the services. This change is administrative in nature and aligns with policy announced under the 2021-22 Budget measure *Guaranteeing Medicare – Changes to the Medicare Benefits Schedule*.

Changes to Colorectal Surgery Services

Part 5 of the Regulations will implement a number of changes to colorectal surgery services, as recommended by the MBS Review Taskforce (the Taskforce) and announced by Government in the 2021-22 Budget under the *Guaranteeing Medicare – Changes to the Medicare Benefits Schedule* measure.

These changes to MBS items will better align colorectal surgery services with contemporary and evidence-based treatment and also seek to simplify and streamline MBS items relating to colorectal surgery services. The changes include deleting outdated items, combining items that are provided together into a single item, and updating the descriptors of items to better describe modern techniques. Patients will benefit from improved patient safety and quality of care, and may also benefit through a reduction in unnecessary services and related out-of-pocket expenses.

Introduction of two new PSMA PET services

Part 1 of the Regulations will introduce two new items for prostate-specific membrane antigen (PSMA) positron emission tomography (PET) (items 61563 and 61564). This change was recommended by the independent Medical Services Advisory Committee (MSAC) and announced under the 2021-22 MYEFO measure *Guaranteeing Medicare – Medicare Benefits Schedule new and amended listings*.

Changes to bulk billing incentive for magnetic resonance imaging

In the 2021-22 Budget under the *Guaranteeing Medicare – improving diagnostic imaging* measure, the Government announced that it would bring funding for MRI services in line with other diagnostic imaging services from 1 July 2022.

Part 2 of the Regulations will amend the DIST so that, from 1 July 2022, the bulk-billing incentive for bulk billed MRI items in Group I5 will be 95% of the schedule fee when provided out of hospital. This change ensures funding for MRI services is consistent with funding for other diagnostic imaging services. It is implemented through Part 7 of the Regulations.

Indexation

Part 7 of the Regulations will implement annual fee indexation by increasing the schedule fee by 1.6 per cent 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 means that patients will receive a higher Medicare benefit for these services from 1 July 2022.

For the first time, from 1 July 2022 indexation will apply to MRI diagnostic imaging services in Group I5. This change was announced by Government in the 2021-22 Budget under the *Guaranteeing Medicare – improving diagnostic imaging* measure.

Administrative changes

Part 6 of the Regulations will make administrative changes to four items in the GMST. These changes will clarify the original policy intent of the services and are considered minor and administrative in nature.

Consultation

MSAC, the Taskforce and medical professional organisations were consulted on the 1 July 2022 changes.

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

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

As part of the MSAC process, consultation was undertaken with key stakeholders, clinical experts, and providers regarding the changes to pathology services.

The Department has consulted with the Royal Australian and New Zealand College of Radiologists, Australian Diagnostic Imaging Association, Australasian Association of Nuclear Medicine Specialists, Consumers Health Forum, Prostate Cancer Foundation Australia and the Medical Oncology Group of Australia on the introduction of new PSMA PET items 61563 and 61564 in Part 1 of the Regulations.

The Royal College of Pathologists of Australasia (RCPA) and the Haematology Society of Australia and New Zealand (HSANZ) were consulted on the change in Part 3 of the Regulations to item 73325 to allow the service to be delivered to patients with primary myelofibrosis and the introduction of new items 73396, 73397, 73398 and 73399 for testing for myeloproliferative neoplasms. The RCPA and HASANZ were also consulted on the introduction of new items 73410, 73411, 73412 and 73413 for genetic testing for alpha thalassaemia in Part 3 of the Regulations.

The RCPA and the Australian Red Cross Lifeblood were consulted on the introduction of new items 73420 and 73421 for Non-Invasive Prenatal Testing for fetal Rhesus D genotype in Part 3 of the Regulations.

The RCPA was consulted on the introduction of new items 73392, 73393, 73394 and 73395 for genetic testing for heritable cardiomyopathies and new items 73416, 73417, 73418 and 73419 for genetic testing for diagnosis of inheritable cardiac arrhythmia disorders in Part 3 of the Regulations.

Key professional groups, including the Transplant Society of Australia and New Zealand and the Renal Society of Australasia were consulted on the introduction of new items 73401, 73402, 73403, 73404, 73405 and 73406 for genetic testing for heritable kidney disease other than Alport syndrome in Part 3 of the Regulations.

Key professional groups, including the RCPA, The Royal Australian College of General Practitioners and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists were consulted on the changes to cervical screening items 73071 and 73073 in Part 4 of the Regulations.

The Taskforce endorsed the recommendations of the Colorectal Surgery Clinical Committee (CSCC) for changes to colorectal surgery services in Part 5 of the Regulations following a public consultation period for the recommendations. The Department established a colorectal surgery Implementation Liaison Group (ILG) to finalise the item changes. The ILG included representatives from the Colorectal Surgical Society of Australia and New Zealand, the Royal Australian College of Surgeons and the Australian Medical Association, amongst others.

