EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Pathology Services Table) Regulations 2020

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 regulations may prescribe a table of pathology services which set out items of pathology services, the fees applicable for each item, and rules for interpreting the table. The table made under this subsection is referred to as the pathology services table (PST).

Subsection 4A(2) of the Act provides that unless repealed earlier, the PST will cease to be in force and will be taken to have been repealed on the day following the 15th sitting day of the House of Representatives after the end of a 12 month period which begins on the day when the regulation is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 Legislation (FRL). The *Health Insurance (Pathology Services Table) Regulations 2019* (the 2019 Regulations) were registered on 8 April 2019.

Purpose

The purpose of the *Health Insurance (Pathology Services Table) Regulations 2020* (the Regulations) is to repeal the 2019 Regulations and prescribe a new table of pathology services from 1 May 2020. This will ensure that Medicare benefits continue to be payable for pathology services.

The Regulations will implement a number of policy changes that were recommended by the Medical Services Advisory Committee (MSAC) and announced by the Government in the 2019-20 Mid-Year Economic and Fiscal Outlook (MYEFO) under the *Guaranteeing Medicare – Medicare Benefits Schedule – new and amended listings* measure.

These changes include the introduction of new items for diagnostic genetic testing for familial hypercholesterolemia (FH) in clinically affected individuals and predictive testing of biological relatives. New items for genetic testing for childhood syndromes and for hereditary colorectal and endometrial cancers, and new items for genetic testing of somatic markers for diagnosis and classification of tumours will also be introduced.

The Regulations will also implement a number of editorial and drafting improvement amendments, which are cost neutral.

Consultation

In accordance with section 17 of the *Legislation Act 2003*, appropriate consultation was conducted with experts in the field of pathology and stakeholders that would be affected by the proposed policy changes resulting in the addition of new items in the Regulations. The Department of Health consulted with the Royal College of Pathologists Australasia, Public Pathology Australia and Australian Pathology on the form and substance of the new items.

Consultation was also undertaken as part of the MSAC application process for the introduction of the new items for diagnostic genetic testing for FH in clinically affected individuals and predictive testing of biological relatives.

Consultation was undertaken as part of the MSAC process for the new items for genetic testing for childhood syndromes and for hereditary colorectal and endometrial cancers and new items for genetic testing of somatic markers for diagnosis and classification of tumours. MSAC reviews new or existing medical services or technology, and the circumstances under which public funding should be supported through listing on the MBS.

The Department of Health did not consult on the editorial changes to the Regulations made by the First Parliamentary Counsel under section 15V of the *Legislation Act 2003*.

Details of the Regulations are set out in the Attachment.

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

The Regulations commence on 1 May 2020.

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

ATTACHMENT

Details of the *Health Insurance (Pathology Services Table) Regulations 2020*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance (Pathology Services Table) Regulations 2020*.

Section 2 – Commencement

This section provides for the Regulations to commence on 1 May 2020.

Section 3 – Authority

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

Section 4 – 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 5 – Dictionary

This section provides for a Dictionary in Part 4 of Schedule 1 at the end of the Regulations.

Section 6 – Schedule 2

This section provides that each instrument that is specified in Schedule 2 to this instrument is amended or repealed as set out in the applicable items in the Schedule, and any other item in a Schedule has effect according to its terms.

Schedule 1 – Pathology services table

This part of the Regulations remakes the existing pathology services table, which is currently prescribed by the *Health Insurance (Pathology Services Table) Regulations 2019* (the 2019 Regulations).

The Regulations will make the following changes to the existing table.

Changes to pathology services recommended by the Medical Services Advisory Committee (MSAC)

Diagnostic genetic testing for familial hypercholesterolemia (MSAC Application 1534)
The Regulations will introduce two new items (73352 and 73353) for genetic testing to confirm a FH diagnosis (in patients who are suspected of having inherited their high blood cholesterol), and will also allow for cascading testing to be conducted in other family members of those affected individuals who show to have relevant mutations.

Genetic testing for childhood syndromes (MSAC Application 1476)
The Regulations will introduce six new items (73358, 73359, 73360, 73361, 73362 and 73363) for genetic testing either using whole exome sequencing or whole genome sequencing

to test clinically affected children for childhood syndromes. These tests are for children aged 10 years or younger with an onset of clinical features/symptoms indicating a syndromic disorder including a minimum of one of the two following indications: at least one major congenital structural anomaly and dysmorphic facial features, or intellectual disability or global development delay of at least moderate severity.

Genetic testing for hereditary colorectal and endometrial cancers (MSAC Application 1504)

The Regulations will introduce four new items (73354, 73355, 73356 and 73357) for the genetic testing for hereditary colorectal and endometrial cancers which aims to improve the identification of people at greater risk of developing these cancers and allows for the appropriate change in management to prevent the progression of the disease.

Genetic testing of somatic markers for diagnosis and classification of tumours (MSAC Applications 1526, 1527 and 1528)

The Regulations will introduce 20 new items (73364 to 73383) for the somatic gene testing for the diagnosis and prognosis of a range of rare cancers including: different lymphomas, T-cell prolymphocytic leukaemia, plasma cell myeloma, central nervous system neoplasms, sarcomas and various carcinomas. These genetic tests will provide a definitive diagnosis and inform subsequent patient interactions and management.

