

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits Supplied By Private Hospitals) Amendment (Budget Measure) Determination 2019 PB 56 of 2019

The purpose of the National Health (Pharmaceutical Benefits Supplied By Private Hospitals) Amendment (Budget Measure) Determination 2019 (the Determination) is to align the Pharmaceutical Benefits Scheme (PBS) storage and handling mark-up, known as the wholesale mark-up, for private 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 *National Health Act 1953* (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 Private Hospitals) Determination 2010 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 private 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 Private Hospitals) Determination 2010 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, which is consistent with the current method in the existing determination.

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 statement to work out the relevant quantity for the pack quantity and the ex-manufacturer price for that relevant quantity.

The Determination also includes a number of administrative amendments to ensure currency of existing clauses. Existing references to the *National Health (Pharmaceutical Benefits) Regulations 1960* have been amended to refer to the replacement regulations, the *National Health (Pharmaceutical Benefits) Regulations 2017*. This includes amending the previous reference to ‘regulation 24’ to refer to ‘section 49’, which reflects renumbering of the provision in the replacement regulations. In addition, an erroneous reference to the dangerous drug fee has been removed in order to rectify a previous drafting error.

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 the Medical Software Industry Association and dispensing software vendors with products operating in hospitals, pharmaceutical wholesalers, the Australian Private Hospitals Association and member hospitals, 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.

Provision by provision description of the National Health (Pharmaceutical Benefits Supplied By Private Hospitals) Amendment (Budget Measure) Determination 2019

Section 1 Name

This section provides that the Determination is the National Health (Pharmaceutical Benefits Supplied By Private Hospitals) Amendment (Budget Measure) Determination 2019 (the Determination) and may also be cited as PB 56 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 4

This item inserts a new section 4A that outlines that Schedule 1 of the National Health (Commonwealth Price- Pharmaceutical Benefits Supplied By Private Hospitals) Determination 2010 sets out the application and transitional arrangements that apply to the amendments made by the Determination.

Item 2 Section 5

This item inserts five new definitions into the Determination, for *brand*, *determined quantity*, *listed brand*, *maximum quantity* and *pharmaceutical item*.

The definition of *brand* has the same meaning as in Part VII of the Act. That is, a brand of pharmaceutical item means a trade name under which the person who is or will be the responsible person supplies the pharmaceutical item, or where there is no trade name, the name of the person who is or will be the responsible person.

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 *listed brand* has the same meaning as in Part VII of the Act. That is, a listed brand of a pharmaceutical item means a brand of the pharmaceutical in relation to which a determination under subsection 85(6) of the Act is in force. Subsection 85(6) provides that the Minister may, by legislative instrument, determine a brand of pharmaceutical item.

The definition of *maximum quantity* of a brand of pharmaceutical item means a quantity or number of units of the pharmaceutical item determined under subsection 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.

The definition of *pharmaceutical item* has the same meaning as in Part VII of the Act. That is, a pharmaceutical item has the meaning given in section 84AB of the Act. Section 84AB of the Act defines a pharmaceutical item as a drug in a form with a manner of administration, if:

- (a) a declaration under subsection 85(2) of the Act is in force in relation to a drug or medicinal preparation (the *drug*); and
- (b) a determination under subsection 85(3) of the Act is in force in relation to the form of the drug; and
- (c) a determination under subsection 85(5) is in force in relation to a manner of administration of that form of the drug.

Item 3 Section 5 (definition of *Regulations*)

Item 3 amends the previous reference to the *National Health (Pharmaceutical Benefits) Regulations 1960* to refer to the replacement *National Health (Pharmaceutical Benefits) Regulations 2017*.

Item 4 Section 5 (definition of *storage and handling mark-up*)

Item 4 repeals the previous definition of *storage and handling mark-up*.

Item 5 Subsection 8(1)

Item 5 omits the previous reference to ‘regulation 24’ in subsection 8(1) and replaces it with a reference to ‘section 49’. This reflects the renumbering of the provision that occurred when the *National Health (Pharmaceutical Benefits) Regulations 1960* were replaced by the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Item 6 Sub-subparagraphs 11(1)(a)(i)(A) and (B)

Item 6 repeals sub-subparagraphs 11(1)(a)(i)(A) and (B). These sub-subparagraphs relate to the calculation of the dispensed price of a ready-prepared pharmaceutical benefit where the quantity of the benefit that is supplied is equal to a multiple of a pack quantity of the benefit.