No consultation was undertaken on the changes to items 73385, 73386 and 73387 in Part 3 of the Regulations nor the remaining changes made to the DIST and GMST in Part 6 as the changes described are considered minor and administrative in nature and reflect the original policy intent of the services.

No consultation was undertaken on the indexation of the MBS services in Parts 2 and 7 of the Regulations, 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 4 (and anything in this instrument not covered elsewhere) of the Regulations will commence the day after the instrument is registered. Schedule 1, Parts 1 to 6 will commence on 1 July 2022. Schedule 1, Part 7 will commence immediately after the commencement of the provisions covered by Parts 1 to 6.

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

ATTACHMENT

Details of the *Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022*.

Section 2 – Commencement

This section provides for Section 1 to 4 (and anything in this instrument not covered elsewhere) of the Regulations to commence the day after the instrument is registered, Parts 1 to 6 to commence on 1 July 2022 and Part 7 to commence immediately after the commencement of the provisions covered by Parts 1 to 6.

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 - Prostate-specific membrane antigen positron emission tomography

Amendment item 1 inserts two new prostate-specific membrane antigen (PSMA) positron emission tomography (PET) items (items 61563 and 61564) for the initial staging of intermediate to high-risk prostate adenocarcinoma and the restaging of recurrent prostate adenocarcinoma, respectively. These new items were recommended by the Medical Services Advisory Committee (MSAC) at its meeting of 30 July 2021 under MSAC application number 1632.

Item 61563, which is for the initial staging of intermediate to high-risk prostate adenocarcinoma, may be provided to a previously untreated patient who is otherwise considered suitable for locoregional therapy with curative intent.

Item 61564, which is for the restaging of recurrent prostate adenocarcinoma, may be performed on a patient who fulfils the criteria listed under paragraph (a). The patient criteria prescribes that a patient may receive a service under item 61564 if they have undergone prior locoregional therapy and are considered suitable for further locoregional therapy to determine appropriate therapeutic pathways and timing of treatment initiation.

Part 2 – Bulk billing incentive – magnetic resonance imaging

Amendment item 2 amends clause 1.2.18 of the DIST, which provides the fee arrangements for bulk billed diagnostic imaging services, to include Division 2.5 (Group I5) in these requirements. Under this change, the fee for a magnetic resonance imaging (MRI) service listed in Group I5 will be 95% of the fee mentioned in the DIST for the service. This change is consistent with the Government’s decision to index services listed in Group I5 of the DIST (refer to **amendment items 44 to 48** of the Regulations).

Amendment item 3 repeals clause 1.2.19 of the DIST, which provided for the bulk billing arrangements for MRI services listed in Group I5. This change is considered administrative in nature as the bulk billing incentive arrangements for these services will be covered under amended clause 1.2.18 (refer to **amendment item 2** of the Regulations).

Part 3 – Genetic testing

Amendment item 4 amends genetic testing item 73325, which is for the diagnosis of polycythaemia vera or essential thrombocythaemia, to amend the service to provide for determination of JAK2 V617F variant allele frequency in a patient with clinical and laboratory evidence of a myeloproliferative neoplasm. This service may be requested by a specialist or consultant physician or by a general practitioner on behalf of the treating specialist or consultant physician.

The amendment to item 73325 is in alignment of the introduction of new items 73396, 73397, 73398, and 73399 (refer to **amendment item 8** of the Regulations), which will expand the Medicare rebates available for the diagnosis of myeloproliferative neoplasms.

Amendment items 5, 6 and 7 amend pre-implantation genetic testing items 73385, 73386 and 73387 to clarify the policy intent of the service. This change is considered minor and administrative in nature.

Amendment item 8 inserts:

- four new items (73392, 73393, 73394 and 73395) for genetic testing for heritable cardiomyopathies;
- four new items (73396, 73397, 73398, and 73399) for genetic testing for myeloproliferative neoplasms (MPNs);
- six new items (73401, 73402, 73403, 73404, 73405 and 73406) for genetic testing for heritable kidney disease other than Alport syndrome;
- four new items (73410, 73411, 73412, and 73413) for genetic testing for alpha thalassemia;
- four new items (73416, 73417, 73418 and 73419) for genetic testing of inheritable cardiac rhythm disorders; and
- two new items (73420 and 73421) for non-invasive prenatal testing for fetal Rhesus D genotype in Rhesus D antigen (RhD) negative women.

The new items will allow for the identification of genetic variants in patients at risk of, or experiencing symptoms of, the abovementioned genetic disorders and diseases

arising from pathogenic or likely pathogenic genetic variants. For several of the abovementioned genetic disorders and diseases, new items will be available for familial testing, and testing to help inform family planning with a reproductive partner. Where family members are found not to have a genetic variant, the testing may provide reassurance and enable avoidance of lifelong clinical surveillance.

