

EXPLANATORY STATEMENT

Select Legislative Instrument No. 84, 2015

Health Insurance Act 1973

Health Insurance (General Medical Services Table) 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 the regulations may prescribe a table of general medical services which sets 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 2014* (GMST) currently prescribes such a table.

Subsection 4(2) of the Act provides that unless repealed earlier, this regulation will cease to be in force and will be taken to have been repealed on the day following the 15th sitting day of the House of Representatives after the end of a 12 month period which begins on the day when the regulation is registered on the Federal Register of Legislative Instruments (FRLI). The GMST was registered on the FRLI on 13 June 2014.

The purpose of the regulation is to repeal the GMST and prescribe a new table of general medical services for the 12 month period beginning on 1 July 2015, to ensure that Medicare benefits continue to be payable for services listed in the GMST. Additionally, this regulation makes machinery amendments to the GMST by:

- Removing reference to items 18356 and 18358 from the item descriptor for item 18292. Reference to items 18356 and 18358 serves no purpose as these items were deleted from the GMST on 1 November 2014,
- Moving four new items (18353, 18365, 18369, and 18374) and the restrictions applied to these items from the *Health Insurance (IncobotulinumtoxinA) Determination 2015* (the Determination) into the GMST. These items were listed in the Determination as an interim arrangement to accommodate for the Government's decision to allow for the payment of Medicare benefits for the administering of Xeomin, which was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 April 2015, to treat the following conditions:
 - cervical dystonia (a painful condition in which neck muscles contract involuntarily, causing your head to twist or turn to one side),
 - blepharospasm (involuntary twitching, blinking, closure or squeezing of the eyelids) in adults, and
 - post-stroke spasticity of the upper limb.

As the Determination will cease on 30 June 2015, the new items are being transferred and continued under the GMST. The items (18352, 18364, 18371, and 18373) which the new items effectively replace are being deleted from the GMST. The only difference between the four new items and the four existing items being replaced is that Xeomin is being added to the new items as another type of botulinum toxin that can be administered as part of the service.

- Amending clause 2.42A.1, which relates to the injection of botulinum toxin. The amendments do not change the current requirements. The amendments provide clearer drafting to specify under which circumstances the administering of botulinum toxin can occur. The amendments:
 - firstly, clarify at subclause 2.42A.1(1) that the services described in items 18350 to 18379 do not include the supply of the botulinum toxin. This ensures that the Medicare benefit is payable for the medical service of administering the toxin, not the cost of the drug, and
 - secondly, clarify at subclause 2.42A.1(2), in the interest of patient safety, that all botulinum toxin items in Group T11, except for four items (18360, 18365, 18366, and 18368), cannot be claimed unless the botulinum toxin that is injected is supplied through the PBS as set out under the *National Health Act 1953*. The current PBS arrangements have practitioner restrictions to ensure that only qualified specialists and consultant physicians can supply botulinum toxin to patients. There are no equivalent PBS arrangements for items 18360, 18365, 18366 and 18368 so the practitioner restrictions have been explicitly stated in subclause 2.42A.1(2) so that only a specialist or consultant physician can provide items 18360, 18365, 18366 and 18368 if the service is provided in the practice of his or her speciality.

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 *Legislative Instruments Act 2003*.

The regulation commences on 1 July 2015.

Consultation

Consultation was not undertaken for this instrument as it is machinery in nature and it does not alter existing arrangements.

Consultation was conducted during the process for the initial listing of the four new items to enable Medicare benefits to be paid for the injection of Xeomin under the *Health Insurance (IncobotulinumtoxinA) Determination 2015*. The four items which are being incorporated into the GMST were introduced in accordance with recommendations of the Medical Services Advisory Committee (MSAC) Executive.

In October 2014, the MSAC Executive supported the creation of new items for the listing of professional services to inject Xeomin for the specific indications. The MSAC Executive advised that the eligible population and conditions of use for the items should reflect the corresponding Pharmaceutical Benefits Scheme restrictions.

During the MSAC Executive's assessment of the application to list items for the injection of Xeomin, the application was made available for public comment. As part of this process, stakeholders and professional groups were given an opportunity to provide feedback on the application. No feedback was received opposing the introduction of the new Xeomin items.

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

ATTACHMENT

DETAILS OF THE HEALTH INSURANCE (GENERAL MEDICAL SERVICES TABLE) REGULATION 2015Section 1 – Name of regulation

This section provides for the instrument to be referred to as the *Health Insurance (General Medical Services Table) Regulation 2015* (the Regulation).

Section 2 – Commencement

This section provides for the instrument to commence on 1 July 2015.

Section 3 – Authority

This instrument is made under the *Health Insurance Act 1973*.

Section 4 – Schedule(s)

This section provides that each instrument specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned.

Section 5 – General medical services table

This section provides that the new table of general medical services set out in Schedule 1 be prescribed for subsection 4(1) of the Act.

