EXPLANATORY STATEMENT

Select Legislative Instrument No. 148, 2014

Health Insurance Act 1973

Health Insurance (Diagnostic Imaging Services Table) 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.

Subsections 4(1) and 4AA(1) of the Act provides that the regulations may prescribe a table of medical and diagnostic imaging services which set out items of medical and diagnostic imaging services, the fees applicable for each item, and rules for interpreting the table. The *Health Insurance (Diagnostic Imaging Services Table) Regulation 2013* (the Principle Regulation) and the *Health Insurance (General Medical Services Table) Regulation 2014* (GMST Regulation) currently prescribe such tables. 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.

Subsection 4AA(2) of the Act provides that unless repealed earlier, the Principle Regulation will cease to be in force and will be taken to have been repealed on the day following the 15th sitting day of the House of Representatives after the end of a 12 month period which begins on the day when the Principle Regulation is registered on the Federal Register of Legislative Instruments. The Principle Regulation was registered on the Federal Register of Legislative Instruments on 26 November 2013 and commenced on 2 December 2013.

The purpose of the regulation is to repeal the Principle Regulation and prescribe a new table of diagnostic imaging services for the 12 month period beginning on 1 November 2014. The regulation also amends the Principle Regulation, the HI Regulations, and the GMST Regulation to implement a 2014-15 Budget measure and otherwise ensure that the diagnostic services funded through the Medical Benefits Schedule (MBS) continue to be up-to-date, representative of best medical practice, and reflective of government commitments.

The regulation amends the Principle Regulation, the HI Regulations and the GMST Regulation to implement the 2014-15 Budget measure, *'MBS – revised capital sensitivity provisions for diagnostic imaging equipment'*, which is to take effect on 1 January 2015. The capital sensitivity requirements in the Principle Regulation provide for reduced Medicare benefits for diagnostic imaging services performed using older diagnostic equipment. Those items with the symbol (NK) have a Schedule fee half that of the corresponding (K) item. The implementation of this Budget measure requires;

- 27 current MBS listed angiography items to be affected by the capital sensitivity requirements by making those items (K) items and listing corresponding (NK) items. This would ensure a consistent approach to the application of the capital sensitivity requirements. Consequentially, amendments are required to the HI Regulations and the GMST Regulation to include reference to the new (NK) angiography items where corresponding (K) items are referenced,

- the introduction of a '*maximum extended life age'* of 15 years for computed tomography (CT) and angiography equipment, to align these modalities with most of the other diagnostic imaging equipment,

- a transitional period of 12 months to enable CT and angiography equipment that has not already been updated during the *'new effective life age'* period to be eligible for the new *'maximum extended life age'*. This will allow providers with equipment that has not been upgraded in the *'new effective life age'* period, but has been upgraded any time before 1 January 2016 to be eligible for the *'maximum extended life age'* provisions for CT and angiography equipment, and

- the '*maximum extended life age'* for magnetic resonance imaging (MRI) equipment to be changed from 15 years to 20 years to more accurately reflect the life of a high quality, well maintained or 'rebuilt' MRI machine. As a consequence, amendments are required to the HI Regulations to reflect the updated '*maximum extended life age'* of the equipment.

The regulation amends the Principle Regulation to implement the 2014-15 Budget measure – *'restrictions on the ability of doctors to claim items associated with administering autologous blood injections',* which is to take effect on 1 January 2015. The implementation of this measure requires a new clause to be inserted 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).

The regulation also makes the following minor changes to Schedule 1 of the Principle Regulation and the HI Regulations, that will take effect on 1 November 2014;

- remove reference to item 55022 in paragraph (c) of item 55085, as item 55022 was removed from the Principle Regulation on 1 July 2014,

- list two new items (57362 and 57363) in the Principle Regulation, to replace items 56025 and 56026 which are to be removed from the MBS by repealing the *Health Insurance (Cone Beam Computed Tomography) Determination 2011.* The new items will be used for dental and temporo-mandibular joint imaging, and a range of restrictions will apply, as recommended by the MSAC. As the new items will be restricted to requesting by specialist dentists, the regulation would insert items 57362 and 57363 in rule 10(1)(c) of the HI Regulations. Other restrictions relate to co-claiming, and the equipment on which services can be performed, and

- update the Principle Regulation to reflect the *Requirements for Position Emission Tomography (PET) Accreditation (Instrumentation & Radiation Safety), 2nd Edition (2012).*

Consultation

The Department of Health has consulted the Diagnostic Imaging Advisory Committee (DIAC). The members of the DIAC include representatives from the Royal College of Radiologists, the Australian Medical Association, the Royal College of General Practitioners, the Australian Diagnostic Imaging Association, and representations from other industry groups. Public consultation was also undertaken as part of the usual Medical Services Advisory Committee process, with submissions received from the Royal Australian and New Zealand College of Radiologists.