Items 73392, 73393, 73394 and 73395

New items 73392, 73393, 73394 and 73395 were recommended by the Medical Services Advisory Committee (MSAC) at its March-April 2021 meeting under MSAC Application 1599.

Item 73392 is for the characterisation of pathogenic or likely pathogenic germline gene variants for patients whom clinical history, family history or laboratory findings suggest a high probability of heritable cardiomyopathy, dilated cardiomyopathy and/or arrhythmogenic cardiomyopathy. Item 73392 must be requested by a specialist or consultant physician and may only apply once per patient lifetime.

Item 73393 is for the characterisation of one or more pathogenic (or likely pathogenic) germline gene variants to assess a patient's present or future risk of hypertrophic cardiomyopathy, dilated cardiomyopathy and/or arrhythmogenic cardiomyopathy. Item 73393 applies to a service where the patient has not previously received a service to which item 73392 applies and if the patient is a first degree biological relative, or a second degree biological relative where a first degree relative is unavailable, of a person with a laboratory confirmed pathogenic (or likely pathogenic) germline gene variant. A service under item 73393 must be requested by a specialist or consultant physician and may only apply once per variant per patient lifetime.

Item 73394 is for the characterisation of one or more recessive pathogenic (or likely pathogenic) germline genes to determine the reproductive risk in a patient who is a reproductive partner of a known carrier of a laboratory confirmed pathogenic (or likely pathogenic) germline gene for heritable cardiomyopathy. The patient receiving the testing, who is the reproductive partner, must not have already been informed of their carrier status and have a clinical history, family history or laboratory findings suggesting there is a low probability of heritable cardiomyopathy. Item 73394 must be requested by a specialist or consultant physician and may only apply once per gene per patient lifetime.

Item 73395 is for the re-analysis of whole exome or genome data that is obtained in performing a service under which item 73392 applies for the characterisation of previously unreported germline variants related to the clinical phenotype of heritable cardiomyopathy. Item 73394 must be requested by a consultant physician practicing as a clinical geneticist or cardiologist for a patient who is strongly suspected of having a heritable cardiomyopathy. The service may be performed twice per patient lifetime, and the reanalysis must be performed at least 18 months after a service to which item 73392 or this item applies.

Items 73396, 73397, 73398, and 73399

New items 73396, 73397, 73398, and 73399 were supported by MSAC at its November 2020 meeting under MSAC application 1532.

Item 73396 is for genetic testing for variants in the JAK2 gene (exon 12) for the diagnosis of a patient with clinical and laboratory evidence of polycythaemia vera, as requested by a specialist or consultant physician.

Item 73397 is for genetic testing for variants in both the CALR and MPL genes for the diagnosis of a patient with clinical and laboratory evidence of essential thrombocythaemia or primary myelofibrosis, as requested by a specialist or consultant physician.

Item 73398 is for genetic testing of at least eight genes for the diagnosis of a patient with clinical and laboratory evidence of polycythaemia vera or essential thrombocythaemia, as requested by a specialist or consultant physician.

Item 73399 is for genetic testing of at least 20 genes for the diagnosis of a patient with clinical and laboratory evidence of primary myelofibrosis who is eligible for a stem cell transplant, as requested by a specialist or consultant physician.

Items 73401, 73402, 73403, 73404, 73405 and 73406

New items 73401, 73402, 73403, 73404, 73405 and 73406 were supported by MSAC at its March 2021 meeting under MSAC application 1600.

Item 73401 is for genetic testing for the diagnosis of heritable cystic kidney disease in a patient who has a renal abnormality and is strongly suspected of having a monogenetic condition. Item 73401 must be requested by a consultant physician practising as a clinical geneticist or as a specialist nephrologist and may only be performed once per patient lifetime.

Item 73402 is for genetic testing for the diagnosis of heritable kidney disease in a patient who has chronic kidney disease (other than cystic disease or Alport syndrome) and is strongly suspected of having a monogenetic condition. Item 73402 must be requested by a consultant physician practising as a clinical geneticist or as a specialist nephrologist and may only be performed once per patient lifetime.

Item 73403 is for the re-analysis of genetic data obtained by genetic testing performed under a service to which items 73401 or 73402 applies to identify previously unreported germline gene variants related to heritable kidney disease. The service must be requested by a consultant physician practising as a clinical geneticist or a specialist paediatrician, and the patient must have a strong clinical suspicion of having a monogenetic condition. Item 73403 may only be performed twice per patient lifetime and must be performed at least 18 months after a service to which this item or items 73401 or 73402 applies.

Item 73404 is for the genetic testing of first-degree relatives of a person with a laboratory confirmed genetic variant associated with heritable kidney disease detected through a service to which items 73401, 73402 or 73403 applies. A service under item 73404 must be requested by a clinical geneticist or a specialist or consultant physician providing professional genetic counselling services and may only be performed once per variant per lifetime.

