**EXPLANATORY STATEMENT**

*Health Insurance Act 1973*

*Health Insurance Legislation Amendment (2021 Measures No. 4) Regulations 2021*

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

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

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

For the purposes of paragraph 10(2)(aa) of the Act, section 28 of the *Health Insurance Regulations 2018* (HIR) provides the items that have a benefit equal to 100% of the fee in respect of the service.

**Purpose**

The purpose of the *Health Insurance Legislation Amendment (2021 Measures No. 4) Regulations 2021* (the Regulations) is to amend the GMST to implement the Government’s response to recommendations form the MBS Review Taskforce (the Taskforce) regarding pain management, anaesthesia, and gynaecological services.

The Regulations will also:

* amend the GMST to expand the eligible patient population for a left atrial appendage closure item, as recommended by the Medical Services Advisory Committee; and
* amend the HIR to enable Medicare benefits to be calculated as 100% of the schedule fee for a number of general practice remote service option items that were created in response to the COVID-19 pandemic. This change is administrative only as the fees for those items will be decreased in the relevant legislative instrument so the amount of benefit paid will not change.

***Changes to pain management services***

Part 1 of Schedule 1 of the Regulations implements the Government’s response to recommendations from the Taskforce regarding pain management services. This includes revision of item terminology to align with best clinical practice, introducing new services and revising existing services to minimise unnecessary treatments from being performed and administrative changes. These changes will improve safety and health outcomes by ensuring patients receive services that align with current best practice guidelines and discourage unnecessary or out-of-date treatments.

The changes to pain management services were announced by Government in the 2021-22 Budget under the *Guaranteeing Medicare — changes to the Medicare Benefits Schedule* measure.

***Changes to anaesthesia services***

Part 1 of Schedule 1 of the Regulations also implements the Government’s response to recommendations from the Taskforce regarding anaesthesia services. The changes align anaesthesia items with contemporary clinical practice and ensure appropriate patient access. These changes include the introduction of one new item for the initiation of management of anaesthesia in association with hip revision surgery, amending four items to clarify their clinical intent, and including a rule which requires the start and end times for a service under the time component anaesthesia items 23010 to 23146 to be documented in writing.

***Changes to gynaecological services***

Parts 2 and 3 of Schedule 1 of the Regulations implement the Government’s response to recommendations from the Taskforce regarding gynaecology services. This includes the amendment of 68 items, introducing 13 new items and deleting 33 items. The changes:

* align services with current clinical best practice and clarify the appropriate use of the items;
* delete outdated and obsolete items that do not reflect current or best clinical practice;
* increase the Medicare benefit for the insertion of intrauterine devices to encourage the use of long-acting reversible contraceptives in Australia;
* amend assisted reproductive technology (ART) items to expand clinical options and promote a higher value of care for those undertaking in-vitro fertilisation;
* amend general gynecology items and increase the Schedule fees of gynaecology items to address the complexity of treating endometriosis;
* amend curettage items to allow these procedures to be performed under sedation, and outside a hospital setting; and
* ensure that new technologies and techniques are appropriately rebated, such as the inclusion of laparoscopic procedures and laser or cryotherapy ablation for cancer services were appropriate.

These changes were announced by Government under the 2021-22 Budget *Guaranteeing Medicare — changes to the Medicare Benefits Schedule* measure.

***Other changes to the GMST and HIR***

Part 1 of Schedule 1 of the Regulations will also amend item 38276, which is for a left atrial appendage closure item, to expand access to patients who have an absolute and permanent contraindication to oral anticoagulation. The patient’s condition must be confirmed in writing by a medical practitioner who is independent of the practitioner rendering the left atrial appendage closure service. This change was recommended by MSAC.

Part 4 of Schedule 1 of the Regulations amends subsection 28(1) of the HIR to include certain general practice items, as performed by a GP or other medical practitioner (excluding specialist and consultant physician), to increase their benefit to 100% of the schedule fee. This change is administrative only and for consistency with the treatment of other GP items available under Medicare. There is no change to the benefit payable as the items will be amended by a separate legislative instrument to reduce their fees from 1 March 2022 in line with the intended benefit amount.

**Consultation**

MSAC, the Taskforce and medical professional organisations were consulted on the policy changes made by the Regulations.

The MBS Review is conducted by expert committees and working groups focusing on specific clinical areas. 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.

The Taskforce endorsed the recommendations of the Pain Management Clinical Committee (PMCC) for changes to pain management services following a public consultation period for the recommendations. The Department has consulted with the Australian Medical Association (AMA), Australian New Zealand College of Anaesthetists, Australian and New Zealand Association of Neurologists, Australian Pain Society, Australian Society of Anaesthetists, Neurological Society of Australia, Pain Specialists Australia, Neuromodulation Society of Australia and New Zealand, Palliative Care Australia, Royal Australasian College of Physicians, Royal Australian College of General Practitioners, and consumer representatives such as Painaustralia on the changes to pain management services listed on the MBS.

The changes to anaesthesia items were recommended by the Anaesthesia Clinical Committee and endorsed by the Taskforce. Representatives from the AMA, the Australian and New Zealand College of Anaesthetists, the Australian Society of Anaesthetists, the Australian College of Rural and Remote Medicine, the Australian Private Hospitals Association, the Consumer Health Forum, Private Healthcare Australia and an independent anaesthetist formed the Anaesthesia Implementation Group responsible for advising on implementation of these changes. This broad membership ensured that stakeholders were supportive of the changes to anaesthesia items on the MBS.

The changes to gynaecology services were recommended by the Gynaecology Clinical Committee, and the Department established a Gynaecology Implementation Liaison Group to advise on implementation of the changes. The Implementation Liaison Group included representatives from Australian Medical Association, National Association of Specialist Obstetricians and Gynaecologists, the Royal Australian and New Zealand College of Obstetricians and Gynaecologist, the Australian Society of Gynaecologic Oncologists, Urogynaecology Society of Australia, Fertility Society of Australia, IVF Director Group, the Australian Gynaecological Endoscopy and Surgery Society, the Royal Australian College of General Practitioners, Private Healthcare Australia and the Australian Private Hospitals Association.

The amendment to cardiac procedural item 38276 (to implement MSAC recommendations in response to application number 1615) was supported by MSAC during its late March to early April meeting in 2021. Consultation was undertaken as part of the MSAC processes with the Cardiac Society of Australia and New Zealand, the Medical Technology Association of Australia, the Australian and New Zealand Society of Cardiac and Thoracic Surgeons, Consumers Health Forum of Australia, the Australia Private Hospitals Association and Private Healthcare Australia.

Details of the Regulationsare set out in the Attachment.

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

The Regulations commence on 1 March 2022.

 Authority: Subsection 133(1) of the

 *Health Insurance Act 1973*

**ATTACHMENT**

**Details of the *Health Insurance Legislation Amendment (2021 Measures No. 4) Regulations 2021***

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2021 Measures No. 4) Regulations 2021.*

Section 2 – Commencement

This section provides for the Regulations to commence on 1 March 2022.

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

**Amendment items 1 to 19 and 27 to 47** make changes to pain management services, **amendment items 20 to 25** make changes to anaesthesia services and **amendment item 26** makes changes to cardiac procedural item 38276.

