EXPLANATORY STATEMENT

National Health Act 1953

National Health (Commonwealth Price – Pharmaceutical Benefits Supplied by Public Hospitals) Amendment (Budget Measure) Determination 2019

PB 57 of 2019

The purpose of the National Health (Commonwealth Price- Pharmaceutical Benefits Supplied by Public Hospitals) Amendment (Budget Measure) Determination 2019 (the Determination) is to align the Pharmaceutical Benefits Scheme (PBS) wholesale mark-up for public hospitals, as applied to ready-prepared pharmaceutical benefits (as per section 85 of the *National Health Act 1953* (the Act)), with the wholesale mark-up arrangements in the community pharmacy setting. This will ensure parity of wholesale mark-up rates across the range of PBS dispensing environments.

Section 99 of the Act prescribe matters for payment for supply of pharmaceutical benefits by the Commonwealth. Under subsection 99(4) of the Act, 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 number of units of pharmaceutical benefits to patients receiving treatment in or at a hospital in respect of which the approved hospital authority is approved.

The National Health (Commonwealth Price- Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017 sets out the details in relation to the amount of the Commonwealth payment for pharmaceutical benefits supplied by an approved hospital authority to a patient receiving treatment in or at a public hospital for which the authority is approved.

The Determination amends the dispensed price for supply of ready-prepared pharmaceutical benefits provisions set out in the National Health (Commonwealth Price- Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017 by changing the mark-up value on the approved ex-manufacturer price or proportional ex-manufacturer price applied for the relevant pack quantity of the benefit supplied.

The Determination sets out a method to calculate the relevant quantity for the pack quantity and the ex-manufacturer price for that relevant quantity. It also sets out a method to calculate the remainder of a quantity supplied if applicable for a broken quantity.

Under the new provisions, where the ex-manufacturer price for the relevant quantity is $930.06 or less, the mark-up for the pack quantity is 7.52 per cent of the approved ex-manufacturer price or the proportional ex-manufacturer price, as applicable for the pack quantity.

Where the ex-manufacturer price for the relevant quantity is more than $930.06:

- if the relevant quantity and the pack quantity are the same, the mark-up for the pack quantity of the brand of the pharmaceutical item is $69.94,

- if the relevant quantity and the pack quantity are not the same, the mark-up is worked out by multiplying $69.94 by the quotient of the pack quantity and the relevant quantity.

The Determination inserts definitions for a number of terms which are consistent with existing definitions in the Act and align with those used for dispensing in community pharmacies. This includes *determined quantity* of a listed brand of a pharmaceutical item and *maximum quantity* of a brand of a pharmaceutical item. These terms have the same meaning as in Part VII and paragraph 85A(2)(a) of the Act respectively, and are used in the method standard to work out the relevant quantity for the pack quantity and the ex-manufacturer price for that relevant quantity.

Consultation

The measure that underpins this legislative amendment was announced on 2 April 2019 as part of Budget 2019-20.

The Department of Health has consulted with affected stakeholders, including state and territory governments, the Medical Software Industry Association and dispensing software vendors with products operating in hospitals, pharmaceutical wholesalers, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia and the Pharmacy Guild of Australia.

Following consultation, the Government delayed implementation of the measure from 1 July 2019 to 1 October 2019 to provide additional time for software vendors to effect relevant software changes and provide a smooth transition for the sector.

This instrument commences on 1 October 2019.

This instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

A provision by provision description of the Determination is contained in Attachment 1.

ATTACHMENT 1

Provision by provision description of the National Health (Commonwealth Price – Pharmaceutical Benefits Supplied by Public Hospitals) Amendment (Budget Measure) Determination 2019

Section 1 Name

This section provides that the Determination is the National Health (Commonwealth Price – Pharmaceutical Benefits Supplied by Public Hospitals) Amendment (Budget Measure) Determination 2019 (the Determination) and may also be cited as PB 57 of 2019.

Section 2 Commencement

This section provides that the Determination commences on 1 October 2019.

