

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Legislation Amendment (2017 Measures No. 3) Regulations 2017

Subsection 133(1) of 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 4(1) and 4A(1) of the Act provides that regulations may prescribe a table of medical and pathology services which set out items of services, the fees applicable for each item, and rules for interpreting the tables. The *Health Insurance (General Medical Services Table) Regulations 2017* (GMST) and the *Health Insurance (Pathology Services Table) Regulations 2017* (PST) currently prescribe such tables.

Paragraph 16A(1)(aa) of the Act provides that Medicare benefits are payable in relation to pathology services when determined to be necessary by a participating midwife if specified in regulations. Regulation 11A of the *Health Insurance Regulations 1975* (HIR) specifies the items which can be determined to be necessary by participating midwives.

Purpose

The purpose of the *Health Insurance Legislation Amendment (2017 Measures No. 3) Regulations 2017* (the Regulations) is to amend the GMST, PST and the HIR from 1 December 2017. The Regulations implement new items for cervical screening as part of the implementation of the National Cervical Screening Program (NCSP) as agreed by Government in the 2015-16 Budget following recommendations of the Medical Services Advisory Committee (MSAC). MSAC reviews new medical services or technology and the circumstances under which public funding should be supported by Medicare.

From 1 December 2017, primary human papillomavirus (HPV) testing with reflex Liquid Based Cytology (LBC), if required, will be the primary screening test used in the NCSP.

The cervical screening changes include:

- the removal of the six existing pap test items (69418, 69419, 73053, 73055, 73057 and 73069) from the PST;
- the creation of seven new HPV items (73070, 73071, 73072, 73073, 73074, 73075 and 73076) in the PST;
- consequential amendments to the PST and HIR to remove references to deleted items and insert references to new items; and
- amendments to 14 practice incentive items in the GMST to reflect the terminology change from “cervical smear” to “cervical screening” and amend the eligible age limits to be consistent with the new pathology (for ‘cervical screening’) items.

The Regulations also make the following amendments:

- amendments to items 69488 (for the quantitation of hepatitis C virus Ribonucleic Acid load in plasma or serum) and 69491 (for nucleic acid amplification and determination of hepatitis C virus genotype) in the PST to allow general practitioners and nurse practitioners to order these tests before prescribing Hepatitis C antiviral agents; and
- amendments to bone densitometry items 12320 and 12322 to clarify the policy intent of the items.

Consultation

The Department of Health has consulted widely on the Renewal of the National Cervical Screening Program. Key consultation partners include states and territories, healthcare providers, pathologists, colposcopists and consumers. The Renewal has been supported by the Royal Australian College of General Practitioners, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal College of Pathologists of Australasia, the Australian Society of Gynaecologic Oncologists and the Australian Society for Colposcopy and Cervical Pathology.

The changes to items 69488 and 69491 (to allow GPs and nurse practitioners to order these tests before prescribing Hepatitis C antiviral agents) came out of an Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) submission considered by the Pharmaceutical Benefits Advisory Committee (PBAC). ASHM consulted with clinicians on the proposed changes. The change is the implementation of a PBAC recommendation.

The changes made on 1 November 2017 in the *Health Insurance Legislation Amendment (2017 Measures No. 2) Regulations 2017* to bone densitometry items 12320 and 12322 inadvertently removed the capacity for patients aged 70 years or over to have the initial bone mineral density test. Amendments to the bone densitometry items to clarify the policy intent are in response to correspondence from the Australian Diagnostic Imaging Association which sought clarification that patients aged 70 years or over, who had not had prior testing, retained their eligibility for an initial bone density test. These amendments also clarify the t-scores required to claim bone densitometry scans. These changes ensure the item descriptions in the Regulations are consistent with the MBS Review Taskforce recommendations and appropriate clinical practice.

Details of the Regulation are 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 *Legislation Act 2003*.

The Regulations commence on 1 December 2017.

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

ATTACHMENT

Details of the *Health Insurance Legislation Amendment (2017 Measures No. 3) Regulations 2017*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Health Insurance Legislation Amendment (2017 Measures No. 3) Regulations 2017*.