**Amendment item 1** repeals pain management item 14209 as this item will be obsolete.

**Amendment item 2** amends pain management item 14218, which is for the refilling of an implanted infusion pump reservoir, to allow for the service to include assessment of catheter patency through the side port. This change will align the service with best practice and clarify appropriate use of the item.

**Amendment item 3** amends pain management item 18213, which is for the injection of intravenous regional anaesthesia to a limb by retrograde perfusion, to clarify the service applies when a local anaesthetic agent is used. This change aligns the service with best practice and clarifies that the administration of agents other than local anaesthetic is not applicable to this item.

**Amendment item 4** amends pain management items 18222 and 18225 to clarify the clinical intent for the services. Under the changes, a service under 18222 or 18225 may be claimed where a continuous infusion or injection by catheter of a therapeutic substance (not contrast agent) is provided.

**Amendment item 5** amends pain management item 18228, which is for an interpleural block, to apply a co‑claiming restriction to the item. Under this change, item 18228 cannot be claimed with a service listed in Group T8, unless the interpleural block is performed using a targeted percutaneous approach. This change clarifies the clinical intent of the service.

**Amendment item 6** amends pain management item 18230, which is for the intrathecal or epidural injection of a neurolytic substance, to clarify the procedure may be performed by any route, including the transforaminal route, and to clarify that the service does not include injection of a contrast agent. This change clarifies the clinical intent of the item and prevents inappropriate claiming of this item for contrast injections during imaging procedures.

**Amendment item 7** amends pain management item 18232, which is for an intrathecal or epidural injection, to clarify that the procedure may be performed by the translaminar or transforaminal route, and includes epidural injection of local anaesthetic, steroid and chemotherapy agents. An additional co-claiming restriction has been applied which prevents the item from being claimed with a service listed in Group T8, unless the nerve block is performed using a targeted percutaneous approach.

**Amendment item 8** amends pain management item 18234, which is for the injection of an anaesthetic agent into the primary branch of the trigeminal nerve (excluding the infraorbital nerve), to clarify the policy intent of the item and apply a co-claiming restriction. Under the changes, item 18234 cannot be claimed with a service listed in Group T8, unless the nerve block is performed using a targeted percutaneous approach.

**Amendment item 9** amends pain management item 18236, which is for the injection of an anaesthetic agent into a peripheral branch of the trigeminal nerve (including the infraorbital nerve), to clarify the policy intent of the item and apply a co-claiming restriction. Under the changes, item 18236 cannot be claimed with a service listed in Group T8, unless the nerve block is performed using a targeted percutaneous approach.

**Amendment items 10, 11, 12 and 14** amend pain management items 18238, 18244, 18252, 18254, 18262, 18264, 18266, 18278 and 18280 to prevent the items from being co-claimed with a service listed in Group T8, unless the nerve block is performed using a targeted percutaneous approach. These changes clarify the policy intent of the service.

**Amendment item 13** repeals pain management item 18274 as this item is obsolete.

**Amendment item 15** amends pain management item 18284 to align the service with best practice and clarify appropriate use of the item. Under this change, item 18284 applies to a service where an anaesthetic agent is injected into the cervical or thoracic sympathetic chain.

**Amendment item 16** amends pain management item 18286 to align the service with best practice and clarify appropriate use of the item. Under this change, item 18286 applies to a service where an anaesthetic agent is injected into the lumbar or pelvic sympathetic chain.

**Amendment item 17** amends pain management item 18288 to apply a co‑claiming restriction against the service. Under this change, item 18288 cannot be claimed with a service listed in Group T8, unless the nerve block is performed using a targeted percutaneous approach. This change clarifies the policy intent of the service.

**Amendment item 18** amends pain management items 18290, 18292 and 18294 to clarify that these services must be performed under image guidance. This change aligns these items with current clinical best practice and clarifies the policy intent of the services.

**Amendment item 19** amends pain management item 18296, which is for the destruction of the lumbar sympathetic chain by a neurolytic agent, to clarify the components of the service and that the service must be performed under image guidance. This change aligns the item with current clinical best practice and clarifies the policy intent of the service.

**Amendment item 20** amends clause 5.9.5 of the GMST to insert subclause (3), which mandates the written recording of start and end times for the time component anaesthesia service items (23010 to 24136).

**Amendment item 21** amends anaesthesia item 20402, which is for the initiation of management of anaesthesia for reconstructive procedures of the breast, to include implant reconstruction and exchange. This change clarifies the clinical intent of the item.

**Amendment item 22** amends anaesthesia item 20403 to clarify the item is for the initiation of management of anaesthesia for axillary dissection or sentinel biopsy. This change aligns with contemporary clinical practice.

**Amendment item 23** amends anaesthesia item 20745, which is for the initiation of management of anaesthesia, to include services for complex upper gastrointestinal procedures. This change aligns item 20745 with contemporary clinical practice.

**Amendments item 24 and 25** amend anaesthesia services for total hip replacement procedures. **Amendment item 24** amends anaesthesia item 21214, which is for the initiation of the management of anaesthesia for a total hip replacement or revision, to instead apply to a primary total hip replacement only. A**mendment item 25** creates a new item 21215 for anaesthesia associated with a procedure for revision of a total hip replacement. This change ensures patients can continue to have access to clinically relevant services.

**Amendment item 26** amends cardiac item 38276, which is for left atrial appendage closure, to expand the eligible patient population. This change expands the eligible group of patients to those who have an absolute and permanent contraindication to anticoagulation by requiring written documentation of the absolute and permanent contraindication by a medical practitioner independent of the practitioner performing the procedure. This change also applies a co-claiming restriction to item 38276, which clarifies that the item does not apply where a service to which items 38200, 38203, 38206 or 38254 applies. These changes align with current clinical practice and clarify the policy intent of the services.

**Amendment item 27** amends pain management item 39013 to clarify the terminology used in the item descriptor and align the service with best practice. Under this change, item 39013 applies to the injection of contrast media, local anaesthetic or corticosteroid into zygo-apophyseal or costo-transverse joints under image guidance.

**Amendment item 28** inserts new pain management item 39014, which is for the injection of an anaesthetic agent into the medial branch block of one or more primary posterior rami under image guidance. The schedule fee for the new item is $129.90. The new item provides greater clarity about current practice and differentiates a medical branch block (as a prelude to radiofrequency neurotomy) from an intra-articular zygaphophyseal joint block (item 39013).

**Amendment item 29** amends pain management item 39100, which is for the injection of substances into the primary branch of the trigeminal nerve, to clarify the policy intent. This change clarifies that item 39100 provides for the injection of alcohol, cortisone, phenol or a similar neurolytic substance into the ophthalmic, maxillary, or mandibular branches (the primary branches) of the trigeminal nerve under image guidance. This change aligns item 39100 with contemporary clinical practice.

**Amendment item 30** inserts new pain management items 39110 and 39111 for left and right lumbar percutaneous zygapophyseal joint denervation, respectively. The new items require that the procedures are performed by radio-frequency probe, or cryoprobe, using radiological imaging control. Items 39110 and 39111 specify that the services cannot be claimed more than three times within a twelve month period. This will minimise unnecessary treatments being performed in relation to the services described under items 39110 and 39111.

**Amendment item 31** inserts new pain management items 39116 and 39117 for left and right thoracic percutaneous zygapophyseal joint denervation, respectively, and repeals item 39115 as this item will be obsolete. The items require that the procedures are performed by radio-frequency probe, or cryoprobe, using radiological imaging control. Items 39116 and 39117 specify that the services cannot be claimed more than three times within a twelve month period. This will minimise unnecessary treatments being performed in relation to the services described under items 39116 and 39117.

