EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Diagnostic Imaging Services Table) Amendment (Equipment Capital Sensitivity) Regulations 2024

The *Health Insurance Act 1973* (the Act) sets out the principles and definitions governing the Medicare Benefits Schedule. The Act provides for payments by way of medical benefits and for other purposes.

Subsection 133(1) of 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 4AA of the Act provides that regulations may prescribe a table of diagnostic imaging services which sets out items of diagnostic imaging services, the fees applicable for each item, and rules for interpreting the table. The table made under this section is referred to as the Diagnostic Imaging Services Table. The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* (DIST).

Purpose

Capital sensitivity sets out when a piece of diagnostic imaging equipment reaches the end of its life age, and Medicare benefits are no longer payable for services performed on that equipment. To perform Medicare-eligible services, diagnostic imaging equipment must be within the "life age" prescribed by clause 1.2.2 of the DIST. This requirement ensures that practices regularly upgrade and replace their equipment so patients can access high-quality services.

The purpose of the *Health Insurance (Diagnostic Imaging Services Table) Amendment (Equipment Capital Sensitivity) Regulations 2024* (the Regulations) is to amend the DIST to allow diagnostic imaging proprietors to apply to the Secretary of the Department of Health and Aged Care to reinstate Medicare eligibility for diagnostic imaging equipment that has reached the end of its new effective life age. Proprietors will be eligible to apply for reinstatement of diagnostic imaging equipment if:

- the equipment has reached the end of its new effective life age as prescribed by clause 1.2.2 of the DIST;
- the proprietor did not apply for an exemption under clause 1.2.8 before the end of the equipment's new life age;
- the proprietor applies before the later of the end of 30 November 2024 and the end of three months after the end of the equipment's new effective life age; and
- the equipment has been, or is expected to be, upgraded within three months after the end of its new effective life age.

Subject to a decision by the Secretary, the new provisions will allow equipment upgraded within three months of reaching its new effective life age to continue to be used to provide

Medicare-eligible services. If an application for reinstatement is affirmed by the Secretary and the relevant equipment is not upgraded at the end of three months after the end of its new effective life age, the equipment will no longer be able to be used to provide Medicare-eligible services.

These amendments will support diagnostic imaging proprietors that are unable to upgrade equipment before the end of the equipment's new effective life age to ensure patients continue to be able to access Medicare-eligible services on appropriately upgraded equipment.

Consultation

Consultation has not been undertaken in relation to the Regulations due to the expedited timing of these amendments. The DIST requires urgent amendments to ensure patients have ongoing access to safe and high-quality Medicare-eligible services performed using appropriately upgraded diagnostic imaging equipment. It is expected that stakeholders will be supportive of the changes, as the Regulations provide clarity and additional eligibility options for stakeholders under the capital sensitivity requirements.

Details of the Regulations are set out in the Attachment.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

Sections 1 to 4 and Schedule 1 of the Regulations will commence the day after registration of this instrument on the Federal Register of Legislation. Schedule 2 of the Regulations will commence on 1 December 2024.

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

ATTACHMENT

Details of the *Health Insurance (Diagnostic Imaging Services Table) Amendment (Equipment Capital Sensitivity) Regulations 2024*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance (Diagnostic Imaging Services Table) Amendment (Equipment Capital Sensitivity) Regulations 2024* (the Regulations).

Section 2 – Commencement

This section provides for sections 1 to 4 and Schedule 1 of the Regulations to commence the day after registration of this instrument and for Schedule 2 to commence on 1 December 2024.

Section 3 – Authority

This section provides that the Regulations are made under the *Health Insurance Act 1973*.

Section 4 – Schedules

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 commencing day after registration

***Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* (DIST)**

Schedule 1 of the Regulations will implement amendments to the DIST to allow diagnostic imaging proprietors to apply for reinstatement of Medicare eligibility for diagnostic imaging equipment that has reached the end of its new effective life age and has been or is likely to be upgraded within three months of the end of its new effective life age. Currently, diagnostic imaging equipment must be upgraded within the new effective life age to continue being used to provide Medicare-eligible diagnostic imaging services. These amendments will support diagnostic imaging proprietors that are unable to upgrade equipment before the end of the equipment's new effective life age to ensure patients continue to be able to access Medicare-eligible services on appropriately upgraded equipment.

Item 1 amends clause 1.2.1 of the DIST to insert "(1)" before the existing provision. Currently, clause 1.2.1 provides the general rule that a service performed on diagnostic imaging equipment that has reached the end of its new effective life age is not eligible for a Medicare benefit under an item listed in the DIST. This change is administrative in nature to support the insertion of new subclauses 1.2.1(2) and (3) (refer to **item 2** of Schedule 1 of the Regulations).

