

EXPLANATORY STATEMENT

Select Legislative Instrument No. 149, 2014

Health Insurance Act 1973

Health Insurance Legislation Amendment (General Medical Services Table and Other Measures) Regulation 2014

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.

Section 4 of the Act provides that regulations may prescribe a table of 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) Regulations 2014* (GMST) currently prescribes such table. The regulation amends the GMST to implement 2014-15 Budget measures and otherwise ensure that the medical services funded through the Medicare Benefits Schedule (MBS) continue to be up-to-date, representative of best medical practice, and reflective of government commitments.

The *Health Insurance Regulations 1975* (HI Regulations) prescribes other 'matters' which the Governor-General may make regulations for in accordance with subsection 133(1) of the Act. The regulation amends the HI Regulations to implement the 2014-15 Budget measure 'Rebuilding general practice education and training'.

The regulation includes the following changes to the GMST, that will take effect on 1 November 2014;

- remove rule 2.34.3 and insert the exact same rule into the item descriptor for item 12250 to clarify the scope of the rule,
- amend subclause 2.42A.1(1) to make clear that items under Division 2.42A, which have corresponding pharmaceutical benefits, must be administered in accordance with the *National Health (Botulinum Toxin Program) Special Arrangement 2011*,
- amend subclause 2.42A.1(2) to make clear that the subclause is to apply to new botox item 18379,
- amend 14 items in Group T11 to reflect a more simplified item structure that does not change existing requirements/restrictions or MBS fees for injecting botulinum toxin. This simplified item structure will result in the removal of items 18356 and 18358 from the GMST as the clinical indications for these items will be incorporated in item 18354,

- introduce new item 18379 for the intravesical injection of Botox® for the treatment of certain patients with urinary incontinence due to idiopathic overactive bladder, and consequentially amend items 36851 and 37339 to ensure that a service to which the new item applies cannot be claimed with items 36851 and 37339,
- amend Division 2.37 to make clear that three assisted reproductive technology items which can only be performed as part of a *'treatment cycle'* can be provided more than 30 days after the start of the treatment cycle, to ensure that patients with an irregular menstrual cycle are not disadvantaged,
- remove the restriction on co-claiming the introduction of an intra-uterine contraceptive device (35503) with a service which removes an etonogestrel subcutaneous implant (30062), as it is clinically appropriate for these two services to occur in the same consultation,
- amend five rhinoplasty items (45632, 45635, 45641, 45644, and 45650) to include reference to clinical indications, and
- clarify the clinical conditions for vulvoplasty item 35533 by splitting it into two separate items (35533 and 35534) to better articulate the clinical conditions to which the service applies.

The regulation will include the following changes to the GMST, that will take effect on 1 January 2015;

- insert a new clause that restricts practitioners from billing MBS items for services provided in connection with injections of blood or blood product that are autologous, as these services have not been assessed by the Medical Services Advisory Committee (MSAC) as suitable for MBS funding,
- amend items 13703 and 13706 to clarify they are intended to be used for transfusions only and not for blood (or other blood product) injections,
- delete paragraph (f) of clause 1.1.1A and the definition of General Practice Education and Training Limited (GPET) in Part 3 to implement the 2014-15 Budget measure *'Rebuilding general practice education and training'*, and
- insert a transitional provision in Schedule 2 to ensure Registrars who commence a placement under Prevocational General Practice Placements Program (PGPPP) before 1 January 2015, will continue to fall within the definition of *'general practitioner'* in clause 1.1.1A for the duration of their placement.

The regulation includes the following amendments to the HI Regulations:

- delete subclauses 27(9) and 27(10) as a result of GPET being wound up,
- insert a transitional provision to enable the Department of Health to give the Chief Executive of Medicare written notice, in accordance with paragraph 3GB(1)(b) of the Act, that a medical practitioner participating in either the PGPPP or the Australian

General Practice Training Program (AGPTP) is no longer enrolled in or undertaking the program,

- delete reference to GPET from item 6 in Part 2 of Schedule 5 and replace it with “Health Department”,
- delete item 7 in Part 2 of Schedule 5 which refers to the PGPPP as this program will cease on 31 December 2014, and
- delete reference to the “RACGP Training Program” as it ceased operating in 2002.