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 commence on the day after this instrument is registered; Sections 5 and 6, Schedule 1 and 2, and Schedule 3, Part 1 commence on 1 November 2014; and Schedule 3, Parts 2 and 3 commence on 1 January 2015.

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

ATTACHMENT

Details of the *Health Insurance (Diagnostic Imagining Services Table) Regulation 2014*

Section 1 – Name

This section will provide for the regulation to be referred to as the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2014*.

Section 2 – Commencement

This section will provide 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 – Sections 5 and 6,
(c) on 1 November 2014 – Schedules 1 and 2,
(d) on 1 November 2014 – Schedule 3, Part 1, and
(e) on 1 January 2015 – Schedule 3, Parts 2 and 3.

Section 3 – Authority

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

Section 4 – Schedules

This section will provide 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 – Diagnostic imaging services table

This section will provide that the new table of diagnostic imaging services set out in Schedule 1 be prescribed for subsection 4AA(1) of the Act.

Section 6 – Dictionary

This section will provide for a Dictionary at the end of the regulation, which will define certain words and expressions used in the regulation, and will include references to certain words and expressions which are defined elsewhere in the regulation.

Schedule 1 – Diagnostic imaging services table

This part of the regulation will contain the following minor changes to Medicare services:

- remove the reference to item 55022 in paragraph (c) of item 55085,
- insert clause 2.2.6 which provides the restrictions to be applied to cone beam computed tomography (CBCT) items 57362 and 57363,
- insert new items 57362 and 57363 for CBCT,
- remove "dated 4 May 2007" from clause 2.4.4 and substitute it with "2nd Edition (2012)", and

- insert a definition of 'CBCT' and 'dental specialist' in Part 3.

Schedule 2 – Repeals

This section will repeal the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2013*.

Schedule 3 – Amendments

Part 1 – Technical amendments

Health Insurance Regulations 1975

Item [1] – Paragraph 10(1)(c)

This item will insert "57362, 57363" after item "56062" of paragraph 10(1)(c).

Item [2] – Subregulation 20C(2)

This item will omit "subclause 1.2.1C(1)" from subregulation 20C(2) and substitute it with "clause 1.2.2".

Item [3] – Subregulation 20C (2)

This item will omit "as the subclause" from subregulation 20C(2) and substitute it with "as that clause".

Part 2 – Capital sensitivity for computed tomography and angiography equipment

Health Insurance (Diagnostic Imaging Services Table) Regulation 2014

Item [4] – Subclause 1.2.2(2) of Schedule 1 (table items 2, column 4)

This item will omit " – " from subclause 1.2.2(2) of Schedule 1 (table item 2, column 4) and substitute it with "15".

Item [5] – Subclause 1.2.2(2) of Schedule 1 (table item 2, column 4)

This item will omit " – " from subclause 1.2.2(2) of Schedule 1 (table item 4, column 4) and substitute it with "15".

Item [6] – Subclause 1.2.2(2) of Schedule 1 (table item 7, column 4)

This item will omit "15" from subclause 1.2.2(2) of Schedule 1 (table item 7, column 4) and substitute it with "20".

Item [7] – After paragraph 1.2.2(3)(a)

This item will insert a new subclause which will provide for a transitional period of 12 months to enable CT and angiography equipment to be eligible for the new *'maximum extended life age'* that has not already been updated during the *'new effective life age'* period.

Item [8] – Schedule 1 (after item 60000)

This item will insert new (NK) item 60001.

Item [9] – Schedule 1 (after item 60003)

This item will insert new (NK) item 60004.

Item [10] – Schedule 1 (after item 60006)

This item will insert new (NK) item 60007.

Item [11] – Schedule 1 (after item 60009)

This item will insert new (NK) item 60010.

Item [12] – Schedule 1 (after item 60012)

This item will insert new (NK) item 60013.

Item [13] – Schedule 1 (after item 60015)

This item will insert new (NK) item 60016.

Item [14] – Schedule 1 (after item 60018)

This item will insert new (NK) item 60019.

Item [15] – Schedule 1 (after item 60021)

This item will insert new item 60022.

Item [16] – Schedule 1 (after item 60024)

This section will insert new (NK) item 60025.

Item [17] – Schedule 1 (after item 60027)

This item will insert new (NK) item 60028.

Item [18] – Schedule 1 (after item 60030)

This item will insert new (NK) item 60031.

Item [19] – Schedule 1 (after item 60033)

This item will insert new item 60034.

Item [20] – Schedule 1 (after item 60036)

This item will insert new (NK) item 60037.

Item [21] – Schedule 1 (after item 60039)

This item will insert new (NK) item 60040.

