

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2020 Measures No. 2) Regulations 2020

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 are calculated by reference to the fees for medical services set out in prescribed tables.

Subsection 4(1), 4A(1) and 4AA(1) of the Act provides that regulations may prescribe a table of general medical, pathology and diagnostic imaging services which sets out items of general medical, pathology and diagnostic imaging services, the fees applicable for each item, and rules for interpreting the table. The tables made under these subsections are referred to as the general medical services table, the pathology services table and the diagnostic imaging services table. The most recent version of these regulations are the *Health Insurance (General Medical Services Table) Regulations (No. 2) 2020* (GMST), *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* (DIST) and the *Health Insurance (Pathology Services Table) Regulations 2020* (PST).

Purpose

The purpose of the *Health Insurance Legislation Amendment (2020 Measures No. 2) Regulations 2020* (the Regulations) is to amend the GMST, PST and DIST from 1 November 2020.

Parts one (chemotherapy services) and two (blood product services) of the Regulations implement decisions of Government taken in the 2019-20 Mid-Year Economic and Fiscal Outlook (MYEFO) under the *Guaranteeing Medicare — Medicare Benefits Schedule Review* measure. These changes include:

- restructuring chemotherapeutic procedures;
- amending blood product services to reflect contemporary clinical practice and improve quality of care.

Parts three (neurology and neurosurgery services) and four (urology services) of the Regulations implement decisions of Government taken the 2019-20 Budget under the *Guaranteeing Medicare — Medicare Benefits Schedule Review — response to Taskforce recommendations* measure. These changes include:

- introducing new items for neurosurgery and promoting the use of higher value neurology items;
- updating item descriptions and relevant application provisions to align with contemporary practice, tightening clinical indicators and restricting inappropriate co-claiming of selected urology services items.

These changes implement the Government's response to the Medicare Benefits Schedule Review Taskforce (the Taskforce). The Taskforce is a clinician-led review of all Medicare services to ensure that they reflect current best clinical practice, align with the latest evidence and promote the provision of health services that improve health outcomes.

Part five of the Regulations make minor consequential and administrative amendments.

Consultation

The Taskforce used expert committees and working groups focusing on specific areas of the MBS. Public consultation of the clinical committee reports assisted to inform the final recommendations to Government.

Once approved by Government, implementation liaison groups involving professional bodies and clinical experts inform development of the Regulations. These include:

- Australian Medical Association
- Australian Private Hospitals Association
- Australian Society of Anaesthetists
- Haematology Society of Australia and New Zealand
- National Blood Authority
- Neurosurgical Society of Australasia
- Private Cancer Physicians of Australia
- Private hospital and private health insurance sectors
- Royal Australian and New Zealand College of Radiologists
- Royal Australian College of General Practitioners
- Royal Australian College of Surgeons
- Urological Society of Australia and New Zealand.

No consultation was undertaken on the other amendments as they are consequential or administrative in nature.

Details of the Regulations are set out in the Attachment.

The Regulations commence on 1 November 2020.

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

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

Details of the *Health Insurance Legislation Amendment (2020 Measures No. 2) Regulations 2020*

Section 1 – Name

This section provides for the Regulations to be referred to as *Health Insurance Legislation Amendment (2020 Measures No. 2) Regulations 2020*.

Section 2 – Commencement

This section provides for the Regulations to commence on 1 November 2020.

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 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 – Chemotherapy services

The amendments in Part 1 repeal the existing 12 chemotherapeutic procedures items in the *Health Insurance (General Medical Services Table) Regulations (No. 2) 2020* (GMST). These are made up by eight time-tiered chemotherapy administration items (four items for administration via the intravenous route; and four items for administration via the intra-arterial route), three items for the administration via other routes (pump or reservoir, ambulatory drug delivery device, body cavity) and one item for accessing long-term implanted drug delivery devices. These items have been replaced with a single item to cover each occasion chemotherapy is parenterally administered to a patient.

In its review, the Taskforce found that time-based items for the administration of chemotherapeutic agents did not adequately reflect the level of clinical complexity and modern clinical practice. Historically, medical practitioners administered chemotherapy directly into a vein or artery. The GMST reflected this practice with higher schedule fees for longer durations of administration reflecting the level of clinical involvement.

In modern practice, the therapeutic agent is increasingly administered into an implanted vascular access device rather than directly into a vein. This reduces the risk of an immediate adverse event, with nurses typically performing the administration of the therapeutic agent under the supervision of a medical practitioner. A medical practitioner would typically spend more of their time in managing the patient's course of treatment, such as determining drug doses, assessing the response to therapy, liaising with other health professionals, and monitoring and managing toxicity.

Item 1 amends subclause 1.2.11(1) to remove references to deleted items 13915 to 13948 (12 items in total).

Item 2 repeals the chemotherapy administration items 13915 to 13948 and replaces with new item 13950. Item 13950 is for the parenteral administration of antineoplastic agents (cytotoxic chemotherapy or monoclonal antibody therapy) but not agents used in anti-resorptive bone therapy or hormonal therapy. The service can be performed by a specialist or consultant physician, or under appropriate supervision of this practitioner.

Item 3 makes a consequential amendment to item 14221 by removing the reference to deleted item 13945 and inserting a reference to new item 13950. This will prevent the claiming of item 14221 where the service is provided in conjunction with new item 13950. This recognises that use or maintenance of long-term vascular access devices with item 13950 is part of the expected standard of care and does not represent a separate and distinct service.

