

EXPLANATORY STATEMENT

National Health Act 1953

Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Amendment Determination 2019

Authority

Paragraph 98B(1)(a) of the *National Health Act 1953* (the Act) provides that a function of the Pharmaceutical Benefits Remuneration Tribunal (the Tribunal) is to determine the manner in which the Commonwealth price for particular quantities or numbers of units for all or any pharmaceutical benefits is to be worked out for the purpose of payments to approved pharmacists for the supply by them of pharmaceutical benefits.

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

Purpose and operation of the instrument

The Sixth Community Pharmacy Agreement (the Sixth Agreement) between the Commonwealth and the Pharmacy Guild of Australia, signed by the Minister of Health on 24 May 2015 and due to expire on 30 June 2020, is an agreement for the purposes of subsection 98BAA(1) of the Act. The Sixth Agreement sets out the manner in which the Commonwealth price for pharmaceutical benefits is to be calculated.

As part of the Sixth Agreement the Commonwealth price structure for wholesale mark-up, dispensing fees for Ready Prepared and Extemporaneously Prepared Pharmaceutical Benefits (RPPBs and EPPBs) and the Dangerous Drug fee remain consistent with the previous Fifth Community Pharmacy Agreement (Fifth Agreement).

The Sixth Agreement includes the three-tiered Administration, Handling and Infrastructure fee (AHI). The AHI fee de-links pharmacy remuneration from the price of medicines and aims to reduce the impact of current and future medicines pricing policies, such as price disclosure, on pharmacy remuneration, thereby providing pharmacists with pricing certainty during the term of the agreement.

The AHI, the dispensing fee for RPPBs (and subsequently the dispensing fee for EPPBs) and the Dangerous Drug fees are all indexed annually in July for the period of the Sixth Agreement. Under the Sixth Agreement, this indexation is based on the Consumer Price Index (CPI).

These arrangements will continue for the period from 1 July 2015 to 30 June 2020.

The *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Amendment Determination 2019* (the Amending Determination) amends the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015* (PB 64 of 2015) (the Principal Determination) to index the AHI, the Dispensing fees for RPPBs and EPPBs and the Dangerous Drug fee as specified in the (Sixth Agreement).

The Amending Determination will also add an additional amount to the AHI fee, on top of the indexed amount for the AHI fee Tiers 1 and 2. This amount gives effect to the additional AHI fee that has been included in the Sixth Agreement from 1 July 2017. While the AHI base fee will continue to be indexed annually in line with CPI, the additional AHI fee amounts is not part of the 'base' AHI fee and will not be indexed. The additional AHI fee is being paid in recognition of the lower than expected Pharmaceutical Benefits Scheme (PBS) prescription volumes under the Sixth Agreement.

The fees compiling the Commonwealth price agreed under the Sixth Agreement are specified below.

PAYMENT TYPE	VALUE OF PAYMENT	
Wholesale mark-up (for RPPBs)	Where the Ex-Manufacturer Price is up to and including \$930.06	7.52% of the Ex-manufacturer Price per dispense
	Where the Ex-Manufacturer Price is over \$930.06	\$69.94 per dispense
Administration, handling and infrastructure fee	For a pack quantity of a listed brand with a price to pharmacists less than \$180.00	\$3.74, plus the Additional AHI Fee for the relevant Financial Year, per dispense (the Additional AHI for the 2018-19 financial year being \$0.35).
	For a pack quantity of a listed brand with a price to pharmacists from \$180.00 to \$2,089.71	\$3.74, plus the Additional AHI Fee for the relevant Financial Year and 3.5% of the amount by which the price to pharmacists exceeds \$180.00 per dispense
	For a pack quantity of a listed brand with a price to pharmacists more than \$2,089.71	\$72.43 per dispense
Dispensing fee (for RPPBs)	\$7.39 per dispense	
Dispensing fee (for EPPBs)	Dispensing fee for RPPBs, plus \$2.04 per dispense	
Dangerous Drug fee (for (RPPBs)	\$3.11 per dangerous drug dispensed	

The Amending Determination revises AHI fee for tiers 1 and 2 from \$4.04 to **\$4.09** (retaining, for tier 2, an additional 3.5% of the amount by which the price to pharmacists exceeds \$180 per dispense) and for tier 3 from \$73.81 to **\$74.79**, the Dispensing Fees for RPPBs from \$7.29 to **\$7.39** and for EPPBs from \$9.33 to **\$9.43** and the Dangerous Drug fee from \$3.07 to **\$3.11**.

An overview of the instrument is set out at Attachment A.

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.

Consultation

The Pharmacy Guild of Australia has agreed, in writing, to the revised values in this Amending Determination. The Pharmacy Guild of Australia is a party to the Sixth Agreement and supports this Amending Determination.

This Amending Determination commences on 1 July 2019.