**Amendment item 32** amends pain management item 39118 to provide for left cervical percutaneous zygaphophyseal joint denervation and inserts new item 39119 for right cervical percutaneous zygapophyseal joint denervation. The items require that the procedures are performed by radio-frequency probe, or cryoprobe, using radiological imaging control. Items 39118 and 39119 specify that the services cannot be claimed more than three times within a twelve month period. This will minimise unnecessary treatments being performed in relation to the services described under items 39118 and 39119.

**Amendment item 33** amends pain management item 39125 to clarify the policy intent of the service. Under this change, item 39125 may be claimed where the insertion or replacement of a spinal catheter and connection to a subcutaneous implanted pump is performed for the management of chronic pain, including cancer pain.

**Amendment items 34 and 36** amend pain management items 39126 and 39128, which are for the implantation or replacement of an infusion pump and filling of reservoir with a therapeutic agent/s, to clarify the policy intent of the services. Placement of the spinal catheter (for connection to pump) is no longer be specified in the items and the changes clarify that the services include the management of cancer pain.

**Amendment item 35** amends pain management item 39127, which is for the insertion of a subcutaneous reservoir and spinal catheter, to clarify the service includes the management of chronic cancer pain. This change is considered minor and administrative in nature.

**Amendment item 37** inserts new pain management item 39129 for the percutaneous placement of a peripheral lead or leads for the management of chronic neuropathic pain. The new item includes intraoperative test stimulation and must be performed in a hospital setting only. This change differentiates percutaneous placement of peripheral leads (item 39129) from surgical placement of peripheral leads (item 39138).

**Amendment item 38** amends pain management item 39130, which is for the percutaneous placement of epidural leads, to clarify that the service provides for the insertion of one or more epidural leads and to enable the claiming of an assistant item for the service when applicable. This change clarifies the policy intent of the service and aligns with best clinical practice.

**Amendment item 39** amends pain management item 39131 to clarify the policy intent of the service. Item 39131 has been revised to clarify that the service provides for the management, adjustment or reprogramming of a neurostimulator.

**Amendment item 40** amends pain management item 39133, which is for the removal of an infusion pump, or removal or repositioning of a spinal catheter, to clarify the policy intent of the service. The change clarifies that the service includes the management of cancer pain. These changes align item 39133 with current clinical practice.

**Amendment item 41** makes a minor amendment to pain management item 39134, to remove the term ‘intractable’ as this term is considered ambiguous. This change is considered minor and administrative in nature and will not impact the service.

**Amendment item 42** amends pain management item 39135, which is for the removal of a neurostimulator or receiver, to clarify the service applies to an open surgical procedure and to allow the claiming of an assistant item for the service, when applicable. These changes align item 39135 with current clinical practice.

**Amendment item 43** amends pain management item 39136, which is for the removal of an epidural or peripheral nerve lead, to clarify that the service applies to an open surgical procedure and to allow the claiming of an assistant item for the service when applicable. Under these changes, item 39136 also must be performed in a hospital setting only. These changes align item 39136 with current clinical practice.

**Amendment item 44** amends pain management item 39137, which is for the surgical repositioning of an epidural or peripheral nerve lead, to clarify that the service applies to an open surgical procedure and to allow the claiming of an assistant item for the service when applicable. Under these changes, item 39137 must be performed in a hospital setting only. These changes align item 39137 with current clinical practice.

**Amendment item 45** amends pain management item 39138, which is for the surgical placement of peripheral nerve leads, to clarify the policy intent of the service. Item 39138 has been revised to clarify that the service provides for the placement of one or more peripheral nerve leads that are intended to remain in situ long term, performed in a hospital setting only. These changes align item 39138 with current clinical practice.

**Amendment item 46** amends pain management item 39139, which is for the surgical replacement of one or more epidural leads by partial or total laminectomy. The item is revised to remove the term ‘intractable’ as this term is ambiguous and to clarify the policy intent of the service. These changes align item 39139 with current clinical practice.

**Amendment item 47** amends pain management item 39323 which provides for the provision of percutaneous denervation (excluding the medial branch nerve) by cryotherapy or radiofrequency. Under the changes, item 39323 may not be claimed more than six times for any given nerve within a 12 month period and an assistant item is no longer be able to be claimed with the service as it is not considered that an assistant is required for this procedure. These changes align item 39323 with current clinical practice and ensure quality patient experience.

**Part 2 – Gynaecological services**

Part 2 makes changes to gynaecological services in the GMST to improve safety and health outcomes of MBS listed gynaecology services by ensuring patients receive services that align with current best practice guidelines and prevent the use of unnecessary or out-of-date treatments.

A number of these changes bring items in line with the National Cervical Screening Program published by the Department of Health in 2017. Details on the program are available at www.health.gov.au, as at 16 December 2021.

**Amendment item 48** amends item 11900, which is for a urine flow study, to apply an additional co-claiming restriction against items 11912 and 11917, which are also amended (refer to **amendment item 49 and 50** of the Regulations). This restriction is being included as urine flow studies are now included in complete medical service items 11912 and 11917 so they no longer need to be claimed in addition to a service under item 11900.

**Amendment item 49** amends item 11912, which is for a cystometrography with simultaneous measurement of rectal pressure, to clarify the policy intent of the item and amend the co-claiming restrictions which apply to the item. Under this change, a cystometrography must be performed with a urine flow rate, urethral pressure profile or urethral sphincter electromyography, either individually or in any combination.

The change also removes references in the descriptor to repealed items 11903, 11915 and 11921 (refer to **amendment item 119** of the Regulations) and inserts a co‑claiming restriction against items 11900 and 11917, which are also amended (refer to **amendment item 48 and 50** of the Regulations). This change is consistent with the restructure of gynaecological services to simplify claiming processes for providers and consolidate items into a complete medical service, as recommended by the Taskforce.

**Amendment item 50** amends item 11917, which is for a cystometrography in conjunction with ultrasound of one or more components of the urinary tract, to clarify the policy intent of the item and amend the co-claiming restrictions which apply to the item. Under these changes, item 11917 must be performed with real time ultrasound and must include simultaneous measurement of rectal pressure, or stomal or vaginal pressure if rectal pressure measurement is not possible.

This change also removes references to repealed items and inserts a co‑claiming restriction against item 11912 (which is amended under **amendment item 49** of the Regulations) and any item in Group I3 of the diagnostic imaging services table.

**Amendment item 51** amends item 13203, which is for ovulation monitoring services for artificial insemination, to allow the service to apply to gonadotrophin stimulated ovulation induction and remove references to repealed item 19206 (refer to **amendment item 119** of the Regulations). This change will enable patients to access fertility services which may assist conception while avoiding more invasive treatment, thereby protecting patient safety and promoting higher value care.

**Amendment item 52** inserts new item 13241 for unilateral open surgical testicular sperm retrieval using an operating microscope. A service under this item includes the exploration of scrotal contents, with biopsy, for the purposes of an intracytoplasmic sperm injection for male factor infertility. This means patients will be able to access a service which tends to yield better surgical outcomes than a service under the existing alternative MBS open non-microsurgical sperm retrieval item 37606. New item 13241 is to be performed in a hospital setting only.