- Part 2 - Blood product services

Part 2 amends blood product services in the GMST to reflect contemporary clinical practice and improve quality of care.

Item 4 makes a consequential amendment to subclause 1.2.11(1) by removing the reference to deleted item 13709.

Item 5 amends item 13703 to include intra-operative normovolaemic haemodilution as a part of the service. This change will update the item in line with clinical best practice, restricting its use to the intention of the procedure, which is for use in patients undergoing surgery or invasive procedures in which blood loss is anticipated. This change will align the service with the National Blood Authority guidelines.

Item 6 repeals item 13709. This item is obsolete because collection of blood from a donor for urgent use is a rare circumstance. The use of item 13709 has steadily declined and there are other services that provide coverage for blood transfusion procedures.

Item 7 amends the service for item 13760 to clarify the malignant conditions where there is evidence for treatment by stem cell therapies in combination with high dose chemotherapy. This amendment is in line with international guidelines for stem cell transplantation, and best clinical practice.

- Part 3 - Neurology / Neurosurgery services

Part 3 amends the neurology and neurosurgery services in the GMST to align the items with best clinical practice and reduce inappropriate claiming.

Items 8 to 14 make amendments to electroencephalography (EEG) items 11003 to 11009. Items 11003, 11004 and 11005 have been amended to specify that these services require multi-channel recording and standard 10-20 electrode placement (based on the standard International Federation of Clinical Neurophysiology) except when item 11003 is used for EEG during neurosurgical procedures (located in Group T8 of the GMST).

Item 11006 has been removed as it is obsolete. The reference to item 11006 have been removed from item 11000.

The fee for item 11009 has been increased to align with the fee for item 11005.

Items 15 to 17 make amendments to other therapeutic procedure items 14230 to 14242. Five items 14230 to 14242 have been removed and replaced with two new items 14234 and 14237. Items 14230, 14233 and 14239 have been consolidated into new item 14234 and items 14236 and 14242 have been consolidated into new item 14237.

New item 14234 is for the removal or replacement of any infusion pump component.

New item 14237 is for the implantation of any infusion pump component. These changes simplify the MBS and improves the calibration of the associated fees.

Item 18 inserts new clause 5.10.19A. This clause prohibits the co-claiming of item 40803 with items 39015, 39503, 39906 or 40104.

Items 19 to 21 delete items 39003, 39006, 39009, 39012 and amend items 39015 and 39018.

New item 39007 consolidates the various intracranial access procedures previously listed in deleted items 39003, 39006, 39009 and 39012 to create a complete medical service.

Item 39015 has been amended to specify that this item is intended for the insertion of a parenchymal pressure monitoring device. The ventricular reservoir and drain insertion procedures from this item have been consolidated into item 39018 to align with the similar techniques to those involved in 39018. Focusing this item towards parenchymal intracranial pressure monitoring device insertion means that it no longer requires the use of stereotaxy. A co-claiming restriction with stereotaxy item 40803 has been applied.

In addition to including the ventricular reservoir and drain insertion procedures from item 39015, item 39018 has been amended to include stereotaxy. Stereotaxy has been included to encourage better patient safety and outcomes, and to clarify the medical service.

Items 22 to 24 make amendments to pain procedure items 39106, 39109 and 39112 and cranial nerve procedure item 39500.

Item 39109 has been amended to include stereotaxy.

New item 39113 has been amended to include stereotaxy and cranioplasty and consolidate the services listed in items 39106, 39112 and 39500. These procedures are very similar in practice and complexity and there is no need for separate items for each procedure.

Items 39106, 39112 and 39500 have been deleted.

Items 25, 26 and 27 make amendments to cranio-cerebral injury items 39600, 39603, 39606, 39609, 39612 and 39615 and skull base surgery items 39640 to 39662.

New item 39604 consolidates items 39600, 39603 39721 and 40015. These services represent alternative approaches to treating intracranial haemorrhages or swelling, which require similar amounts of time. This new item covers procedures for intracranial haemorrhage or swelling involving one or more burr-holes, craniotomy or craniectomy. It also includes stereotaxy, which improves the accuracy of the burr-hole/craniotomy placement, thereby improving outcomes and safety. Items 39600, 39603, 39721 and 40015 have been deleted.

New item 39610 consolidates items 39606 and 39609 as separate items are not required to distinguish between the types of fractures. The new item covers fractures without brain laceration or dural penetration. Items 39606 and 39609 have been deleted.

Item 39612 has been amended to cover services for skull fractures with brain laceration or dural penetration but without cerebrospinal fluid rhinorrhoea or otorrhoea.

Item 39615 has been amended to specify that it is for traumatic skull fractures with cerebrospinal fluid rhinorrhoea or otorrhoea. The item includes stereotaxy and dermofat graft.

Items 39640 to 39662 have been restructured based on which of the two “zones” of the skull base they involve and who provides the service.

New items 39638 (principal surgeon), 39639 (co-surgeon) and 39641 (one surgeon) consolidate anterior and middle cranial fossae and cavernous sinus items 39640, 39642, 39646, 39650 and 39660. The new items include stereotaxy and cranioplasty.