Section 2 – Commencement

This section provides that the Regulations commence on 1 December 2017.

Section 3 – Authority

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

Section 4 – Schedule(s)

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

Schedule 1 – Amendments

Part 1—Cervical screening

Health Insurance (General Medical Services Table) Regulations 2017

Item 1 – Division 2.19 of Schedule 1 (Subgroup 1 of Group A18 table, heading)

This item makes a consequential amendment by repealing the current subheading for division 2.19, subgroup 1 of group A18 and substituting with “Collection of a cervical screening specimen from an unscreened or significantly underscreened person”. This change was made to reflect the terminology change from cervical smear to cervical screening.

Item 2 – Schedule 1 (cell at item 2497, column headed “Description”)

This item makes a consequential amendment by repealing and replacing the current description of item 2497. This change was made to reflect the terminology change from “cervical smear” to “cervical screening” and amend the eligible age limits to be consistent with the new pathology (for ‘cervical screening’) items.

Item 3 – Schedule 1 (items 2501, 2503, 2504, 2506, 2507 and 2509, column headed “Description”)

This item makes a consequential amendment by omitting “at which a papanicolaou smear is taken from a person at least 20 years old and not older than 69 years old, who has not had a papanicolaou smear in the last 4 years”, and substituting with “at which a specimen for a cervical screening service is collected from the patient, if the patient is at least 24 years and 9 months of age but is less than 75 years of age and has not been provided with a cervical screening service or a cervical smear service in the last 4 years”. This change is to reflect the

terminology change from “smear” to “cervical screening” and amend the eligible age limits to be consistent with the new pathology (for ‘cervical screening’) items.

Item 4 – Division 2.19 of Schedule 1 (Subgroup 1 of Group A19 table, heading)

This item makes a consequential amendment by repealing the current subheading for division 2.19, subgroup 1 of group A19 and substituting with “Collection of a cervical screening specimen from an unscreened or significantly underscreened person”. This change is to reflect the terminology change from cervical smear to cervical screening.

Item 5 – Schedule 1 (item 2598, column headed “Description”)

This item makes a consequential amendment by omitting “at which a cervical smear is taken from a person between the ages of 20 and 69 years (inclusive) who has not had a cervical smear in the last 4 years”, and substituting with “at which a specimen for a cervical screening service is collected from the patient, if the patient is at least 24 years and 9 months of age but is less than 75 years of age and has not been provided with a cervical screening service or a cervical smear service in the last 4 years”. This change is to reflect the terminology change from “cervical smear” to “cervical screening” and amend the eligible age limits to be consistent with the new pathology (for ‘cervical screening’) items.

Item 6 – Schedule 1 (items 2600, 2603, 2606, 2610, 2613 and 2616, column headed “Description”)

This item makes a consequential amendment by omitting “at which a cervical smear is taken from a person between the ages of 20 and 69 (inclusive) who has not had a cervical smear in the last 4 years”, and substituting with “at which a specimen for a cervical screening service is collected from the patient, if the patient is at least 24 years and 9 months of age but is less than 75 years of age and has not been provided with a cervical screening service or a cervical smear service in the last 4 years”. This change is to reflect the terminology change from “cervical smear” to “cervical screening” and amend the eligible age limits to be consistent with the new pathology (for ‘cervical screening’) items.

Item 7 – Schedule 1 (item 35614, column headed “Description”)

This item makes a consequential amendment by inserting “, an abnormal result from a cervical screening service” after “smear”. This makes it clear that this item could be used for a patient who has had a previous abnormal result from a cervical smear or a cervical screening service.

Item 8 – Clause 3.1 of Schedule 1

This item inserts the meaning of “cervical screening service” and “cervical smear service” into the dictionary. This is to help providers differentiate between the new cervical screening items and the former items for a cervical smear service.

Health Insurance (Pathology Services Table) Regulations 2017

Item 9 – Subclause 1.2.6(1) of Schedule 1 (definition of set of pathology services)

This item makes a minor amendment to subclause 1.2.6(1) by repealing the reference to where the definition of ‘set of pathology services’ can be found. This is because the dictionary already refers readers to clause 1.2.7 for the definition of ‘set of pathology services’.

