EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2024 Measures No. 3) Regulations 2024

The *Health Insurance Act 1973* (the Act) sets out the principles and definitions governing the Medicare Benefits Schedule (MBS). The Act provides for payments by way of medical benefits and for other purposes.

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

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

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

The *Health Insurance Regulations 2018* (HIR) provide the overarching policy framework supporting the provision of appropriate Medicare services.

Purpose

The purpose of the *Health Insurance Legislation Amendment (2024 Measures No. 3) Regulations 2024* (the Regulations) is to amend the GMST and the HIR from 1 July 2024. The Regulations will implement the Government's response to the MBS Review Taskforce (the Taskforce) recommendations relating to radiation oncology services, as agreed to in the 2023-24 Mid-Year Economic and Fiscal Outlook under the *An Effective and Clinically Appropriate Medicare* measure.

The Taskforce Oncology Clinical Committee (OCC) made recommendations to restructure the current MBS services for radiation oncology in Group T2 to align with contemporary clinical practice and improve health outcomes for patients. The new structure for radiation therapy comprises modern descriptors and fees weighted to reflect service complexity. It was determined that a restructured schedule will reflect a fairer distribution of funding and better alignment with service complexity.

The restructure will modernise, consolidate and delete radiation oncology MBS items as follows:

- restructure and simplify megavoltage items according to a two-part (planning and treatment) payment model tiered by five levels of procedural complexity;
- inclusion of seven replan items in association with some megavoltage and brachytherapy planning items. This will allow for one replan only to be claimed for each relevant megavoltage or brachytherapy treatment course. The fee for the replan will be set at 50% (standard fee type) of the original treatment planning item;

- consolidate orthovoltage and superficial radiation therapy items into three items for kilovoltage therapy;
- introduce a new item for the planning of kilovoltage therapy;
- restructure brachytherapy items into four items tiered by three levels of procedural complexity;
- delete clinically obsolete brachytherapy items; and
- delete clinically obsolete items for cobalt and caesium radiation therapy.

Consultation
A number of medical professional organisations were consulted on the radiation oncology changes as part of the Taskforce process. These include the Australian Medical Association, the Royal Australian and New Zealand College of Radiologists and the Australasian College of Physical Scientists and Engineers in Medicine, among others. Further consultation was also undertaken with the Radiation Oncology Implementation Liaison Group in the development of the changes. There was general support from stakeholders on the changes that will be implemented by the Regulations. Additional consultation information is outlined in the Attachment.

Details of the Regulations are set out in the Attachment.

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

Sections 1 to 4 of the Regulations will commence the day after registration of this instrument and Schedule 1 of the Regulations will commence immediately after the commencement of Schedule 1 of the *Health Insurance Legislation Amendment (2024 Measures No. 2) Regulations 2024*.

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

ATTACHMENT

Details of the *Health Insurance Legislation Amendment (2024 Measures No. 3) Regulations 2024*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2024 Measures No. 3) Regulations 2024* (the Regulations).

Section 2 – Commencement

This section provides for sections 1 to 4 of the Regulations to commence the day after registration of this instrument and Schedule 1 of the Regulations to commence immediately after the commencement of Schedule 1 of the *Health Insurance Legislation Amendment (2024 Measures No. 2) Regulations 2024*.

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

Schedule 1 of the Regulations will implement the Government's response to recommendations from the MBS Review Taskforce (the Taskforce) relating to radiation oncology. The Taskforce Oncology Clinical Committee (OCC) made recommendations to restructure the current MBS services for radiation oncology in Group T2 to align with contemporary clinical practice and improve health outcomes for patients. The new structure for radiation therapy would comprise modern descriptors and fees weighted to reflect service complexity. It was determined that a restructured schedule would reflect a fairer distribution.

Extensive consultation was undertaken with peak professional bodies through the Radiation Oncology Implementation Liaison Group, which comprised of representatives from the radiation oncology sector, including:

- Royal Australian and New Zealand College of Radiologists;
- Australasian College of Physical Scientists and Engineers in Medicine;
- Australian Society of Medical Imaging and Radiation Therapy;
- Radiation Therapy Advisory Group;
- Australian Medical Association;
- Cancer Voices NSW;
- GenesisCare;
- ICON; and
- an independent adviser.