**Amendment item 53** amends item 35503, which is for the introduction of an intra-uterine contraceptive device, to expand the scope of the service, introduce a co-claiming restriction exception for amended items 55506 and 35620 (refer to **amendment items 54 and 81** ofthe Regulations), and amend the schedule fee of the item. These changes increase the scope of item 35503 to provide that the service may be claimed for the introduction of an intra-uterine device for contraception, the treatment of abnormal uterine bleeding or endometrial production during oestrogen replacement therapy. This change improves accessibility to long acting reversible contraception, health outcomes and value of care for the community.

Under these changes, endometrial biopsy can be co‑claimed as a separate procedure using item 35620 (refer to **amendment item 81** of the Regulations), to incentivise higher value care. These changes also increase the schedule fee of item 35503 from $55.70 to $83.40, consolidate a service under repealed item 35502 (refer to **amendment item 119** of the Regulations) into item 35503, and prescribe that the item may not be claimed for a service to which another item in Group T8 applies, other than a service described in items 30062, 35620 or 35506.

**Amendment item 54** amends item 35506, which is for the removal of a retained or embedded intra‑uterine contraceptive device under general anaesthesia, to expand the scope of the service and introduce a co-claiming restriction exemption for amended item 35503 (refer to **amendment item 53** of the Regulations). Under these changes, a service under item 35506 applies where any retained or embedded intra-uterine device is removed under general anaesthesia. This change aligns the service with current clinical best practice and clarifies the appropriate use of the item. Item 35506 does not apply to a service associated with a service to which another item in Group T8 applies, other than a service described in item 35503.

**Amendment item 55** amends item 35513, which is for the excision of a Bartholin’s cyst, to make administrative changes to the item descriptor and expand the service to include the excision of a Bartholin’s gland or abscess. Under this change, item 35513 applies to a service where a Bartholin’s abscess, cyst or gland is excised. This change aligns the service with current clinical best practice.

**Amendment item 56** amend item 35517, which is for the marsupialisation of a Bartholin’s cyst or gland to make administrative changes to the item descriptor. This change clarifies that the service applies to a Bartholin’s abscess, cyst or gland and aligns the service with current clinical best practice.

**Amendment item 57** amends item 35518, which is for ovarian cyst aspiration, to clarify the service does not apply in cases of suspected or possible malignancy. This change aligns item 35518 with best clinical practice and clarifies the appropriate use of the item.

**Amendment item 58** amends item 35527, which is for the excision of a urethral caruncle, to clarify the clinical circumstances in which the service applies. Under this change, item 35527 may be claimed for the symptomatic excision of a urethral caruncle if conservative management has failed or there is a suspicion of malignancy.

**Amendment item 59** amends item 35536, which is for the wide local excision or hemivulvectomy for suspected malignancy, to expand the service to include vulval lesions with a high risk of malignancy. These changes reflect best clinical practice and clarify the appropriate use of the item.

**Amendment item 60** amends item 35539, which is for colposcopically directed CO2 laser therapy, to remove the requirement for the use of CO2 technology, clarify the service applies to histologically confirmed high grade intraepithelial neoplastic changes and remove the application of the item to the cervix. These changes will encourage the use of new technologies and techniques in gynaecology services delivered through the MBS, align the item with best clinical practice and clarify the appropriate use of the item.

**Amendment item 61** amends item 35545, which is for colposcopically directed CO2 laser therapy for condylomatas, to remove the requirement for the use of CO2 technology. This change will encourage the use of new technologies and techniques in gynaecology services delivered through the MBS.

**Amendment item 62** amends item 35548, which is for a radical vulvectomy for malignancy, to increase the schedule fee for the item from $867.85 to $1,301.75. This fee increase recognises the complexity of the service.

**Amendment item 63** amends item 35552, which is for the unilateral radical excision of pelvic lymph nodes, to expand the service to also be performed for a sentinel node dissection by radical excision of pelvic lymph nodes. This change aligns item 35552 with best clinical practice and clarifies the appropriate use of the item.

**Amendment item 64** amends item 35557, which is for the removal of a simple tumour from the vagina, to clarify the policy intent of the service. Under these changes, item 35557 applies to a service for the complete excision of a benign tumour (including a Gartner duct cyst) from the vagina, with histological documentation. These changes align the item with clinical best practice and clarify the appropriate use of the item.

Where a vaginal biopsy is required during the service, practitioners should use amended item 35615 (refer to **amendment item 79** of the Regulations).

**Amendment item 65** amends item 35560 to include indications of use, which restrict the item for partial or complete vaginectomy for removal of deeply infiltrating endometriosis where accompanied by histological evidence of pre-invasive and invasive lesions. Item 35560 does not apply to a service associated with a hysterectomy for non‑invasive indications and must be performed in a hospital setting only. This change promotes clinical best practice and addresses previous uncertainty in clinical application of the item by specifying the intention of the item more clearly.

**Amendment items 66 and 67** increases the schedule fee for vaginectomy items 35561 and 35562, respectively, to align with the schedule fees of items with a similar complexity. Under these changes, the schedule fee for item 35561 is increased from $1,435.35 to $1,597.25 and the schedule fee for item 35562 is increased from $1,178.45 to $1,345.55. These changes recognise that a contemporary procedure under these items requires more clinical expertise to perform the abdominal and vagina components of the service.

**Amendment item 68** increases the schedule fee for vaginectomy item 35564 to align with the schedule fees of items with a similar complexity. Under this change, the schedule fee for item 35564 is increased from $544.00 to $672.80, which is equivalent to 50 per cent of the schedule fee for item 35562 (refer to **amendment item 67** of the Regulations).

This change not only recognises that the second clinician spends approximately half of the total operating time for item 35562 performing this part of the operation, but also recognises that a contemporary procedure under these items requires more clinical expertise to perform the abdominal and vagina components of the service.

**Amendment item 69** amends item 35568, which is for a sacrospinous colpopexy for the management to upper vaginal prolapse, to expand the service to include iliococcygeus fixation as an alternative surgical technique for this procedure. Under this change, item 35568 applies to a procedure for the management of symptomatic upper vaginal (vault or cervical) prolapse by sacrospinous or iliococcygeus fixation. This change reflects the observed increase in the provision of iliococcygeus fixation for this type of procedure and recognises the skill and time required of the practitioner to perform the service.

**Amendment item 70** amends item 35578, which is for a Le Fort operation for genital prolapse, to rename the procedure and align the item description with terminology used by the Therapeutic Goods Administration. Under this change, item 35578 applies to a colpoclesis for pelvic organ prolapse. Item 35578 does not apply to a service to which another item in Subgroup 4 of Group T8 applies, however this change also introduces an exemption to allow co-claiming with item 35599. This change aligns item 35578 with contemporary clinical practice.

**Amendment item 71** inserts new gynaecology items 35591 and 35592 which are intended to modernise and improve the clarity of gynaecology services listed on the MBS.

New item 35591 is for the repair of a rectovaginal fistula by the vaginal route. This change reflects contemporary clinical practice. New item 35591 must be performed in a hospital setting only and cannot be performed in association with a service to which items 35592, 35596, 37029, 3733 or 37336 also apply.

New item 35592 is for the closure of a vesicovaginal fistula by the vaginal route. This change reflects modern clinical practice. New item 35591 must be performed in a hospital setting only and cannot be performed in association with a service to which items 35591, 35596, 37029, 3733 or 37336 also apply.