Consultation

The Department of Health has consulted with the Department of Human Services, the Department of Veterans’ Affairs, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal Australian College of General Practice, the Australian Medical Association, the Thoracic Society of Australia, the Australasian Sleep Association, the Australian Society of Plastic Surgeons, the Australian Society of Otolaryngology Head and Neck Surgery, the Australian and New Zealand Association of Oral and Maxillofacial Surgeons, and all other relevant professional medical groups as well as the Medical Services Advisory Committee.

Stakeholder groups have expressed their approval for the changes to proceed.

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 as follows: Sections 1 to 4 of the regulation commence on the day after this instrument is registered; Schedule 1, Parts 1 to 6 of the regulation commence on 1 November 2014; and Schedule 1, Parts 7 to 8 of the regulation commence on 1 January 2015.

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

ATTACHMENT

Details of the Health Insurance Legislation Amendment (General Medical Services Table and Other Measures) Regulation 2014**Section 1 – Name**

This section provides for the regulation to be referred to as the *Health Insurance Legislation Amendment (General Medical Services Table and Other Measures) Regulation 2014*.

Section 2 – Commencement

This section provides for the regulation to commence as follows:

- (a) on the day after this instrument is registered – Sections 1 to 4,
- (b) on 1 November 2014 – Schedule 1, Parts 1 to 6, and
- (c) on 1 January 2015 – Schedule 1, Parts 7 to 8.

Section 3 – Authority

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

Section 4 – Schedules

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.

Schedule 1 – Amendments**Part 1 – Home-based sleep studies****Item [1] – Clause 2.34.3 of Schedule 1**

This item repeals clause 2.34.3 to allow for the restriction to be included in item 12250.

Item [2] – Schedule 1 (item 12250, column headed “description”, after paragraph (e))

This item inserts paragraph (f) in item 12250 which restricts item 12250 from being provided on the same occasion as another service mentioned in items 11000 to 11005, 11503, 11700 to 11709, 11713 and 12203.

Item [3] – Clause 2.35.1 of Schedule 1

This item omits “home-based sleep studies” from clause 2.35.1 of Schedule 1 and substitute it with “the service described in item 12250”.

Part 2 – Botulinum toxin

Item [4] – Subclause 2.42A.1(1) of Schedule 1

This item repeals subclause 2.42A.1(1) and substitute it with a new subclause that provides that services in items 18350 to 18354, 18361, 18362 and 18370 to 18379 are to be administered in accordance with the *National Health (Botulinum Toxin Program) Special Arrangement 2011*.

Item [5] – Subclause 2.42A.1(2) of Schedule 1

This item amends subclause 2.42A.1(2) to remove reference to item “18377” and substitute it with reference to item “18379”.

Item [6] – Schedule 1 (items 18350 to 18377)

This item repeals items 18350 to 18377 and substitute these items with fourteen simplified items that do not change existing requirements and restrictions, and new item 18379.

Item [7] – Schedule 1 (item 36851, column headed “Description”)

This item amends item 36851 to include reference to item 18379. The reference to item 18379 makes clear that the service in item 36851 is not a service associated with a service to which item 18379 applies.

Item [8] – Schedule 1 (item 37339, column headed “Description”)

This item amends item 37339 to include reference to item 18379. The reference to item 18379 makes clear that the service in item 37339 is not a service associated with a service to which item 18379 applies.

Part 3 – Assisted reproductive technology

Item [9] – Clause 2.37.3 of Schedule 1

This item amends clause 2.37.3 by replacing items “13212 to 13221” in the clause with items “13215 and 13218”.

Item [10] – Clause 2.37.3 of Schedule 1 (paragraph (b) of the definition of *treatment cycle*)

This item repeals paragraph (b) of clause 2.37.3 and substitute it with a new paragraph that makes clear that a treatment cycle for assisted reproductive services ends either on the day after the day on which item 13212, 13215 or 13221 is provided or not more than 30 days after the day on which the treatment begins.