Section 3 Authority

This section provides that the Determination is made under subsection 99(4) of the *National Health Act 1953* (the Act).

Section 4 Schedules

This section provides that each schedule in the instrument is amended or repealed as set out in the applicable items in that Schedule.

Schedule 1 Amendments

Item 1 After Section 2D

This section inserts a new section 2E that outlines that Schedule 1 of the National Health (Commonwealth Price – Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017 sets out the application and transitional arrangements that apply to the amendments made by the Determination.

Item 2 Section 3

This item inserts two new definitions into the Determination, for *determined quantity* and *maximum quantity*.

The definition of *determined quantity* of a listed brand of pharmaceutical item has the same meaning as in Part VII of the Act. That is, a listed brand of pharmaceutical item may have one or more quantities or numbers of units of the pharmaceutical item identified as a *determined quantity* under a legislative instrument made under section 84AK(3) of the Act.

The definition of *maximum quantity* of a brand of pharmaceutical item means a quantity or number of units of the pharmaceutical item determined under paragraph 85A(2)(a) of the Act in relation to that brand. The *maximum quantity* is the maximum quantity or number of units that may, in one prescription, be directed to be supplied on any one occasion.

Item 3 Paragraph 9(a)

Item 3 repeals the existing paragraph 9(a) and inserts a new paragraph for the purposes of determining the dispensed price for the supply of a ready-prepared pharmaceutical benefit.

The new paragraph 9(a) outlines that the dispensed price of a supplied quantity that is equal to a multiple of a pack quantity of the benefit is the sum of:

- The approved ex-manufacturer price (AEMP) or the proportional ex-manufacturer price (PEMP) for each quantity, and
- The mark-up amount worked out in section 14 for each pack quantity.

See Attachment 2 for a step-by-step example.

Item 4 Paragraph 9(c)

Item 4 repeals the existing paragraph 9(c) and inserts a new paragraph for the purposes of determining the dispensed price for the supply of a ready-prepared pharmaceutical benefit.

The new paragraph 9(c) outlines that the dispensed price of a supplied quantity that is more than a multiple of a pack quantity of the benefit is the sum of:

- The AEMP or the PEMP for each quantity, and
- The mark-up amount worked out in section 14 for each pack quantity, and
- The amount worked out under section 11 in respect of the remainder of the quantity supplied that is a broken quantity.

See Attachment 2 for a step-by-step example.

Item 5 Section 11

Item 5 repeals the existing section 11 'Dispensed price – broken quantities'. A new section 11 is substituted which outlines the method statement for determining the dispensed price for broken quantities (consistent with the method that applies for community pharmacies). This section outlines calculation of the amount referred to in paragraph 9(b) or paragraph 9(c)(iii), as outlined above.

Step 1 of the method statement directs that the mark-up for the AEMP or PEMP of the pack quantity be calculated in accordance with section 14.

Step 2 directs that the mark-up calculated in step 1 be added to the AEMP or PEMP (whichever applies) for the pack quantity.

Step 3 directs that the percentage that the broken quantity bears to the pack quantity be ascertained.

Step 4 directs to take the percentage worked out in step 3 and apply it to the amount worked out in step 2. The resulting amount is the dispensed price for the supply of the broken quantity.

Item 6 At the End of Part 3

Item 6 inserts a new section 14 that outlines the process for calculating the mark up on a pack quantity of a ready-prepared pharmaceutical benefit. Paragraph 1 specifies that section 14 is used for the purposes of subparagraphs 9(a)(ii) and 9(c)(ii) and step 1 in section 11.

Paragraph 2 specifies that the following method statement is used to work out the *relevant quantity* for the pack quantity, and the ex-manufacturer price for that *relevant quantity.*

Step 1 of the method statement directs that the AEMP of the PEMP (whichever applies) be identified for the pack quantity.