New items 39651 (one surgeon), 39654 (principal surgeon) and 39656 (co-surgeon) consolidate petro-clival, clival and foramen magnum tumour resection items 39653, 39654, 39656, 39658 and 39662. The new items include stereotaxy and cranioplasty.

Items 39640, 39642, 39646, 39650, 39653, 39658, 39660 and 39662 have been deleted.

Item 27 also amends intracranial neoplasm items 39700 to 39721 and cerebrovascular disease items 39800 to 39812.

Item 39700 has been amended to include stereotaxy and cranioplasty. Including stereotaxy in this item will reduce the need for reoperation and improve the post-operative functional outcomes of patients. The full extent of skull tumour spread is not always visible, and stereotaxy is often required (or should be used) to ensure tumour removal with adequate surgical margins. Cranioplasty has been added to improve cosmetic outcomes and decrease the incidence of post-operative headaches. This is because this service usually requires a section of the skull to be excised.

Item 39703 has been amended to include stereotaxy. Stereotaxy has been added in order to more safely and precisely target an intracranial lesion for biopsy.

New item 39710 consolidates items 39706 and 39709. The new item covers all surgery on one or more intracranial tumours performed through a single craniotomy. It includes stereotaxy and cranioplasty.

Item 39712 has been amended to cover all surgery on one or more transcranial tumours performed through a single craniotomy and includes stereotaxy and cranioplasty.

Item 39715 has been amended to specify a transphenoidal approach and to include stereotaxy and dermis, dermofat or fascia grafting, and restrict co-claiming with reconstructive cranioplasty item 40600. The fee for this item has been increased to reflect the requirement of the additional services.

Item 39718 has been amended to include neuroendoscopy and stereotaxy to the service.

New item 39720 is for awake craniotomy for functional neurosurgery. This service is for patients with tumours in locations where there is a high risk of neurological deficit following surgery, and who would have been previously had a craniotomy under item 39709. The new item is to provide coverage for awake craniotomy.

New item 39801 consolidates items 39800, 39806 and 39812 and includes stereotaxy and cranioplasty as a part of the service.

Item 39803 has been amended to include the treatment of fistula via craniotomy. Any related angiography is covered. The item has also been amended to include stereotaxy and cranioplasty.

Items 39706, 39709, 39721, 39800, 39806 and 39812 have been deleted.

Item 28 amends cerebrovascular disease items 39818 and 39821, neurosurgical infection items 39900 to 39906 and cerebrospinal fluid circulation disorders items 40000 to 40015.

Items 39818 and 39821 have been amended to include stereotaxy and better clarify the service. These items refer to a form of vascular bypass used to improve blood flow to the brain to decrease the risk of stroke, often indicated in children suffering from moyamoya disease. The two items approach this surgery in different ways, resulting in low- and high-flow bypasses. However, the current descriptors use outdated and unclear terminology, are unnecessarily specific and do not account for changes in surgical technique over time.

Items 39900 and 39903 have been amended to include stereotaxy and exclude cranioplasty. The use of stereotaxy improves patient safety and outcomes because abscesses are often located deep within the brain and can distort surrounding structures. It is now standard practice to use stereotaxy. Cranioplasty must not be provided with this service because cranial defects should not be repaired in the presence of infection.

Item 33906 has been amended to exclude stereotaxy. Co-claiming this item with stereotaxy constitutes low-value care and has been restricted. The procedure is usually performed after a previous cranial surgery, which means that there is already an existing scar, and that pathology is usually limited to superficial structures. As a result, there is no need to use stereotaxy. The presence of infection also precludes the use of cranioplasty during this service.

New item 40004 consolidates items 40000, 40003, 40006 and 40009 as they all involve similar levels of complexity. Sterotaxy has also been added to this service.

Item 40012 has been amended to specify that endoscopy must be used for this service and that the intention of this service is for the treatment of cerebrospinal fluid circulation disorders. The use of endoscopy is now standard practice for ventriculostomy procedures and should be a required part of this item. An endoscope is passed through the brain, lateral ventricle and third ventricle and then a tiny hole is made in front of the basilar artery. This is very delicate work and requires stereotaxy.

Items 40000, 40003, 40006, 40009 and 40015 have been deleted.

Item 29 amends congenital disorder items 40100 to 40118 and lists new item 40119.

New item 40104 consolidates items 40100 and 40103 as there is no need to retain separate items for these services. The procedures are of similar complexity and use the same surgical technique and approach, and item 40103 is very rarely performed. This service also restricts the co-claiming with stereotaxy and cranioplasty because they are unnecessary in these patients.

Item 40106 has been amended to include reconstruction. In addition, laminectomy, stereotaxy and dermofat graft must also be a part of this service. The co-claiming with cranioplasty item 40600 has been restricted.

Item 40109 has been amended to include cranial meningoceles and reconstruction. In addition, stereotaxy and dermofat graft have also been included as part of the service.

Item 40112 has been amended to include laminectomy and spinal rhizolysis as part of this service. This item has also been amended to exclude co-claiming with cranioplasty.

New item 40119 consolidates 40115 and 40118. This has been done because the technical differences between treating skull deformities with single or multiple sutures are minimal. The new item also excludes the co-claiming with cranioplasty.

Items 40100, 40103, 40115, 40118 have been deleted.