Section 6 – Dictionary

This section provides for a Dictionary at the end of the instrument, which defines certain words and expressions used in the instrument, and includes references to certain words and expressions which are defined elsewhere in the instrument.

Part 2 of Schedule 1 – General medical services table

This part of the instrument continues the general medical services table and makes the following machinery amendments to the previous table by:

- Removing reference to items 18356 and 18358 from the item descriptor for item 18292
- Moving the substance of the *Health Insurance (IncobotulinumtoxinA) Determination 2015* into the GMST at clauses 2.42A.1 and 2.42A.2, and removing items 18352, 18364, 18371, and 18373 from the GMST
- Amending clause 2.42A.1 to clarify that items 18350 to 18379 do not include the supply of the botulinum toxin to which the service relates and that all items in Group T11, except items 18360, 18365, 18366, and 18368, do not apply if the injection of botulinum toxin is not supplied through the PBS. Subclause 2.42A.1(2), limits the

provision of items 18360, 18365, 18366 and 18368 to specialists and consultant performing the service in the practice of their speciality.

Schedule 2 – Repeal

This section repeals the *Health Insurance (General Medical Services Table) Regulation 2014*.

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) 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 *Health Insurance (General Medical Services Table) Regulation 2015* repeals the *Health Insurance (General Medical Services Table) Regulation 2014* (GMST) to ensure that Medicare benefits continue to be payable for services listed in the GMST.

In accordance with section 4(1) of the Act, the regulation prescribes a table of general medical services containing: items of services, the amounts of fees applicable for each item, and rules for interpretation. The amendments to the regulation involve the:

- Removal of reference to items 18356 and 18358 from the item descriptor for item 18292. Reference to items 18356 and 18358 serves no purpose as these items were deleted from the GMST on 1 November 2014,

Transfer of four items (18353, 18365, 18369, and 18374) and the restrictions applied to these items from the *Health Insurance (IncobotulinumtoxinA) Determination 2015* (the Determination) into the GMST. These items were listed in the Determination as an interim measure to accommodate for the Government's decision to allow the services described in items 18352, 18364, 18371, and 18373 to also cover the provision of Xeomin, which was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 April 2015. As the Determination will cease on 30 June 2015, the items in the Determination will be transferred to the GMST. The items which the new items effectively replace (18352, 18364, 18371, and 18373) are to be deleted from the GMST. The only difference between the four new items and the four existing items being replaced is that Xeomin is being added as another type of botulinum toxin that can be administered as part of the service.

- Amendment to clause 2.42A.1, which relates to the injection of botulinum toxin to:
 - firstly, clarify at subclause 2.42A.1(1) that the services described in items 18350 to 18379 do not include the supply of the botulinum toxin. This ensures that the Medicare benefit is payable for the medical service of administering the toxin, not the cost of the drug, and
 - secondly, clarify at subclause 2.42A.1(2) that all botox items in Group T11, except for four items (18360, 18365, 18366, and 18368), cannot be claimed unless the botulinum toxin that is injected is supplied through the PBS as set

out under the *National Health Act 1953*. The current PBS arrangements have practitioner restrictions to ensure that only qualified specialists and consultant physicians can supply botulinum toxin to patients. There are no equivalent PBS arrangements for items 18360, 18365, 18366 and 18368 so the practitioner restrictions have been explicitly stated in subclause 2.42A.1(2) so that only a specialist or consultant physician can provide items 18360, 18365, 18366 and 18368 if the service is provided in the practice of his or her speciality.

Human rights implications

The regulations engage Articles 2, 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 is one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

Analysis

The amendments to the regulation maintain current rights to health and social security by maintaining access to publicly subsidised health services. The amendment to the item descriptor for item 18292 ensures that it no longer makes reference to two redundant items.

The Determination introduced four new items to the Medicare Benefits Schedule (MBS) to enable Medicare benefits to be paid for the injection of IncobotulinumtoxinA (Xeomin), for the treatment of cervical dystonia (a painful condition in which neck muscles contract

involuntarily), blepharospasm (involuntary twitching, blinking, closure or squeezing of the eyelids) in adults, and post-stroke spasticity of the upper limb in adults. The new items were introduced in accordance with the recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC) Executive. As the Determination will cease on 30 June 2015, the substance of this Determination will be transferred to the GMST for Medicare benefits to continue to be paid for these services for the benefit of patients.

The amendments to clause 2.42A.1 clarify current arrangements; that services described in Group T11 are not to include the supply of the botulinum toxin, and that most items in Group T11 cannot be claimed unless the botulinum toxin is supplied through the PBS. The PBS currently includes practitioner restrictions for the supply of the botulinum toxin to ensure that patients receive services from appropriately qualified practitioners. In the instances of items 18360, 18365, 18366 and 18368 where there is no equivalent PBS arrangements, the practitioner restrictions to ensure patient safety are provided explicitly in clause 2.42A.2.

Conclusion

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

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