Editorial and drafting improvement changes

Group P3—Microbiology – item 69319

The Regulations will amend item 69319 to include 'or more' for when '2 tests or more' are performed under item 69494 for a detection of a virus, microbial antigen or microbial nucleic acid which clarifies the intent of the item.

Amendments and removal of definitions

Some minor changes will be incorporated to improve the clarity and consistency of the Regulations. This includes changing the references of 'this table' to this Schedule', using the term 'Restriction of items' as an indication of the nature of the restriction in the clause instead of 'Application of items', and adding subclause headings where it will be useful.

The Regulations will also improve the clarity of clause 2.1.2 'Restrictions on items in *Group P1'* by separating out the paragraphs. The Regulations will also separate out the paragraphs in clause 2.5.1 'Restrictions on items in *Group P5'* to improve clarity.

The Regulations will amend clause 1.2(1) to become clause 1.1B *methodology for services* which will then apply to the whole pathology services table.

The Regulations will incorporate the definition of abnormal level of TSH in clause 2.2.4 into item 66719 as it is part of the conditions for that item. The definition for approved collection centre under clause 2.10.1 will be moved into Part 4.1 of the Dictionary.

The Regulations will amend the definition of *Commonwealth concession card holder*, which is in clause 2.12.1, so it is consistent with the definition in the general medical services table. Consequential amendments will also occur to Part 4.1 of the Dictionary and items 74990 and 74991 to reflect this change. Item descriptor 74991 will also be amended to clarify the practice location eligible area.

The definition of compatibility tests by crossmatch under clause 2.1.2 will be removed and the material incorporated into item descriptors 65090 and 65093. Clause 2.7.1 *Elevated serum ferritin* will also be incorporated into the descriptor for item 73317.

The Regulations also remove the definition of *Group in Part 4.1 – Dictionary*, as the definition is not required. The definition of *institution* under clause 2.10.1 will be amended to *care institution* and the limitations will also be removed. Consequential amendments to reflect this change will occur to items 73932, 73933, 73934 and 73935.

The Regulations will remove the limitations to clause 2.10.1 *prescribed laboratory* and clause 2.5.1 *separately identified specimen* to enable the definitions to become general definitions in *Part 4.1 of the Dictionary*.

The definition of *residential care facility* will be amended in the Regulations to be *residential aged care facility* to reflect the terminology in section 41-3 of the *Aged Care Act 1997*.

The Regulations will amend the definition of *serial examinations* under *Part 4.1 of the Dictionary* to include cultures, and to ensure it aligns with clause 2.3.1.

The Regulations will make improvements to clarify the application of clause 1.3 *Services to which clause 1.2 (Circumstances in which services rendered following 2 requests to be taken to have been rendered following one request)* does not apply by moving related clauses together.

The Regulations will also move the definition of *complexity level* from clause 2.5.2(4) into clause 2.5.1 and will also include this definition in *Part 4.1 of the Definitions*.

The Regulations will amend the definition *unreferred services* so it is consistent with the definition in the general medical services table.

The amendments and removal of definitions are cost neutral and administrative in nature.

Incorporate cystic fibrosis gene testing services
The Regulations will incorporate six items (73345, 73346, 73347, 73348, 73349 and 73350) from the *Health Insurance (Section 3C Pathology Services – Cystic fibrosis gene testing) Determination 2018*. These changes are machinery in nature.

Incorporate alport syndrome testing services
The Regulations will incorporate two items (73298 and 73299) from the *Health Insurance (Section 3C Pathology Services – Alport Syndrome Testing) Determination 2019.* These changes are machinery in nature.

Schedule 2 – Repeals

This section repeals the 2019 Regulations.

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) Regulations 2020

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 Regulations

The purpose of the *Health Insurance (Pathology Services Table) Regulations 2020* (the Regulations) is to repeal the *Health Insurance (Pathology Services Table) Regulations 2019* and prescribe a new table of pathology services from 1 May 2020. This will ensure that Medicare benefits continue to be payable for pathology services.

The Regulations will implement a number of policy changes that were recommended by the Medical Services Advisory Committee (MSAC) and announced by the Government in the 2019-20 Mid-Year Economic and Fiscal Outlook (MYEFO) under the *Guaranteeing Medicare – Medicare Benefits Schedule – new and amended listings measure.*

These changes include the introduction of new items for diagnostic genetic testing for familial hypercholesterolemia (FH) in clinically affected individuals and predictive testing of biological relatives. New items for genetic testing for childhood syndromes and for hereditary colorectal and endometrial cancers, and new items for genetic testing of somatic markers for diagnosis and classification of tumours will also be introduced.

The Regulations will also implement a number of editorial and drafting improvement amendments, which are cost neutral.

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.

Analysis

The Regulations maintain rights to health and social security by ensuring access to publicly-subsidised pathology services which are clinically and cost-effective.

Conclusion

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

Greg Hunt

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