EXPLANATORY STATEMENT

Select Legislative Instrument 2009 No. 62

Health Insurance Act 1973

Health Insurance (Pathology Services Table) Amendment Regulations 2009 (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 2008* (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. The changes are necessary to reflect the current state of pathology in Australia as both a science and an industry. The following are some of the changes recommended to take effect from 1 May 2009:

- Item 71200 of the table provides a rebate for the detection and quantitation of two particular molecules in a patient's blood. This is used in the diagnosis and monitoring of a number of conditions (amyloidosis, myeloma and plasma cell dycrasias). At present, the wording of this item indicates that the fee is payable for one molecule *or* the other. This may have led to some claiming confusion. Therefore, the amendments specify testing for the first molecule *and* the second, to clarify claiming procedures.
- Item 66605 provides a rebate for measuring the levels of vitamins in blood, urine or other bodily fluids. Close consultation with the peak pathology bodies has revealed that measuring the levels of vitamins A and E in particular is more costly for labs than measuring the levels of other vitamins. Therefore, the amendments separate testing for these out by the creation of a new item, to make rebates more specific to the type of test performed.
- Measuring a patient's level of prostate-specific antigen (PSA) is valuable in the diagnosis of prostate problems. Item 66659 provides a rebate for measuring PSA levels as a follow-up to an initial reading that is concerning, but not conclusive. The amendments specify more accurately what constitutes an inconclusive initial result, thereby removing the potential for confusion.

These changes have been developed in close consultation with the pathology industry. They have been discussed by the Pathology Services Table Committee (PSTC) and its eight subcommittees, whose members represent all the specialised branches of pathology. They have also been examined by the Pathology Consultative Committee (PCC), which contains representatives of the three peak pathology bodies, the Royal College of Pathologists of Australasia, the Australian Association of Pathology Practices and the National Coalition of Public Pathology. Practicing pathologists and representatives of Medicare Australia sit on

these committees and have considered the practical impact on the day-to-day business of pathology. It has been concluded that the proposed 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.

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 May 2009.

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

ATTACHMENT

DETAILS OF THE *HEALTH INSURANCE (PATHOLOGY SERVICES TABLE) AMENDMENT REGULATIONS 2009 (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 2009 (No. 1).*

Regulation 2 – Commencement

This regulation provides for the Regulations to commence on 1 May 2009.

Regulation 3 – Amendment of the *Health Insurance (Pathology Services Table) Regulations 2008*

This regulation provides that Schedule 1 amends the *Health Insurance (Pathology Services Table) Regulations 2008*, (the Principal Regulations).

Schedule 1 – Amendments

Schedule 1 sets out a number of changes to the following provisions in Schedule 1 to the Principal Regulations:

- Part 2 – Rules of interpretation;
- Part 3 – Services and fees.

Part 2 - Rules of interpretation

Item [1]
Rule 13, which lists the specific rules that apply to tests on biopsy material, including a list of items for which only the most expensive can be claimed, once, for a given patient episode, is amended to include immunocytochemical items 73064 and 73065.

Item [2]
Rule 25 which lists limitations on the frequency of use of certain items, is amended to include chemical testing item 66607.

Item [3]
Rule 25 is also amended to include chemical testing item 66660.

Part 3 – Services and fees

Item [4]
Item 66605 no longer includes vitamins A and E.

Item [5]
New chemical pathology item 66607 is added for the quantitation of vitamins A and E in blood, urine or other bodily fluid separately from item 66605, which is for testing of other vitamins, to reflect the greater complexity of these tests.

Item [6]
The scheduled fee for chemical testing item 66638 is increased to more accurately reflect test costs.

Items [7] and [8]
Prostate specific antigen (PSA) testing item 66659 is split into two items (66659 and 66660) with reference to age related medians for PSA levels to reflect best pathology practice.

Item [9]
New item 66900 for breath testing to determine CO2 levels is a mirror item for 12533, and is created to solve a Medicare Australia billing issue resulting from a recent system change. Item 12533 has previously received policy approval.

Item [10]
Item 71200 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 is amended to aid clarification when requesting.

Item [11]
Item 73049 is amended to specify fine needle aspiration from one site only, to transfer claims for 2 or more to a new item (73062, below).

Item [12]
A reference to new fine needle aspiration item 73062 is added to item 73059 to allow for immunocytochemical examination of material obtained by this method, for 1 to 3 antibodies.

Item [13]
A reference to new fine needle aspiration item 73062 is added to item 73060 to allow for immunocytochemical examination of material obtained by this method, for 4 to 6 antibodies.

Item [14]
Item 73060 is amended to specify a limit of 6 antibodies, to accommodate the creation of a new item for higher numbers of antibodies.

Item [15]
A reference to new fine needle aspiration item 73062 is added to item 73061 to allow for immunocytochemical examination of material obtained by this method, for 1 to 3 from a list of antibodies that attract a higher fee [oestrogen, progesterone and c-erb-B2 (HER2)].

Item [16]
New item 73062 is introduced for fine needle aspiration of 2 or more sites, with a higher fee to reflect the additional work involved.

New item 73063 is added for the cytology of material obtained directly from a patient by fine needle aspiration where an employee of the Approved Pathology Authority (APA) also attends the aspiration for confirmation of sample adequacy, to reduce repeat testing due to inadequate samples and reduce the burden on pathologists travelling themselves.

New item 73064 provides a fee for immunocytochemical examination of material, for 7 to 10 antibodies. This item creates an item ladder to cover testing for multiple antibodies.

New item 73065 provides a fee for immunocytochemical examination of material, for 11 or more antibodies. This item creates an item ladder to cover testing for multiple antibodies.

Item [17]
The wording of item 73300 is amended to refer to intellectual disability, ataxia, neurodegeneration, or premature ovarian failure consistent with an FMR1 mutation rather than fragile X syndrome, to better reflect current genetic testing.