EXPLANATORY STATEMENT

Select Legislative Instrument 2012 No. 165

Health Insurance Act 1973

Health Insurance Amendment Regulation 2012 (No. 2)

Health Insurance (Pathology Services) Amendment Regulation 2012 (No. 1)

Health Insurance (Pathology Services Table) Amendment Regulation 2012 (No. 2)

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.

The Health Insurance Regulations 1975 (the HI Regulations) provide, in part, for:

- information that must be included in a request for diagnostic imaging services for the purposes of subsection 23DQ(1) of the Act; and
- particulars to be recorded on an account, receipt or bulk billing agreement issued for a professional service for the purposes of subsection 19(6) of the Act.

Subsection 23DP(3) of the Act provides that a pathology provider may not provide a requester of pathology services with a form for use in requesting pathology services (a pathology request form) that is not in accordance with the regulations.

The *Health Insurance (Pathology Services) Regulations 1989* (the PS Regulations) impose requirements relating to requests for pathology services for the purposes of subsection 16A(4) of the Act.

Subsection 4A(1) of the Act provides that the regulations may prescribe a table of pathology services, the amount of fees applicable for each item and the rules for interpretation of the table. Schedule 1 to the *Health Insurance (Pathology Services Table) Regulations 2011* (the PST Regulations) prescribes such a table.

The regulations amend provisions in the HI Regulations, the PS Regulations and the PST Regulations, as appropriate to support the amendments made to the Act by the *Health Insurance Amendment (Pathology Requests) Act 2010* (the Amendment Act).

The Amendment Act removed the requirement that a request for a Medicare-eligible pathology service must specify a particular pathology provider to whom the request is directed. This allows a patient to take his or her pathology request to a pathology provider of their own choice. There is still a legislative requirement for a request to be made, but there is no longer a

requirement that the request be made to a particular approved pathology practitioner or authority.

The regulations remove from the Principal Regulations all references to pathology requests 'made to' an approved pathology practitioner or approved pathology authority and, where relevant, substitute these references with references to requests 'received by' an approved pathology practitioner or approved pathology authority.

The regulations also introduce a requirement for pathology and diagnostic imaging providers who provide, or make available, branded request forms for use by requesting practitioners, to include a 'patient advisory statement' on such forms. The purpose of this statement is to ensure that patients are aware that even though their request may be branded with the name of a particular provider, they are free to take the request to a provider of their choice to receive their services.

Details of the *Health Insurance Amendment Regulation 2012 (No. 2)* are set out in <u>Attachment A</u>. Details of the *Health Insurance (Pathology Services) Amendment Regulation 2012 (No. 1)* are set out in <u>Attachment B</u> and details of the *Health Insurance (Pathology Services Table) Amendment Regulation 2012 (No. 2)* are set out in <u>Attachment Regulation 2012 (No. 2)</u> are set out in <u>Attachment C</u>.

Consultation

The decision to require a patient advisory statement on pathology and diagnostic imaging request forms was taken as part of a broad package of reforms announced in the 2009-10 Budget following a review of pathology and diagnostic imaging.

The review was conducted by an Interdepartmental Committee, which invited submissions from industry and professional representatives.

Following the Budget announcement, consultations occurred with both pathology and diagnostic imaging industry and professional bodies, consumer health representatives and the Australian Medical Association to develop the final wording of the statement, and discuss implementation issues.

The Act specifies no conditions that need to be met before the power to make the regulations may be exercised.

The regulations are legislative instruments for the purposes of the *Legislative Instruments Act* 2003.

The regulations commence on 1 August 2012.

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

ATTACHMENT A

Details of the Health Insurance Amendment Regulation 2012 (No. 2)

Section 1 – Name of Regulation

This section provides for the regulation to be referred to as the *Health Insurance Amendment Regulation 2012 (No. 2).*

Section 2 – Commencement

This section provides for the regulation to commence on 1 August 2012.

Section 3 – Amendment of the Health Insurance Regulations 1975

This section provides that Schedule 1 amends the *Health Insurance Regulations* 1975 (the HI Regulations).

Schedule 1 - Amendments

Item [1] – Subregulation 9A(1)

This item amends the subregulation to remove reference to paragraph 16A(4)(b), and insert reference to section 16A. This is a technical amendment to correct a minor drafting error made during previous amendments to subregulation 9A(1), which deals with requests for pathology services made electronically.

Item [2] – Subregulation 13(12)

Subregulation 13(12) of the *Health Insurance Regulations 1975* (the HI Regulations) specifies particulars which, for the purposes of subsection 19(6) of the Act, must be recorded on an account or bulk-billing agreement provided in relation to certain medicare eligible pathology services. This item substitutes a new subregulation 13(12), which replaces the reference in paragraph 13(12)(c) to a request 'made to' an approved pathology practitioner or approved pathology authority with reference to a request 'received by' an approved pathology practitioner or authority.

This item also makes drafting changes to subregulation 13(12) to reflect modern drafting practices. These changes do not affect the application of the subregulation.