**Amendment item 72** repeals and replaces items 35595 and 35596 to promote patient safety and appropriate claiming of gynaecology services listed on the MBS.

Item 35595, which is a procedure for the management of symptomatic upper vaginal vault prolapse, is amended to reduce the schedule fee from $1,201.80 to $649.90, expand the service to include any symptomatic vaginal vault or cervical prolapse and add additional specifications which cover surgical approach, procedural detail and a requirement to check ureteric integrity as part of the procedure. The schedule fee for item 35595 is reduced to align the item with comparable vaginal procedures which are listed on the MBS.

Under these changes, a service under item 35595 must be performed by uterosacral ligament suspension, without a graft by any approach, if the uterosacral ligaments are separately identified, transfixed and then incorporated into the rectovaginal and pubocervical fascia of the vaginal vault. These changes also amend item 35595 to include a cystoscopy to check ureteric integrity.

Item 35596, which is for the repair of the fistula between the genital and urinary or alimentary tracts, is amended to increase the schedule fee of the service from $711.60 to $962.20 to reflect contemporary clinical practice and recognise the complexity of the service. This change also introduces a co-claiming restriction against new items 35591 and 35592 (refer to **amendment item 71** of the Regulations), as it would be inappropriate to perform these services on the same occasion.

**Amendment item 73** amends item 35597, which is for a sacral colpopexy, to clarify that the procedure can be performed using any approach, including laparoscopic, open, or robotic techniques. This change aligns item 35597 with clinical best practice and clarifies the appropriate use of the item.

**Amendment item 74** amends item 35608, which is for the cauterisation (other than by chemical means), ionisation diathermy or biopsy of the cervix, to restructure the item descriptor and add the option for an endocervical cutterage of the cervix. This change improves the clarity of item 35608 and aligns the service with clinical best practice.

**Amendment item 75** inserts new items 35609 and 35610 to allow patients to continue to access cone biopsy and amputation services of the cervix, replacing repealed item 35618 (refer to **amendment item 119** of the Regulations). This change simplifies the gynaecology services listed on the MBS.

New item 35609 is for the cone biopsy or amputation of the cervix. New item 35609 retains the original fee of 35618, which is $226.80. New item 35610 is for the cone biopsy for histologically proven malignancy of the cervix. The schedule fee for new item 35610 is $396.95, which is a higher fee than a service under repealed item 35618 to reflect the complexity of the service and the requirement for more intensive peri-operative care.

**Amendment item 76** amends item 35611 to clarify the service applies to the removal of cervical or vaginal polyp or polypi. This change clarifies the clinical intent of the service.

**Amendment item 77** amends item 35612, which is for the removal of a residual stump of the cervix, to specify that the item applies to non-malignant lesions only. This change clarifies the clinical intent of the service.

**Amendment item 78** amends colposcopy item 35614 to amend the clinical terminology used in the item descriptor and clarify the clinical circumstances to which the item applies. Under this change, the term ‘Hinselmann type’ to describe the colposcope procedure is removed and the referral requirement of the item is also removed.

This change also restructures and clarifies the patient indications for the item to assist practitioners in identifying the patient population to which a service under item 35614 applies. This change acknowledges that colposcope types other than a Hinselmann type may be used to improve access without decreasing quality of care, reflects the new National Cervical Screening Program guidelines which came into effect in 2017 and recognises that colposcopy is also used for the assessment and surveillance of benign vulvovaginal disease where there is a risk of malignancy.

The National Cervical Screening Program was published by the Department of Health in 2017. Details on the program are available at www.health.gov.au, as at 16 December 2021.

**Amendment item 79** amends item 35615, which is for a biopsy of the vulva, to expand the service to include a vulva or vaginal biopsy. The schedule fee for this item is increased from $55.85 to $73.25. This change will improve patient safety and outcomes and discourage misuse of vaginectomy items to perform a vulval and/or vaginal biopsy.

**Amendment item 80** amends item 35616, which is for the endoscopic examination of and ablation of the endometrium, to update the descriptor to reflect modern terminology and contemporary best practice. These changes remove the specification that chronic refractory menorrhagia is the only indication for use, remove the specific inclusion of uterine curettage procedure and remove the reference to microwave endometrial ablation.

**Amendment item 81** amends item 35620, which is for endometrial biopsy, to remove the criteria of a suspicion of malignancy as the only indication for use. This change reflects contemporary clinical practice for the investigation of abnormal bleeding.

**Amendment item 82** amends the item descriptor for item 35622, which is for endometrial ablation, to specify use of hysteroscopy in electrosurgery, refer to abnormal uterine bleeding in general and allow endometrial sampling as needed. This change will improve the items overall clarity and more closely reflect modern clinical practice.

**Amendment item 83** amends item 35623, which is for endometrial ablation and resection of myoma and/or uterine septum, to specify that abnormal uterine bleeding is the indication for use and to improve the overall clarity of the item. This change also consolidates a service that was formerly listed under item 35634 but has been repealed (refer to **amendment item 119** of the Regulations). This change will encourage appropriate use of the item and ensure the item more closely reflects modern clinical terminology.

**Amendment item 84** repeals and replaces item 35626, which is for a hysteroscopy, to specify abnormal or postmenopausal uterine bleeding as the indications for use and remove the co-claiming exclusion for item 35627. Under these changes, the schedule fee for item 35626 also increases from $86.10 to $233.10. These changes will encourage appropriate use of the item, increase patient access and incentivise better clinical practice.

**Amendment item 85** amends item 35630, which is for a hysteroscopy, to specify the service is to be provided under general anaesthesia and specify abnormal or postmenopausal uterine bleeding as indications for use. This change consolidates a service that was formerly listed under item 35627 but has been repealed (refer to **amendment item 119** of the Regulations). These changes will not only encourage appropriate use of this item, but also align item 35630 with current clinical practice.

**Amendment item 86** inserts new items 35631 and 35632 to accommodate for the splitting of item 35638 into two items, and the repeal of item 35638 (refer to **amendment item 119** of the Regulations). This change simplifies the gynaecology services listed on the MBS by listing clear service options with differing complexities for providers.

New item 35631 is for operative laparoscopy, including at least one of unilateral or bilateral ovarian cystectomy, salpingo-oophorectomy, salpingectomy for tubal pathology (excluding sterilisation, but including ectopic pregnancy by tubal removal or salpingostomy), or excision of stage II (mild) endometriosis.

New item 35631 provides for a lower complexity service as compared to new item 35632, that the service must be provided in a hospital setting only, and cannot be performed in association with a service to which a service associated with any other intraperitoneal or retroperitoneal procedure applies, except items 30724 and 30725.

New item 35632 is for complicated operative laparoscopy, excision of stage III endometriosis or laparoscopic myomectomy for a myoma of at least 4cm including incision and repair of the uterus. New item 35632 provides for a higher complexity service as compared to new item 35631, must be provided in a hospital setting only, and cannot be performed in association with a service to which a service associated with any other intraperitoneal or retroperitoneal procedure applies, except items 30724, 30725 or 35658.

**Amendment item 87** amends hysteroscopy item 35633 to restructure the item descriptor to reflect contemporary best practice and improve transparency of the procedure. Under these changes, item 35633 applies to a service for the removal of an intra-uterine device, removal of polyps by any method, and the division of minor adhesions typed as European Society for Hysteroscopy (ESH) Classification Grade 1, in any combination. This change also adds the requirement for the service to be performed under visual guidance in alignment with best practice for these services.