Item 73405 is for the genetic testing of heritable kidney disease germline variants for the purposes of reproductive decision making. The patient undertaking the test must be the reproductive partner of a person who is known to be a carrier of pathogenic variants that cause heritable kidney disease where the carrier status of the reproductive partner with known genotype status received a service to which item 73401, 73402, 73403 or 74304 applies. The detection method used for the service must have sufficient diagnostic range and sensitivity to detect at least 95% of pathogenic variants likely to be present in the patient. Item 73405 must be requested by a consultant physician practising as a clinical geneticist or a specialist nephrologist.

Item 73406 is for the purpose of genetic testing to determine variant/s in a fetus where one or both parents are carriers of a genetic variant that is known to cause heritable kidney disease. Item 73406 must be requested by a consultant physician practising as a clinical geneticist or a specialist nephrologist and be performed for a fetus at a risk of at least 25% of inheriting a monogenetic variant known to cause kidney disease.

Items 73410, 73411, 73412, and 73413

New items 73410, 73411, 73412, and 73413 were recommended by MSAC at its March 2020 meeting under MSAC application 1531.

Item 73410 is for genetic testing for the diagnosis of alpha thalassemia in patients of reproductive age who have abnormal red cell indices, for whom thalassemia screening for beta-thalassemia was not conclusive, who do not have a concurrent iron deficiency or are pregnant, and who have no historic normal cell indices. This service is also available for the determination of carrier status in reproductive partners of a person with diagnosed alpha thalassaemia.

Item 73411 is for genetic testing for the diagnosis of alpha thalassemia in the event the testing described in item 73410 was inconclusive and a less common or rare variant is suspected. This item applies to patients of reproductive age, or for the determination of carrier status in reproductive partners of a person with diagnosed alpha thalassaemia. Item 73411 may be performed once per gene per lifetime.

Item 73412 is for genetic testing (deletion testing) for the diagnosis of alpha thalassemia in the event the testing described in item 73410 was inconclusive and a large deletion variant is suspected. This item applies to a person of reproductive age, or for the determination of carrier status in reproductive partners of a person with diagnosed alpha thalassaemia.

Item 73413 is for genetic testing (non-deletion testing) for the diagnosis of alpha thalassemia in the event the testing described in item 73410 was inconclusive. This item applies to patients of reproductive age, or for the determination of carrier status in reproductive partners of a person with diagnosed alpha thalassaemia.

Items 73416, 73417, 73418 and 73419

New items 73416, 73417, 73418 and 73419 were recommended by MSAC at its November 2020 meeting under MSAC Application 1598.

Item 73416 is for the detection of germline gene variants, including copy number variation, for a patient for whom clinical or family history criteria is suggestive of inherited cardiac arrhythmias or channelopathies that place the patient at greater than 10 per cent risk of having a pathogenic variant. Item 73416 must be requested by a specialist or consultant physician and may only be performed once per patient lifetime.

Item 73417 is for the characterisation of one or more pathogenic (or likely pathogenic) germline variants of a gene for the purpose of assessing a patient's present or future risk of a cardiac arrhythmia or channelopathy. Item 73417 will be performed on a patient who is a first or second-degree biological relative of a person with a laboratory confirmed pathogenic (or likely pathogenic) gene variant and does not apply to a patient who has previously received a service under item 73416. A service under item 73417 must be requested by a specialist or consultant physician and may only be performed once per variant per patient lifetime.

Item 73418 is for the characterisation of one or more pathogenic (or likely pathogenic) germline variants of a gene in a patient who is a reproductive partner of a person who is a known carrier of a pathogenic (or likely pathogenic) germline variant of a gene known to be associated with inheritable cardiac arrhythmia or channelopathy confirmed by laboratory findings. Item 73418 may be provided to a patient for whom carrier status of the gene variant of interest is unknown and has a clinical history, family history or laboratory findings suggesting there is a low probability of cardiac arrhythmia or channelopathy. A service under item 73418 must be requested by a specialist or consultant physician, may not be performed on a patient who has previously received a service to which item 73416 applies and may only be performed once per variant per patient lifetime.

Item 73419 is for the re-analysis of whole exome or genome data obtained in performing a service to which item 73416 applies, for characterisation of previously unreported germline variants related to the clinical phenotype which prompted a test under item 73416. To receive a service under item 73419, the patient must be strongly suspected of having inheritable cardiac arrhythmia or channelopathies and the service must be requested by a consultant physician practicing as a clinical geneticist or cardiologist. Item 73419 must be performed at least 18 months after a service to which this item or item 73416 applies and may only be performed twice per patient lifetime.

Items 73420 and 73421

New items 73420 and 73421 were supported by the Medical Services Advisory Committee (MSAC) at its November 2020 meeting under MSAC Application 1574. These new items will be used to guide the management of rhesus D antigen (RhD) negative women who are pregnant and avoid over-treatment with anti-D immunoglobulin, preserving the supply for when it is truly required.

