EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2017 Measures No. 1) Regulations 2017

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.

Subsections 4(1) and 4A(1) of the Act provides that regulations may prescribe a table of medical and pathology services which set out items of services, the fees applicable for each item, and rules for interpreting the table. The *Health Insurance (General Medical Services Table) Regulation 2016* (GMST) and the *Health Insurance (Pathology Services Table) Regulation 2016* (PST) currently prescribe such tables.

Purpose

The purpose of the *Health Insurance Legislation Amendment (2017 Measures No. 1) Regulations 2017* (the Regulation) is to amend the GMST and PST from 1 May 2017. The Regulation would make a number of changes to the Medicare Benefits Schedule (MBS) as recommended by the Medical Services Advisory Committee (MSAC) or the MSAC Executive. The changes were announced in the *Investing in Medicare — Medicare Benefits Schedule — new and amended listings* in the 2016-17 Mid-Year Economic and Fiscal Outlook (MYEFO), and include:

- List a new item for ovarian repositioning.
 - This change adds a new item (35730) to allow patients access to ovarian repositioning to preserve ovarian function, prior to gonadotoxic radiotherapy when the treatment volume and dose of radiation have a high probability of causing infertility.
- List a new item for partially implantable active middle ear implants for patients with mild to severe sensorineural hearing loss.

 This change adds a new item (41(18) for the insertion of partially implantable active)
 - This change adds a new item (41618) for the insertion of partially implantable active middle ear implants for patients with mild to severe sensorineural hearing loss. The new item is restricted to patients who cannot wear conventional hearing aids for a range of medical reasons, for whom the alternative would be no treatment. These patients have considerable unmet clinical need for the service as they are ineligible for cochlear and bone conduction implants.
- List a new item for radical orchidectomy.
 - This change adds a new item (30642) for radical orchidectomy. Radical orchidectomy is the surgical removal of the testicle and spermatic cord, generally as part of treatment for testicular cancer.
- Removal of age restrictions for treating certain bowel and bladder problems. This change amends the following items to remove the restriction requiring patients to be aged 18 years or older to access these services:
 - o items 32213–32218 for sacral nerve stimulation for treatment of faecal incontinence; and

o items 36663-36664 and 36666-36668 for the treatment of detrusor (muscle) overactivity or urinary incontinence.

This restriction was in place because no evidence was available on the efficacy of these services in patients under 18 years of age at the time of listing. New evidence now supports the procedures in these groups.

• Amend existing item 31340 to allow it to be performed in association with MBS items 31000-31002.

This change amends item 31340 (for excision of muscle, bone or cartilage) to allow it to be performed in association with MBS items 31000-31002 (for micrographically controlled serial excision) to allow surgeons to close defects created by cancer which can include the invasion of cartilage.

• Amend certain ophthalmology items to clarify their intent to prevent inappropriate co-claiming.

This change amends items 42725, 42734, 42758, 42788, 42789, 42791, 42792 to clarify the intent of the items and prevent inappropriate co-claiming. The amendments are as follows:

- capsulotomy item 42734 has been amended to prevent it being co-claimed inappropriately as an add-on for other ophthalmology services (42725 or 42731):
- item 42725 has been amended to make it clear that the service can include capsulotomy;
- o goniotomy item 42758 has been amended to prevent its use for the insertion of eye stent devices for treating glaucoma. The insertion of these devices needs to be assessed by the MSAC for its safety, effectiveness and cost effectiveness before it can be made available on the MBS;
- o laser capsulotomy items 42788 and 42789 have been amended to prevent the services being co-claimed during a lens extraction (MBS item 42702). The intent of these items is for it to be claimed following lens extraction, not at the same time the patient is having the lens extraction; and
- o laser vitreolysis or corticolysis items 42791 and 42792 have been amended to prevent the services being claimed for a new treatment available using laser technology to treat vitreous 'floaters' or detachments. Laser technology to treat vitreous 'floaters' or detachments needs to be assessed by MSAC for its safety, effectiveness and cost effectiveness before it can be made available on the MBS.
- Amend Interferon Gamma Release Assay (IGRA) to expand the eligible patient population.

This change amends item 69471 (a pathology blood test for tuberculosis) to expand the eligible patient population.

The Regulation also makes other minor amendments from 1 May 2017:

- Patch testing items 12012, 12022 and 12024 have been amended in the GMST to clarify consultant physicians are able to provide the service, per the items policy intent.
- Genetic pathology test item 73336 has been removed from the PST. To maintain the legal basis for Medicare benefits for this service, this item will be prescribed under ministerial determination under section 3C(1) of the Act from 1 May 2017.