Item [11] – Subclauses 2.37.4(1) and (2) of Schedule 1

This item repeals subclauses 2.37.4(1) and (2) and substitute the subclauses with two new subclauses that make clear that services that are *associated* with services provided as part of a treatment cycle under Subgroup 3 of Group T1, would not be claimable for the period of the treatment cycle if the *associated* services do not fall within Subgroup 3 of Group T1.

Item [12] – Schedule 1 (items 13212, 13215 and 13221)

This item amends the item descriptors for items 13212, 13215 and 13221, to make clear that they must be rendered in “connection” with other items in Subgroup 3 of Group T1.

Item [13] – Part 3 of Schedule 1 (definition of *treatment cycle*)

This item removes reference to items “13212 to 13221” in the definition of treatment cycle in Part 3 and replace it with reference to items “13215 and 13218”.

Part 4 – Intra-uterine contraceptive devices**Item [14] – Schedule 1 (cell at item 35503, column headed “Description”)**

This item repeals the descriptor for item 35503 and substitutes it with a new descriptor that makes clear that in situations where item 30062 is associated with item 35503 the service described in item 35503 is eligible for a Medicare benefit.

Part 5 – Rhinoplasty services**Item [15] – Schedule 1 (item 45632)**

This item amends the item descriptor for item 45632 to include “for correction of nasal obstruction”.

Item [16] – Schedule 1 (item 45635)

This item amends the item descriptor for item 45635 to include “for correction of nasal obstruction or post-traumatic deformity (other than deformity resulting from previous elective cosmetic surgery), or both”.

Item [17] – Schedule 1 (item 45641)

This item amends the item descriptor for item 45641 to include “for correction of nasal obstruction or post-traumatic deformity (other than deformity resulting from previous elective cosmetic surgery), or both”.

Item [18] – Schedule 1 (item 45644)

This item amends the item descriptor for item 45644 to include “total, including correction of all bony and cartilaginous elements of the external nose” and “for correction of nasal obstruction or post-traumatic deformity (other than deformity resulting from previous elective cosmetic surgery) or significant developmental deformity”.

Item [19] – Schedule 1 (item 45650)

This item amends the item descriptor for item 45644 to include “for correction of nasal obstruction, post-traumatic deformity (other than deformity resulting from previous elective cosmetic surgery) or significant developmental deformity”.

Part 6 – Vulvoplasty services**Item [20] – Schedule 1 (item 35533)**

This item effectively splits item 35533 into two items (35533 and 35534) to better articulate the clinical conditions to which the service applies.

Part 7 – Autologous blood injections**Item [21] – Clause 1.2.7 of Schedule 1 (heading)**

This item introduces a new heading for clause 1.2.7 - “Application of items – services provided with non-medicare services”.

Item [22] – After clause 1.2.7 of Schedule 1

This item introduces new clause 1.2.7A to restrict items in the table from being claimed if the service in that item is provided to the patient at the same time, or in connection with, an injection of blood or a blood product that is autologous.

Item [23] – Schedule 1 (items 13703 and 13706)

This item omits “Administration” from items 13703 and 13706 and substitute it with “Transfusion”.

Part 8 – General Practice Education and Training Limited**Item [24] – After section 6**

This item inserts new regulation 7 that provides for transitional provisions to be included in Schedule 1A.

Item [25] – Clause 1.1.1A of Schedule 1 (paragraph (f) of the definition of *general practitioner*)

This item repeals paragraph (f) to implement the 2014-15 Budget measure ‘*Rebuilding general practice education and training*’.

Item [26] – Part 3 of Schedule 1 (definition of GPET)

This item removes the definition of GPET from part 3 to implement the 2014-15 Budget measure ‘*Rebuilding general practice education and training*’.

Item [27] – After Schedule 1

This item inserts a transitional provision to ensure Registrars who commence a placement under PGPPP before 1 January 2015, continue to fall within the definition of ‘*general practitioner*’ in clause 1.1.1A for the duration of their placement.

Item [28] – Subregulation 2(1)

This item inserts a definition for ‘Health Department’ into the *Health Insurance Regulations 1975* to implement the 2014-15 Budget measure ‘*Rebuilding general practice education and training*’.