Item 73420 is for the non-invasive prenatal testing of blood from a RhD negative pregnant patient. The item will allow for the detection of RHD from fetal DNA circulating in maternal blood.

Item 73421 is for the non-invasive prenatal testing of blood from a RhD negative pregnant patient who is alloimmunised with immune anti-D. The item will allow for the detection of RHD from fetal DNA circulating in maternal blood, for a singleton pregnancy only.

Part 4 – Cervical screening tests

Amendment item 9 amends cervical screening test item 73071, which is for a cervical screening test through a self-collected vaginal specimen, to lower the eligible patient age and amend the claiming frequency under which the service may be performed. Under these changes, a patient who is at least 24 years and 9 months of age may access a service under item 73071 once in a 57 month period. These changes align with the Department of Health’s National Cervical Screening Program, accessible on 1 March 2022 at www.health.gov.au.

Amendment item 10 amends cervical screening test item 73073 to remove the claiming frequency of once in a 21 month period. Under this change, the follow-up management of a patient with oncogenic human papillomavirus infection or cervical pre-cancer or cancer which was detected under item 73071 may receive a service under 73073 as often as is clinically necessary. This change aligns with the Department of Health’s National Cervical Screening Program, accessible on 1 March 2022 at www.health.gov.au.

Part 5 – Colorectal surgery services

Amendment items 11 and 12 amend clause 5.10.14, which describes instances when artificial bowel sphincter is contraindicated for items 32220 and 32221, of the general medical services table to remove reference to item 32220, which will be repealed (refer to **amendment item 37** of the Regulations).

Amendment item 13 amends items 32004 and 32005 to include a restriction on co-claiming the services at the same time as item 32030 (refer to **amendment item 18** of the Regulations). This change is considered minor and administrative in nature.

Amendment item 14 amends item 32006, which is for a left hemicolectomy, to include a restriction on co-claiming the services at the same time as items 32024, 32025, 32026 and 32028. This change reflects the evolution over time of a procedure under item 32006 and co-claiming these items at the same time is no longer necessary.

Amendment item 15 amends items 32024 and 32025 to remove references to items which will be repealed (refer to **amendment item 37** of the Regulations) and include a restriction on co-claiming the services with items 32000, 32030 and 32232.

Amendment item 16 amends item 32026, which is for an ultra-low restorative resection of the rectum, to allow the service to be performed with or without covering stoma and with or without a colonic reservoir and include a restriction on co-claiming this item at the same time as items 32000, 32030, 32106 and 32117. The schedule fee for this item has been increased to \$2,126.60 to reflect the incorporation of

constructing a colonic reservoir as part of this procedure. These changes will align item 32026 with contemporary clinical practice.

Amendment item 17 amends item 32028, which is for a low or ultra low restorative resection of the rectum, to allow the service to be performed with or without a colonic reservoir and include a restriction on co-claiming this item at the same time as items 32000, 32030, 32106 and 32117. The schedule fee for this item has been increased to \$2,259.00 to reflect the incorporation of constructing a colonic reservoir as part of this procedure. These changes will align item 32028 with contemporary clinical practice.

Amendment item 18 amends item 32030, which is for a rectosigmoidectomy, to remove the word “Hartmann’s” from the item descriptor as it is considered unnecessarily specific and rarely performed by contemporary clinicians. Under this change, a service under item 32030 will also include formation of a stoma. This change aligns item 32030 with contemporary clinical practices.

Amendment item 19 amends item 32033, which is for a restoration of the bowel, to clarify the service is for the restoration of bowel continuity and remove the word “Hartmann’s” from the item descriptor as it is considered unspecific and rarely performed by contemporary clinicians. Instead of a “Hartmann’s” operation, item 32033 will now refer to a rectosigmoidectomy operation. This change aligns item 32033 with contemporary clinical practices.

Amendment item 20 amends item 32060 to specify the item applies to a restorative proctectomy involving rectal resection. This change will also amend the item to prescribe the service to include the formation of an ileal reservoir as well as ileoanal anastomosis, including ileostomy mobilisation, and allow for the service to be performed with or without mucosectomy or temporary loop ileostomy. This amendment will better describe a service under 32060, reduce confusion of the service with a standard ileostomy closure and more accurately describe contemporary clinical practice.

Amendment item 21 amends item 32096, which is for a rectal biopsy, to clarify the item applies to the diagnosis or exclusion of Hirschsprung’s Disease. This change will provide patients with the appropriate information regarding the purpose of the procedure and better describe why the procedure is done.

Amendment item 22 amends item 32106, which is for excision of an anterolateral intraperitoneal rectal tumour, to clarify the service is to use a rectoscopy digital viewing system and pneumorectom if clinically appropriate and exclude use of a colonoscope as the operating platform. This change allows item 32106 to more accurately describe the technology used in the service by contemporary practitioners. It also provides for a point of differentiation to the removal of rectal polyps during colonoscopy.