Item [22] – Schedule 1 (after item 60042)

This item will insert new (NK) item 60043.

Item [23] – Schedule 1 (after item 60045)

This item will insert new (NK) item 60046.

Item [24] – Schedule 1 (after item 60048)

This item will insert new (NK) item 60049.

Item [25] – Schedule 1 (after item 60051)

This item will insert new (NK) item 60052.

Item [26] – Schedule 1 (after item 60054)

This item will insert new (NK) item 60055.

Item [27] – Schedule 1 (after item 60057)

This item will insert new (NK) item 60058.

Item [28] – Schedule 1 (after item 60060)

This item will insert new (NK) item 60061.

Item [29] – Schedule 1 (after item 60063)

This item will insert new (NK) item 60064.

Item [30] – Schedule 1 (after item 60066)

This item will insert new (NK) item 60067.

Item [31] – Schedule 1 (after item 60069)

This item will insert new (NK) item 60070.

Item [32] – Schedule 1 (after item 60072)

This item will insert new (NK) item 60073.

Item [33] – Schedule 1 (after item 60075)

This item will insert new (NK) item 60076.

Item [34] – Schedule 1 (after item 60078)

This item will insert new (NK) item 60079.

Item [35] – Schedule 1 (items 60918 and 60927)

This item will omit "60078" from items 60918 and 60927, and substitute it with "60079".

Item [36] – Amendments of listed items – extending capital sensitivity to angiography equipment

This item will insert the symbol (K) into the item descriptor for items 60000, 60003, 60006, 60009, 60012, 60015, 60018, 60021, 60024, 60027, 60030, 60033, 60036, 60039, 60042, 60045, 60048, 60051, 60054, 60057, 60060, 60063, 60066, 60069, 60072, 60075, and 60078.

Health Insurance (General Medical Services Table) Regulation 2014

Item [37] – Subclause 2.44.12(2) of Schedule 1

This item will omit "60072, 60075 or 60078" from subclause 2.44.12(2) and substitute it with "60010, 60072, 60073, 60075, 60076, 60078 or 60079".

Item [38] – Schedule 1 (item 35412)

This item will omit "60072, 60075 or 60078" from item 35412 and substitute it with "60010, 60072, 60073, 60075, 60076, 60078 or 60079".

Health Insurance Regulations 1975

Item [39] – Paragraph 10(1)(a)

This item will omit "60009" from paragraph 10(1)(a) and substitute it with "60010".

Item [40] – Paragraph 10(1)(d)

This item will omit "60000, 60003, 60006, 60009" from paragraph 10(1)(d) and substitute it with "60000 to 60010".

Item [41] – Subregulation 20C(1) (after table item 6)

This item will insert new item 6A for computed tomography equipment K-type where the equipment is 10 years old or less.

Item [42] – Subregulation 20C(1) (table item 7, column 1)

This item will insert "upgraded" after "K-type" in subregulation 20C(1) (table item 7, column 1).

Item [43] – Subregulation 20C(1) (table item 7, column 4)

This item will insert in subregulation 20C(1) (table item 7, column 4) "the equipment is more than 10 years old and no more than 15 years old, and was upgraded on or before it was 10 years old or before 1 January 2016".

Item [44] – Subregulation 20C(1) (table item 8, column 4)

This item will insert in subregulation 20C(1) (table item 8, column 4) "the equipment is more than 10 years old and has not been upgraded, or was upgraded on or before it was 10 years old or before 1 January 2016, and is more than 15 years old".

Item [45] – Subregulation 20C(1) (table item 10, column 4, paragraph (a))

This item will omit "15" from subregulation 20C(1) (table item 10, column 4, paragraph (a)) and substitute it with "20".

Item [46] – Subregulation 20C(1) (table item 11, column 4, paragraph (b))

This item will omit "15" from subregulation 20C(1) (table item 11, column 4, paragraph (b)) and substitute it with "20".

Item [47] – Subregulation 20C(1) (after table item 18)

This item will insert new table item 18A to cover diagnostic radiology equipment for angiography (K-type) where the equipment is 10 years old or less.

Item [48] – Subregulation 20C(1) (table item 19, column 1)

This item will insert "upgraded" after "K-type" in subregulation 20C(1) (table item 19, column 1).

Item [49] – Subregulation 20C(1) (table item 19, column 4)

This item will insert in subregulation 20C(1) (table item 19, column 4) "the equipment is more than 10 years old and no more than 15 years old, and was upgraded on or before it was 10 years old or before 1 January 2016.

Item [50] – Subregulation 20C(1) (table item 20, column 4)

This item will insert in subregulation 20C(1) (table item 20, column 4) "the equipment is more than 10 years old and had not been upgraded, or was upgraded on or before it was 10 years old or before 1 January 2016 and is more than 15 years old.