Step 2 directs that the *maximum quantities* and any *determined quantities* for each listed

brand of the pharmaceutical item concerned be identified. This should not include any maximum quantity that relates to a supply of any of those brands that can only be made in accordance with a special arrangement under section 100 of the Act.

Step 3 directs that the *relevant quantity* for the pack quantity be identified. The *relevant quantity* is:

(a) the *maximum quantity* (if any) identified in step 2 that is the highest whole number multiple of the pack quantity. If there is no such *maximum quantity*, the *determined quantity* identified in step 2 that is the highest whole number multiple of a pack quantity; or
(b) if (a) does not apply, the *maximum quantity* (if any) that is closest to the pack quantity. If two *maximum quantities* are equally close, the *relevant quantity* is the greater of those *maximum quantities*; or
(c) if (a) does not apply and there are no *maximum quantities*, the *determined quantity* (if any) that is closest to the pack quantity. If two *determined quantities* are equally close, the *relevant quantity* is the greater of those *determined quantities*.

Step 4 specifies that the *ex-manufacturer price for the relevant quantity* is the *relevant quantity* multiplied by the AEMP or PEMP (whichever applies) for the pack quantity.

Paragraph 3 outlines that if the *ex-manufacturer price for the relevant quantity*, as calculated above, is $930.06 or less, the mark-up for the pack quantity is calculated as 7.52% of the AEMP or PEMP (whichever applies) for the pack quantity.

Paragraph 4 outlines that if the *ex-manufacturer price for the relevant quantity*, as calculated above, is more than $930.06, and the pack quantity and *relevant quantity* are the same, the mark-up for the pack quantity is $69.94.

Paragraph 5 outlines that if the *ex-manufacturer price for the relevant quantity*, as calculated above, is more than $930.06, and the pack quantity and *relevant quantity* are **different,** the mark-up for the pack quantity is calculated as follows:

$$\$69.94 \times \frac{\text{Pack quantity}}{\textit{Relevant quantity}}$$

Item 7 At the end of the instrument

Item 7 inserts a new schedule to the instrument, entitled ‘Schedule 1 – Application and transitional arrangements’. This schedule is referred to in the new section 2E as inserted by Item 1.

Part 1 of the new schedule refers to the amendments made by the National Health (Commonwealth Price – Pharmaceutical Benefits Supplied By Public Hospitals) Amendment (Budget Measure) Determination 2019.

Paragraph 1 of the new schedule outlines that the amendments made to Part 3 of the National Health (Commonwealth price – pharmaceutical benefits supplied by public hospitals) Determination 2017 by the Determination apply in relation to the supply of pharmaceutical benefits on or after 1 October 2019.

Example 1: Where the AEMP for the relevant quantity is under $930.00

A public hospital pharmacist wishes to supply a pack quantity of one. In this example, the AEMP for a pack quantity of one is $100 and the dispensed price for a supply under section 9(a) is the sum of the following:

Section 9(a)(i)	AEMP for each pack quantity	$100.00
Section 9(a)(ii)	The mark-up worked out under section 14 for the whole pack quantity of one (see below)	$7.52
	Dispensed price where supply is equal to a multiple of a pack quantity of the benefit: one	**$107.52**

Section 9(a)(ii) refers to section 14, which outlines the method statement for the dispensed price. The calculation for section 14 is as follows:

- Step 1: identify the AEMP for the pack quantity: $100 per pack quantity;
- Step 2: identify the *maximum quantity* of each listed brand of the pharmaceutical item: in this example, the highest *maximum quantity* is one;
- Step 3: identify the *relevant quantity*: the *maximum quantity* of one is the highest whole number multiple of the pack quantity. As there is no *determined quantity*, one is the *relevant quantity*.
- Step 4: the *ex-manufacturer price for the relevant quantity* is the *relevant quantity* multiplied by the AEMP for the pack quantity. This is 1 x $100 = $100.

