# EXPLANATORY STATEMENT

Select Legislative Instrument No. 85, 2015

*Health Insurance Act 1973*

*Health Insurance (Pathology Services Table) Regulation 2015*

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.

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.

Subsection 4A(1) of the Act provides that the regulations may prescribe a table of pathology services which sets out items of pathology services, the fees applicable for each item, and rules for interpreting the table. The *Health Insurance (Pathology Services Table) Regulation 2014* (PST) currently prescribes such a table.

Subsection 4A(2) of the Act provides that unless repealed earlier, this regulation will cease to be in force and will be taken to have been repealed on the day following the 15th sitting day of the House of Representatives after the end of a 12 month period which begins on the day when the regulation is registered on the Federal Register of Legislative Instruments (FRLI). The PST was registered on the FRLI on 20 October 2014.

The purpose of the regulation is to repeal the PST and prescribe a new table of pathology services for the 12 month period beginning on 1 July 2015. The PST will be remade on 1 July 2015 to align the timing with the General Medical Services Table which is 1 July 2015. The Diagnostic Imaging Services Table, made under subsection 4AA(1) of the Act, will also be remade to commence on 1 July 2015. Aligning the commencement dates of the three components of the full Medical Benefits Schedule (MBS) is a coherent approach as there is no administrative or policy reason to have the three components of the MBS remade at different times of the year. Standardising the remake of the full MBS gives practitioners and patients more clarity and certainty on the MBS remake process.

Additionally, machinery amendments will be made by inserting the substance of the *Health Insurance (HbA1c Test for Diagnosis of Diabetes) Determination 2014* (Diabetes Determination) and the *Health Insurance (RET Gene Testing) Determination 2014* (RET Gene Determination) into the PST. The Diabetes Determination created a new MBS item for the diagnosis of diabetes in asymptomatic patients at high risk. The RET Gene Determination created two new MBS items for the detection of certain mutations in the RET Gene. Allowing the substance of these determinations to be moved into the PST will allow the current arrangements to continue under the authority of the PST

Details of the regulationare set out in the Attachment.

The Act specifies no conditions which 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 on 1 July 2015.

Consultation

Consultation was not undertaken for this instrument as it is of a machinery nature and it does not alter existing arrangements.

Consultation was undertaken prior to the making of the *Health Insurance (HbA1c Test for Diagnosis of Diabetes) Determination 2014* and the *Health Insurance (RET Gene Testing) Determination 2014.*

RET mutation testing, and the associated genetic counselling, of patients suspected of having multiple endocrine neoplasia type II (MEN2) and their close family members is currently standard clinical practice offered in state and territory hospitals and private facilities.  An application for public funding for RET gene test was received in October 2010.  This application was sponsored by the Royal College of Pathologists of Australasia (RCPA) and considered by the Medical Services Advisory Committee (MSAC) in August 2013.

After considering the evidence relating to the safety, effectiveness and cost-effectiveness, MSAC made a recommendation to the Australian Government to publicly fund these services.

An application requesting Medicare listing of HbA1c testing for the diagnosis of diabetes mellitus (diabetes) was received from the Australian Diabetes Society, the Royal College of

Pathologists of Australasia and the Australasian Association of Clinical Biochemists by the

Department of Health in May 2012. The application was considered by MSAC in April 2014.  MSAC considered that access to HbA1C testing for diabetes diagnosis was clinically relevant and would provide a safe, effective and cost effective alternative to conventional testing and would improve patient compliance and early detection of diabetes. Therefore, MSAC recommended that public funding be supported for this service.

Authority: Subsection 133(1) of the

*Health Insurance Act 1973*

**ATTACHMENT**

DETAILS OF THE HEALTH INSURANCE (PATHOLOGY SERVICES TABLE) REGULATION 2015

# Section 1 – Name of regulation

# This section provides for the regulation to be referred to as the *Health Insurance (Pathology Services Table) Regulation 2015* (the Regulation).

Section 2 – Commencement

This section provides for the regulation to commence on 1 July 2015.

Section 3 – Authority

This 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 instrument is amended or repealed as set out in the applicable items in the Schedule concerned.

Section 5 – Pathology services table

This section provides that the new table of pathology services set out in Schedule 1 be prescribed for subsection 4A(1) of the Act.

Section 6 – Dictionary

This section provides for a Dictionary at the end of the regulation, which defines certain words and expressions used in the regulation, and includes references to certain words and expressions which are defined elsewhere in the regulation.

Part 2 of Schedule 1 – Pathology services table

This part of the regulation continues the Pathology Services Table and makes machinery amendments by:

* Inserting the item and relevant clauses of the *Health Insurance (HbA1c Test for Diagnosis of Diabetes) Determination 2014* in Group P2 and at subclause 2.2.6(1), and
* Inserting the items and relevant clauses of the *Health Insurance (RET Gene Testing) Determination 2014* in Group P7 and at clause 2.7.3.

Schedule 2 – Repeal

This section repeals the *Health Insurance (Pathology Services Table) Regulation 2014*.

**Statement of Compatibility with Human Rights**

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

***Health Insurance (Pathology Services Table) Regulation 2015***

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 *Health Insurance (Pathology Services Table) Regulation 2015*repealsthe *Health Insurance (Pathology Services Table) Regulation 2014* to align the timing of the Pathology Services Table (PST) remake with the General Medical Services Table remake which is also 1 July 2015.

In accordance with section 4A(1) of the Act, the regulation prescribes a table of pathology services containing: items of services, the amounts of fees applicable for each item, and rules for interpretation. The minor amendments to the regulation involve the insertion of the substance of the *Health Insurance (HbA1c Test for Diagnosis of Diabetes) Determination 2014* (Diabetes Determination) and the *Health Insurance (RET Gene Testing) Determination 2014* (RET Gene Determination) into the PST.

**Human rights implications**

The regulations engage Articles 2, 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 is 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.

Analysis

The amendments to the regulation maintain current rights to health and social security by maintaining access to publicly subsidised health services. The Diabetes Determination created a new item for the diagnosis of diabetes in asymptomatic patients at high risk. The RET Gene Determination created two items for the detection of certain mutations in the RET Gene. Transferring these items into the PST maintains current rights to health.

**Conclusion**

The Legislative Instrument is compatible with human rights because it maintains existing arrangements and the protection of human rights.

**Sussan Ley**

**Minister for Health**