Amendment item 23 amends item 32117, which is for abdominal rectopexy of a rectal prolapse, to prevent the item being used for ventral mesh rectopexy, include a restriction on co-claiming the service on the same day as items 32025 or 32026, and increase the schedule fee for the item from \$1,040.20 to \$1,307.10. This change clarifies the clinical intent of item 32117 and better reflects contemporary practice.

Amendment item 24 amends item 32129, which is for anal sphincter repair, to remove the term “direct” from the item descriptor. This change does not affect how item 32129 is to be provided by practitioners and is considered minor and administrative in nature.

Amendment item 25 amends item 32135, which is for the treatment of haemorrhoids or rectal prolapse, to reflect contemporary practice. Under this change, item 32135 includes all non-operative haemorrhoid treatments including rubber band ligation and sclerotherapy. Item 32135 may not be claimed where a service under item 32139 also applies.

Amendment item 26 amends item 32139, which is for the treatment of haemorrhoids, to reflect contemporary practice. Under this change, item 32139 includes all forms of operative haemorrhoid treatments but excludes procedures for rectal prolapse (under items 32135 or 32233) which should not be co-claimed on the same occasion.

Amendment item 27 amends item 32150, which is for the treatment of anal fissures, to reflect more contemporary nomenclature and the words “injection of Botulinum toxin” has been added to the descriptor. This change reflects current practice and will allow practitioners to provide an accepted alternative therapy to a sphincterotomy.

Amendment item 28 amends item 32156 to reflect more contemporary nomenclature. Under this change, “fistula-in-ano” will be amended to read “anal fistula”.

Amendment item 29 amends item 32165, which is for the repair of an anal fistula, to reflect contemporary practice more accurately. Under these changes, item 32165 applies to a service for the operative repair of anal fistula by mucosal advancement flap, including ligation of inter-sphincteric fistula tract (LIFT) or other complex sphincter sparing surgery.

Amendment item 30 amends item 32171, which is for anorectal examination, to allow the service to include an option for faecal disimpaction, where clinically necessary. Faecal disimpaction was initially included within item 32153, however this item will be repealed (refer to **amendment item 37** of the Regulations) as it is considered obsolete.

Amendment item 31 amends item 32213, which is for the placement of sacral nerve leads, including intraoperative test stimulation and programming, for the management of faecal incontinence. This amendment removes the previous restrictions on who is eligible for sacral nerve stimulation, which were provided by the initial clinical trial in order to minimise heterogeneity. Published evidence supports the use of sacral nerve stimulation, showing significant clinical benefit and improved quality of life in patients. These changes will allow for the item to reflect contemporary practice and represent a complete service.

Amendment item 32 amends item 32215, which is for the sacral nerve electrode or electrodes, management, adjustment and electronic programming of the neurostimulator by a medical practitioner, to manage faecal incontinence. This

amendment removes the previous restrictions on who is eligible for sacral nerve stimulation and aligns with the changes made under **amendment item 31** of the Regulations. It also includes a restriction on claiming, so that the item is not to be claimed more than once per day by the same practitioner for the same patient, and so that this item cannot be co-claimed with items 32213, 32216, 32218 and 32237.

Amendment item 33 amends item 32216, which is for the surgical repositioning of sacral nerve leads, inserted for the management of faecal incontinence in a patient with faecal incontinence refractory to conservative non-surgical treatment, in order to correct displacement or unsatisfactory positioning, and intraoperative test stimulation. This amendment removes the previous restrictions on who is eligible for sacral nerve stimulation and aligns with the changes made under **amendment item 31** of the Regulations. It also includes a restriction on claiming, so that the item is not to be co-claimed with item 32213.

Amendment item 34 amends item 32218, which is for the removal of sacral nerve lead(s). This amendment removes the previous restrictions on who is eligible for sacral nerve stimulation. This change is in alignment with the changes made under **amendment item 31** of the Regulations and will assist practitioners in interpreting the item.

Amendment item 35 inserts seven new colorectal surgery items into the GMST. These seven new items are complete services that represent the combination of 15 deleted items where similar procedures were separated, with no clinical reason to have separate items (refer to **amendment item 38** of the Regulations). These changes simplify and streamline MBS items, and more accurately describe contemporary clinical practice.

New item 32231 is for the anal excision of rectal tumours and applies per tumour excised from a patient. This new item combines a service under repealed items 32099 and 32102, and has a schedule fee of \$346.75. A service under item 32231 must be performed in a hospital setting only.

New item 32232 is for the anal excision of rectal tumours using a rectoscopy digital viewing system and pneumorectum, if clinically appropriate. This new item combines a service under repealed items 32103 and 32104, applies per tumour excised from a patient and has a schedule fee of \$940.10. This new item refers to the current technology used, and does not make reference to the tumour sizes previously included in items 32103 and 32104.