These changes were announced in the 2023-24 Mid-Year Economic and Fiscal Outlook under the *An Effective and Clinically Appropriate Medicare* measure.

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

Item 1 amends subclause 1.2.6(1) to insert references to new radiation therapy items 15942, 15944, 15946 and 15948 (refer to **item 6** of the Regulations) in the list of items to which clause 1.2.6 applies. Clause 1.2.6 provides requirements for personal attendance services. The items inserted into this subclause require precision techniques which are performed by a medical practitioner. This amendment will also remove a reference to radiation therapy item 15600, which will cease on 30 June 2024 (refer to **item 6** of the Regulations), from subclause 1.2.6(1).

Item 2 amends subclause 1.2.7(1) to insert references to new radiation therapy items 15942, 15944, 15946 and 15948 (refer to **item 6** of the Regulations) in the list of items to which clause 1.2.7 applies. Clause 1.2.7 provides additional requirements for personal attendance services, including where another person provides essential assistance to the medical practitioner in accordance with accepted medical practice. The amendment will also remove a reference to radiation therapy item 15600, which will cease on 30 June 2024 (refer to **item 6** of the Regulations).

Item 3 amends subclause 1.2.11(1) to remove references to existing radiation therapy items, which will cease on 30 June 2024, and insert references to new radiation therapy items 15900 to 15984 (refer to **item 6** of the Regulations). Clause 1.2.11 provides the list of services that may be provided by persons other than medical practitioners and relevant requirements.

Items 4 and 5 amend subparagraphs 1.3.1(3)(c)(iv) and (v) to remove the reference to clause 5.3.1 in subclause 1.3.1(3), as the existing table of derived fees listed in clause 5.3.1 will be repealed following the removal of existing radiation oncology services (refer to **item 6** of the Regulations).

Item 6 repeals and replaces Division 5.3 of Part 5 of Schedule 1 of the GMST to replace all existing radiation oncology services in Group T2 (except item 15900) and relevant provisions with a new restructured list of radiation oncology services in Group T2.

New clause 5.3.1 provides the derived fee for item 15952.

New clause 5.3.2 provides that ***radiation oncologist*** means a specialist practising in the specialty of radiation oncology. This new term is intended to simplify the item descriptors for new radiation oncology services.

New clause 5.3.3 sets out the new radiation oncology items (15902 to 15984) in Group T2. These new items align with contemporary clinical practice and supports fairer fees based on service complexity.

The new radiation oncology items in Group T2 sit in four subgroups:

1. Targeted intraoperative radiation therapy;
2. Megavoltage;
3. Kilovoltage; and
4. Brachytherapy.

Existing item 15900 will be moved to Subgroup 1.

New Subgroup 2 contains megavoltage simulation and dosimetry for treatment planning services, including a limited number of replanning items (items 15902 to 15928), and megavoltage treatment and verification services (items 15930 to 15948). There are several complexity levels for megavoltage services and each complexity level has a respective treatment planning item and treatment and verification item.

New item 15902 will provide a Medicare benefit for simple complexity planning to one site without the need for imaging for the field setting. Only one simple complexity plan can be performed per course of treatment.

New item 15904 will provide a Medicare benefit for simple complexity two-dimensional radiation therapy planning. Only one two-dimensional complexity plan can be performed per course of treatment.

New item 15906 will provide a Medicare benefit for three-dimensional complexity radiation therapy planning without motion management. Only one three-dimensional complexity plan without motion management can be performed per course of treatment.

New item 15908 will provide a Medicare benefit for three-dimensional radiation therapy planning with motion management. Only one three-dimensional complexity plan with motion management can be performed per course of treatment.

New item 15910 will provide a Medicare benefit for single-dose standard intensity modulated radiation therapy (IMRT) planning without motion management. Only one single-dose IMRT plan without motion management can be performed per course of treatment.

New item 15912 will provide a Medicare benefit for an additional dosimetry standard IMRT plan and is only applicable if an initial treatment plan has been prepared under item 15910 and further treatment adjustments are required to the initial plan.

