EXPLANATORY STATEMENT

Select Legislative Instrument No. 247, 2013

Health Insurance Act 1973

Health Insurance (Diagnostic Imaging Services Table) Regulation 2013

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.

The Act provides, in part, for payments of Medicare benefits in respect of professional services rendered to eligible persons. Section 9 of the Act provides that Medicare benefits shall be calculated by reference to the fees for medical services, including diagnostic imaging services, set out in prescribed tables.

Section 4AA of the Act provides that the regulations may prescribe a table of diagnostic imaging services that sets out items of R-type and NR-type diagnostic imaging services, the amount of fees applicable in respect of each item, and rules for interpretation of the diagnostic imaging services table. The *Health Insurance (Diagnostic Imaging Services Table) Regulation 2012* (the 2012 Regulation) currently prescribes such a table.

Subsection 4AA(2) of the Act provides that, unless repealed sooner, regulations made under subsection 4AA(1) cease to be in force and are taken to have been repealed on the day after the fifteenth sitting day of the House of Representatives after the end of the 12 month period, commencing on the day on which the regulations were notified on the Federal Register of Legislative Instruments. The 2012 Regulation was registered on the Federal Register of Legislative Instruments on 26 October 2012 and commenced on 1 November 2012.

The regulation repeals the 2012 Regulation and prescribes a new diagnostic imaging services table for the 12 month period commencing on the day after it is registered. The regulation sets out items of diagnostic imaging services that are eligible for Medicare benefits, the amount of fees applicable for each item and rules for interpretation of the table. The new table reproduces the table contained in the 2012 Regulation with some amendments to the rules and schedule of services.

Amendments to the Capital Sensitivity Measure
This arrangement was part of the 2009-10 Budget announcement for a *Review of Funding Arrangements for Diagnostic Imaging,* to ensure that the Government is paying the right amount in the right way to support patient access to quality diagnostic imaging services. From 1 July 2011 all diagnostic imaging services, with the exception of positron emission tomography (PET) and some angiography services, provided on equipment that has not been upgraded to the equivalent of new equipment, trigger a 50 per cent reduction in the Medicare rebates ((NK) items).

Capital sensitivity arrangements for diagnostic imaging services other than computed tomography (CT) and angiography are currently applied through the *Health Insurance (Diagnostic Imaging Capital Sensitivity) Determination 2011* (the CS Determination), which creates reduced fee (NK) items corresponding to all items in the 2012 Regulation (with the exception of CT, angiography and PET items). All CT and some angiography items have had

their own capital sensitivity arrangements in the diagnostic imaging services table from 1997 and 2001 respectively. The regulation applies capital sensitivity arrangements directly through the diagnostic imaging services table by moving 351 (NK) items and rules for their use previously contained in the CS Determination into the regulation. The CS Determination will be repealed on the day after the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2013* is registered.

Changes to items 61360, 61361, 61667 and 61668

The amendments substitute the generic word 'cholagogue' in the descriptor of items 61360, 61361, 61667 and 61668 for the word 'cholecystokinin'. Cholecystokinin is the name of a brand of the agent cholagogue which is required for this diagnostic imaging procedure. Cholecystokinin is no longer available in Australia.

Details of the regulation are set out in the Attachment.

The Act specifies no conditions that 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 the day after registration on the Federal Register of Legislative Instruments.

Consultation

There has been significant consultation with the relevant craft groups in the development of these measures under the *Diagnostic Imaging Reform Package* through the Diagnostic Imaging Advisory Committee (DIAC). Stakeholders who have been consulted include the Royal Australian and New Zealand College of Radiologists, the Australian Medical Association, the Australian Institute of Radiography, the Rural Doctors Association of Australia, the Royal Australian College of General Practitioners, the Australian College of Rural and Remote Medicine and the Australasian Association of Nuclear Medicine Specialists.

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

ATTACHMENT

Details of the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2013*

Part 1 – Preliminary

Section 1 – Name of regulation

This section provides for the regulation to be referred to as the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2013*.

Section 2 – Commencement

This section provides for the regulation to commence on the day after it is registered.

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 specified in a schedule to the regulation is amended or repealed as set out in the applicable item and any other item in a schedule is to have effect according to its terms.

Section 5 – Diagnostic imaging services table

This section provides that for the purpose of subsection 4AA(1) of the Act, this regulation prescribes a table of diagnostic imaging services (the Table) set out in Schedule 1.

Section 6 – Dictionary

This section provides that the dictionary in Part 3 of Schedule 1 defines certain words and expressions used in the regulation.

Section 7 – Transitional provisions

This section establishes transitional provisions relating to the transfer of capital sensitivity arrangements from the *Health Insurance (Diagnostic Imaging Capital Sensitivity) Determination 2011* (the CS Determination) to the regulation.