Sub-subparagraph 11(1)(a)(i)(A) has been amended to refer to the approved ex-manufacturer price (AEMP) or the proportional ex-manufacturer price (PEMP), whichever is applicable. This change is to remove any ambiguity regarding whether the AEMP or the PEMP applies.

Sub-subparagraph 11(1)(a)(i)(B) replaces the previous reference to the ‘storage and handling mark-up’ and replace it with a reference to the storage and handling mark-up worked out in the new section 11A (inserted below).

Item 7 Sub-subparagraphs 11(1)(c)(i)(A) and (B)

Item 7 repeals sub-subparagraphs 11(1)(c)(i)(A) and (B). These sub-subparagraphs relate to the calculation of the dispensed price of a ready-prepared pharmaceutical benefit where the quantity of the benefit that is supplied is greater than a multiple of a pack quantity of the benefit.

Sub-subparagraph 11(1)(c)(i)(A) has been amended to refer to the AEMP or the PEMP, whichever is applicable. This change is to remove any ambiguity regarding whether the AEMP or the PEMP applies.

Sub-subparagraph 11(1)(c)(i)(B) replaces the previous reference to the ‘storage and handling mark-up’ and replace it with a reference to the storage and handling mark-up worked out in the new section 11A (inserted below).

Item 8 After section 11

Item 8 inserts a new section 11A ‘Storage and handling mark-up’. Paragraph 1 outlines that for the purposes of sub-subparagraphs 11(1)(a)(i)(B) and 11(1)(c)(i)(B), and paragraph (b) of step 1 in section 14 (inserted below), the storage and handling mark-up for a ready prepared

pharmaceutical benefit is calculated in accordance with this section.

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 or 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:

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

Item 9 Section 14 (paragraphs (a) to (d) of Step 1)

Item 9 repeals paragraphs (a) to (d) of Step 1 of Section 14, and replaces them with the following steps.

Paragraph (a) specifies the AEMP or PEMP (whichever applies) for the pack quantity. This change is to remove any ambiguity regarding whether the AEMP or the PEMP applies.

Paragraph (b) specifies the storage and handling mark-up as calculated under section 11A, as inserted by the Determination.

Paragraph (c) specifies the mark-up worked out under section 12 ('private hospital mark-up'). This is consistent with wording in the existing determination, however has been amended to remove the word 'and', as paragraph (d) has been removed.

The previous paragraph (d), which refers to the dangerous drug fee (if applicable), has been

repealed. This was an erroneous reference, as the dangerous drug fee is already captured in the relevant parts of Section 11.

Item 10 At the end of the instrument

Item 10 inserts a new schedule to the instrument, entitled ‘Schedule 1 – Application and transitional arrangements’. This schedule is referred to in the new section 4A as inserted by Item 1.

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

Paragraph 1 of the new schedule outlines that the amendments made by items 3 to 6 of Schedule 1 of the National Health (Pharmaceutical Benefits Supplied By Private Hospitals) Amendment (Budget Measure) Determination 2019 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 private hospital pharmacist wishes to supply a pack quantity of one. In this example, the AEMP for a pack quantity of one is \$100, a dangerous drug fee under section 11(1)(a)(iii) does not apply and the dispensed price for a supply under section 11(1)(a) is the sum of the following:

Section 11(1)(a)(i)(A)	AEMP for each pack quantity	\$100.00
Section 11(1)(a)(i)(B)	The storage and handling mark-up worked out under section 11A for the whole pack quantity of one (see below)	\$7.52
Section 11(1)(a)(i)(C)	The private hospital mark-up, worked out under section 12 (see below)	\$1.51
Section 11(1)(a)(ii)	A ready-prepared dispensing fee	\$7.29
Section 11(1)(a)(iii)	Dangerous drug fee	n/a
	Dispensed price for a pack quantity of one	\$116.32

Section 11(1)(a)(i)(B) refers to section 11A, which outlines the method statement to calculate the storage and handling mark-up. The calculation for section 11A 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 $1 \times \$100 = \underline{\$100}$.