The ESH Classification grades are a system which classifies intrauterine adhesions as grades I through IV with several subtypes and incorporates a combination of hysteroscopic and hysterosalpingography findings and clinical symptoms. The ESH Classification grades are largely used in clinical practice and health research, and a reference table of the grades can be found on researchgate.net at <https://www.researchgate.net/figure/Classifications-of-IUA-by-the-European-Society-for-Hysteroscopy-ESH-1989_tbl2_225801894>, as at 16 December 2021.

**Amendment item 88** amends hysteroscopy item 35635 to restructure the item descriptor to improve the overall clarity of the service description and include a division of intrauterine adhesions ESH Grade 2 or higher. This change more accurately describes the appropriate procedure, aligns with contemporary clinical practice and aligns the procedure with relevant training guidelines.

The ESH Classification grades are a system which classifies intrauterine adhesions as grades I through IV with several subtypes and incorporates a combination of hysteroscopic and hysterosalpingography findings and clinical symptoms. The ESH Classification grades are largely used in clinical practice and health research, and a reference table of the grades can be found on researchgate.net at <https://www.researchgate.net/figure/Classifications-of-IUA-by-the-European-Society-for-Hysteroscopy-ESH-1989_tbl2_225801894>, as at 16 December 2021.

**Amendment item 89** amends hysteroscopy item 35636 to restructure the item descriptor to improve the overall clarity of the service description. This change is considered administrative in nature and aligns the service with contemporary clinical practice.

**Amendment item 90** amends operative laparoscopy item 35637 to clarify the appropriate use of the item. It also expands the scope of the service to consolidate procedures that were formally listed under item 35688 which have been repealed (refer to **amendment item 119** of the Regulations).

Under these changes, item 35637 is amended to remove the indication for puncture of cysts and the reference to ‘ventrosuspension’, and specify the item includes the excision or ablation of stage 1 (minor) endometriosis, division of pathological adhesions and/or sterilisation by application of clips, division, destruction or removal of tubes. These changes more accurately describe a service under item 35637 and align the item with current contemporary practice and improve patient safety. It is the rendering practitioner’s responsibility to ensure a service performed under item 35637 meets the requirements of all state and territory legislation for medical procedures.

**Amendment item 91** amends item 35640, which is for the curettage of the uterus, to allow the procedure to be performed under sedation and outside a hospital setting. This change also removes a reference to item 35627, as this item is repealed (refer to **amendment item 119** of the Regulations). This change aligns item 35640 with contemporary clinical practice and facilitates increased access for patients in rural and metropolitan non-hospital settings without compromising the safety of the procedure.

**Amendment items 92** **and 93** amend item 35641, which is for the laparoscopic resection of endometriosis, to remove the reference to the minimum operating time and update the clinical classification of endometriosis to which the service applies. Under this change, item 35641 will apply to rAFS stage IV endometriosis which is commonly referred to as severe endometriosis. This change allows a specific item to be listed on the MBS to promote patient access to services which require a high level of surgical skill and experience to perform.

The rAFS staging (or grading) system applies to the staging of endometriosis. This system allows surgeons to record the location, extent and depth of endometriosis implants, the severity and presence of adhesions and also ovarian endometriomas (cysts) seen during surgery. A table of the grading system can be found on jeanhailes.org.au at <https://www.jeanhailes.org.au/health-a-z/endometriosis/diagnosis#stages-or-grades-of-endometriosis>, as at 16 December 2021.

**Amendment item 94** amends item 35643, which is for the evacuation of the contents of the gravid uterus by curettage or suction curettage, to allow the procedure to be performed under sedation. This change also removes a reference to item 35627, as this item is repealed (refer to **amendment item 119** of the Regulations). This change aligns item 35643 with contemporary clinical practice and facilitates increased access for patients in rural and metropolitan settings without compromising the safety of the procedure.

**Amendment item 95** amends item 35644, which is for electrocoagulation diathermy of the cervix, to clarify the intent of the service, include laser and cryotherapy as therapeutic techniques, align the item with the National Cervical Screening Program guidelines published in 2017 and apply a co-claiming restriction against item 35648 (refer to **amendment item 98** of the Regulations). This change also removes a co‑claiming restriction against item 35640 (refer to **amendment item 91** of the Regulations).

The National Cervical Screening Program was published by the Department of Health in 2017. Details on the program are available at www.health.gov.au, as at 16 December 2021.

**Amendment item 96** amends item 35645, which is for electrocoagulation diathermy of the cervix, to clarify the intent of the service, include laser and cryotherapy as therapeutic techniques, align the item with the National Cervical Screening Program guidelines published in 2017 and apply a co-claiming restriction against item 35648 (refer to **amendment item 98** of the Regulations). This change also removes a co-claiming restriction against item 35649 (refer to **amendment item 99** of the Regulations).

The National Cervical Screening Program was published by the Department of Health in 2017. Details on the program are available at www.health.gov.au, as at 16 December 2021.

**Amendment item 97** amends item 35647, which is for the large loop excision of the endocervical transformation zone of the cervix, to align the item with the criteria for appropriate treatment described in the current National Cervical Screening Program guidelines published in 2017 for the prevention of cervical cancer. This change also removes a co‑claiming restriction against item 35644 (refer to **amendment item 95** of the Regulations). This change will promote patient safety and encourage high‑quality treatment and discourage unnecessary treatment in patients where there are contraindications or where other procedures would be more appropriate.

The National Cervical Screening Program was published by the Department of Health in 2017. Details on the program are available at www.health.gov.au, as at 16 December 2021.

**Amendment item 98** amends item 35648, which is for the complete excision of the endocervical transformation zone of the cervix, to align the item with the criteria for appropriate treatment described in the current National Cervical Screening Program guidelines published in 2017 for the prevention of cervical cancer. This change also removes a co-claiming restriction against item 35645 (refer to **amendment item 96** of the Regulations). This change will promote patient safety and encourage high‑quality treatment and discourage unnecessary treatment in patients where there are contraindications or where other procedures would be more appropriate.

The National Cervical Screening Program was published by the Department of Health in 2017. Details on the program are available at www.health.gov.au, as at 16 December 2021.

**Amendment item 99** amends item 35649, which is for a hysterotomy or uterine myomectomy, to remove the word ‘hysterotomy’ from the item descriptor and specify that this item refers to the removal of one or more myomas. This change more accurately describes the procedure, as used in contemporary clinical practice.

**Amendment item 100** amends item 35653, which is for an abdominal hysterectomy, to specify that uterine adnexae is included. This change improves the clarity of the service described in the item.

**Amendment item 101** amends item 35657, which is for a vaginal hysterectomy, to include the term ‘McCall-type culdoplasty’ in order to improve clarity and reduce inappropriate co-claiming. This change modernises the MBS and encourages clinical best practice as McCall culdoplasty forms part of an appropriately comprehensive vaginal hysterectomy procedure.

**Amendment item 102** amends item 35658, which is for debulking of the uterus, to state that debulking of the uterus may be performed prior to vaginal or laparoscopic removal. It also provides for the debulking of a myoma of at least four centimetres prior to laparoscopic removal. The change includes a requirement for documenting uterine or myoma size.