New item 15914 will provide a Medicare benefit for multiple-dose level IMRT planning or single dose level IMRT planning requiring motion management. Only one plan is applicable per course of treatment.

New item 15916 will provide a Medicare benefit for an additional complex IMRT treatment plan and is only applicable if an initial treatment plan has been prepared under item 15914 and further treatment adjustments are required to the initial plan.

New item 15918 will provide a Medicare benefit for intracranial stereotactic radiation therapy (SRT) simulation and dosimetry treatment planning and is only applicable oncer per course of treatment.

New item 15920 will provide a Medicare benefit for stereotactic body radiation therapy (SBRT) simulation and dosimetry treatment planning and is only applicable once per course of treatment.

New item 15922 will provide a Medicare benefit for an additional intracranial SRT or SBRT plan and is only applicable if the initial treatment plans as described in items 15918 or 15920 have been prepared, and further treatment adjustments are required to the initial plan.

New item 15924 will provide a Medicare benefit for specialised radiation therapy simulation and dosimetry planning requiring high quality three-dimensional or four-dimensional imaging for treatment under general anaesthetic or requiring sedation supervised by an anaesthetist.

New item 15926 will provide a Medicare benefit for specialised radiation therapy simulation and dosimetry planning requiring total skin electron therapy (TSE) or total body irradiation (TBI) using three-dimensional radiation therapy, IMRT or a specialised total body treatment delivery method. Only one plan is applicable per course of treatment.

New item 15928 will provide a Medicare benefit for an additional plan of specialised radiation therapy if the initial treatment plan described in item 15924 or 15926 has been prepared, and further treatment adjustments are required to the initial plan.

New item 15930 will provide a Medicare benefit for simple, single-field treatment that does not require imaging for field setting. Treatment can be delivered with a one-dimensional plan. This treatment item is only applicable once per plan per day.

New item 15932 will provide a Medicare benefit for simple treatment and verification using image guided radiation therapy (IGRT) to deliver two-dimensional treatment. This treatment item is only applicable once per plan per day.

New item 15934 will provide a Medicare benefit for three-dimensional treatment and verification, without motion management. This treatment item is only applicable once per plan per day.

New item 15936 will provide a Medicare benefit for three-dimensional treatment using IGRT imaging is used to implement a complex three-dimensional plan. This treatment is delivered using motion management and is applicable once per plan per day.

New item 15938 will provide a Medicare benefit for standard single dose level IMRT treatment and image verification, without motion management. This treatment item is only applicable once per plan per day.

New item 15940 will provide a Medicare benefit for complex multiple dose level IMRT treatment, or single dose level IMRT treatment requiring motion management, and image verification. This treatment and verification item is only applicable once per plan per day.

New item 15942 will provide a Medicare benefit for intracranial SRT treatment and image verification if an IGRT or minimally invasive stereotactic frame localisation is used to implement an intracranial stereotactic treatment plan. This treatment item is only applicable once per day.

New item 15944 will provide a Medicare benefit for SBRT treatment and image verification if IGRT is used (with motion management functionality if required) to implement a SBRT plan. This treatment item is only applicable once per day.

New item 15946 will provide a Medicare benefit for specialised radiation therapy treatment and verification if a specialised technique is used with general anaesthetic or sedation supervised by an anaesthetist. This treatment item is only applicable once per plan per day.

New item 15948 will provide a Medicare benefit for specialised radiation therapy treatment and verification if a specialised technique, such as TSE or TBI, is used to implement a treatment plan, and IGRT is used (with motion management functionality, if required) to implement three-dimensional radiation therapy. This treatment item is only applicable once per day.

New Subgroup 3 contains one kilovoltage planning service (item 15950) and kilovoltage treatment services (items 15952 to 15956).

New item 15950 will provide a Medicare benefit for simple complexity single field radiation therapy treatment planning without imaging for field setting. This planning service is applicable once per course of treatment.

New item 15952 will provide a Medicare benefit for the treatment of one anatomical site, excluding orbital structures where there is placement of an internal eye shield.

New item 15954 will provide a Medicare benefit for the treatment of two or more anatomical sites, excluding orbital structures where there is placement of an internal eye shield.