Explanatory Statement to the Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Amendment Determination 2019

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

Regulatory impact assessment

Indexation involving the PBS is considered to be part of the standing exemption dated 26 May 2011, OBPR reference number 12116, therefore no Regulation Impact Statement is required.

Details of the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Amendment Determination 2019*

Section 1 Name

This section provides that the title of the instrument is the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Amendment Determination 2019* (the Amending Determination). It provides that the Amending Determination may also be referred to as PB 51 of 2019.

Section 2 Commencement

Section 2 provides that the instrument is to commence on 1 July 2019.

Section 3 Authority

Section 3 provides that the instrument is made under paragraph 98B(1) (a) of the *National Health Act 1953*.

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Amending Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item has effect according to its terms.

Schedule 1 Amendments

Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015

Item 1

This item amends the definition of ‘dangerous drug fee’ in section 6 of the *Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015* (the Primary Determination) to increase the amount of the dangerous drug fee, in order to give effect to the indexation arrangements in the Sixth Agreement.

Item 2

This item amends the definition of ‘extemporaneously-prepared dispensing fee’ in section 6 of the Primary Determination to increase the amount of the extemporaneously-prepared dispensing fee, in order to give effect to the indexation arrangements in the Sixth Agreement.

Item 3

This item amends the definition of ‘ready-prepared dispensing fee’ in section 6 of the Primary Determination to increase the amount of the ready-prepared dispensing fee in order to give effect to the indexation arrangements in the Sixth Agreement.

Item 4

This item replaces the table in paragraph 13(1)(a) of the Primary Determination to increase the amount of the AHI fee for ready prepared pharmaceutical benefits for 2019, in order to give effect to the Sixth Agreement. This amount includes both indexation and the additional AHI fee for 2019, as set out in the Sixth Agreement.

Item 5

This item replaces the table to section 21 of the Primary Determination to increase the amount of the AHI fee for extemporaneously-prepared pharmaceutical benefits for 2019, in order to give effect to the Sixth Agreement. This amount includes both indexation and the additional AHI fee for 2019, as set out in the Sixth Agreement.

Statement of Compatibility with Human Rights

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

COMMONWEALTH PRICE (PHARMACEUTICAL BENEFITS SUPPLIED BY APPROVED PHARMACISTS) AMENDMENT DETERMINATION 2019

This 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 Legislative Instrument

The purpose of this legislative instrument, made under paragraph 98B (1)(a) of the *National Health Act 1953* (the Act), is to amend the Administration, Handling and Infrastructure fee (AHI), the dispensing fees for Ready Prepared and Extemporaneously Prepared Pharmaceutical Benefits (RPPBs and EPPBs) and the Dangerous Drug fee for payments to approved pharmacists for the supply of these pharmaceutical benefits.

Payments are calculated in accordance with the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015* (the Principal Determination). In accordance with section 98BAA of the Act, the manner in which these payments are calculated must be in accordance with the Sixth Community Pharmacy Agreement (the Sixth Agreement) between the Commonwealth and the Pharmacy Guild of Australia. The Pharmaceutical Benefits Remuneration Tribunal (the Tribunal) makes a determination pursuant to paragraph 98B(1)(a) of the Act to give effect to the terms of the Sixth Agreement with respect to the application of an agreed annual indexation adjustment to these payments.

This instrument gives effect to the annual indexation adjustment and additional AHI fee and 2019 Dispensing fee adjustment for these remuneration payments. The legislative instrument increases tiers 1 and 2 of the AHI fee from \$4.04 to **\$4.09** (retaining, for tier 2, an additional 3.5% of the amount by which the price to pharmacists exceeds \$180 per dispense) and tier 3 of the AHI fee from \$73.81 to **\$74.79**, Dispensing fees for RPPBs from \$7.29 to **\$7.39** and EPPBs from \$9.33 to **\$9.43** and the Dangerous Drug fee from \$3.07 to **\$3.11**.

Human rights implications

The Primary Determination engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).

The Pharmaceutical Benefits Scheme (PBS) is a statutory benefit scheme which assists with providing Australians subsidised access to medicines. This 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.

The Tribunal is an independent statutory body established under section 98A of the Act. The main functions of the Tribunal are to make a determination to give effect to the terms of agreement between the Commonwealth and the Pharmacy Guild of Australia in relation to the remuneration that is to be paid to pharmacists for dispensing pharmaceutical benefits and to perform other functions required by that agreement (currently the Sixth Community Pharmacy Agreement).

Explanatory Statement to the Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Amendment Determination 2019

The legislative instrument continue to support Article 12 of the ICESCR and the amendments made by the instrument are only in relation to annual indexation changes.

Conclusion

The Legislative Instrument is compatible with human rights because it maintains the protection of human rights to health.

**Abbeygail Beaumont
Chairperson
Pharmaceutical Benefits Remuneration Tribunal**