The CS Determination currently allows diagnostic imaging providers whose equipment is located in an inner regional area to apply, where certain conditions are met, for an exemption from the capital sensitivity arrangements (an inner regional exemption) to be granted by the Secretary of the Department of Health and Ageing (the Department). Where a proprietor holds an exemption, diagnostic imaging services provided on depreciated equipment could be claimed using the higher fee (K) items rather than the reduced fee (NK) items.

Under section 7:

- unfinalised applications for an inner regional exemption made under the CS Determination will be treated as having been made under the regulation (subsection 7(1));
- notifications of receipt of a valid application made under the CS Determination or refusal or grant an exemption will be treated as having been made under the regulation (subsections 7(2) and 7(5));
- current inner regional exemptions granted under the CS Determination will continue to have effect under the regulation (subsection 7(3));
- where a proprietor has been refused an inner regional exemption under the CS Determination but the time to apply for a reconsideration decision has not expired, or the Secretary has not notified the proprietor of a reconsideration decision, the refusal will be treated as having been made under the regulation (subsection 7(4));
- an application for a reconsideration decision made under the CS Determination will be treated as having been made under the regulation (subsection 7(6)); and
- a current delegation of the powers of the Secretary of the Department under the CS Determination continues in force despite the repeal of the CS Determination.

Schedule 1 – Diagnostic imaging services table

Schedule 1 sets out a diagnostic imaging service table which is similar to the Table in the 2012 Regulation with the following changes:

New Schedule 1, Part 1, Division 1.2, Subdivision A – Capital sensitivity

New Subdivision A of Division 1.2 sets out the capital sensitivity arrangements applying to the majority of items in the Table. As a result of the alignment of CT and angiography capital sensitivity arrangements with those applying to other modalities, clauses 1.2.4 and 2.2.1 of the 2012 Regulation, which set out capital sensitivity rules for angiography and CT services respectively, have been omitted from the regulation.

Schedule 1, Part 1, Division 1.2, Subdivision A – Clause 1.2.1

Clause 1.2.1 establishes when a reduced fee (NK) item for use on depreciated equipment applies to a diagnostic imaging service. Subclause 1.2.1(1) provides that reduced fee (NK) items apply to services performed on equipment:

- that has not been 'upgraded' (i.e. had additional reasonable investment and the age of which exceeds the 'new effective life age'; or
- that has been upgraded and the age of which exceeds the 'maximum extended life age for the equipment'.

The new effective life age and maximum extended life ages for the majority of diagnostic imaging modalities are 10 and 15 years, respectively (see clause 1.2.2). Equipment will be considered to have been upgraded if additional reasonable investment has been made within the new effective life age that improves the performance of the equipment to the standard of new equipment (see clause 1.2.2). Equipment will also be considered to be upgraded if it is accredited under the Royal Australian and New Zealand College of Radiologists' (RANZCR) Mammography Quality Assurance Program.

Subclause 1.2.1(2) provides that a higher fee (K) item does not apply to a service to which an (NK) item applies.

Clause 1.2.1 corresponds to subsection 6(1) of the CS Determination.

Schedule 1, Part 1, Division 1.2, Subdivision A – Clause 1.2.2

Clause 1.2.2 sets out the method of calculating the age of diagnostic imaging equipment, the new effective life age and maximum extended life age for the various imaging modalities and defines when equipment has been upgraded.

Subclause 1.2.2(1) provides that the age of equipment is worked out from the date the equipment is first installed in Australia or, where equipment is imported as used equipment, the date of manufacture of its oldest component.

Subclause 1.2.2(2) prescribes a table setting out the new effective life age and the maximum extended life age for each diagnostic imaging modality.

Subclause 1.2.2(3) defines equipment to be 'upgraded' if:

- reasonable additional investment has been made within the new effective life age of the equipment that has improved its overall performance to equivalent to new equipment supplied in Australia; or
- it is accredited under RANZCR's Mammography Quality Assurance Program.

Clause 1.2.2 corresponds to subsections 5(4) to (6) of the CS Determination.

Schedule 1, Part 1, Division 1.2, Subdivision A – Clause 1.2.3

Clause 1.2.3 sets out the classes of exemptions from the capital sensitivity measure, being services provided on:

- equipment ordinarily located in diagnostic imaging premises that are located in an outer regional (RA2), remote (RA3) or very remote (RA4) area (subclause 1.2.3(1));
- equipment ordinarily located at a base for mobile diagnostic imaging when not being used and that base is located in RA2, RA3 or RA4 (subclause 1.2.3(2)); or
- equipment located at premises or a base for mobile diagnostic imaging in an inner regional area and in respect of which the Secretary of the Department (the Secretary) has granted an exemption (paragraph 1.2.3(3)(b)).

Clause 1.2.3 also provides exemptions where:

- the Department has notified the proprietor of equipment that it has received a valid application for an inner regional area exemption but the Secretary is yet to make a decision (paragraph 1.2.3(3)(a)); or
- the Secretary has refused to grant an exemption and the time in which a proprietor may apply for reconsideration of the decision has not yet expired, or the proprietor has applied for reconsideration but has not been notified of the reconsideration decision (paragraph 1.2.3(3)(c)).

