

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Legislation Amendment (Commonwealth Price-Mark-ups) Determination 2020

Authority

Subsection 99(4) of the *National Health Act 1953* (the Act) provides that an approved hospital authority is entitled to payment from the Commonwealth, at such rates and subject to such conditions as the Minister determines, in respect of the supply of particular quantities or numbers of units of pharmaceutical benefits to patients receiving treatment in or at a hospital in respect of which the approved hospital authority is approved.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Purpose

The *National Health (Pharmaceutical Benefits) Legislation Amendment (Commonwealth Price-Mark-ups) Determination 2020* (the Amendment Determination) amends the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied by Private Hospitals) Determination 2020* and the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017*, to maintain the alignment of wholesale, storage and handling mark-ups across the range of Pharmaceutical Benefits Scheme (PBS) dispensing environments following changes to take effect from 1 January 2021 to the structure of the wholesale mark-up component of the Commonwealth Price for ready-prepared pharmaceutical benefits. These changes were agreed as a part of the Seventh Community Pharmacy Agreement (the 7th CPA), and given force by the *Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Amendment Determination 2020*, which came into effect on 1 July 2020.

The Amendment Determination establishes, via an incorporation by reference to the *Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Amendment Determination 2020*, the mark-up applicable to supplies of pharmaceutical benefits by an approved public hospital authority, and also the storage and handling mark-up applicable to supplies of pharmaceutical benefits by an approved private hospital authority, in accordance with the Act.

As a part of the 7th CPA, the parties agreed that the wholesale mark-up applying for the period from 1 July 2020 to 31 December 2020 would be the wholesale mark-up applying in the last year of the Sixth Community Pharmacy Agreement, but that from 1 January 2021 the wholesale mark-up structure would comprise:

- (a) a new, fixed \$0.41 wholesale mark-up on a pharmaceutical item for which the ex-manufacturer price is up to and including \$5.50, replacing a mark-up applied to these items of 7.52 per cent of the ex-manufacturer price;
- (b) retention of a 7.52 per cent wholesale mark-up on pharmaceutical items for which the ex-manufacturer price is more than \$5.50 and less than or equal to \$720.00; and
- (c) a new, fixed wholesale mark-up of \$54.14 on pharmaceutical items for which the ex-manufacturer price is more than \$720.00, replacing a fixed \$69.94 wholesale mark-up applied to pharmaceutical items for which the ex-manufacturer price was more than \$930.06.

Subsection 98BAA(1) of the Act requires that, where the Commonwealth and the Pharmacy Guild of Australia, or another pharmacists' organisation that represents a majority of approved pharmacists, have entered into an agreement relating to the manner in which the Commonwealth price for pharmaceutical benefits is to be calculated, the Pharmaceutical Benefits Remuneration Tribunal (the Tribunal), when making a determination pursuant to paragraph 98B(1)(a) of the Act, is to give effect to the terms of that agreement.

The 7th CPA was signed on 11 June 2020 by the Commonwealth, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia, and constitutes an agreement between the Commonwealth and the Pharmacy Guild of Australia for the purposes of subsection 98BAA(1) of the Act. The 7th CPA sets out the manner in which the Commonwealth price for a pharmaceutical benefit is to be calculated.

No other components of the dispensed price for the supply of a pharmaceutical benefit by an approved hospital authority are affected by the Amendment Determination.

Some minor and technical changes have also been made to clarify existing policy, and to update obsolete and incorrect references.

Role of the Pharmaceutical Benefits Remuneration Tribunal

Paragraph 98B(1)(a) of the Act provides that a function of the Tribunal is to determine the manner in which the Commonwealth price for all or any pharmaceutical benefits is to be worked out for the purpose of payments to approved pharmacists for the supply of pharmaceutical benefits.

Consultation

The Department of Health consulted Services Australia, and the Medical Software Industry Association and dispensing software vendors with products operating in hospitals. State and territory governments, and private hospitals, were not consulted on the Amendment Determination as it is a consequential amendment due to changes introduced through the 7th CPA (which was announced by the Minister for Health on 12 June 2020), and simply maintains the alignment of wholesale mark-ups that commenced on 1 October 2019.

The Amendment Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the *National Health (Pharmaceutical Benefits) Legislation Amendment (Commonwealth Price-Mark-ups) Determination 2020*

Section 1 Name

Section 1 provides that the name of the instrument is the *National Health (Pharmaceutical Benefits) Legislation Amendment (Commonwealth Price—Mark-ups) Determination 2020*.

Section 2 Commencement

Section 2 provides that the instrument commences on 1 January 2021.

Section 3 Authority

Section 3 provides that the Amendment Rules are made under subsection 99(4) of the *National Health Act 1953*.

Section 4 Schedules

Section 4 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

National Health (Commonwealth Price - Pharmaceutical benefits supplied by private hospitals) Determination 2020 (PB 99 of 2020)

Item 1 – Section 3 (definition of *Approved Pharmacists Determination*)

This item repeals the definition of ‘Approved Pharmacists Determination’ at section 3 of the Instrument and substitutes a new definition which states that ‘Approved Pharmacists Determination’ means the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020* (PB 66 of 2020).