Item 30 amends cranioplasty item 40600 to restrict it from being used with 39113, 39638, 39639, 39641, 39651, 39654, 39656, 39700, 39710, 39712, 39715, 39801, 39803 or 40703. The fees for these services have been increased to include cranioplasty. Item 40600 should not also be claimed with these items.

Item 31 amends item 40700 to allow different approaches to corpus callosotomy and include stereotaxy.

Item 32 amends item 40703 to include stereotaxy and cranioplasty.

Item 33 amends item 40706 to include functional hemispherectomy and stereotaxy.

Item 34 amends items 40709 and 40712. Item 40709 has been amended to provide greater clarity and include stereotaxy, as it is essential to this service.

Item 40712, for the placement of intracranial electrodes by craniotomy, has been amended to clarify that the service includes the placement of single or multiple electrodes and to include stereotaxy.

Item 35 repeals obsolete item 40800.

Item 36 amends item 40801 to clarify that the item is agnostic to the type of method used for lesion production.

Item 37 amends stereotaxy item 40803 to restrict it from being used with 39018, 39109, 39113, 39604, 39615, 39638, 39639, 39641, 39651, 39654, 39656, 39700, 39703, 39710, 39712, 39715, 39718, 39720, 39801, 39803, 39818, 39821, 39900, 39903, 40004, 40012, 40106, 40109, 40700, 40703, 40706, 40709 or 40712. The fees for these services have been increased include stereotaxy. Therefore, item 40803 should not also be claimed with these items.

Item 38 repeals obsolete item 40903. This item describes a technology rather than a procedure. The procedure itself is already described in item 40012, and included as part of the surgical technique in other procedures where it is needed.

Item 39 amends item 40905 to limit usage by neurosurgeons. It removes the specified items to be performed in conjunction with craniofacial abnormality corrections. Specifying these

items is redundant as craniotomy performed by a neurosurgeon for craniofacial disorders is of similar complexity.

Item 40 amends dermis, dermofat or fascia graft item 45018 to restrict it from being used with 39615, 39715, 40106 or 40109. The fees for these services have been increased include dermis, dermofat or fascia graft. Therefore, item 45018 should not be claimed with these items.

- Part 4 - Urology services

Part 4 amends the urology services in the GMST to ensure item descriptors align with contemporary practice, to better define clinical indicators, and to restrict inappropriate co-claiming.

Item 41 amends cystometrography item 11919 by removing the reference to the inclusion of all imaging associated with cystometrography from the item descriptor. This will allow the fluoroscopic imaging associated with the procedure to be claimed by a radiology provider under fluoroscopic screening items (60506 or 60509) in the diagnostic imaging services table. The inclusion of this reference previously prevented the radiology provider from charging separately for the fluoroscopic screening required for this item.

Item 42 makes a consequential amendment to 30450 by removing reference to deleted items.

Item 43 and 45 amends orchidectomy and exploration of spermatic cord items.

Item 30642 has been amended to make it clear that the service is for radical orchidectomy, including spermatic cord (as opposed to items 30643 and 30644, which are used for exploration of the spermatic cord).

New item 30629 is for radical orchidectomy without prosthesis. The creation of this item recognises that there are some instances where patients decide to undergo a radical orchidectomy without prosthesis insertion. These patients may later decide they wish to have a prosthesis inserted, in which case that later operation would be covered by new item 30630 (for the insertion of the testicular prosthesis).

Item 44 amends existing item 30635 to specify that microsurgical techniques can be used in this service. The amendment will also restrict the co-claiming of this item with diagnostic laparoscopy items (30390 and 30627). Co-claiming this item with diagnostic laparoscopy items has been restricted because the placement of a port and laparoscope (with the initial observation of the operative field) is considered an integral part of the procedure and should not be claimed separately.

Items 46 and 47 make amendments to circumcision items 30654 and 30658. These changes will mandate the use of analgesia for these procedures to ensure patient wellbeing.

Item 48 amends existing item 35551 and creates new item 35552 for the radical excision of pelvic lymph nodes.

Item 35551 has been amended to include sentinel node dissection (including any pre-operative injection). Sentinel node dissection is increasingly used to assess the spread of cancers, including cancers of the cervix and endometrium.

New item 35552 is for radical excision of pelvic lymph nodes following previous similar dissection, radiotherapy and/or chemotherapy. This item has been listed with an increased fee in recognition of the complexity and time required to remove pelvic lymph nodes in a patient who has previously undergone treatment as treatment may have caused significant fibrosis, scarring and adhesions.

Item 49 amends existing item 35599. This item has been amended to clarify that the service is for stress incontinence using a female synthetic sling with diagnostic cystoscopy to assess the integrity of the lower urinary tract.

Items 50 to 59 and 66 amend nephrectomy items 36516, 36519, 36522, 36525, 36526, 36527, 36528, 36529, 36531, 36532, 36533 and 36576. These items have been amended to specify that these operations can be conducted using open, laparoscopic or robot-assisted approaches and provide a co-claiming restriction with diagnostic laparoscopy items (30390 and 30627).

Item 36525 has also been expanded to include partial nephrectomies performed after another ablative procedure on the kidney, in patients with a solitary kidney or patients with an eGFR of less than 60ml/min/1.73m². This recognises the complexity of this surgical procedure. When performing a partial nephrectomy in patients with solitary kidneys or impaired renal function, the surgeon has to preserve as much renal tissue as possible to maintain sufficient renal function to keep the patient off dialysis.

