EXPLANATORY STATEMENT

Select Legislative Instrument No. 238, 2015

Health Insurance Act 1973

Health Insurance (General Medical Services Table) Amendment (Lipectomy and Other Measures) Regulation 2015

Subsection 133(1) of the *Health Insurance Act 1973* (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 medical services which set out items of medical services, the fees applicable for each item, and rules for interpreting the table. The *Health Insurance (General Medical Services Table) Regulation 2015* (GMST) currently prescribes such tables.

Purpose

The purpose of the *Health Insurance (General Medical Services Table) Amendment (Lipectomy and Other Measures) Regulation 2015* (the Regulation) is to create new items for Intensity Modulated Radiation Therapy (IMRT) and Image-Guided Radiation Therapy (IGRT) for the treatment of cancer, and make amendments to existing lipectomy items (removal of excess skin and fatty tissue) to prevent the use of these services for cosmetic purposes. The Regulation will introduce the following changes:

- New MBS items for IMRT and IGRT in the treatment of cancer
 This change will introduce four new MBS items for the treatment of various
 forms of cancer. The treatment, known as IMRT, and the associated
 verification scans, known as IGRT, is already being provided through existing,
 non-specific MBS items for radiotherapy. The changes will list four new
 items:
 - two items for IMRT planning (one item for simulation and one item for dosimetry);
 - o one item for IMRT treatment; and
 - o one item for IGRT verification imaging.

The listing of specific items for IMRT and IGRT will allow better identification of usage and need. IMRT is currently billed under existing MBS items for three-dimensional conformal radiotherapy (3D-CRT), and IGRT is billed under existing MBS items for external-beam radiation verification.

• The amendment of four existing items, deletion of an existing item and addition of three new items for lipectomy

These amendments are being made to ensure that eligible patients have access to clinically relevant lipectomy services related to significant weight loss,

refractory skin conditions and impeded function, while preventing the use of these services for cosmetic purposes. The changes include:

- o amend the descriptors of existing items 30165, 30168, 30171 and 30177 to limit availability of these lipectomy services to patients who have undergone massive weight loss and have skin integrity issues, who as a result, are being impeded in their daily activities;
- o list three new items 30172, 30176 and 30179;
- o delete item 30174; and
- o make minor amendments to the descriptors of items 45530, 45564, 45565 to remove references to 30174 and list the three new items as services which are not associated.

Consultation

Consultation was undertaken on the changes in the Regulation. All changes were considered and agreed to by the Medical Services Advisory Committee (MSAC).

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 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.

During the MSAC process, relevant organisations and individuals interested (or directly involved) in cancer, radiation oncology and radiotherapy, as well as those who subscribe to the MSAC Bulletin, provided feedback on the IMRT and IGRT applications. These included:

- The Faculty of Radiation Oncology (FRO) within the Royal Australian and New Zealand College of Radiologists (RANZCR);
- The Australasian College of Physical Scientists and Engineering in Medicine (ACPSEM);
- The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA);
- Cancer Voices Australia,
- Individual consumers and specialists:
- Device companies; and
- Researchers.

The Department also worked with a lipectomy review working group to draft the amendments to Medicare Benefits Schedule items for lipectomy services. The group comprised representatives of the Australian Society of Plastic Surgeons (ASPS), the Australian Medical Association, and the Obesity Surgery Society of Australia and New Zealand (OSSANZ). It met in December 2013, June 2014, September and December 2014.

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 will be a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulation will commence on 1 January 2016.

Authority: Subsection 133(1) of the

Health Insurance Act 1973

ATTACHMENT

Details of the Health Insurance (General Medical Services Table) Amendment (Lipectomy and Other Measures) Regulation 2015

Section 1 – Name of regulation

This section provides for the Regulation to be referred to as the *Health Insurance (General Medical Services Table) Amendment (Lipectomy and Other Measures) Regulation 2015.*

Section 2 – Commencement

This section provides for the Regulation to commence on 1 January 2016.

Section 3 – Authority

This section provides that this instrument 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

Part 1—Lipectomy procedures

Health Insurance (General Medical Services Table) Regulation 2015

Item [1] – Schedule 1 (repeals items 30165 to 30177)

This item will repeal items 30165 to 30177 and replace with items 30165, 30168, 30171, 30172, 30176, 30177 and 30179. This change will incorporate the amendments to items 30165, 30168, 30171 and 30177; remove item 30174; and add new items 30172, 30176 and 30179.

Item [2] – Schedule 1 (item 45530, column headed "Description")

This item will remove item 30174 from the list of items that cannot be used in association with item 45530 and add new items 30172, 30176 and 30179.

Item [3] – Schedule 1 (item 45564, column headed "Description")

This item will remove item 30174 from the list of items that cannot be used in association with item 45564 and add new items 30172, 30176 and 30179.

Item [4] – Schedule 1 (item 45565, column headed "Description")

This item will remove item 30174 from the list of items that cannot be used in association with item 45565 and add new items 30172, 30176 and 30179.

Part 2—Radiation oncology

Health Insurance (General Medical Services Table) Regulation 2015

Item [5] – Schedule 1 after clause 2.38.2

This item will insert clauses "2.38.2A Meaning of IGRT" and "2.38.2B Meaning of IMRT" to clarify the meanings of IGRT and IMRT in the four new items.

Item [6] – Schedule 1 after clause 2.38.3

This item will insert clause "2.38.3A Application of items 15215 to 15272" to restrict the use of these items if the new dosimetry item 15565 had been claimed.

Item [7] – Schedule 1 (insert item 15275)

This item will insert new item 15275 for radiotherapy treatment by IMRT treatment delivery. The new item will be inserted into Subgroup 3 – Megavoltage.

Item [8] – Schedule 1 (insert item 15555)

This item will insert item new 15555 for simulation for IMRT. The new item will be inserted into Subgroup 5 – Computerised planning.

Item [9] – Schedule 1 (insert item 15565)

This item will insert new item 15565 for the preparation of an IMRT dosimetry plan. The new item will be inserted into Subgroup 5 – Computerised planning.

Item [10] – **Schedule** 1 (insert item 15715)

This item will insert new item 15715 for IGRT verification of radiation oncology treatment delivered using IMRT.

Item [11] – Schedule 1, Part 3

This item will insert a reference in the dictionary to the meanings of IGRT and IMRT in clauses 2.38.2A and 2.38.2B.

Statement of Compatibility with Human Rights

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

Health Insurance (General Medical Services Table) Amendment (Lipectomy and Other Measures) Regulation 2015

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 will create new items for Intensity Modulated Radiation Therapy (IMRT) and Image-Guided Radiation Therapy (IGRT) for the treatment of cancer, and make amendments to existing lipectomy items (removal of excess skin and fatty tissue) to prevent the use of these services for cosmetic purposes.

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 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.

Sussan Ley Minister for Health