Item 32232 excludes use of a colonoscope as the operating platform and may not be claimed for a service associated with a service to which items 32024, 32025 or 32106 applies. Item 32232 must also be performed in a hospital setting only.

New item 32233 is for the perineal repair of rectal prolapse. This new item combines a service under repealed items 32111 and 32112, and has a schedule fee of \$667.70. Item 32233 may not be claimed for a service associated with a service to which item 32139 applies, and must be performed in a hospital setting only.

New item 32234 is for the treatment of a rectal stricture. This new item combines a service under repealed items 32114 and 32115 and has a schedule fee of \$132.05.

New item 32235 is for the excision of one or more anal skin tags or anal polyps. This new item combines a service under repealed items 32142 and 32145, and has a schedule fee of \$127.45 regardless of where the procedure is performed. The service can be performed in or out-of-hospital.

New item 32236 is for the removal of anal warts. The service must be performed under general anaesthesia or under a regional or field nerve block (excluding pudendal block). This new item combines a service under repealed items 32177 and 32180 and has a schedule fee of \$181.30. Item 32236 may not be claimed for a service associated with a service to which items 35507 or 35508 applies and must be performed in a hospital setting only.

New item 32237 is for the subcutaneous placement of, replacement of or removal of a neurostimulator or receiver for the management of faecal incontinence. Item 32237 includes the programming and placement and connection of an extension wire or wires to sacral nerve electrode(s). This item combines a service under repealed items 32210, 32214 and 32217 but it does not include the previous patient restrictions, meaning more patients will now be able to receive sacral nerve treatment. The item has a schedule fee of \$294.05 and must be performed in a hospital setting only.

Amendment item 36 amends items 35507 and 35508 to implement a co-claiming restriction against item 32236, as it would be inappropriate to perform these services on the same occasion.

Amendment item 37 repeals 27 items, as these items are considered obsolete or encompassed in other colorectal surgery items.

Part 6 – Miscellaneous amendments

Amendment item 38 and 39 amend clause 2.5.9A of the DIST to remove the use of “subsection” and substitute “subclause”, which is most appropriate for this clause. This change is considered minor and administrative in nature.

Amendment item 40 amends clause 1.1.6, which prescribes the meaning of a single course of treatment, to include item 132 under this clause. A single course of treatment for a patient is taken to include the initial attendance, continuing management or treatment and any subsequent review. Item 132 is an initial attendance and was not included in the clause in error. This change is considered minor and administrative in nature.

Amendment item 41 amends ambulant blood pressure monitoring item 11607 to clarify the service may not be co-claimed with item 715. This change clarifies the policy intent of the item and is considered minor and administrative in nature.

Amendment item 42 amends gynaecology item 35750 to clarify the service is to be performed in a hospital setting only. This change clarifies the policy intent of the item and is considered minor and administrative in nature.

Amendment item 43 amends subclause 5.2.4(1) of the GMST, which prescribes items which don't apply as part of a treatment cycle relating to assisted reproductive services, to clarify items 73384, 73385, 73386 and 73387 of the pathology services table are exempt from this clause under paragraph b. This change is considered minor and administrative in nature.

Part 7 – Indexation

Part 7 will apply annual indexation of the schedule fees of Medicare items. 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 Act. Indexation will be applied by 1.6%, which is represented as 1.016 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).

Amendments items 44 to 48 will apply indexation to imaging services in Groups I1 (ultrasound), I2 (computed tomography), I3 (diagnostic radiology), I5 (MRI) and I6 (bulk-billing incentive for unreferral) of the diagnostic imaging services table. Nuclear medicine services in Group I4 will not be indexed.

Amendments items 49 to 121 will apply indexation to all medical services in the general medical services table, other than the following items for services performed by other medical practitioners which are not indexed:

- all items in Group A2, A19, A23;
- item 173 in Group A7; and
- items 90092, 90093, 90095, 90096 in Group A35.

Most items will have indexation applied by the usual indexation parameter per **amendment item 50**. However, items specified in paragraph 1.3.1(2)(f) and (g) are indexed but under a different calculation than the general indexation calculation.

Items in paragraph (f) relate to certain eating disorder services performed by a medical practitioner. These items are calculated as 80% of the fee for the equivalent GP service. This calculation has been applied to the fees specified in **amendment item 120**.

Items in paragraph (g) relate to anaesthesia services. The fees for these services are calculated by applying indexation to a base unit and multiplying that unit by the number of units allocated for each service. This calculation, known as the Relative Value Guide, has been applied to the fees specified in **amendment item 121**.