Items 36526 and 36527 have been deleted as they no longer reflect best clinical practice.

Items 60 to 62 amend nephrolithotomy and nephrostomy items 36540, 36543 and 36549. Item 36540 has been consolidated into item 36543. Item 36543 is now for nephrolithotomy or pyelolithotomy (or both) for the removal of one or more renal stones - including one or more of the following: nephrostomy, pyelostomy, pedicle control with or without freezing, calyorrhaphy or pyeloplasty. Item 36540 has been deleted.

Item 36549 has been amended to specify that this service can be conducted using open, laparoscopic or robot-assisted approaches.

Item 63 amends item 36561 to clarify that the closed renal biopsy must be done under image guidance to ensure safe practice.

Items 64 and 65 amend pyeloplasty items 36564, 36567 and 36570. These items have been amended to specify that these operations can be conducted using open, laparoscopic or robot-assisted approaches and with or without the use of a retroperitoneal approach. The retroperitoneal approach is accepted as equivalent to a laparoscopic approach.

Item 67 amends ureterectomy item 36579 to clarify that this item can only be claimed where there is a prior cancer diagnosis.

Items 68 to 71 amend ureteric stent items 36604, 36605, 36607 and 36608. These items have been amended to specify that these procedures should only be performed using interventional radiology techniques. Item 36605 has been deleted as it does not reflect clinical best practice.

Item 72 amends item 36609 to include revision of intestinal urinary reservoir. This has been included because there is currently no items for this specific procedure on the MBS.

Item 73 creates two new items 36610 and 36611. New item 36610 consolidates items 36603 and 30566 to combine resection of the small intestine with anastomosis and bilateral ureter transplant into an isolated intestinal segment. Items 30566 and 36603 have been retained as individual items because in certain circumstances both need to be claimed separately and independently of each other. For instance, sometimes a general surgeon will perform the small intestine component of the procedure (item 30566) while a urologist completes the bilateral ureter transplant into the intestinal segment (item 36603). In such a case, the surgeons would claim their respective items separately.

New item 36611 consolidates items 36606 and 30566 to create a complete medical procedure by combining resection of the small intestine with anastomosis and continent formation of intestinal urinary reservoir. Items 30566 and 36605 have also been retained because in certain circumstances both need to be claimed separately and independently of each other. For instance, sometimes a general surgeon will perform the small intestine component of the procedure (item 30566) while a urologist completes the continent formation of intestinal urinary reservoir (item 36606). In such a case, the surgeons would claim their respective items separately.

Item 74 amends item 36615 to clarify that the item can only be claimed if there is biopsy-proven fibrosis, endometriosis or cancer in the area of the ureter causing the ureteric obstruction at the time of the operation. The item descriptor has also been amended to accommodate unilateral ureterolysis procedures, recognising that the disease causing the ureteric obstruction can be unilateral.

Item 75 amends item 36624 to clarify that this service must be performed using interventional radiology techniques, but not including imaging. This change has been made to align with changes made to items 36604, 36607 and 36608 to ensure that contemporary interventional radiology techniques can be appropriately claimed by interventional radiologists.

Items 76 to 80 amend nephroscopy items 36627, 36630, 36633, 36636, 36639, 36642 and 36648. These changes make minor consequential amendments by removing references to deleted items. These changes also remove items 36630, 36642 and 36648 which are obsolete due to low service utilisation and can now be performed under other items.

Items 81 and 82 amend nephrostomy items 36649 and 36650 to specify that these procedures can only be performed using interventional radiology techniques. This is to ensure that these procedures are performed with image guidance.

Items 83, 84, 85 and 92 amend ureteroscopy items 36806 and 36809. Item 36806 has been amended to consolidate the intent of item 36825 by specifying that the procedure can be performed "with or without endoscopic incision of pelviureteric junction or ureteric stricture".

Item 36825 has been deleted.

Consequential amendments have been made to items 36803 and 36809 to remove reference to deleted item 36857.

Items 86, 87 and 126 amend cystoscopy items 36811, 36812 and urethroscopy item 37315.

Item 36811 has been amended to cover prostatic as well as urethral prosthesis, restrict co-claiming with items 37203 and 37207 and cap the number of times item 36811 can be claimed once per episode.

Item 36812 has been amended to clarify that the item can be used for standalone urethroscopy procedures, in addition to cystoscopies with urethroscopies. As the amended item now covers procedures which were performed under item 37315, item 37315 has been deleted.

Items 88 to 94 amends cystoscopy items 36818, 36821, 36824, 36825, 36827 and 36833 and creates new items 36822 and 36823.

Item 36818 has been amended to remove the assistance requirement. This is because surgical assistants are not required for this procedure.

Item 36821 has been amended to remove the co-claiming restriction with items 36824 and 36830 because these items are separate procedures to item 36821 and are different enough from dilatation that it is appropriate for providers to claim each item. Items 36830 and 36824 also use different equipment.

New item 36822 incorporates items 36818 and 36821 to provide a complete medical service. Current items 36818 and 36821 have been retained as individual items because both need to be claimed separately and independently of each other in other clinical situations.

New item 36823 incorporates items 36833, 36818 and 36821 to provide a complete medical service. Current items 36833, 36818 and 36821 have been retained as individual items because both need to be claimed separately and independently of each other in other clinical situations.

Item 36824 has been amended to remove the co-claiming restriction with 36821.