This change suggests that total or subtotal laparoscopic hysterectomies should largely replace abdominal hysterectomies and allows for the contemporary best practice of performing the debulking procedure at the time of laparoscopic hysterectomy. The change also allows additional rebate when one or more complex surgery is required to facilitate the removal of a uterus or myoma.

**Amendment item 103** repeals and replaces item 35661, which is for an abdominal hysterectomy requiring extensive retroperitoneal dissection to specify that side wall dissection and exposure of the uterus is required. When other procedures may be required, this item now specifies what items are considered to be part of the procedure. Under these changes, the schedule fee for item 35661 increases from $906.65 to $1,755.35. The changes are intended to improve patient safety and improve the clarity of the service described in the item.

**Amendment item 104** repeals and replaces item 35667, which is for a radical hysterectomy without gland dissection and introduce new items 35668 and 35669. The changes are intended to modernise the MBS, and facilitate access to new surgical techniques for patients.

The change consolidates repealed items 35664 and 35670 (refer to **amendment item 119** of the Regulations) into a service under item 35667 by excluding specificity around surgical approach and including radical trachelectomy, and specifications for nerve-sparing surgery and performance of ureterolysis. Under these changes, the schedule fee for item 35667 increases from $1,284.25 to $1,658.00.

New item 35668 is for a new radical hysterectomy item for previous pelvic radiation or chemotherapy. This item has a specification for nerve-sparing surgery and ureterolysis. This new item provides greater access for patients with complex disease.

New item 35669 is for a new peripartum hysterectomy when complicated placenta accreta, increta and percreta. This item is intended for use only in patients where they have been referred to another practitioner for the management of severe intractable peripartum haemorrhage. This new item provides access to this procedure for patients with these life threatening conditions.

**Amendment item 105** inserts new item 35671 for a peripartum hysterectomy for ongoing intractable haemorrhage where other haemorrhage control techniques have failed. This new item covers most difficult cases of hysterectomy at the time of caesarean section. New item 36571 cannot be performed in association with a service to which items 35667, 35668 or 35669 applies.

**Amendment item 106** amends item 35673, which is for a vaginal hysterectomy, to include the term ‘culdoplasty’ in order to improve clarity and reduce inappropriate co‑claiming. This change modernises the MBS and encourages clinical best practice as culdoplasty forms part of an appropriately comprehensive vaginal hysterectomy procedure.

**Amendment item 107** amends item 35694, which is for unilateral or bilateral tuboplasty, to remove tubal implantation as an indication for use. The change modernises the MBS by removing clinical practices that are no longer appropriate.

**Amendment item 108** amends item 35697, which is for microsurgical tuboplasty, to include the use of laparoscopic techniques. The change modernises the MBS by applying modern clinical practice.

**Amendment item 109** amends item 35700, which is for the unilateral microsurgical anastomosis of fallopian tubes, to include the use of laparoscopic techniques, and remove the requirement to use an operating microscope. The change provides more clarity and modernises the MBS by applying modern clinical practice.

**Amendment item 110** amends item 35703, which is for hydrotubation of fallopian tube, by removing the reference to other items in the sub-group. The item is limited to once per lifetime except in cases where a woman has had a successful pregnancy after a previous procedure and is attempting to have another child.

**Amendment item 111** repeals and replaces item 35717, which is for a laparotomy (2 or more procedures), amends items 35720 and 35723 and inserts new items 35721 and 35724. The changes are intended to modernise the MBS and facilitate access to new surgical techniques for patients.

Item 35717 is repealed and replaced to consolidate with item 35713, which is repealed (refer to **amendment item 119** of the Regulations). Under this change, the schedule fee for item 35717 also increases from $567.35 to $887.75. The changes are intended to simplify the MBS, as well as improving access to this procedure by setting a schedule fee that accurately reflects its complexity.

Item 35720, which is for radical or debulking operations for advanced gynaecological malignancy, is amended to split the service into two items, reflecting two different levels of complexity for radical debulking procedures. Amended item 35720 covers treatment for macroscopically disseminated malignancy limited to the pelvis, and new item 35721 covers treatment for macroscopically disseminated malignancy involving the pelvic and abdominal cavities. Under these changes, the schedule fee for item 35720 increases from $701.85 to $1,659.55. The changes are intended to modernise the MBS, and improve patient access by providing rebates that reflect the complexity of the procedures.

Item 35723, which is for retroperitoneal lymph node biopsies from above the level of the aortic bifurcation, are amended to specify that the item is intended to cover unilateral procedures and include a reference to nerve-sparing surgical techniques. Under this change, the schedule fee for item 35723 increases from $502.70 to $1,143.25.

New item 35721 is for the radical debulking involving the radical excision of a macroscopically disseminated gynaecological malignancy from the abdominal and pelvic cavity where the cancer has extended beyond the pelvis. This new item reflects the amendment to item 35720, which limits a service under item 35720 to cover treatment for a macroscopically disseminated limited to the pelvis. This new item improves the clarity of gynaecology services listed on the MBS and allows for the staging or restaging of gynaecological malignancy where there is no upper abdominal disease which requires debulking.

A service under new item 35721 must be performed in a hospital setting only and cannot be performed in association with a service to which 35720 applies.

New item 35724 is for a para‑aortic lymph node dissection in the pelvic region or above the aortic bifurcation, after prior similar dissection, radiotherapy or chemotherapy for malignancy. New item 35724 allows for the use of a specific item in more surgically challenging situations than the service described in amended item 35724 and promotes access to the procedure, which in turn can reduce the need for other treatments such as further chemotherapy or radiotherapy.

**Amendment item 112** amends item 35726, which is for infracolic omentectomy with multiple peritoneal biopsies, to include performed ‘with or without’ multiple peritoneal biopsies and restricts co-claiming with new item 35721 (refer to **amendment item 111** of the Regulations). The changes improve the clarity of the MBS.

**Amendment item 113** splits item 35750, which is for laparoscopically assisted hysterectomy, including any associated laparoscopy, into two items that reflect the two major classes of procedure: item 35750, laparoscopic assisted vaginal hysterectomy (LAVH) and new item 35751 for a total laparoscopic hysterectomy (TLH) (refer to **amendment item 114** of the Regulations). The changes restrict co-claiming of items 35673 and 35595 and modernises the MBS, encouraging clinical best practice and improving the value of care for less-complex procedures.

**Amendment item 114** inserts new gynaecology item 35751 for a total laparoscopic hysterectomy by any approach. This new item reflects the amendment to item 35750 (refer to **amendment item 113** of the Regulations), which has been amended to apply to laparoscopic assisted vaginal hysterectomy only. This change allows for differentiation to provide consumers with better insight into the exact procedure they have undergone.

A service under new item 36751 must be performed in a hospital setting only and cannot be claimed in association with a service to which item 35595 applies.

**Amendment item 115** amends item 35753, which is for laparoscopically assisted hysterectomy with either or both of the following procedures: salpingectomy, oophorectomy, excision of ovarian cyst or treatment of moderate endometriosis, one or both sides, including any associated laparoscopy. The item is amended to specify that the item should be used for TLH procedures and restricts co-claiming with item 35595. The changes encourage clinical best practice as the item now covers a more complex procedure and includes a requirement for the collection of photographic and histological documentation to demonstrate the severity of the patient’s condition.