New item 15956 will provide a Medicare benefit for the treatment only of orbital structures where there is placement of an internal eye shield.

New Subgroup 4 contains brachytherapy insertion and construction services (items 15958 to 15968), brachytherapy dosimetry and planning (items 15970 to 15980) and brachytherapy treatment and verification services (items 15982 to 15984).

New item 15958 will provide a Medicare benefit for simple placement or insertion of a brachytherapy device, without image guidance, including the removal of applicators, catheters or needles.

New item 15960 will provide a Medicare benefit for complex construction and manufacture of a personalised brachytherapy applicator or mould, based on three-dimensional imaging.

New item 15962 will provide a Medicare benefit for complex insertion of a brachytherapy device including: intrauterine tubes with or without ovoids, ring or cylinder; endocavity applicators; intraluminal catheters or endovascular catheters; and including the removal of applicators, catheters or needles, with image guidance.

New item 15964 will provide a Medicare benefit for complex insertion and removal of hybrid intracavitary and interstitial brachytherapy applicators, or intracavitary and multi-catheter applicators, with image guidance.

New item 15966 will provide a Medicare benefit for complex insertion of interstitial brachytherapy implants not requiring surgical exposure, with image guidance, including: catheters or needles for temporary implants; radioactive sources for permanent implants; or

breast applicators, single channel and multi-channel strut devices; and including the removal of applicators, catheters or needles.

New item 15968 will provide a Medicare benefit for complex insertion of interstitial brachytherapy implants requiring surgical exposure, including: catheters, needles or applicators; radioactive sources for permanent implants; surface moulds during intraoperative brachytherapy; plastic catheters or stainless steel needles; and including removal of applicators, catheters or needles.

New item 15970 will provide a Medicare benefit for simple level dosimetry for brachytherapy plans prescribed to surface or depth from catheter.

New item 15972 will provide a Medicare benefit for simple level dosimetry replan if treatment adjustments are required to the initial plan. This replanning item is only applicable once per course of treatment.

New item 15974 will provide a Medicare benefit for intermediate level dosimetry plan that has three-dimensional image datasets for intracavitary or intraluminal or endocavity applicators. This planning item is only applicable once per course of treatment.

New item 15976 will provide a Medicare benefit for intermediate level dosimetry replanning of an initial brachytherapy treatment plan if treatments adjustments are required to the initial plan. This replanning item is only applicable once per course of treatment.

New item 15978 will provide a Medicare benefit for complex level dosimetry plans that contain multiple needles, catheters or radiation sources. This planning item is only applicable once per course of treatment.

New item 15980 will provide a Medicare benefit for complex level dosimetry replanning of an initial treatment plan if treatment adjustments are required to the initial plan. This replanning item is only applicable once per course of treatment.

New item 15982 will provide a Medicare benefit for implementing a brachytherapy treatment plan described in any of items 15970, 15972, 15974, 15976, 15978 and 15980.

New item 15984 will provide a Medicare benefit for verifying the positioning of brachytherapy applicators, needles, catheters or radioactive sources.

Item 7 amends item 37220, which provides for a urological procedure to implant radioactive seeds for brachytherapy, to substitute a reference to existing brachytherapy item 15338 with the equivalent new brachytherapy item 15966. Item 37220 relates to the urological component of the service and item 15966 relates to the brachytherapy component (refer to **item 6** of the Regulations).

Item 8 amends item 37227, which provides for a urological procedure to insert transperineal catheters for high dose rate brachytherapy, to substitute a reference to brachytherapy items 15331 and 15332 with the equivalent new brachytherapy item 15966. Item 37227 relates to the urological component of the service and item 15966 relates to the brachytherapy component (refer to **item 6** of the Regulations).

Item 9 amends clause 7.1.1 to insert definitions for the terms ***Australian Register of Therapeutic Goods,*** which is used throughout the new radiation therapy items to ensure treatment is being delivered using a device that is included in the register, and ***radiation oncologist***, which has the meaning given by clause 5.3.2 (refer to **item 6** of the Regulations).

Item 10 amends clause 7.1.1 to make a consequential amendment to the definition of ***registered vaccine*** following the insertion of the new definition for ***Australian Register of Therapeutic Goods*** (refer to **item 9** of the Regulations).