Item 36825 has been deleted due to its low service utilisation. Broadening the item descriptor for 36806 to include "endoscopic incision of pelviureteric junction or ureteric stricture" allows for the deletion of item 36825 (cystoscopy, with endoscopic incision of pelviureteric junction or ureteric stricture).

Item 36827 has been amended to restrict the co-claiming with items 37011 (suprapubic stab cystotomy) and 37245 (holmium laser enucleation of the prostate). The use of these items with 36827 constitutes an unnecessary additional procedure and has been restricted.

Item 36833 has been amended to remove "Assist" as surgical assistants are not required to perform this procedure. The amendment to this item also specifies that this is a unilateral procedure.

Items 95 to 97 amend cystoscopy items 36840, 36842 and 36845.

Item 36840 has been amended to specify the size and characteristics of the tumour (must be in one quadrant of the bladder or a solitary tumour of 2 cm or less in diameter).

Item 36842 has been amended to remove the reference to "diathermy" and replace with the word "cautery". This is to allow the use of other energy sources to achieve haemostasis. The assistant requirement has also been removed as surgical assistants are not required in order to perform this procedure.

A minor editorial amendment has been made to item 36845 to complement changes to item 36840.

Items 98, 99 and 142 make changes to renal items 37444, 36857 and 36863.

Item 36863 has been amended to remove the assistant requirement. Surgical assistants are not required in order to perform this procedure.

Items 36857 and 37444 have been deleted. Item 36857 is redundant as all extraction procedures will be covered by ureteroscopy and pyeloscopy items, and there is no longer a need for stone manipulation, given the advent of modern technology. Item 37444 has been deleted due to low service utilisation and can now be claimed under 36549.

Items 100 and 101 amend bladder repair and cystotomy items 37008 and 37011.

Item 37008 has been amended to clarify that the service can be provided via open suprapubic cystotomy and that an assistant is required in order to perform this procedure safely.

A surgical assistant is required because this is an open abdominal procedure that may require abdominal laparotomy to ensure safe suprapubic catheter placement and avoid bowel injury. This item has also been restricted from being co-claimed with item 37245. Item 37245 (which includes morcellation of the prostate to remove bladder tissue) is the ideal technique, resulting in a shorter hospital stay and duration of catheterisation when compared with an open prostatectomy. Performing a cystotomy is similar to the first stage of an open prostatectomy, which should be used as an alternative procedure for appropriately selected patients, rather than as an addition to 37008.

Item 37011 has been amended to restrict co-claiming with item 36827. The restriction has been made because controlled hydrodistension is a standard (and integral) part of the procedure.

Items 102 and 103 create five new bladder excision or transection items to create a complete medical service.

New item 37015 is for complex total cystectomy following prior surgery, radiation therapy or chemotherapy.

New item 37016 is for cystectomy including prostatectomy and lymph node dissection and group's current items 37014, 37209 and 36502.

New item 37018 is for cystectomy including prostatectomy and lymph node dissection, where performed after prior surgery or radiation therapy, grouping current items 37014, 37209 and 36502. It is a more complex version of the procedure described in item 37016.

New item 37019 is for cystectomy, including anterior exenteration and lymph node dissection, grouping current items 30714, 36502 and 35653.

New item 37021 is for cystectomy, including anterior exenteration and lymph node dissection, grouping current items 30714, 36502 and 35653. It is a more complex version of the procedure covered by item 37019.

Items 104 to 108 amend bladder sling procedure items 37040, 37042, 37043 and 37044 and inserts new items 37039, 37046 and 37048.

Items 37040, 37042, 37043 and 37044 have been amended to remove the reference to the procedures being performed “with or without” mesh. This recognises mesh insertion is potentially unsafe and an outdated method and has been replaced with reference to “sling procedure”.

New item 37039 is for the use of biological sling material. The item has been created to describe the use of biological slings in stress urinary incontinence surgery. There is a need to differentiate between (and create different items for) stress urinary incontinence surgery using various types of slings. This new item describes surgery using non-autologous biological materials (xenografts).

New item 37046 creates a new service for the suprapubic or perineal removal of graft removal. This item was created because there were no MBS items for this procedure.

New item 37048 is for bladder neck closure. This new item is for complicated cases of incontinence where there has been previous surgery, catheter-related complications or a devastated bladder outlet, and for patients with congenital and neurological conditions affecting their continence.

Items 109 to 111 amend benign prostatic hyperplasia, prostatectomy items 37200, 37203 and 37206.

Item 37200 has been amended to specify that the item covers laparoscopic or robot-assisted surgical approaches, in addition to an open approach. Although these procedures traditionally used an open surgical approach, technological development in this area of practice has introduced possible alternative approaches, which have been included in this item.

Items 37203 and 37206 have been amended to remove references to obsolete techniques (cold punch) and update with new and accepted techniques.

Items 112 and 113 amend prostatectomy items 37210 and 37211. These items have been amended to restrict co-claiming with diagnostic laparoscopy items (30390 and 30627) and clarify that the procedures should include sparing of the nerves around the prostate, where clinically indicated. This recognises that the erectile nerves are anatomically adjacent to the prostate, and at times it is clinically appropriate to spare the nerves if cancer has spread outside the prostate and greater clearance is required.