Part 3 – Autologous blood injections

Health Insurance (Diagnostic Imaging Services Table) Regulation 2014

Item [51] – After clause 1.2.12 of Schedule 1

This item will introduce new clause 1.2.13 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.

Statement of Compatibility with Human Rights

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

Health Insurance (Diagnostic Imagining Services Table) 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 (Diagnostic Imaging Services Table) Regulation 2014* amends the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2013* (DIST), 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 diagnostic imaging 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 subsection 4AA(1) of the *Health Insurance Act 1973* (the Act) the regulation may prescribe a table of diagnostic imaging services which sets out items of services, the fees applicable for each item, and rules for interpreting the table. Schedule 1 of the DIST will be amended on 1 November 2014 by;

- the removal of reference to item 55022 in paragraph (c) of item 55085, as item 55022 was removed from the DIST on 1 July 2014 and is effectively non-existent,
- the listing of two new items (57362 and 57363) as a substitute for items 56025 and 56026 which are to be removed from the MBS by repealing the *Health Insurance (Cone Beam Computed Tomography) Determination 2011*. The new items will be used for dental and temporo-mandibular joint imaging, and a range of restrictions will apply, as recommended by the Medical Services Advisory Committee (MSAC). As the new items will be restricted to requesting by specialist dentists, the regulation would insert items 57362 and 57363 in rule 10(1)(c) of the HI Regulations. Other restrictions relate to co-claiming and the equipment on which services can be performed, and
- an amendment to reflect the *Requirements for Position Emission Tomography (PET) Accreditation (Instrumentation & Radiation Safety), 2nd Edition (2012).*

The regulation will also amend the DIST, the HI Regulations and the GMST Regulation on 1 January 2015 by;

- ensuring 27 current MBS listed angiography items are affected by the capital sensitivity requirements by making those items (K) items and listing corresponding (NK) items. This ensures a consistent approach to the application of the capital sensitivity requirements. Consequentially, amendments are required to the HI Regulations and the GMST Regulation to include reference to the new (NK) angiography items where corresponding (K) items are referenced,
- the introduction of a '*maximum extended life age'* of 15 years for computed tomography (CT) and angiography equipment, to align these modalities with most of the other diagnostic imaging equipment,

- a transitional period of 12 months to enable CT and angiography equipment that has not already been updated during the *'new effective life age'* period to be eligible for the new *'maximum extended life age'*. This will allow providers with equipment that has not been upgraded in the *'new effective life age'* period, but has been upgraded any time before 1 January 2016 to be eligible for the *'maximum extended life age'* provisions for CT and angiography equipment,
- the *'maximum extended life age'* for magnetic resonance imaging (MRI) equipment will be changed from 15 years to 20 years to more accurately reflect the life of a high quality, well maintained or 'rebuilt' MRI machine. As a consequence, amendments would be required to the HI Regulations to reflect the updated *'maximum extended life age'* of the equipment, and
- a new clause to be inserted in the DIST 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 MSAC.

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 to the regulation advance rights to health and social security primarily by increasing the quality of MBS subsidised services;

- the removal of reference to item 55022 in paragraph (c) of item 55085 is purely administrative and does not raise any human rights issues as item 55022 was removed from the MBS on 1 July 2014,
- the listing of two new Cone Beam Computed Tomography (CBCT) items to replace two interim funded CBCT items, supports the delivery of safe and clinically appropriate CBCT service provision by *inter alia* restricting those services to requesting dental specialists. This advances rights to quality, safe, and effective MBS subsidised services,
- the amendment to ensure the *Requirements for Position Emission Tomography (PET) Accreditation (Instrumentation & Radiation Safety), 2nd Edition (2012)* are reflected in the DIST, enhance the right of Australians to the highest attainable standard of health as it ensures providers comply with the most up-to-date requirements for PET accreditation,
- amendments to 27 angiography items to ensure they are affected by the capital sensitivity requirements effectively enhances the right of Australians to the highest attainable standard of health as it encourages providers to update their equipment in a reasonable time,
- the introduction of a '*maximum extended life age'* for CT and angiography equipment encourages providers to update their equipment in a time deemed suitable, thereby advancing the right of Australians to the highest attainable standard of health care,
- to accommodate for the introduction of a '*maximum extended life age'* for CT and angiography equipment, a twelve month transitional period will be introduced to allow providers time to update their equipment. This ensures health and social security rights are maintained while providers adjust to new arrangements,
- an amendment to the '*maximum extended life age'* for MRI equipment by changing it from 15 years to 20 years, ensures the requirements in the DIST more accurately reflect the life of a high quality, well maintained or 'rebuilt' MRI machine. This amendment maintains rights to health and social security, and
- the insertion of 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 ensures MBS subsidised services are safe and effective.

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