Item [29] – Subregulations 27(9) and (10)

This item removes subregulations 27(9) and (10) from the *Health Insurance Regulations 1975* to implement the 2014-15 Budget measure ‘*Rebuilding general practice education and training*’.

Item [30] – After regulation 31

This item inserts a transitional provision into the *Health Insurance Regulations 1975* to enable the Department of Health to give the Chief Executive of Medicare written notice, in accordance with paragraph 3GB(1)(b) of the Act, that a medical practitioner participating in either the PGPPP or the Australian General Practice Training Program (AGPTP) is no longer enrolled in or undertaking the program.

Item [31] – Part 2 of Schedule 5 (cells at table items 1 to 5, column headed “Body”)

This item removes references to the “Commonwealth Department of Health and Ageing” in Part 2 of Schedule 5 (table items 1 to 5) of the *Health Insurance Regulations 1975* and replace it with references to the “Health Department”.

Item [32] – Part 2 of Schedule 5 (table items 6 and 7)

This item removes reference to GPET in Part 2 of Schedule 5 (table items 6 and 7) of the *Health Insurance Regulations 1975* and replace it with reference to the ‘Health Department’, to implement the 2014-15 Budget measure ‘*Rebuilding general practice education and training*’.

Item [33] – Part 2 of Schedule 5 (table item 13)

This item removes reference to the “RACGP Training Program” from Part 2 of Schedule 5 (table item 13) of the *Health Insurance Regulations 1975* as it ceased operating in 2002.

Statement of Compatibility with Human Rights

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

Health Insurance Legislation Amendment (General Medical Services Table and Other Measures) Regulation 2014

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 Legislation Amendment (General Medical Services Table and Other Measures) Regulation 2014* (the Amendment Regulation) amends the *Health Insurance (General Medical Services Table) Regulation 2014* (GMST) and the *Health Insurance Regulations 1975* (HI Regulations), to implement 2014-15 Budget measures and otherwise ensure that services funded through the Medicare Benefits Schedule (MBS) continue to be up-to-date, representative of best medical practice, and reflective of government commitments.

In accordance with section 4(1) of the *Health Insurance Act 1973* (the Act), the GMST prescribes a table of medical services containing items of medical services, the amounts of fees applicable for each item, and rules for interpretation. The HI Regulations prescribe other 'matters' which the Governor-General may make regulations for in accordance with subsection 133(1) of the Act.

The regulation will amend the GMST on 1 November 2014 by;

- removing rule 2.34.3 and inserting the exact same rule into the item descriptor for item 12250 to clarify the scope of the rule,
- amending subclause 2.42A.1(1) to make clear that items under division 2.42A of the GMST, which have corresponding pharmaceutical benefits, must be administered in accordance with the *National Health (Botulinum Toxin Program) Special Arrangement 2011*,
- amending subclause 2.42A.1(2) to ensure it applies to new botox item 18379,
- amending 14 items in Group T11 to reflect a more simplified item structure that does not change existing requirements/restrictions or MBS fees for injecting botulinum toxin. The simplified item structure will result in the removal of items 18356 and 18358 as the clinical indications for these items will be incorporated in item 18354,
- introducing new item 18379 for the intravesical injection of Botox® for the treatment of certain patients with urinary incontinence due to idiopathic overactive bladder, and consequentially amending items 36851 and 37339 to ensure that a service to which the new item applies cannot be claimed with items 36851 and 37339,
- amending Division 2.37 to make clear that three assisted reproductive technology items which can only be performed as part of a 'treatment cycle' can be provided more than 30 days after the start of the treatment cycle, to ensure that patients with an irregular menstrual cycle are not disadvantaged,

- removing the restriction on co-claiming the introduction of an intra-uterine contraceptive device (35503) with a service which removes an etonogestrel subcutaneous implant (30062), as it is clinically appropriate for these two services to occur in the same consultation,
- amending five rhinoplasty items (45632, 45635, 45641, 45644, and 45650) to include reference to clinical indications, and
- clarifying the clinical conditions for vulvoplasty item 35533 by splitting it into two separate items (35533 and 35534) to better articulate the clinical conditions to which the service applies.

