

## ***EXPLANATORY STATEMENT***

### ***NATIONAL HEALTH ACT 1953***

#### ***COMMONWEALTH PRICE (PHARMACEUTICAL BENEFITS SUPPLIED BY APPROVED PHARMACISTS) DETERMINATION 2020***

#### **PB 66 of 2020**

##### **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 all or any pharmaceutical benefits is to be worked out for the purpose of payments to approved pharmacists for the supply 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, is to give effect to the terms of that agreement.

##### **Purpose**

The Seventh Community Pharmacy Agreement (the Seventh Agreement) between the Commonwealth, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia, signed on 11 June 2020 and due to expire on 30 June 2025, includes an agreement between the Commonwealth and the Pharmacy Guild of Australia for the purposes of subsection 98BAA(1) of the Act. The Seventh Agreement sets out the manner in which the Commonwealth price for pharmaceutical benefits is to be calculated.

As part of the Seventh Agreement it has been agreed that the Commonwealth price structure will retain existing fees for wholesale mark-up, dispensing fees for ready prepared and extemporaneously prepared pharmaceutical benefits (RPPBs and EPPBs) and the dangerous drug fee consistent with previous Sixth Community Pharmacy Agreement (Sixth Agreement). These fees recognised the clinical input from pharmacy when dispensing PBS medicines.

The Seventh Agreement continues the three tiered administration, handling and infrastructure (AHI) fee adopted in the Sixth Agreement.

The Seventh Agreement includes a remuneration adjustment mechanism which is triggered if the actual number of Commonwealth subsidised prescriptions dispensed differs from estimates. If triggered, the remuneration adjustment mechanism will result in an annual increase or decrease in components of the Commonwealth price.

The AHI fee, the dispensing fees for RPPBs and EPPBs and the Dangerous Drug fees will all be indexed annually for the period of the Seventh Agreement, beginning 1 July 2021. Under the Seventh Agreement, indexation will be 0.5 per cent in the first two financial years of the Seventh Agreement, after which indexation will revert to the Consumer Price Index (CPI).

These arrangements will continue for the period from 1 July 2020 to 30 June 2025.

The components of the Commonwealth price agreed under the Seventh Agreement and commencing on 1 July 2020 are specified below:

<b>PAYMENT TYPE</b>	<b>VALUE OF PAYMENT</b>		
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	<b>Tier One AHI Fee</b>	For a pack quantity of a listed brand with a price to pharmacists less than \$100.00	\$4.28 per dispense of maximum quantity
	<b>Tier Two AHI Fee</b>	For a pack quantity of a listed brand with a price to pharmacists from \$100.00 to \$2,000.00	\$4.28 plus 5% of the amount by which the price to pharmacists exceeds \$100.00 per dispense of maximum quantity
	<b>Tier Three AHI Fee</b>	For a pack quantity of a listed brand with a price to pharmacists more than \$2,000.00	\$99.28 per dispense of maximum quantity
Dispensing fee (for RPPBs)	\$7.74 per dispense		
Dispensing fee (for EPPBs)	\$9.78 per dispense		
Dangerous Drug free	\$4.80 per dangerous drug dispensed		

This Determination pursuant to paragraph 98B(1)(a) of the Act (the Determination) will commence on 1 July 2020 and will remain in effect until revoked by the Tribunal. This Determination revokes the previous Determination made on 29 June 2015 which gave effect

to the terms of the Sixth Agreement concerning the Commonwealth price for pharmaceutical benefits.

Further details of the Determination are set out in the Attachment.

### **Consultation**

The Pharmacy Guild of Australia is a signatory to the part of the Seventh Agreement reflected in this Determination and has been consulted in relation to this Determination.

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

**ATTACHMENT*****COMMONWEALTH PRICE (PHARMACEUTICAL BENEFITS SUPPLIED BY APPROVED PHARMACISTS) DETERMINATION 2020*****PART 1 - Preliminary****Section 1 – Name of Determination**

This Section provides that the name of the Determination is the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020*. It may be cited as PB 66 of 2020.

**Section 2 – Commencement**

This Section provides that the Determination commences on 1 July 2020.

**Section 3 – Revocation**

This Section revokes, as of 1 July 2020, the previous Determination made on 29 June 2015.

**Section 4 – Purpose**

This Section describes that the purpose of the Determination is to determine the manner in which the Commonwealth price for pharmaceutical benefits is to be worked out.

**Section 5 – Application**

This Section provides that the Determination does not apply to pharmaceutical benefits supplied by medical practitioners pursuant to section 93 of the Act.

**Section 6 – Definitions**

This Section includes definitions of common terms used in the Determination, including the dollar amounts for the dangerous drug fee, the extemporaneously-prepared dispensing fee and the ready-prepared dispensing fee, and describes the types of manufacturers' packs of pharmaceutical benefits on which the prices to pharmacists are based.