Consultation

Consultation was undertaken by the Department with the following stakeholders:

• the Australian Society of Otolaryngology Head and Neck Surgery;

- the Royal Australasian College of Surgeons;
- the Urological Society of Australia and New Zealand;
- the Colorectal Surgical Society of Australia and New Zealand; and
- the Australasian College of Dermatologists.

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

As part of the MSAC process, consultation was undertaken with professional bodies, consumer groups, the public and clinical experts for proposals put forward for consideration by the Committee.

No consultation was undertaken on the minor amendments as the changes are machinery in nature and will not impact on patient or provider access.

Details of the Regulation are set out in the Attachment.

The Act specifies no conditions which need to be met before the power to make the Regulation may be exercised.

The Regulation is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulation commences on 1 May 2017.

<u>Authority</u>: Subsection 133(1) of the

Health Insurance Act 1973

Details of the *Health Insurance Legislation Amendment (2017 Measures No. 1)*Regulations 2017

Section 1 - Name

This section provides for the Regulation to be referred to as the *Health Insurance Legislation Amendment (2017 Measures No. 1) Regulations 2017.*

Section 2 – Commencement

This section provides for the Regulation to commence on 1 May 2017.

Section 3 – Authority

This section provides that the Regulation is made under the *Health Insurance Act 1973*.

Section 4 – Schedule(s)

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

Health Insurance (General Medical Services Table) Regulation 2016

Item [1] – Schedule 1 (item 6024, column headed "Description")

This item inserts a comma after "20 minutes".

Item [2] – Schedule 1 (item 6058, column headed "Description")

This item inserts a comma after "20 minutes".

Item [3] – Schedule 1 (items 12021, 12022 and 12024, column headed "Description")

This item inserts ", or consultant physician," after "specialist" to clarify consultant physicians are eligible to provide this service.

Item [4] – Schedule 1 (items 30631, 30634 and 30635, column headed "Description")

This item restricts MBS items 30631, 30634 and 30635 from being co-claimed with the new radical orchidectomy service (see item 5).

Item [5] – Schedule 1 (insert new item 30642)

This item inserts new MBS item 30642 after 30641. This item is for radical orchidectomy (the surgical removal of the testicle and spermatic cord).

Item [6] – Schedule 1 (item 31340, column headed "Description", paragraph (b))

This item amends item 31340 to allow the item to be co-claimed with micrographically controlled serial excision items 31000-31002. This amendment allows item 31340 to be

claimed with these items to close defects created by cancer which can include the invasion of cartilage.

Item [7] – Clause 2.44.15A of Schedule 1

This item repeals clause 2.44.15A. The contents of this clause have been inserted into the item descriptors of MBS items 32213 to 32218.

Item [8] – Schedule 1 (item 32213, column headed "Description", paragraph (b)) This item makes an editorial amendment to substitute "12 months" with "12 months;".

Item [9] – Schedule 1 (item 32213, column headed "Description", after paragraph (b)) This item adds the contraindications (subparagraphs i-ix) in repealed clause 2.44.15A. The age restrictions will not apply.

Item [10] – Schedule 1 (item 32214, column headed "Description", paragraph (b)) This item makes an editorial amendment to substitute "12 months" with "12 months;".

Item [11] – Schedule 1 (item 32214, column headed "Description", after paragraph (b)) This item adds the contraindications (subparagraphs i-ix) in repealed clause 2.44.15A. The age restrictions will not apply.

Item [12] – Schedule 1 (item 32215, column headed "Description")

This item adds the contraindications (subparagraphs i-ix) in repealed clause 2.44.15A. The age restrictions will not apply.

Item [13] – Schedule 1 (item 32216, column headed "Description", after paragraph (b)) This item adds the contraindications (subparagraphs i-ix) in repealed clause 2.44.15A. The age restrictions will not apply.

Item [14] – Schedule 1 (item 32217, column headed "Description", paragraph (b)) This item makes an editorial amendment to substitute "12 months" with "12 months;".

Item [15] – Schedule 1 (item 32217, column headed "Description", after paragraph (b)) This item adds the contraindications (subparagraphs i-ix) in repealed clause 2.44.15A. The age restrictions will not apply.

Item [16] – Schedule 1 (item 32218, column headed "Description", paragraph (b)) This item makes an editorial amendment to substitute "12 months" with "12 months;".

Item [17] – Schedule 1 (item 32218, column headed "Description", after paragraph (b)) This item adds the contraindications (subparagraphs i-ix) in repealed clause 2.44.15A. The age restrictions will not apply.

Item [18] - Schedule 1 (after item 35729)

This item inserts new item 35730. Item 35730 is for the provision of ovarian repositioning for one or both ovaries to preserve ovarian function, prior to radiotherapy when the treatment volume and dose of radiation have a high probability of causing infertility.

Item [19] – Schedule 1 (item 36663, column headed "Description", subparagraph (b)(ii)) This item omits "treatment;" and substitute with "treatment", removing the semi colon.