Co-claiming these items with diagnostic laparoscopy items (30390 and 30627) has been restricted because placement of a port and laparoscope (with initial observation of the operative field) is considered an integral part of these procedures and should not be claimed separately.

Item 114 deletes item 37212 and creates two new items (37213 and 37214). Item 37212 has been deleted because the procedure is rarely used and obsolete. In modern clinical practice prostate abscesses are opened endoscopically rather than through an open procedure. The open approach is now obsolete.

New items 37213 is for complex radical prostatectomy without pelvic lymphadenectomy, specifically in patients who have previously undergone radiation therapy or focal therapies.

New item 37214 is for complex radical prostatectomy with pelvic lymphadenectomy, specifically in patients who have previously undergone radiation therapy or focal therapies.

These items reflect the added time and complexity required to perform these operations.

Items 115 to 119 amend prostate biopsy items 37215, 37218, 37219 and radiation therapy and brachytherapy item 37217 and creates new item 37216.

Item 37215 has been amended to remove the need for an assistant. Surgical assistants are not required in order to perform this procedure.

Item 37217 has been amended to specify that the procedure is performed under ultrasound guidance to ensure consistency of phrasing between this item and other items in this section. The item descriptor has also been amended to associate this item with item 55603 (ultrasound scan of the prostate, bladder base and urethra) in the diagnostic imaging services table. Ultrasound is required for accurate fiducial seed placement.

Item 37218 has been amended to remove the requirement for needle biopsy to be performed in this service, because it is unnecessary. Needle biopsy is covered by item 37219.

Item 37219 has been amended to remove the need for an assistant and been repurposed to describe transperineal prostate biopsies. Surgical assistants are not required to perform this procedure. Transperineal biopsies are safer for the patient but more technically challenging and expensive, compared to transrectal biopsies. New item 37216 has been created for biopsy of the prostate by the transrectal route.

Item 120 amends item 37220 to increase the number of services which are associated with the procedure. Imaging is a crucial aspect of this procedure, as evidenced by the existing association with item 55603 (ultrasound). This amendment will associate the service with:

- fluoroscopy (imaging) items 60507 and 60510, which is required for the safe performance of the procedure by checking the position of needles and radioactive seeds both during and after implantation; and
- the radiation oncologist component of brachytherapy for the implantation of radioactive seeds into the prostate under item 15338.

The amendments will also update the clinical terminology used to describe the Gleason score.

Item 121 amends item 37221 to remove the need for an assistant. Surgical assistants are not required to perform this procedure.

Item 122 amends item 37224 by replacing the words "visual laser destruction of a lesion" with "cauterisation". This better describes the procedure, which is mainly used for bleeding from the prostate as a result of benign prostatic hyperplasia, prostate cancer or radiation damage.

Items 123 and 124 amend benign prostatic hyperplasia, microwave thermotherapy items 37230 and 37233. These items have been amended to clarify that the items are for use in prostate ablation by electrocautery or high-energy transurethral microwave thermotherapy. Item 37230 is for the initial procedure, and item 37233 is for the continuation (within ten days) of a urological procedure of the prostate that had to be discontinued for medical reasons.

Item 125 amends item 37245 to replace the reference to "high powered Holmium: YAG laser and an end-firing, non-contact fibre" with "endoscopic enucleation" to ensure that different energy sources can be used. This item has also been amended to mandate the use of a morcellator and restrict the co-claiming with items 36827 and 37008. The use of a morcellator is necessary to remove prostatic tissue that has been effectively endoscopically excised and manipulated into the bladder.

Item 127 amends item 37318 remove the requirement for a surgical assistant and include cystoscopy as one of the procedures that is grouped with urethroscopy in this item. A surgical assistant is not required in order to perform this procedure. Cystoscopy has been included in the item descriptor because it is often claimed as a concurrent procedure with this item.

Item 128 amends item 37324 to allow a surgical assistant if required. An external urethrostomy, although not common, can be a challenging procedure.

Items 129 to 132 amend urethral sling or urethral injection items 37338, 37339, 37340 and 37341.

Items 37338, 37340 and 37341 have been amended to expand the services to cover sling erosion and include removal for infection or pain. The expansion of these descriptors in these ways ensures comprehensive patient care.

Item 37339 has been amended to clarify that this procedure does not cover material injected into the bladder, which is covered by items 36851, 18375 or 18379. This item is specifically for the injection of urethral bulking agents, which are injected into the urethra (not the bladder) to treat stress urinary incontinence.

Item 133 creates a new item for pubovaginal fascial autologous slings (37344). The creation of this new item will allow differentiation between synthetic urethral slings used in item 37340 and pubovaginal fascial autologous fascial slings.

Item 134 increases the fee for item 37372. The fee has been increased to reflect the complexity, reconstruction and sub-specialisation required to perform this surgery.

Item 135 creates a new item for artificial urinary sphincter (37387). This item has been created to allow for artificial urinary sphincters that can be and may need to be, adjusted by the office-based, percutaneous addition or aspiration of filling liquid.

Item 136 amends item 37415 update the terminology used in this item, from 'impotence' to 'erectile dysfunction'.

Items 137 and 138 amends correction of chordee items 37417 and 37418 to update the service requirement for these items, better describing contemporary care and techniques while ensuring that the service aligns with professional standards.

Item 139 deletes item 37420. This item is obsolete as there is no evidence that the procedure is clinically effective.