The particulars specified by subregulation 13(12) are the name and either the address, or the provider number, for the place of practice of:

- the approved pathology practitioner who provided the pathology service, or on whose behalf the service was provided; or
- if the pathology service was provided wholly in one accredited pathology laboratory, any approved pathology practitioner who renders professional services in that laboratory; or
- any approved pathology practitioner who renders pathology services in an accredited pathology laboratory that is owned and controlled by a single approved pathology

authority, if:

- (a) a request for the service was received by either an approved pathology practitioner who provides services in the accredited pathology laboratory, or the approved pathology authority which owns and controls the laboratory; and
- (b) the service was provided partly in the accredited pathology laboratory, and partly in a different accredited pathology laboratory which is owned and controlled by the approved pathology authority.

Item [3] – After regulation 18

This item inserts a new subregulation 18A 'Branded Pathology Request form' specifying the wording of the patient advisory statement which must be included on a branded pathology request form to ensure that patients are aware of their right to take the request to a provider of their choice, and the limitations on that right where the treating practitioner has specified a particular pathologist on clinical grounds. Under subsection 16A(3) of the Act, where a treating practitioner has specified a particular pathologist on the request on clinical grounds, the service must be provided by that pathologist for medicare benefits to be payable.

This item also provides a definition of the term 'branded pathology request form'. Where a request form is provided by an approved pathology authority, it will be a branded request form if it includes the name of the authority and the location of one or more pathology specimen collection centres. Where a form is provided by an approved pathology practitioner, it will be a branded request form if it includes the name of the approved pathology authority at which the practitioner works and the location of one or more pathology specimen collection centres.

From 1 August 2012 a pathology provider commits an offence if the provider directly or indirectly distributes to a medical or dental practitioner, participating midwife or participating nurse practitioner a branded request form without the required patient advisory statement, without a reasonable excuse (see subsection 23DP(3) of the Act).

Item [4] – Paragraph 19(1)(c)

This item amends paragraph 19(1)(c) to refer to 'the diagnostic imaging service' rather than the 'requested diagnostic imaging service'. This change does not affect the paragraph's meaning.

Item [5] – Paragraph 19(1)(d)

This item replaces the current paragraph 19(1)(d) of the HI Regulations. Regulation 19 of the HI Regulations sets out the information that must be included in a request for diagnostic imaging services. Currently paragraph 19(1)(d) requires a practitioner requesting a diagnostic imaging service to include on the request form the letter "A" where they believe the diagnostic imaging services is a hospital-related service. The definition of a hospital-related service is removed by item [6] below. This requirement was previously used for data gathering purposes and is now obsolete.

The new paragraph 19(1)(d) specifies the requirement for a diagnostic imaging request made on a branded request form to include a 'patient advisory statement' informing the patient that they can take the request to a provider of their choice. The exact wording of the patient advisory statement to appear on branded diagnostic imaging request forms is not prescribed by the regulations.

This statement is only required on request forms which:

- contain relevant information about the diagnostic imaging provider at the time the form is supplied or made available to a requester; and
- are supplied, or made available to, a requesting practitioner on or after 1 August 2012.

These conditions are necessary to ensure that the requirement for the patient advisory statement is not imposed in relation to request forms distributed prior to the commencement of these amendments.

From 1 August 2012 a medical practitioner who provides R-type diagnostic imaging services will commit an offence if he or she directly or indirectly distributes to a requester a branded request form that does not include the patient advisory statement, without a reasonable excuse (see subsection 23DQ(3) of the Act).

Item [6] – Subregulations 19(1A) and (1B)

This item omits subregulations 19(1A) and 19(1B) of the HI Regulations, which define a hospital-related service, and specify the particulars to which a practitioner must have regard in forming the opinion that a service is a hospital-related service for the purposes of paragraph 19(1)(d), respectively. As paragraph 19(1)(d) is omitted by item [5] above, subregulations 19(1A) and 19(1B) are obsolete.

Item [7] – Subregulation 19(2)

This item removes redundant references to 'requested' in the subregulation.

Item [8] – After subregulation 19(2)

This item defines who is considered a 'diagnostic imaging provider' for the purposes of subregulation 19(d), and specify what constitutes 'relevant information'. A diagnostic imaging provider is a person who renders diagnostic imaging services, carries on a business rendering diagnostic imaging services or employs or otherwise engages such a person. Relevant information about a diagnostic imaging provider is the registered or trading name of the provider and one or more locations at which the provider renders diagnostic imaging services.

ATTACHMENT B

Details of the *Health Insurance (Pathology Services) Amendment Regulation 2012 (No. 1)*

Section 1 – Name of Regulation

This section provides for the regulation to be referred to as the *Health Insurance* (*Pathology Services*) Amendment Regulation 2012 (No. 1).

Section 2 – Commencement

This section provides for the regulation to commence on 1 August 2012.

Section 3 – Amendment of the Health Insurance (Pathology Services) Regulations 1989

This section provides that Schedule 1 amends the *Health Insurance (Pathology Services) Regulations 1989* (the PS Regulations).