In this case, because the *ex-manufacturer price for the relevant quantity*, \$100, is less than \$930.00, section 11A(3) would apply and the mark-up for the pack quantity of one is worked out as follows: $\$100 \times \frac{7.52}{100} = \underline{\$7.52}$

Section 11(1)(a)(i)(C) refers to section 12, which calculates the private hospital mark-up. The calculation for section 12 is as follows:

The sum of sections 11(1)(a)(i)(A) and 11(1)(a)(i)(B) = \$107.52.

The private hospital mark-up = $\$107.52 \times \frac{1.4}{100} = \underline{\$1.51}$.

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 private hospital pharmacist wishes to supply a pack quantity of 0.5. In this example, the AEMP for a pack quantity of one is \$100, a dangerous drug fee under section 11(1)(a)(iii) does not apply and the dispensed price for a supply under section 11(1)(b) is the sum of the following:

Section 11(1)(b)(i)	The amount worked out under section 14	\$67.60
Section 11(1)(b)(ii)	A read-prepared dispensing fee	\$7.29
Section 11(1)(b)(iii)	Dangerous drug fee	n/a
	Dispensed price for a supply of a quantity of 0.5	\$75.12

Section 14 outlines the method statement for calculating the dispensed price for broken quantities. The calculation for the broken quantity of 0.5 under section 14 is as follows:

- Step 1: add together the AEMP for the pack quantity, the storage and handling mark-up as worked out under section 11A for the pack quantity and the mark-up worked out under section 12. This is $\$100 + \$7.52 + \$1.51 = \109.03
- Step 2: divide the quantity or number of units in the broken quantity by the pack quantity and express as a percentage. In this case, $0.5 = 50\%$
- Step 3: referring to the table in the Determination, select the percentage amount in column 2. In this case, 50% is matched with column 2 = 62% .
- Step 4: multiply the amount worked out under step 3 by the amount worked out in step 1. $\$109.03 \times \frac{62}{100} = \mathbf{\$67.60}$. 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 private hospital pharmacist wishes to supply a pack quantity of one. In this example, the AEMP for a pack quantity of one is \$1000, a dangerous drug fee under section 11(1)(a)(iii) does not apply and the dispensed price for a supply under section 11(1)(a) is the sum of the following:

Section 11(1)(a)(i)(A)	AEMP for each pack quantity	\$1000.00
Section 11(1)(a)(i)(B)	The storage and handling mark-up worked out under section 11A for the whole pack quantity of one (see below)	\$69.94
Section 11(1)(a)(i)(C)	The private hospital mark-up, worked out under section 12 (see below)	\$14.98
Section 11(1)(a)(ii)	A ready-prepared dispensing fee	\$7.29
Section 11(1)(a)(iii)	Dangerous drug fee	n/a
	Dispensed price for a pack quantity of one	\$1092.21

Section 11(1)(a)(i)(B) refers to section 11A, which outlines the method statement to calculate the storage and handling mark-up. The calculation for section 11A 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 $1 \times \$1000 = \underline{\$1000}$.

In this case, because the *ex-manufacturer price for the relevant quantity*, \$1000, is over \$930.00, section 11A(4) would apply and the mark-up for the pack quantity of one is **\$69.94**.

Section 11(1)(a)(i)(C) refers to section 12, which calculates the private hospital mark-up. The calculation for section 12 is as follows:

The sum of sections 11(1)(a)(i)(A) and 11(1)(a)(i)(B) = \$1069.94.

The private hospital mark-up = $\$1069.94 \times \frac{1.4}{100} = \mathbf{\$14.98}$.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits Supplied By Private Hospitals) Amendment (Budget Measure) Determination 2019 PB 56 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 (Pharmaceutical Benefits Supplied By Private Hospitals) Amendment (Budget Measure) Determination 2019 (the Determination) amends the National Health (Commonwealth Price-Pharmaceutical Benefits Supplied By Private Hospitals) Determination 2010.

The purpose of the Determination is to align the Pharmaceutical Benefits Scheme (PBS) storage and handling mark-up, known as the wholesale mark-up, for private 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 private 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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