Item 2 inserts new subclauses (2) and (3) at the end of clause 1.2.1 of the DIST. New subclause 1.2.1(2) provides that if a reinstatement under new clause 1.2.10B is granted in respect of diagnostic imaging equipment (refer to **item 8** of Schedule 1 of the Regulations), a service performed on the equipment is not eligible for a Medicare benefit under an item listed in the DIST if the service is performed on a day that is both before the reinstatement is granted and after the equipment has exceeded its new effective life age.

New subclause 1.2.1(3) provides that if a reinstatement under new clause 1.2.10B is granted in respect of equipment that has not been upgraded and the equipment is not upgraded within three months after the end of its new effective life age, a service performed on the equipment is not eligible for a Medicare benefit under an item listed in the DIST if the service is performed on a day that is after the end of three months after the end of the equipment's new effective life age. This provision is intended to ensure, for diagnostic imaging equipment that has been reinstated under new clause 1.2.10B, only equipment upgraded within three months after the end of its new effective life age is able to continue to provide Medicare eligible services.

Item 3 amends paragraph 1.2.2(4)(a) of Schedule 1 of the DIST to update the definition of ***upgraded*** for the purposes of diagnostic imaging equipment. This amendment replaces "within the new effective life age for the equipment" with "within the period mentioned in subclause (5)". New subclause (5) provides circumstances, in addition to within the new effective life age for the equipment, when an additional reasonable investment can be made that will mean the equipment has been upgraded for the purposes of subclause 1.2.2(4) (refer to **item 4** of Schedule 1 of the Regulations).

Item 4 inserts new subclause 1.2.2(5), which provides "the period" for the purposes of subclause 1.2.2(4). Under the new subclause, the period in which an additional reasonable investment can be made that improves the overall performance of the equipment so that it is equivalent to new equipment supplied in Australia at the time of the improvement and meets the definition of ***upgraded*** is:

- the new effective life age for the equipment; or
- for equipment for which an exemption under clause 1.2.8 has been granted, the exemption period of the exemption; or
- for equipment for which reinstatement under new clause 1.2.10B has been granted (refer to **item 8** of Schedule 1 of the Regulations), 3 months after the end of the equipment's new effective life age.

Part 3.1 of Schedule 1 of the DIST provides that ***exemption period*** of the exemption means the period mentioned in paragraph 1.2.8(2)(a) (as extended or further extended under clause 1.2.10 if applicable). Accordingly, the reference to the exemption period of the exemption in the new subclause also includes an extension or further extension of an exemption period under clause 1.2.10.

Items 5 and 6 repeal and replace the heading of Subdivision 1.2 of Part 1 of Schedule 1 of the DIST to insert this heading after clause 1.2.4. This change is an administrative amendment to move clause 1.2.4, which defines the term ***relevant proprietor***, into Subdivision A of Division 1.2 of Schedule 1 of the DIST. The term ***relevant proprietor*** is

used in Subdivision B and new Subdivision BA of Division 1.2 of Schedule 1 (refer to **item 8** of Schedule 1 of the Regulations). Subdivision A of Division 1.2 provides general provisions relating to capital sensitivity requirements and is an appropriate location for the definition of this term following the introduction of new Subdivision BA of Division 1.2.

Item 7 amends the heading of subclause 1.2.10(2) of Schedule 1 to replace the term "extension" with "exemption" to better reflect the content of subclause 1.2.10(2). This change is administrative in nature.

Item 8 inserts new Subdivision BA, which specifies provisions relating to reinstatement for capital sensitivity requirements for diagnostic imaging equipment that has exceeded its new effective life age, after clause 1.2.10 of Schedule 1 of the DIST. These new provisions are intended to support diagnostic imaging proprietors with equipment that:

- has reached the end of its new effective life age;
- was not upgraded before the end of its new effective life age;
- has not been subject to an application for an exemption under clause 1.2.8; and
- has been or is expected to be upgraded within three months of its new effective life age.

The changes will ensure patients continue to have access to Medicare benefits for diagnostic imaging services performed using appropriately upgraded diagnostic imaging equipment.

New clause 1.2.10A provides the requirements relating to applications for reinstatement under clause 1.2.10B of diagnostic imaging equipment that has reached the end of its new effective life age as set out in Table 1.2.2 of the DIST.

Subclause 1.2.10A(1) provides that a relevant proprietor for diagnostic imaging equipment may apply to the Secretary of the Department of Health and Aged Care for reinstatement of the equipment under clause 1.2.10B, if:

- the equipment was not upgraded before the end of its new effective life age; and
- the relevant proprietor did not apply for an exemption under clause 1.2.8 in respect of the equipment before the end of its new effective life age.