Item 2 – Section 3 (definition of *dispensed price*)

This item repeals the definition of ‘dispensed price’ at section 3 of the Instrument and substitutes a new definition which states:

- (a) for a ready-prepared pharmaceutical benefit—has the meaning given by section 9; and
- (b) for an extemporaneously-prepared pharmaceutical benefit—has the meaning given by subsection 16(1).

Item 3 – Sub-subparagraph 9(1)(a)(i)(B)

This item omits “worked out under section 11A”, and substitutes “under section 10”. The effect of this amendment is to correct references in the Instrument.

Item 4 – Sub-subparagraph 9(1)(a)(i)(C)

This item omits “12”, and substitutes “11”. The effect of this amendment is to correct references in the Instrument.

Item 5 – Subparagraph 9(1)(b)(i)

This item omits “14”, and substitutes “13”. The effect of this amendment is to correct references in the Instrument.

Item 6 – Subparagraph 9(1)(b)(iv)

This item omits “13”, and substitutes “12”. The effect of this amendment is to correct references in the Instrument.

Item 7 – Subparagraph 9(1)(c)(i)(B)

This item omits “worked out under section 11A”, and substitutes “under section 10”. The effect of this amendment is to correct references in the Instrument.

Item 8 – Sub-subparagraph 9(1)(c)(i)(C)

This item omits “12”, and substitutes “11”. The effect of this amendment is to correct references in the Instrument.

Item 9 – Subparagraph 9(1)(c)(ii)

This item omits “14”, and substitutes “13”. The effect of this amendment is to correct references in the Instrument.

Item 10 – Section 10

This item repeals the section and substitutes:

10 Storage and handling mark-up (same as wholesale mark-up for approved pharmacists)

For the purposes of sub-subparagraphs 9(1)(a)(i)(B) and (c)(i)(B) and paragraph (b) of step 1 in section 13, the storage and handling mark-up for a pack quantity of a ready-prepared pharmaceutical benefit is the same as the wholesale mark-up for the pack quantity of the benefit would have been under section 11 of the Approved Pharmacists Determination if the benefit had been supplied by an approved pharmacist.

Item 11 – Section 13 (method statement, step 1, paragraph (b))

This item omits “worked out”. The effect of this amendment is to correct references in the Instrument.

National Health (Commonwealth Price—Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017 (PB 25 of 2017)

Item 12 – Subparagraphs 9(a)(ii) and (c)(ii)

This item omits “worked out”. The effect of this amendment is to correct references in the Instrument.

Item 13 – Section 11 (method statement, step 1)

This item repeals step 1 of the method statement at section 11 of the Instrument and substitutes a new step:

Step 1. Ascertain the mark-up for the pack quantity under section 14.

Item 14 – Section 14

This item repeals the section and substitutes:

14 Dispensed price—mark-up (same as wholesale mark-up for approved pharmacists)

For the purposes of subparagraphs 9(a)(ii) and (c)(ii) and step 1 in section 11, the mark-up for a pack quantity of a ready-prepared pharmaceutical benefit is the same as the wholesale mark-up for the pack quantity of the benefit would have been under section 11 of the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020* (PB 66 of 2020) if the benefit had been supplied by an approved pharmacist.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Legislation Amendment (Commonwealth Price-Mark-ups) Determination 2020

Overview of the Legislative Instrument

The amendments to the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied by Private Hospitals) Determination 2020* and the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017* by the *National Health (Pharmaceutical Benefits) Legislation Amendment (Commonwealth Price-Mark-ups) Determination 2020* (the Amendment Determination) are made under the *National Health Act 1953*. The amendments maintain a consistent framework for the pricing of pharmaceutical benefits, ensuring that wholesale, storage and handling mark-ups remain aligned across the range of PBS dispensing environments.

The Amendment Determination implements current Government policy and preserves the changes given effect on 1 October 2019 through the *National Health (Commonwealth Price – Pharmaceutical Benefits Supplied By Public Hospitals) Amendment (Budget Measure) Determination 2019*. Some minor and technical changes have also been made in the Amendment Determination to clarify existing policy and update obsolete and incorrect references.

Human rights implications

The Amendment Determination engages article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health.

Right to Health

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. Whilst the UN Committee on Economic, Social and Cultural Rights has stated that the right to health is not to be understood as a right to be healthy, it does entail a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. In addition, the right to health must meet certain key requirements, including health care must be scientifically and medically appropriate and of good quality.

Analysis

The Amendment Determination ensures that the calculation of the dispensed price for pharmaceutical benefits supplied in public and private hospitals will remain aligned with the corresponding calculations that apply in community pharmacy.

More broadly, the PBS is a benefit scheme that provides subsidised access to medicines for people in the Australian community. The Amendment Determination engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), as it is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the scheme. In addition, it also assists in the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The effect of the Amendment Determination is to ensure that legislative provisions reflect arrangements agreed by Government.

Conclusion

The Amendment Determination is compatible with human rights because it supports the protection of human rights, in particular the right to health.

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