Schedule 1 Amendments

Item [1] – Subregulation 4(2), except the note

Subregulation 4(2) of the *Health Insurance (Pathology Services) Regulations 1989* (the PS Regulations) specifies the particulars which must be contained in a request for pathology services. Subregulation 4(2) currently provides that a request for pathology services must, subject to subregulation 4(8), contain the particulars required by subregulations 4(3) to 4(7) to be included in a request. This item substitutes a new subregulation 4(2), providing that a request for pathology services must, subject to new subregulation 4(9), (to be inserted by item [5] below), contain the particulars required by subregulations 4(3), 4(5), 4(6) and 4(8).

The amendments which are made by this item are technical in nature, and are consequential to:

- the removal of subregulation 4(4) of the PS Regulations by item [2] below;
- the inclusion of new subregulations 4(8) and 4(9), made by item [5] below; and
- the reference to subregulation 4(7) becoming redundant following amendments made by item [5] below.

Item [2] – Subregulation 4(4)

This item omits subregulation 4(4) from the PS Regulations. Subregulation 4(4) currently requires requests for pathology services to include certain particulars of the person 'to whom the request is made'. As requests no longer need to be directed to a particular person or authority, this requirement is now redundant.

Item [3] – Paragraph 4(6)(c)

This item makes a technical amendment to paragraph 4(6)(c) of the PS Regulations by inserting a full stop after the word 'patient', as a consequence of the deletion of paragraph 4(6)(d) by item [4] below.

Item [4] – Paragraph 4(6)(d)

This item deletes paragraph 4(6)(d) of the PS Regulations. This paragraph requires requesting practitioners to include the letter "A" on request forms where they believe the service is a hospital-related service. The definition of a hospital-related service is removed by item [5] below. This requirement was previously used for data gathering purposes and is now obsolete.

Item [5] – Subregulations 4(6A) to (8)

This item omits subregulations 4(6A) and 4(6B) from the PS Regulations. Subregulation 4(6A) currently defines a hospital-related service, and subregulation 4(6B) sets out particulars to which a practitioner must have regard in forming the opinion that a service is a hospital-related service, for the purposes of paragraph 4(6)(d). As all reference to hospital-related services are removed from the PS Regulations by the deletion of paragraph 4(6)(d) by item [4] above, subregulations 4(6A) and 4(6B) therefore become obsolete.

This item omits current subregulations 4(7) and 4(8) of the PS Regulations and substitute new subregulations 4(7), 4(8) and 4(9). These amendments clarify the drafting of the subregulations and do not affect their intended operation.

New subregulation 4(7) provides that new subregulations 4(8) and 4(9) apply where an approved pathology practitioner receives a request for a pathology service from a patient's treating practitioner and refers that request on to another approved pathology practitioner or an approved pathology authority.

New subregulation 4(8) provides that a request for pathology services referred from one approved pathology practitioner to another approved pathology practitioner or an approved pathology authority must contain the name, address and provider number of the patient's treating practitioner as mentioned in the original request from the treating practitioner.

New subregulation 4(9) provides that the referred request made from an approved pathology provider to another approved pathology provider or authority does not need to comply with subregulations 4(5), 4(6) and 4(8) of the PS Regulations if the referred request relates solely to the pathology service to which the first request relates, and the first request is attached to the referred request. Subregulations 4(5) and 4(6) set out certain particulars which must be recorded relating to the patient, and the service which has been requested, respectively.

ATTACHMENT C

Details of the *Health Insurance (Pathology Services Table) Amendment Regulation* 2012 (No. 2)

Section 1 – Name of Regulation

This section provides for the regulation to be referred to as the *Health Insurance* (*Pathology Services Table*) Amendment Regulation 2012 (No. 2).

Section 2 – Commencement

This section provides for the regulation to commence on 1 August 2012.

Section 3 – Amendment of the *Health Insurance (Pathology Services Table) Regulations* 2011.

This section provides that Schedule 1 amends the *Health Insurance (Pathology Services Table) Regulations 2011* (the PST Regulations).

Schedule 1 – Amendments

Item [1] – Dictionary, definition of *referring APP*, paragraph (a)

This item amends paragraph (a) of the definition of a 'referring APP' to refer to an approved pathology practitioner who has received a request for a pathology test or tests to be rendered, rather than to an approved pathology practitioner who has been requested to render the test or tests.

Item [2] – Dictionary, definition of request

The PST Regulations currently provides that a reference to a request to an approved pathology practitioner includes a reference to a request for a pathologist-determinable service. This item amends the definition to replace reference to a 'request to' an approved pathology practitioner with reference to a 'request received by' an approved pathology practitioner, as pathology requests no longer need to be directed to a particular person. The effect of the definition of 'request' in the PST Regulations is that a request for a pathologist-determinable service received by an approved pathology provider is subject to the same regulations as a request for any other pathology service that they may receive.

Statement of Compatibility with Human Rights

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

Health Insurance Amendment Regulation 2012 (No. 2)

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 Instruments

The Amendment Regulation will have the effect of requiring providers of both pathology and diagnostic imaging services to include a patient advisory statement on their pre-printed referral forms, which will ensure the patient is aware of their right to choose a different provider. This is intended to promote patient choice, and encourage competition within the pathology and diagnostic imaging sectors.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

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

Tanya Plibersek

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