Subclause 1.2.10A(2) provides that the application for reinstatement of equipment must:

- be in writing;
- be made before the later of the end of three months after the end of the equipment's new effective life age and the end of 30 November 2024; and
- set out:
    - reasons why the proprietor was unable to upgrade the equipment and apply for an exemption under clause 1.2.8 of the DIST before the end of the equipment's new effective life age;
    - an explanation of how the equipment has been, or will be, upgraded; and
    - if the equipment has not been upgraded at the time of the application, the steps taken by the proprietor to ensure the equipment will be upgraded within three months after the end of its new effective life age and when the upgrade will occur.

Until 30 November 2024, proprietors will be able to apply for reinstatement for more than three months after the end of the relevant equipment's new effective life age if the equipment was upgraded within the three months. This transitional provision will support diagnostic imaging proprietors during the period after implementation of the new provisions to give sufficient time for applications to be made for equipment that was upgraded within three months of the end of its new effective life age. From 1 December 2024, proprietors will need to apply for reinstatement within three months of the equipment's new effective life age.

Subclause 1.2.10A(3) provides that if the Secretary receives an application under subclause 1.2.10A(1) and the application complies with subclause 1.2.10A(2), the Secretary must notify the relevant proprietor for the equipment in writing that the Secretary has received the application.

New clause 1.2.10B provides the requirements relating to granting reinstatement for equipment that has reached the end of its new effective life age.

Subclause 1.2.10B(1) provides that this clause only applies if the Secretary has notified the relevant proprietor for diagnostic imaging equipment that the Secretary has received an application for reinstatement.

Subclause 1.2.10B(2) to (4) provides that the Secretary must:

- grant or refuse to grant reinstatement by notice in writing to the proprietor;
- not grant reinstatement unless they are satisfied that:
    - the proprietor was unable to upgrade the equipment before the end of its new effective life age;
    - the equipment has been or is likely to be upgraded within three months after the end of its new effective life age; and
- make a decision on the application within 28 days after notifying the proprietor that they have received the application.

Item 8 also inserts a new heading for Subdivision BB of Division 1.2, which will contain existing clauses 1.2.11, 1.2.12 and 1.2.13 of the DIST. Clauses 1.2.11, 1.2.12 and 1.2.13 relate to the review of decisions made under clauses 1.2.8 and 1.2.10 and following the amendments in the Regulations include the review of decisions made under new clause 1.2.10B (refer to **item 8** and **items 9** to **13** of Schedule 1 of the Regulations). This new subdivision will ensure that provisions relating to the review of decisions are appropriately located following the introduction of new Subdivision BA of Division 1.2 (refer to **item 8** of Schedule 1 of the Regulations). This change is administrative in nature.

Item 9 inserts new paragraph (c) at the end of subclause 1.2.11(1) of Schedule 1 of the DIST to apply clause 1.2.11 to decisions made under new clause 1.2.10B (refer to **item 8** of Schedule 1 of the Regulations). Clause 1.2.11 provides requirements relating to applications for reconsideration of a decision.

This amendment will also have the effect of applying clauses 1.2.12 and 1.2.13 to decisions made under 1.2.10B where relevant. Clauses 1.2.12 provides requirements for reconsidering a decision made under the specified clauses and clause 1.2.13 provides that an application may

be made to the Administrative Appeals Tribunal for review of decisions made under clause 1.2.12.

Item 10 amends the heading of subclause 1.2.11(6) to insert "—exemption decisions" at the end of the heading. This change is intended to ensure that the heading of subclause 1.2.11(6) appropriately reflects the contents of the subclause in accordance with the changes to the subclause (refer to **item 11** of Schedule 1 of the Regulations).

Item 11 amends subclause 1.2.11(6) to specify that this provision only applies to a service performed on equipment *to which a decision mentioned in paragraph (1)(a) or (b) relates*. Subclause 1.2.11(6) provides the circumstances in which clause 1.2.1 does not apply to a service. This change will ensure that this subclause does not apply to equipment subject to a decision made under new clause 1.2.10B (refer to **item 8** of Schedule 1 of the Regulations). Equipment granted reinstatement under clause 1.2.10B will only be able to perform services attracting a Medicare benefit from the date the Secretary grants reinstatement in accordance with the changes to clause 1.2.1 (refer to **item 2** of Schedule 1 of the Regulations).

Item 12 amends the heading of subclause 1.2.12(4) to replace "decision" with "exemption decisions". This change is intended to ensure that the heading of subclause 1.2.12(4) appropriately reflects the contents of the subclause in accordance with the changes to the subclause (refer to **item 13** of Schedule 1 of the Regulations).