In this case, because the *ex-manufacturer price for the relevant quantity*, $100, is less than $930.00, section 14(3) would apply and the mark-up for the pack quantity of one is worked out as follows: $100 x $\frac{7.52}{100}$ = **$7.52**

Example 2: Where the AEMP for the relevant quantity is under $930.00 and the quantity of the benefit supplied is less than a pack quantity of the benefit

A public hospital pharmacist wishes to supply a pack quantity of 0.5. In this example, the AEMP for a pack quantity of one is $100 and the dispensed price for a supply under section 9(b) relies on the method statement in section 11 for calculating the dispensed price for broken quantities.

- Step 1: work out the mark-up on the approved ex-manufacturer price for the pack quantity in accordance with section 14. From example 1, we know this is $7.52
- Step 2: add that to the approved ex-manufacturer price for the pack quantity, bringing a total of $107.52
- Step 3: ascertain the percentage that the broken quantity bears to the pack quantity: 50%
- Step 4: apply that percentage to step 2. $107.52 x $\frac{50}{100}$ = **$53.76**. This is the dispensed price for the supply of the broken quantity of 0.5.

Example 3: Where the AEMP for the relevant quantity is over $930.00

A public hospital pharmacist wishes to supply a pack quantity of one. In this example, the AEMP for a pack quantity of one is $1000 and the dispensed price for a supply under section 9(a) is the sum of the following:

Section 9(a)(i)	AEMP for each pack quantity	$1000
Section 9(a)(ii)	The mark-up worked out under section 14 for the whole pack quantity of one (see below)	$69.94
	Dispensed price where supply is equal to a multiple of a pack quantity of the benefit: one	**$1069.64**

Section 9(a)(ii) refers to section 14, which outlines the method statement for the dispensed price. The calculation for section 14 is as follows:

- Step 1: identify the AEMP for the pack quantity: $1000 per pack quantity;
- Step 2: identify the *maximum quantity* of each listed brand of the pharmaceutical item: in this example, the highest *maximum quantity* is one;
- Step 3: identify the *relevant quantity*: the *maximum quantity* of one is the highest whole number multiple of the pack quantity. As there is no *determined quantity*, one is the *relevant quantity*.
- Step 4: the *ex-manufacturer price for the relevant quantity* is the *relevant quantity* multiplied by the AEMP for the pack quantity. This is 1 x $1000 = $1000.

In this case, because the *ex-manufacturer price for the relevant quantity*, $1000, is more than $930.00, section 14(4) would apply and the mark-up for the pack quantity of one is $69.94.

Statement of Compatibility with Human Rights

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

National Health (Commonwealth Price – Pharmaceutical Benefits Supplied by Public Hospitals) Amendment (Budget Measure) Determination 2019 PB 57 of 2019

This Determination 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 Determination

The National Health (Commonwealth Price – Pharmaceutical Benefits Supplied by Public Hospitals) Amendment (Budget Measure) Determination 2019 (the Determination) amends the National Health (Commonwealth Price- Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017.

The purpose of the Determination is to align the Pharmaceutical Benefits Scheme (PBS) wholesale mark-up for public hospitals, as applied to ready-prepared pharmaceutical benefits (as per section 85 of the *National Health Act 1953*), with the wholesale mark-up arrangements in the community pharmacy setting. This will ensure parity of wholesale mark-ups across the range of PBS dispensing environments.

Human rights implications

The Determination adds new clauses for the calculation for the dispensed price for pharmaceutical benefits supplied in public hospitals. These new clauses revise the existing wholesale mark-up calculations and align them with the calculations that apply in community pharmacy. These changes do not engage any of the applicable rights or freedoms and do not raise any human rights issues.

More broadly, the PBS is a benefit scheme which assists with providing subsidised access to medicines for people in the community. It engages Articles 2 and 12 of the 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 Determination has no net effect on the Articles engaged by the principal Determination; its effect is to ensure that legislative provisions reflect arrangements as agreed by Government.

Conclusion

The Determination is compatible with human rights, as they apply to Australia, as it does not raise any human rights issues and does not impinge on any rights or freedoms.

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