Item [20] – Schedule 1 (item 36663, column headed "Description")

This item omits "in a patient who is at least 18 years old" to remove the restriction that previously limited this service to patients aged 18 years and older.

Item [21] – Schedule 1 (item 36664, column headed "Description")

This item omits "in a patient who is at least 18 years old—" to remove the restriction that previously limited this service to patients aged 18 years and older.

Item [22] – Schedule 1 (item 36666, column headed "Description", paragraph (b)) This item omits "treatment;" and substitute with "treatment", removing the semi colon.

Item [23] – Schedule 1 (item 36666, column headed "Description")

This item omits "in a patient who is at least 18 years old" to remove the restriction that previously limited this service to patients aged 18 years and older.

Item [24] – Schedule 1 (item 36667, column headed "Description", paragraph (b)) This item omits "treatment;" and substitute with "treatment", removing the semi colon.

Item [25] – Schedule 1 (item 36667, column headed "Description")

This item omits "in a patient who is at least 18 years old" to remove the restriction that previously limited this service to patients aged 18 years and older.

Item [26] – Schedule 1 (item 36668, column headed "Description", paragraph (b)) This item omits "treatment;" and substitute with "treatment", removing the semi colon.

Item [27] – Schedule 1 (item 36668, column headed "Description")

This item omits "in a patient who is at least 18 years old" to remove the restriction that previously limited this service to patients aged 18 years and older.

Item [28] - Schedule 1 (after item 41617)

This item inserts new MBS item 41618 after item 41617. Item 41618 is for the insertion of partially implantable active middle ear implants for patients with mild to severe sensorineural hearing loss. The new item contains abbreviations that would be readily understood by health professionals e.g. audiologists and otolaryngologists. Abbreviations are as follows:

- o PTA = pure tone average
- o PTA4 = the pure tone average of air-conduction thresholds at 0.5, 1, 2 and 4 kHz
- o dBHL = decibels hearing level
- \circ kHz = kilohertz

The requirement in paragraph (d) defines stable symmetrical sensorineural hearing loss without specifying further and the requirement in paragraph (h) to "across all frequencies" is to help define the population for this service more clearly.

Item [29] – Schedule 1 (item 42725, column headed "Description", paragraph (c))

This item omits "membranes" and substitute with "membranes, adding a semi colon in order to list capsulotomy as an additional procedure that may be provided under MBS item 42725.

Item [30] – Schedule 1 (item 42725, column headed "Description", after paragraph (c)) This item inserts "(d) capsulotomy" as an additional procedure that may be provided under item 42725.

Item [31] – Schedule 1 (item 42734, column headed "Description")

This item inserts ", and other than a service associated with a service to which item 42725 or 42731 applies" after "laser" to restrict the item from being inappropriately performed with items 42725 or 42731.

Item [32] – Schedule 1 (item 42758, column headed "Description")

This item inserts the words "for the treatment of primary congenital glaucoma, excluding the minimally invasive implantation of glaucoma drainage devices" after "Goniotomy". This change prevents the item's use for the insertion of eye stent devices for treating glaucoma.

Item [33] – Schedule 1 (items 42788 and 42789, column headed "Description")

This item inserts the words "—other than a service associated with a service to which item 42702 applies" after "2 year period". This change prevents these services from being coclaimed during a lens extraction (MBS item 42702).

Item [34] – Schedule 1 (items 42791 and 42792, column headed "Description")

This item inserts ", excluding vitreolyis in the posterior vitreous cavity" after "fibrinolysis". This amendment prevents the service being claimed for a new treatment available using laser technology to treat vitreous 'floaters' or detachments, which has not been assessed by MSAC.

Health Insurance (Pathology Services Table) Regulation 2016

Item [35] – Schedule 1 (cell at item 69471, column headed "Pathology service")

This item repeals and substitutes the descriptor of MBS item 69471 to expand the eligible patient population eligible for this service.

Item [36] – Schedule 1 (item 73336)

This item removes item 73336 from the pathology services table. The legal basis for item 73336 will be prescribed in a ministerial determination from 1 May 2017.

Statement of Compatibility with Human Rights

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

Health Insurance Legislation Amendment (2017 Measures No. 1) Regulations 2017

This Legislative Instrument 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 Legislative Instrument

The Regulation amends the GMST and PST to implement measures announced in the 2016-17 MYEFO in the *Investing in Medicare — Medicare Benefits Schedule — new and amended listings* measure. The Regulation commences from 1 May 2017.

Human rights implications

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

The Right to Health

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

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

The Right to Social Security

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

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

Analysis

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

Conclusion

The Legislative Instrument is compatible with human rights because it maintains existing arrangements and the protection of human rights.

Greg Hunt
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