Item 13 amends subclause 1.2.14(4) to specify that this provision only applies, in circumstances where the Secretary affirms a decision mentioned in paragraph 1.2.11(1)(a) or (b), to a service performed on equipment to which the decision relates. Subclause 1.2.12(4) provides the circumstances in which clause 1.2.1 does not apply to a service. This change will ensure that this subclause does not apply to equipment subject to a decision made under new clause 1.2.10B (refer to **item 8** of Schedule 1 of the Regulations). Equipment granted reinstatement under clause 1.2.10B will only be able to perform services attracting a Medicare benefit from the date the Secretary grants reinstatement in accordance with the changes to clause 1.2.1 (refer to **item 2** of Schedule 1 of the Regulations).

Schedule 2 – Amendments commencing 1 December 2024

Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020 **(DIST)**

Item 1 repeals and replaces subparagraph 1.2.10A(2)(b) to remove the reference to applications made before the end of 30 November 2024. This paragraph relates to when an application for reinstatement under 1.2.10B must be made. In accordance with the amendments at **item 8** of Schedule 1 of the Regulations, until the end of 30 November 2024, diagnostic imaging proprietors will be able to make an application for reinstatement under clause 1.2.10B in respect of equipment until the later of the end of three months after the end of the equipment's new life age and the end of 30 November 2024. From 1 December 2024, new applications for reinstatement under clause 1.2.10B will need to be made before the end of three months after the end of the equipment's new life age. Accordingly, this amendment is administrative in nature.

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) Amendment (Equipment Capital Sensitivity) Regulations 2024

This Regulation 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 Disallowable Legislative Instrument

The *Health Insurance Act 1973* (the Act) sets out the principles and definitions governing the Medicare Benefits Schedule. The Act provides for payments by way of medical benefits and for other purposes.

Subsection 133(1) of 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 4AA of the Act provides that regulations may prescribe a table of diagnostic imaging services which sets out items of diagnostic imaging services, the fees applicable for each item, and rules for interpreting the table. The table made under this section is referred to as the Diagnostic Imaging Services Table. The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* (DIST).

Purpose

Capital sensitivity sets out when a piece of diagnostic imaging equipment reaches the end of its life age, and Medicare benefits are no longer payable for services performed on that equipment. To perform Medicare-eligible services, diagnostic imaging equipment must be within the "life age" prescribed by clause 1.2.2 of the DIST. This requirement ensures that practices regularly upgrade and replace their equipment so patients can access high-quality services.

The purpose of the *Health Insurance (Diagnostic Imaging Services Table) Amendment (Equipment Capital Sensitivity) Regulations 2024* (the Regulations) is to amend the DIST to allow diagnostic imaging proprietors to apply to the Secretary of the Department of Health and Aged Care to reinstate Medicare eligibility for diagnostic imaging equipment that has reached the end of its new effective life age. Proprietors will be eligible to apply for reinstatement of diagnostic imaging equipment if:

- the equipment has reached the end of its new effective life age as prescribed by clause 1.2.2 of the DIST;
- the proprietor did not apply for an exemption under clause 1.2.8 before the end of the equipment's new life age;
- the proprietor applies before the later of the end of 30 November 2024 and the end of three months after the end of the equipment's new effective life age; and

- the equipment has been or is expected to be upgraded within three months after the end of its new effective life age.

Subject to a decision by the Secretary, the new provisions will allow equipment upgraded within three months of reaching its new effective life age to continue to be used to provide Medicare-eligible services. If an application for reinstatement is affirmed by the Secretary and the relevant equipment is not upgraded at the end of three months after the end of its new effective life age, the equipment will no longer be able to be used to provide Medicare-eligible services.

These amendments will support diagnostic imaging proprietors that are unable to upgrade equipment before the end of the equipment's new effective life age to ensure patients continue to be able to access Medicare-eligible services on appropriately upgraded equipment.

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.

The right of equality and non-discrimination

The rights of equality and non-discrimination are contained in articles 2, 16 and 26 of the International Covenant on Civil and Political Rights (ICCPR). Article 26 of the ICCPR requires that all persons are equal before the law, are entitled without any discrimination to the equal protection of the law and in this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Analysis

The Regulations maintain and advance the rights to health and social security and the right of equality and non-discrimination by ensuring access to publicly subsidised diagnostic imaging services performed using appropriately upgraded diagnostic imaging equipment in circumstances where the equipment was not upgraded before the end of its new effective life age.

Conclusion

This instrument is compatible with human rights because it maintains and advances existing arrangements and the protection of human rights.

Mark Butler

Minister for Health and Aged Care