**Amendment item 116** repeals and replaces item 35754, which is for laparoscopically assisted hysterectomy which specifies procedures that may be included as part of the procedure, and restricts co-claiming with item 35595. Under these changes, the schedule fee for item 35754 increases from $1,136.15 to $1,744.35.

This changealsorepeals and replaces item 35756, which is for laparoscopically assisted hysterectomy, when the procedure is completed by open hysterectomy, to specify that the item should only be used in the presence of extensive pathology or for control of bleeding. Under these changes, the schedule fee for item 35754 increases from $816.40 to $1,488.90.

The changes modernise the MBS, improving compliance and encouraging clinical best practice.

**Amendment item 117** amends item 35759, which is for a procedure for the control of post‑operative haemorrhage following gynaecological surgery, to include the use of a laparoscopic approach. This change more accurately reflects the procedure as it is performed in contemporary clinical practice.

**Amendment item 118** amends item 37044, which is for a suprapubic procedure for bladder stress incontinence, to clarify the service described in the item, include a requirement to perform a diagnostic cystoscopy as part of the procedure and insert a co‑claiming restriction against items 35599 and 36812. This change also increases the schedule fee for the item from $719.75 to $806.50.

**Part 3 – Miscellaneous amendments**

Part 3 of Schedule 1 of the Regulations amends the GMST as part of the changes to gynaecological services. Division 1 repeals 33 gynaecological items in subgroup 4 of Group T8 of the GMST and Division 2 makes consequential amendments to nine clauses and six items to remove references to repealed gynaecological items.

**Division 1 – Repeals of table items**

**Amendment item 119** repeals 33 gynaecological items in subgroup 4 of Group T8. Under this change, outdated and obsolete items that do not reflect current or best practice, or have been replaced by new items in Part 2 of the Regulations, are deleted.

**Division 2 – Consequential amendments**

Division 2 of Part 3 amends Schedule 1 of the GMST to make consequential changes to seven clauses and six items referring to repealed gynaecological items.

**Amendment items 120 to 127** make consequential amendments to various clauses and items in the GMST to remove references to repealed items (refer to **amendment item 119** of the Regulations).

***Changes to the Health Insurance Regulations 2018***

**Part 4 – Medicare benefits**

In 2004, the Government announced a number of policies to increase the bulk-billing rate for general practitioner (GP) services. One of those measures was to increase the benefit for GP items from 85% of the schedule fee to 100% of the fee.

The *Health Insurance Amendment (100% Medicare Rebate and Other Measures) Act 2004* commenced on 1 January 2004 to amend section 10 of the *Health Insurance Act 1973* to provide a regulation-making power to prescribe services (that are not hospital services) that have a benefit calculated as 100% of the schedule fee. All ongoing GP items are prescribed in the subsection 28(1) of the HIR.

**Amendment item 128** amends subsection 28(1) of the *Health Insurance Regulations 2018* (the HIR) to include all GP and medical practitioner (excluding specialist and consultant physician) items in Group A40, A41, A42, A43 and A45 of the MBS. Under this change, the benefit for the items listed will be calculated as 100% of the schedule fee, where the service provided is not a hospital service**.**

**Statement of Compatibility with Human Rights**

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

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

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

**Overview of the Disallowable Legislative Instrument**

The purpose of the *Health Insurance Legislation Amendment (2021 Measures No. 4) Regulations 2021* (the Regulations) is to amend the GMST to implement the Government’s response to recommendations form the MBS Review Taskforce (the Taskforce) regarding pain management, anaesthesia, and gynaecological services.

The Regulations also:

* amend the GMST to expand the eligible patient population for a left atrial appendage closure item, as recommended by the Medical Services Advisory Committee; and
* amend the HIR to prescribe certain general practice remote service option items that were created in response to the COVID-19 pandemic to enable the Medicare benefit to be calculated as 100% of the schedule fee. This change is administrative only as the fees for those items will be decreased in the relevant legislative instrument that makes the item so the amount of benefit paid will not change.

***Changes to pain management services***

Part 1 of Schedule 1 of the Regulations implements the Government’s response to recommendations from the Taskforce regarding pain management services. This includes revision of item terminology to align with best practice, introducing new services and revising existing services to minimise unnecessary treatments being performed and administrative changes. These changes will improve safety and health outcomes by ensuring patients receive services that align with current best practice guidelines and discourage unnecessary or out-of-date treatments.

The changes to pain management services were announced by Government in the 2021-22 Budget under the *Guaranteeing Medicare — changes to the Medicare Benefits Schedule* measure.

***Changes to anaesthesia services***

Part 1 of Schedule 1 of the Regulations also implements the Government’s response to recommendations from the Taskforce regarding anaesthesia services. The changes align anaesthesia items with contemporary clinical practice and ensure appropriate patient access. These changes include the introduction of one new item for the initiation of management of anaesthesia in association with hip revision surgery, amend four items to clarify their clinical intent, and include a rule which requires the start and end times for a service under the time component anaesthesia items 23010 to 23146 to be documented in writing.

***Changes to gynaecological services***

Parts 2 and 3 of Schedule 1 of the Regulations implement the Government’s response to recommendations from the Taskforce regarding gynaecology services. This includes the amendment of 68 items, introducing 13 new items and deleting 33 items. The changes:

* align services with current clinical best practice and clarify the appropriate use of the items;
* delete outdated and obsolete items that do not reflect current or best practice;
* increase the Medicare benefit for the insertion of intrauterine devices to encourage the use of long-acting reversible contraceptives in Australia;
* amend assisted reproductive technology (ART) items to expand clinical options and promote a higher value of care for those undertaking in-vitro fertilisation;
* amend general gynecology items and increase the Schedule fees of gynaecology items to address the complexity of treating endometriosis;
* amend curettage items to allow these procedures to be performed under sedation, and outside a hospital setting; and
* ensure that new technologies and techniques are being rebated appropriately, such as the inclusion of laparoscopic procedures and laser or cryotherapy ablation for cancer services were appropriate.

These changes were announced by Government under the 2021-22 Budget *Guaranteeing Medicare — changes to the Medicare Benefits Schedule* measure.

***Other changes to the GMST and HIR***

Part 1 of Schedule 1 of the Regulations also amends item 38276, which is for a left atrial appendage closure item, to expand access to patients who have an absolute and permanent contraindication to oral anticoagulation. The patient’s condition must be confirmed in writing by a medical practitioner who is independent of the practitioner rendering the left atrial appendage closure service. This change was recommended by MSAC.

Part 4 of Schedule 1 of the Regulations amends subsection 28(1) of the HIR to include certain general practice items, as performed by a GP or other medical practitioner (excluding specialist and consultant physician), to increase their benefit to 100% of the schedule fee. This change is administrative only and for consistency with the treatment of other GP items available under Medicare. There is no change to the benefit payable as the items will be amended by a separate legislative instrument to reduce their fees on 1 March 2022 in line with the intended benefit amount.

**Human rights implications**

The Regulations engage Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

*The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the *‘highest attainable standard of health’* takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

*The Right to Social Security*

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The Committee reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

*The right of equality and non-discrimination*

The rights of equality and non-discrimination are contained in articles 2, 16 and 26 of the International Covenant on Civil and Political Rights (ICCPR).  Article 26 of the ICCPR requires that all persons are equal before the law, are entitled without any discrimination to the equal protection of the law and in this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Analysis

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

**Conclusion**

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

**Greg Hunt**

**Minister for Health and Aged Care**