**Section 7 – Rounding up and rounding down**

This Section provides that if the calculation of a price in the Determination includes a fraction of a cent, the result of the calculation will be rounded accordingly.

**Section 8 – Dangerous drug fee**

This Section provides that where indicated in this Determination, the Commonwealth must pay a dangerous drug fee if a pharmaceutical benefit is a dangerous drug. The fee is defined under Section 6.

## **Section 9 – Repeat Supply**

This Section provides the manner in which the Commonwealth price is to be calculated in circumstances where a medical practitioner, authorised midwife, or authorised nurse practitioner prescribes that, instead of directing a repeated supply of a pharmaceutical benefit, directs the supply of a quantity or number of units of the benefit on one occasion.

## **Part 2– Ready-Prepared Pharmaceutical Benefits**

### **Section 10 – Ready-prepared pharmaceutical benefits—Commonwealth price**

This section provides that the components and amount of the Commonwealth price in respect of ready-prepared pharmaceutical benefits will differ, depending on whether the amount of the benefit ordered and supplied is equal to, less than or more than the amount contained in a pack quantity of the pharmaceutical benefit. The components of the Commonwealth price comprise of:

- an amount based on the approved ex-manufacturer price or proportional ex-manufacturer price of a pack quantity of the pharmaceutical benefit, which together with the wholesale mark-up gives the price to pharmacists;
- a container fee worked out in accordance with Section 12 (where the quantity of a benefit ordered and supplied is less than the quantity in a pack quantity);
- an administration, handling and infrastructure fee worked out in accordance with Section 13;
- either a ready-prepared dispensing fee or an extemporaneously-prepared dispensing fee; and
- a dangerous drug fee, where applicable.

### **Section 11– Ready-prepared pharmaceutical benefits—wholesale mark-up**

This section provides the manner for calculating the wholesale mark-up for a for a pack quantity of a ready-prepared pharmaceutical benefit.

### **Section 12 – Ready-prepared pharmaceutical benefits—administration, handling and infrastructure fee**

This section provides a three tiered structure for the administration, handling and infrastructure fee in respect of calculating the Commonwealth price for ready-prepared pharmaceutical benefits.

### **Section 13 – Ready-prepared pharmaceutical benefits—container price**

This section provides the manner for calculating the price for containers in respect of calculating the Commonwealth price for ready-prepared pharmaceutical benefits.

### **Section 14 – Price for broken quantities**

This section provides the manner for calculating a component of the Commonwealth price for ready-prepared pharmaceutical benefits, where the quantity of a benefit used or supplied is less than the pack quantity (see Section 10).

### **Section 15 – Ready-prepared pharmaceutical benefits—limit on Commonwealth price**

This section provides a maximum in calculating the Commonwealth price for ready-prepared pharmaceutical benefits that are broken quantities.

### **Section 16 – Pharmaceutical benefits that are to be supplied as complete packs**

This section provides that, where a lesser quantity of a pharmaceutical benefit which is specified in Schedule 4 to the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019* (about benefits to be supplied as complete packs) is prescribed, the Commonwealth price shall be calculated as if the complete pack of the pharmaceutical benefit was supplied.

## **Part 3 – Extemporaneously-prepared pharmaceutical benefits**

### **Section 17 – Definition**

This section defines the term “wastage”, which relates only to Part 3 of the Determination.

### **Section 18 – Extemporaneously-prepared pharmaceutical benefits—Commonwealth price**

This section provides that, subject to Section 30, the Commonwealth price in respect of extemporaneously-prepared pharmaceutical benefits comprises of:

- the amount in respect of the quantity of the ingredients, calculated in accordance with Sections 19 to 21;
- the applicable container fee calculated in accordance with Section 25; and
- an extemporaneously-prepared dispensing fee.

### **Section 19 – Ingredient amount**

This section provides the manner for calculating the ingredient cost for an extemporaneously-prepared pharmaceutical benefit, where the quantity of the ingredients is equal to the agreed purchase quantity. The components of the ingredient cost include the basic wholesale price of the ingredient, an administration, handling and infrastructure fee worked out in accordance with Section 20 and, where applicable, a mark-up for wastage, worked out in accordance with Appendix A.

**Section 20 – Extemporaneously-prepared pharmaceutical benefits—administration, handling and infrastructure fee**

This section provides the calculation for the administration, handling and infrastructure fee in respect of calculating the ingredient cost for extemporaneously-prepared pharmaceutical benefits.

**Section 21 – Ingredient amount**

This section provides the manner for calculating the ingredient cost for an extemporaneously-prepared pharmaceutical benefit, where the quantity of the ingredient is less than the agreed purchase quantity.

**Section 22 – Quantity greater than the agreed purchase quantity**

This section provides the manner for calculating the ingredient cost for an extemporaneously-prepared pharmaceutical benefit, where the quantity of the ingredient is more than the agreed purchase quantity.