Health Insurance Regulations 2018 **(HIR)**

Item 11 amends section 46 of the HIR to remove the reference to "Subgroup 3, 4 or 5 of" Group T2 in the general medical services table. Section 46 of the HIR provides the meaning of a ***radiation oncology service***. The new radiation therapy services will continue to be listed in Group T2 and the reference to the subgroups of Group T2 at section 46 is no longer necessary.

Item 12 amends paragraph 51(1)(a) of the HIR to substitute the reference to existing radiation therapy items 15000 to 15600 with the new radiation therapy items 15900 to 15984 (refer to **item 6** of the Regulations). Section 51 of the HIR prescribes which particulars of a person rendering a service are required for specified. This change will mean section 51 of the HIR does not apply to the new radiation therapy items.

Item 13 amends subsection 52(1) of the HIR to substitute the reference to existing radiation therapy items 15000 to 15600 with the new radiation therapy items 15900 to 15984 (refer to **item 6** of the Regulations). Section 52 of the HIR prescribes which particulars of a person rendering a certain radiation or nuclear service, and a person claiming or receiving fees, are required. This change will mean section 52 of the HIR applies to the new radiation therapy items.

Item 14 amends paragraph 80(a) of the HIR to substitute the reference to Subgroup 3 with Subgroup 2 to reflect new Subgroup 2, which contains megavoltage services. Section 80 of the HIR lists types of radiation oncology equipment for the purposes of subsection 23DZZQ(2) of the *Health Insurance Act 1973* and the related subgroups of Group T2.

Item 15 inserts new paragraph (ab) into section 80 of the HIR to include kilovoltage equipment, used in the rendering of a service specified in an item in Subgroup 3 of Group T2, in the lists of types of radiation oncology equipment for the purposes of subsection 23DZZQ(2) of the *Health Insurance Act 1973*.

Item 16 amends paragraph 80(b) of the HIR to make a minor administrative amendment following the removal of paragraph (c) of section 80 (refer to **item 17** of the Regulations).

Item 17 repeals paragraph 80(c) of the HIR, which lists planning equipment currently covered under Subgroup 5 of Group T2, following the restructure of the radiation therapy services in Group T2 (refer to **item 6** of the Regulations). Planning services will no longer sit in a separate subgroup, but rather will be included within the respective subgroups for each type of treatment 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 (2024 Measures No. 3) Regulations 2024

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 *Health Insurance Act 1973* (the Act) sets out the principles and definitions governing the Medicare Benefits Schedule (MBS). The Act provides for payments by way of medical benefits and for other purposes.

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

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Purpose

The purpose of the *Health Insurance Legislation Amendment (2024 Measures No. 3) Regulations 2024* (the Regulations) is to amend the GMST and the HIR from 1 July 2024. The Regulations will implement the Government's response to MBS Review Taskforce (the Taskforce) recommendations relating to radiation oncology services, as agreed to in the 2023-24 Mid-Year Economic and Fiscal Outlook under the *An Effective and Clinically Appropriate Medicare* measure.

The Taskforce Oncology Clinical Committee (OCC) made recommendations to restructure the current MBS services for radiation oncology in Group T2 to align with contemporary clinical practice and improve health outcomes for patients. The new structure for radiation therapy comprises modern descriptors and fees weighted to reflect service complexity. It was determined that a restructured schedule will reflect a fairer distribution of funding and better alignment with service complexity.

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- restructure and simplify megavoltage items according to a two-part (planning and treatment) payment model tiered by five levels of procedural complexity;
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- consolidate orthovoltage and superficial radiation therapy items into three items for kilovoltage therapy;
- introduce a new item for the planning of kilovoltage therapy;
- restructure brachytherapy items into four items tiered by three levels of procedural complexity;
- delete clinically obsolete brachytherapy items; and
- delete clinically obsolete items for cobalt and caesium radiation therapy.

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 the rights to health and social security and the right of equality and non-discrimination by ensuring access to publicly subsidised radiation oncology services that are clinically relevant and cost-effective as intended.

Conclusion

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

Mark Butler

Minister for Health and Aged Care