The regulation will amend the GMST on 1 January 2015 by;

- inserting a new clause that restricts practitioners from billing MBS items for services provided in connection with injections of blood or blood product that are autologous, as these services have not been assessed by the Medical Services Advisory Committee (MSAC) as suitable for MBS funding,
- amending items 13703 and 13706 to clarify they are intended to be used for transfusions only and not for blood (or other blood product) injections,
- deleting paragraph (f) of clause 1.1.1A and the definition of General Practice Education and Training Limited (GPET) in Part 3 to implement the 2014-15 Budget measure *'Rebuilding general practice education and training'*, and
- inserting a transitional provision to ensure Registrars who commence a placement under Prevocational General Practice Placements Program (PGPPP) before 1 January 2015, will continue to fall within the definition of *'general practitioner'* in clause 1.1.1A for the duration of their placement.

The regulation will amend the HI Regulations by:

- deleting subclauses 27(9) and 27(10) as a result of GPET being wound up by 31 December 2014,
- inserting a transitional provision to enable the Department of Health to give the Chief Executive of Medicare written notice, in accordance with paragraph 3GB(1)(b) of the Act, that a medical practitioner participating in either the PGPPP or the Australian General Practice Training Program (AGPTP) is no longer enrolled in or undertaking the program,
- deleting reference to GPET from item 6 in Part 2 of Schedule 5 and replacing it with "Department of Health",
- deleting item 7 in Part 2 of Schedule 5 which refers to the PGPPP as this program will cease on 31 December 2014, and
- deleting reference to the "RACGP Training Program" as it ceased operating in 2002.

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 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

The amendments primarily advance rights to health and social security by increasing access to publicly subsidised health services which are safe, clinically effective, and cost-effective. Specifically, the human rights implications are as follows;

- the removal of rule 2.34.3 and the insertion of the exact same rule into the item descriptor for item 12250 is administrative in nature and maintains the status quo,
- amendments to subclause 2.42A.1(1) ensures practitioners safely and appropriately administer botox services where a PBS benefit is payable, thereby advancing rights to safe and effective health care,
- the amendment to subclause 2.42A.1(2) to include reference to new botox item 18379, ensures the rule is consistently applied to MBS subsidised botox items, and does not change existing rights to health and social security,
- amendments to 14 botox items in Group T11 is administrative in nature and maintains the status quo,
- the introduction of new botox item 18379 effectively increases access to publicly subsidised health services and social security rights,
- amendments which allow for three assisted reproductive technology items to no longer be time bound to a 30 day *'treatment cycle'*, increases access to publicly subsidised health services and social security rights,
- the removal of the restriction on co-claiming the introduction of an intra-uterine contraceptive device with a service which removes an etonogestrel subcutaneous implant, increases access to publicly subsidised health services and social security rights,
- amendments to five rhinoplasty items to include reference to clinical indications clarifies the correct use of these services, thereby advancing rights to safe and effective health care,
- amendments to vulvoplasty item 35533 by splitting it into two separate items to better articulate the clinical conditions to which the service applies, advances rights to safe and effective health care,

- amendments that restricts practitioners from claiming experimental services related to injections of blood or a blood product that are autologous ensures Australians have access to quality and safe health care,
- amendments that reflect the winding up of GPET and its functions and programmes being transferred to the Department of Health, are part of the Government's initiative to rebuild general practice education and training to deliver more general practitioners and consequently increase rights to health,
- inserting a transitional provision to ensure practitioners, who commence a placement under the PGPPP in 2014, continue to fall within the definition of '*general practitioner*' until the duration of the placement ends ensures the status quo is maintained while practitioners have time to adapt to the new arrangements, and
- inserting a transitional provision to enable the Department of Health to give the Chief Executive of Medicare written notice referred to in paragraph 3GB(1)(b) of the Act in respect of practitioners under the PGPPP and AGPRT ensures the status quo is maintained while practitioners have time to adapt to new arrangements.

Conclusion

The Legislative Instrument is compatible with human rights because it advances the protection of human rights, and to the extent that it may limit human rights, those limitations are reasonable, necessary, and proportionate.

Peter Dutton
Minister for Health