Item 140 amends item 37423 to specify that this item is only for procedures performed in conjunction with a partial penectomy. This ensures that the item will not be claimed inappropriately. The item descriptor has also been broadened to include "penile epispadias secondary repair" to ensure that the item can be used in epispadias reconstruction, especially secondary reconstruction, where the penis is disassembled and the urethra placed ventrally.

Item 141 amends item 37438 to clarify that the service is for histologically proven cancer or infection.

Item 143 amends item 37604 to include bilateral orchidopexy as a part of the service. Bilateral orchidopexy for testicular torsion is the standard of care.

Item 144 amends lymph node dissection items 37607 and 37610. These items have been amended to remove the term "unilateral" and replace with "bilateral". Retroperitoneal lymph node dissection is based on templates due to patterns of tumour spread, and bilateral retroperitoneal lymph node dissection is the standard of care. The schedule fee for these items have been increased accordingly.

The removal of the word "unilateral" also means that the co-claim restriction with item 36528 can be removed from these items. The items should be able to be co-claimed with item 36528 provided the tumour is of testicular germ cell origin as nephrectomy is sometimes unavoidable due to entrapment of the renal vessels.

Item 145 amends items 37833 and 37834 to remove the reference to "post-operative" from the item descriptor. This change has been made because urethrocutaneous fistula can have a delayed presentation. The current reference to "post-operative" in the item descriptors means that the items only covers those fistula that present in the immediate post-operative period (i.e. over a few weeks).

Item 146 amends item 37842 to include primary as well as secondary repair to the exstrophy of the bladder, better describing contemporary care and techniques while ensuring that the service aligns with professional standards.

Items 147 to 149 amend paediatric genitourinary items 37845, 37848, 37851 and 37854. Items 37845, 37848, 37851 have been amended to update the language used in these items better describing contemporary care and aligning with professional standards.

Item 37854 has been amended to remove the need for an assistant. Surgical assistants are not required in order to perform this procedure.

- Part 5—Other amendments

Part 5 makes minor, editorial or consequential amendments to the GMST (items 155 to 160) the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* (items 152 to 154) and the *Health Insurance (Pathology Services Table) Regulations 2020* (item 161).

Items 150 to 152 amends nine DIST items to remove the co-claiming restriction between items 55248, 55252, 55274, 55276, 55278, 55280, 55282, 55284 and 55292 and 55880, 55881, 55882, 55883, 55884, 55885, 55886, 55887, 55888, 55889, 55890, 55891, 55892, 55893, 55894 or 55895. This will allow (where clinically appropriate) for these items to be claimed.

Item 153 corrects a drafting error in the co-claiming restriction in psychiatry item 293 to clarify the intended purpose. The intended purpose of item 293 is that it should not be billed if item 359 has been provided in the preceding 12 months.

Items 154 and 158 make an editorial amendment by repealing clause 2.14.3 (meaning of after-hours rural area) and moving it to the dictionary. This meaning provides that an after- hours rural area means an area that is a Modified Monash 2 area, Modified Monash 3 area, Modified Monash 4 area, Modified Monash 5 area, Modified Monash 6 area or Modified Monash 7 area.

Item 155 makes a consequential amendment to item 15338 to update the item in line with the amendments to urology item 37220.

Item 156 makes a consequential amendment by removing the reference to deleted item 18361 from clause 5.8.2.

Item 157 removes item 18361 from the GMST. This service will still be available to patients, however, the legal basis of this item will be provided in a ministerial determination made under section 3C of the *Health insurance Act 1973*.

Item 159 amends PST item 73354 to correct a typographical error. This amendment will correct the reference to “SH6” with ‘MSH6’.

Statement of Compatibility with Human Rights

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

Health Insurance Legislation Amendment (2020 Measures No. 2) Regulations 2020

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 (2020 Measures No. 2) Regulations 2020* (the Regulations) is to amend the GMST, PST and DIST from 1 November 2020.

Parts one (chemotherapy services) and two (blood product services) of the Regulations implement decisions of Government taken in the 2019-20 Mid-Year Economic and Fiscal Outlook (MYEFO) under the *Guaranteeing Medicare — Medicare Benefits Schedule Review* measure. These changes include:

- restructuring chemotherapeutic procedures;
- amending blood product services to reflect contemporary clinical practice and improve quality of care.

Parts three (neurology and neurosurgery services) and four (urology services) of the Regulations implement decisions of Government taken the 2019-20 Budget under the *Guaranteeing Medicare — Medicare Benefits Schedule Review — response to Taskforce recommendations* measure. These changes include:

- introducing new items for neurosurgery and promoting the use of higher value neurology items;
- updating item descriptions and relevant application provisions to align with contemporary practice, tightening clinical indicators and restricting inappropriate co-claiming of selected urology services items.

These changes implement the Government's response to Medicare Benefits Schedule Review Taskforce (the Taskforce). The Taskforce is a clinician-led review of all Medicare services to ensure that they reflect current best clinical practice, align with the latest evidence and promote the provision of health services that improve health outcomes.

Part five of the Regulations make minor consequential and administrative amendments.

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 will maintain or advance rights to health and social security by ensuring access to publicly subsidised health services which are clinically effective and cost-effective.

Conclusion

This is the Regulations are compatible with human rights as they maintain the right to health and the right to social security.

Greg Hunt

Minister for Health