**Section 23 – Extemporaneously-prepared pharmaceutical benefit comprising vehicle specified in prescription under particular name, etc**

This section provides the manner for calculating the Commonwealth price for an extemporaneously-prepared pharmaceutical benefit, which consists of a vehicle specified in the prescription and one or more additional ingredients.

**Section 24– Extemporaneously-prepared pharmaceutical benefit—basic wholesale price**

This section provides the manner for calculating the basic wholesale price of a drug used in the preparation of an extemporaneously-prepared pharmaceutical benefit, when calculating the Commonwealth price for extemporaneously-prepared pharmaceutical benefits.

**Section 256 – Extemporaneously-prepared pharmaceutical benefit—container price**

This section provides the manner for calculating the container costs for extemporaneously-prepared pharmaceutical benefits under various circumstances, and that these amounts will be rounded to the nearest cent.

**Section 26 – Extemporaneously-prepared pharmaceutical benefit—container price for bulk powders**

This section provides the price for the container for bulk powders is the price for a screw cap jar that is nominally rated to hold at least double the quantity supplied.

### **Section 27 – Extemporaneously-prepared pharmaceutical benefit—orders in excess of largest size container**

This section provides the manner for calculating the price for the container if a prescription directs the supply of a quantity of an extemporaneously-prepared pharmaceutical benefit that exceeds the capacity of the largest size of the container for that benefit.

### **Section 28 – Extemporaneously-prepared pharmaceutical benefit—limit on Commonwealth price**

This section provides a maximum in calculating the Commonwealth price for the supply of a quantity of an extemporaneously-prepared pharmaceutical benefit.

### **Section 29 – Extemporaneously-prepared pharmaceutical benefit—calculation limit for ingredients**

This section provides a maximum in calculating the Commonwealth price for an ingredient of an extemporaneously-prepared pharmaceutical benefit.

### **Section 30 – Extemporaneously-prepared pharmaceutical benefit—non-standard formula preparations**

This section provides the manner for calculating the Commonwealth price of extemporaneously-prepared pharmaceutical benefits which are not a standard formula preparation. The two exceptions to this are for exceptional prescriptions or where the pharmacist makes an election as described in Section 31.

### **Section 31 - Calculation of Commonwealth price under section 18**

This section describes when the Commonwealth price for extemporaneously-prepared pharmaceutical benefits can be calculated using the methodologies under Section 18 or Section 30.

### **Section 32 - Exceptional prescriptions**

This section provides that, in respect of exceptional prescriptions, the method for calculating the Commonwealth price may be done in accordance with Section 18, even where a pharmacist has not made an election as described in Section 31.

### **Appendix A – Classification, Fee and Mark-up Tables**

Tables 1, 2 and 3 of Appendix A provide the method to calculate the different wastage factors in relation to extemporaneously-prepared pharmaceutical benefits, as described in Sections 18 and 19.

The pharmaceutical benefits are divided into the following categories:

- Table 1 – Basic wholesale price for agreed purchase quantity less than \$100.00
- Table 2 – Basic wholesale price for agreed purchase quantity \$100.00 to \$2,000.00
- Table 3 – Basic wholesale price for agreed purchase quantity more than \$2,000.00



**Appendix B – Basic Pricing Units**

Appendix B provides quantities and respective pricing units for calculating the ingredient cost in respect of extemporaneously-prepared pharmaceutical benefits, as described in Sections 18 to 21.

**Appendix C – Quantity Factors**

Appendix C provides quantities and respective factors for calculating the ingredient cost in respect of extemporaneously-prepared pharmaceutical benefits, as described in Section 18 to 21.

## **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) DETERMINATION 2020**

***PB 66 of 2020***

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 revoke and remake the previous Determination made by the Pharmaceutical Benefits Remuneration Tribunal (the Tribunal) on 29 June 2015. This new Determination gives effect to the new Commonwealth Price remuneration structure for payments to approved pharmacists for the supply of pharmaceutical benefits as set out within the Seventh Community Pharmacy Agreement.

The Commonwealth price is calculated in accordance with the Seventh Community Pharmacy Agreement (the Seventh Agreement) between the Commonwealth and the Pharmacy Guild of Australia. The Pharmaceutical Society of Australia is also a signatory to parts of the Seventh Agreement that are unrelated to this determination. The Tribunal makes this determination to give effect to the terms of the Seventh Agreement with respect to the calculation of the Commonwealth price and the application of an agreed annual indexation adjustment to these payments.

#### **Human rights implications**

This legislative instrument engages Articles 2, 7 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The legislative instrument assists with the provision favourable conditions of work to ensure remuneration for workers with fair wages. 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 Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with providing subsidised access for people 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 Seventh Community Pharmacy Agreement).

#### **Conclusion**

The Legislative Instrument is compatible with human rights because it advances the protection of human rights.

**Abbeygail Beaumont**

**Chairperson**

**Pharmaceutical Benefits Remuneration Tribunal**