Amendments items 122 to 123 will apply indexation to the bulk-billing incentives for unreferral pathology services (Group P12) in the pathology services table. Indexation will not apply to any other pathology 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 (2022 Measures No. 1) Regulations 2022

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

Overview of the Disallowable Legislative Instrument

The purpose of the *Health Insurance Legislation Amendment (2022 Measures No. 1) Regulations 2022* (the Regulations) is to amend the general medical services table (GMST), diagnostic imaging services table (DIST) and pathology services table (PST) to:

- implement the Government’s response to recommendations from the MBS Review Taskforce (the Taskforce) regarding colorectal surgery services and recommendations from the independent Medical Services Advisory Committee (MSAC) on pathology services and prostate-specific membrane antigen (PSMA) positron emission tomography (PET) services; and
- implement annual indexation of Medicare schedule fees by 1.6 per cent, which includes indexation of MRI diagnostic imaging services for the first time. Indexation will be applied to the schedule fees of GP and specialist attendances, diagnostic investigations, therapeutic and procedural items, and diagnostic imaging services (other than nuclear medicine). This reflects the Government’s policy regarding Medicare indexation and means that patients will receive an increased Medicare benefit for these services.

The Regulations also make minor administrative changes to four general medical service items.

Changes to Pathology Services

Parts 3 and 4 of the Regulations will implement the following changes to genetic testing and cervical screening services announced by Government in the 2021-22 Mid-Year Economic and Fiscal Outlook (MYEFO) measure *Guaranteeing Medicare – Medicare Benefits Schedule new and amended listings*:

- introduce four new items for genomic testing for heritable cardiomyopathies;
- introduce four new items for genetic testing for diagnosis of inheritable cardiac arrhythmia disorders;
- introduce two new items for Non-Invasive Prenatal Testing for fetal Rhesus D genotype;
- introduce six new items for genetic testing for heritable kidney disease other than Alport syndrome;
- introduce four new items for genetic testing for alpha thalassaemia;
- amend item 73325 to allow the service to be delivered to patients with primary myelofibrosis and introduce four new items for testing for myeloproliferative neoplasms; and
- amend cervical screening items 73071 and 73073 to expand access to self-collected cervical screening tests.

Part 3 will also amend pre-implantation genetic testing items 73385, 73386 and 73387 to clarify the policy intent of the services. This change is administrative in nature and aligns with policy announced during the 2021-22 Budget measure *Guaranteeing Medicare — Changes to the Medicare Benefits Schedule*.

Changes to Colorectal Surgery Services

Part 5 of the Regulations will implement a number of changes to colorectal surgery services, as recommended by the MBS Review Taskforce (the Taskforce) and announced by Government in the 2021-22 Budget under the *Guaranteeing Medicare – Changes to the Medicare Benefits Schedule* measure.

These changes to MBS items will better align colorectal surgery services with contemporary and evidence-based treatment and also seek to simplify and streamline MBS items relating to colorectal surgery services. The changes include deleting outdated items, combining items that are provided together into a single item, and updating the descriptors of items to better describe modern techniques. Patients will benefit from improved patient safety and quality of care, and may also benefit through a reduction in unnecessary services and related out-of-pocket expenses.

Introduction of two new PSMA PET services

Part 1 of the Regulations will introduce two new items for prostate-specific membrane antigen (PSMA) positron emission tomography (PET) (items 61563 and 61564). This change was recommended by the independent Medical Services Advisory Committee (MSAC) and announced under the 2021-22 MYEFO measure *Guaranteeing Medicare – Medicare Benefits Schedule new and amended listings*.

Changes to bulk billing incentive for magnetic resonance imaging

In the 2021-22 Budget under the *Guaranteeing Medicare – improving diagnostic imaging* measure, the Government announced that it would bring funding for MRI services in line with other diagnostic imaging services from 1 July 2022.

Part 2 of the Regulations will amend the DIST so that, from 1 July 2022, the bulk-billing incentive for bulk billed MRI items in Group I5 will be 95% of the schedule fee when provided out of hospital. This change ensures funding for MRI services is consistent with funding for other diagnostic imaging services. It is implemented through Part 7 of the Regulations.

Indexation

Part 7 of the Regulations will implement annual fee indexation by increasing the schedule fee by 1.6 per cent 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 means that patients will receive a higher Medicare benefit for these services from 1 July 2022.

For the first time, from 1 July 2022 indexation will apply to MRI diagnostic imaging services in Group I5. This change was announced by Government in the 2021-22 Budget under the *Guaranteeing Medicare – improving diagnostic imaging* measure.

Administrative changes

Part 6 of the Regulations will make administrative changes to four items in the GMST. These changes will clarify the original policy intent of the services and are considered minor and administrative in nature.

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 positively affect rights to health and social security by ensuring access to publicly subsidised general medical services are clinically and cost-effective. The Regulations act to increase the range of genetic testing services available to assist patients in the management of lifelong conditions and increases the Medicare benefit patients will receive when accessing many MBS services.

Conclusion

This instrument is compatible with human rights because it advances arrangements and the protection of human rights by increasing the investment in the existing arrangements.

Greg Hunt

Minister for Health and Aged Care