Item 10 – Subclause 1.2.7 of Schedule 1 (heading)

This item makes a minor wording change by repealing the heading “Meaning of set of pathology services” and substituting it with “Definition of set of pathology services”. This is to clarify the contents of subclause 1.2.7.

Item 11 – Subclause 1.2.7(1) of Schedule 1 (paragraph (d) of the definition of set of pathology services)

This item makes a consequential amendment by removing existing items 73053, 73055 and 73069 and inserting the new cervical screening items 73070, 73071, 73072, 73073, 73074, 73075 and 73076 in paragraph 1.2.7(1)(d). This means these items are not considered a set of pathology services.

Item 12 – Paragraph 1.2.7(2)(b) of Schedule 1

This item makes a consequential amendment by removing item 69419 from paragraph 1.2.7(2)(b). This is because item 69419 has been removed from 1 December 2017.

Item 13 – Subclause 2.3.4(3) of Schedule 1

This item makes a consequential amendment by removing subclause 2.3.4(3) which contains a reference to items 69418 and 69419. This is because items 69418 and 61419 have been replaced with new items for cervical screening.

Item 14 – Schedule 1 (items 69418 and 69419)

This item removes items 69418 and 69419 from the PST. These items have been removed and replaced with new items for cervical screening.

Item 15 – Subparagraph 2.5.2(1)(a)(iii) of Schedule 1

This item makes a consequential amendment by removing existing items 73053, 73055, 73057 and 73069 and inserting the new cervical screening items 73070, 73071, 73072, 73073, 73074, 73075 and 73076.

Item 16 - Schedule 1 (item 73045, column headed “Pathology service”)

This item makes a consequential amendment by removing references to existing items 73053 and 73069 and adding new item 73076 in the descriptor for item 73045.

Item 17 – Schedule 1 (items 73053, 73055 and 73057)

This item removes existing items 73053, 73055 and 73057 from the PST. These items give effect to the former cervical screening program and are no longer relevant following the introduction of the new program.

Item 18 – Schedule 1 (item 73069)

This item removes item 73069 and inserts new cervical screening items 73070, 73071, 73072, 73073, 73074, 73075 and 73076. New items 73070 to 73075 are a test for oncogenic human papillomavirus with partial genotyping and item 73076 is for cytology of a liquid-based cervical or vaginal specimen.

Item 19 - Schedule 1 (items 73922 and 73923)

This item makes a consequential amendment by removing references to items 73053, 73055, 73057 and 73069 in the descriptors for items 73922 and 73923 (for patient episode initiation). This change also inserts the new cervical screening items 73070, 73071, 73072, 73073,

73074, 73075 and 73076 into the descriptors of items 73922 and 73923, allowing them to be used as patient episode initiation items for the new items.

Item 20 – Clause 3.1 of Schedule 1 (table)

This item makes a consequential amendment by removing the abbreviation for Cervix—cytology—abnormalities for item 73055, and the abbreviation for Cervix—cytology—routine for item 73053 from the table in clause 3.1. These abbreviations relate to the former cervical screening program and are no longer relevant following the introduction of the new program.

Item 21 – Clause 3.1 of Schedule 1 (table)

This item makes a consequential amendment by removing the abbreviation for Cytology—from cervix—abnormalities for item 73055, and the abbreviation for Cytology—from cervix—routine for item 73053 from the table in clause 3.1. These abbreviations relate to the former cervical screening program and are no longer relevant following the introduction of the new program.

Item 22 – Clause 3.1 of Schedule 1 (table)

This item makes a consequential amendment by removing the abbreviation for cytology—from vagina for item 73057 from the table in clause 3.1. This abbreviation relates to the former cervical screening program and is no longer relevant following the introduction of the new program.

Item 23 – Clause 3.1 of Schedule 1 (table)

This item inserts an abbreviation for diethylstilboestrol in the table in clause 3.1 for new item 73072.

Item 24 – Clause 3.1 of Schedule 1 (table item for Human papillomaviruses, column headed “item”)

This item makes a consequential amendment by removing item 69418 in the column titled ‘Item’ in the row that specifies the abbreviation for Human papillomaviruses, and inserting the new cervical screening items 73070, 73071, 73072, 73073, 73074 and 73075 in the column.