Subclause 1.2.3(6) provides that a proprietor of diagnostic imaging equipment may only apply for an exemption if:

- the age of the equipment exceeds the maximum extended life age for the equipment by less than 3 years; and
- the equipment is ordinarily located at premises or a base for mobile diagnostic imaging and the premises or base is located in RRMA4 (a small rural centre) or RRMA5 (a rural centre with a limited urban centre population).

Subclause 1.2.3(4) provides that the Secretary may grant an exemption in respect of equipment if satisfied that the equipment is operated on rare and sporadic basis and provides crucial patient access to diagnostic imaging services. The Secretary must make a decision within 28 days of the date the proprietor was notified of receipt of the application (subclause 1.2.3(5)).

Clause 1.2.3 corresponds to section 5 of the CS Determination.

Schedule 1, Part 1, Division 1.2, Subdivision B – Clause 1.2.4

Clause 1.2.4 deals with reconsiderations of decision not to grant an inner regional exemption and corresponds to section 8 of the CS Determination.

Subclause 1.2.4(1) provides that proprietors may apply for a reconsideration decision within 28 days of the original decision or, if the Secretary is satisfied that special circumstances exist, such further period as the Secretary allows. New material may be provided for the reconsideration decision (subclause 1.2.4(2)).

Subclause 1.2.4(3) provides that the Secretary must decide within 28 days to affirm or vary the decision, or set the decision aside and substitute a new decision.

Schedule 1, Part 1, Division 1.2, Subdivision B – Clause 1.2.5

Clause 1.2.5 provides that the Secretary may delegate any of her powers under Division 1.2 to an APS employee in the Department.

Specification of 351 new (NK) items

The regulation specifies 351 reduced fee (NK) items for use on depreciated equipment. A number of rules of interpretation have consequential amendments to refer to the (NK) items. The CS Determination currently operates so that these items are taken to be specified in the Table and in any relevant rules of interpretation. All higher fee items for use on equipment that is not fully depreciated is identified with the suffix *(K)*.

Technical amendments to management of bulk-billed services

Schedule 1, Part 2, Division 2.6, Clause 2.6.1 – Application of items 64990 and 64991

Technical amendments are made to clause 2.6.1 and item 64991 to improve drafting and move the list of geographical areas in which item 64991 must be provided from the item descriptor to the subclause 2.6.1(3).

Removal of redundant terms from the Dictionary

Schedule 1, Part 3 – Dictionary

Redundant terms ‘ANZAPNM’, ‘concessional beneficiary’ and ‘CT equipment’ are omitted.

Renumbering of clauses

The regulation takes the opportunity to renumber clauses to the diagnostic imaging services table to improve ease of reading.

Schedule 2 – Repeal

Item 1 – The whole of the regulation

Item 1 of Schedule 2 repeals the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2012*.

Statement of Compatibility with Human Rights

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

Health Insurance (Diagnostic Imaging Services Table) Regulation 2013

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 instrument repeals the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2012* with effect from the day after registration to ensure that the medical services funded through the Medicare Benefits Schedule continues to be up-to-date and representative of best medical practice.

The *Health Insurance (Diagnostic Imaging Services Table) Regulation 2013* prescribes a new diagnostic imaging services table for the 12 month period following registration. The regulation sets out items of diagnostic imaging services that are eligible for Medicare benefits, the amount of fees applicable for each item and rules for interpretation of the table. The new table reproduces the table contained in the 2012 Regulation with some amendments to the rules and schedule of services.

The amendments that were made to the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2012:*

- introduces eight new MRI services (items 64551 to 63561) that can be requested by medical practitioners other than specialists and consultation physicians for patients 16 years and over for particular prescribed medical indications such as unexplained headaches;
- apply capital sensitivity arrangements directly through the diagnostic imaging services table by moving 351 (NK) items and rules for their use previously in the *Health Insurance (Diagnostic Imaging Capital Sensitivity)Determination 2011* into the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2013;* and
- substitute the generic word 'chologogue' in the descriptor of items 61360, 61361, 61667 and 61668 for the word 'cholecystokinin'. Cholecystokinin is the name of a brand of the agent chologogue which is required for this diagnostic imaging procedure. Cholecystokinin is no longer available in Australia.

Human rights implications

The right to health

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 International Covenant on Economic, Social and Cultural Rights (ICESCR). The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as a right to be healthy, but rather entails 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 has stated that the notion of 'the highest attainable standard of health' takes into account both the conditions of the individual and the country's available resources. The right may be understood as a right of access to a variety of public health and health care

facilities, goods, services, programs and the conditions necessary for the realisation of the highest attainable standard of health.

There is no incompatibility with the right to health or social security because the legislation is for a legitimate objective and reasonable, necessary and proportionate in the circumstances.

Conclusion

This legislative Instrument is compatible with human rights as it does not raise any human rights issues.

The Hon. Peter Dutton MP

Minister for Health