EXPLANATORY STATEMENT

Select Legislative Instrument 2011 No. 101

Health Insurance Act 1973

Health Insurance (Pathology Services Table) Amendment Regulations 2011 (No. 1)

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 pathology services, set out in prescribed tables.

Section 4A of the Act provides that the regulations may prescribe a table of pathology services that sets out items of pathology services, the amount of fees applicable in respect of each item, and rules for interpretation of the pathology services table. The *Health Insurance (Pathology Services Table) Regulations 2010* (the Principal Regulations) currently prescribe such a table.

The Regulations amend the current table of pathology services in the Principal Regulations, as part of the ongoing management of the table. New items are introduced and existing items amended to reflect evidence-based best clinical practice and better value for money for both the Australian Government and the Australian people.

Details of the Regulations are set out in the Attachment.

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

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

The Regulations commence on 1 July 2011.

Consultation

These changes relate to the ongoing maintenance of the Pathology Services Table (PST) to reflect evidence-based best practice and appropriate funding; and the listing of new items on the PST to reflect new procedures and technology. They result from advice from both the Pathology Services Table Committee (PSTC) and the Medical Services Advisory Committee (MSAC).

Where a change to the PST related to an application for public funding for a new technology or procedure, the application went through a MSAC process which included consultation with craft groups, the public and clinical experts. MSAC and its two sub-committees are composed of expert members from a wide range of fields including pathology.

The PSTC is composed of members from the Royal College of Pathologists of Australasia, the Australian Association of Pathology Practices and the National Coalition of Public Pathology, the Australian Medical Association, Medicare Australia and the Department of Health and Ageing. The changes have been developed in consultation with these organisations.

In addition, the Pathology Services Table Committee has established sub-committees that discussed the changes relating to their areas of expertise and made recommendations to the PSTC. These experts are nominated from both the private and public pathology sectors. Medicare Australia was consulted concerning the impact of the changes on their business operations. The Department of Veterans' Affairs was advised of the changes to ensure that their schedule of benefits for veterans could be amended if necessary.

It has been concluded that the changes will have minimal impact on pathology practice in terms of costs to business and will lead to a closer correspondence between Medicare benefit structure and pathology practice.

The changes implement the pathology component of a 2011-12 Budget Measure for new and revised listings on the Medicare Benefits Schedule and are effective from 1 July 2011.

ATTACHMENT

DETAILS OF THE *HEALTH INSURANCE (PATHOLOGY SERVICES TABLE) AMENDMENT REGULATIONS 2011 (NO. 1)*

Regulation 1 – Name of Regulations

This regulation provides for the Regulations to be referred to as the *Health Insurance (Pathology Services Table) Amendment Regulations 2011 (No. 1).*

Regulation 2 – Commencement

This regulation provides for the Regulations to commence on 1 July 2011.

Regulation 3 – Amendment of the *Health Insurance (Pathology Services Table) Regulations 2010*

This regulation provides that Schedule 1 amends the *Health Insurance (Pathology Services Table) Regulations 2010* (the Principal Regulations).

Item [1] – Paragraph 1.2.7(3)(a)

This item amends paragraph 1.2.7(3)(a) to provide that the new referral item 66610 be excluded from a set of pathology services mentioned in clause 1.2.6 for the purposes of 'coning' benefits within a single patient episode.

The episode coning clauses require that where more than three pathology services are requested in a single patient episode, only Medicare benefits equivalent to the fees for the three items with the highest Schedule fee are payable.

Item [2] – Paragraph 2.2.3(1)(b)

This item amends paragraph 2.2.3(1)(b) to provide that the new referral item 66610 be limited to being claimed not more than twice in a 12 month period for a particular patient in a similar way to item 66607 to which it relates.

Item [3] – Items 66605 to 66609

This item substitutes the existing listing of five items for a revised listing of six items.

The descriptors for existing items 66605 and 66607 are amended to reflect that not all vitamins listed have to be tested for the items to be eligible for a Medicare benefit.

Existing items 66606, 66608 and 66609 do not change.

New item 66610 is introduced, to provide for a test which is referred from one laboratory to another unrelated laboratory, to remunerate the receiving laboratory appropriately. The new item is the referral item for existing item 66607 that quantifies vitamin A or E in blood, urine or other body fluid.

Items [4] and [5] – Items 66659 and 66660, column 3

These items amend the schedule fees for existing items 66659 and 66660 to the same amount. The timing of the listing of item 66660 resulted in there being a discrepancy between the schedule fees. These are two similar prostate antigen fractions items and the schedule fees should be identical.

Item [6] – Subclause 2.3.4(4)

This item amends subclause 2.3.4(4) to provide that the new item for genotypic antiretroviral resistance testing, item 69380, be limited to being applicable not more than twice in a 12 month period for a particular patient.

Item [7] – Item 69333, paragraph (g)

This item amends the descriptor of the existing item 69333 to examine urine for 'protein' rather than 'albumin'.

Item [8] – After item 69379

This item introduces a new item for genotypic antiretroviral resistance testing to assist patients with HIV with a plasma HIV-RNA level > 1000 copies/ml who are planning to commence their initial regimen or about to change an existing regimen of combination antiretroviral therapy.

Item [9] – Items 71057 to 71059

This item substitutes the schedule fees for existing immunology items 71057 and 71059 and the item descriptor for item 71059 to reflect the relevant complexity of the tests.

Item 71058 does not change.

Item [10] – Item 71200, column 3

This item amends the schedule fee for existing item 71200 that provides for the detection and quantitation of free kappa and lambda light chains in serum for the diagnosis or monitoring of amyloidosis, myeloma or plasma cell dyscrasias. The amendment reflects the need to cover additional consumable costs resulting from a previous change to the regulations that required the testing of both light chains rather than one.

Item [11] – After subclause 2.6.1(3)

This item inserts a new subclause to provide for the payment of Medicare benefits for no more than one of items 73049, 73051, 73062, 73063, 73066 and 73067 in a single patient episode. The new subclause specifies that only the higher or highest of the claimed schedule fees is paid.

Item [12] – Item 73051

This item substitutes the wording for the existing fine needle aspiration item 73051 to clarify that this item is now for 'one identified site', as a new item 73066 is introduced for 2 or more separately identified sites.

Item [13] – Item 73063

This item substitutes the wording for the existing fine needle aspiration item 73063 to clarify that this item is now for ‘one identified site’ as a new item 73067 (see item [14] below) is introduced for 2 or more separately identified sites.

Item [14] – After item 73065

This item inserts two new items, 73066 and 73067 to provide for cytology of material obtained directly from a patient at 2 or more separately identified sites by fine needle aspiration in specific circumstances.

Item [15] – After item 73324

This item inserts three new genetic tests, two (items 73325 and 73326) for the molecular testing of myeloproliferative disorders, which cause blood cells to grow abnormally in the bone marrow and one (item 73327) for new genetic testing to enable identification of those patients who cannot produce the thiopurine S-methyltransferase (TPMT) enzyme either adequately or at all, and thereby guide clinicians' prescribing of thiopurine medication.

Item [16] – Item 74991, subparagraph (e)(iii)

This item amends the wording in the subparagraph from “Metropolitan” to “Metropolitan Perth” as the word Perth was omitted in the initial listing of the item.