Item 25 – Clause 3.1 of Schedule 1 (table item for Liquid based cytology, column headed “Item”)

This item makes a consequential amendment by removing item 73069 in the column titled “Item” in the row that specifies the abbreviation for liquid based cytology, and inserting the new cervical screening item 73076 in the column.

Item 26 – Clause 3.1 of the Schedule 1 (table)

This item makes a consequential amendment by removing the abbreviations for pap smears and papanicolaou test for item 73053. These abbreviations relate to the former cervical screening program and are no longer relevant following the introduction of the new program.

Item 27 – Clause 3.1 of Schedule 1 (table)

This item makes a consequential amendment by removing the abbreviation for Vagina—cytology on specimens for item 73057 from the table in clause 3.1. This abbreviation relates to the former cervical screening program and is no longer relevant following the introduction of the new program.

Item 28 – At the end of Schedule 1

This item inserts a transitional provision to allow items 73053, 73055, 73057 and 73069 to continue to apply after the introduction of the new cervical screening program (on 1 December 2017) if they were requested before 1 December 2017 but not performed until after 1 December 2017. The transitional provision applies until the end of 31 January 2018.

Health Insurance Regulations 1975**Item 29 - Subregulation 11A(1)**

This item makes a consequential amendment by removing item 73053 and inserting the new cervical screening items 73070, 73071, 73075, 73076 into subregulation 11A(1). This allows these new items to be requested by a participating midwife.

Part 2—Hepatitis C testing***Health Insurance (Pathology Services Table) Regulations 2017*****Item 30 - Schedule 1 (item 69488, column headed “Pathology service”)**

This item omits the reference to specialist or consultant physicians requesting this test. This is to allow general practitioners and nurse practitioners to order these tests before prescribing Hepatitis C antiviral agents.

Item 31 - Schedule 1 (cell at item 69491, column headed “Pathology service”)

This item omits the reference to specialist or consultant physicians requesting this test. This is to allow general practitioners and nurse practitioners to order these tests before prescribing Hepatitis C antiviral agents.

Part 3 – Bone densitometry***Health Insurance (General Medical Services Table) Regulations 2017*****Item 32 - Schedule 1 (item 12320, column headed “Description”, paragraph (b))**

This item amends bone densitometry item 12320 to clarify that the item can be claimed for a patient that has not previously had bone densitometry if they are 70 years old or older. This item also clarifies that patients 70 years or older, who have previously had their bone density measured, can access the test every five years if their t-score is -1.5 or more.

Item 33 - Schedule 1 (item 12322, column headed “Description”, paragraph (b))

This item amends bone densitometry item 12322 to clarify that patients 70 years or older, who have previously had their bone density measured, can access the test every two years if their t-score is less than -1.5 but more than -2.5.

Statement of Compatibility with Human Rights

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

Health Insurance Legislation Amendment (2017 Measures No. 3) Regulations 2017

This Disallowable 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 Disallowable Legislative Instrument

The purpose of the Health Insurance Legislation Amendment (2017 Measures No. 3) Regulations 2017 (the Regulations) is to amend the GMST, PST and the HIR from 1 December 2017. The Regulations implement new items for cervical screening as part of the implementation of the National Cervical Screening Program (NCSP) as agreed by Government in the 2015-16 Budget following recommendations of the Medical Services Advisory Committee (MSAC). MSAC reviews new medical services or technology and the circumstances under which public funding should be supported by Medicare.

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The Regulations also make the following amendments:

amendments to items 69488 (for the quantitation of hepatitis C virus Ribonucleic Acid load in plasma or serum) and 69491 (for nucleic acid amplification and determination of hepatitis C virus genotype) in the PST to allow general practitioners and nurse practitioners to order these tests before prescribing Hepatitis C antiviral agents; and amendments to bone densitometry items 12320 and 12322 to clarify the policy intent of the items.

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

This Regulation will maintain rights to health and social security by ensuring access to publicly subsidised health services which are clinically effective and cost-effective.

Conclusion

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

Greg Hunt

Minister for Health