EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

COMMONWEALTH PRICE (PHARMACEUTICAL BENEFITS SUPPLIED BY APPROVED PHARMACISTS) DETERMINATION 2015

PB 64 of 2015

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 Sixth Community Pharmacy Agreement (the Sixth Agreement) between the Commonwealth and the Pharmacy Guild of Australia, signed 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 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 Fifth Community Pharmacy Agreement (Fifth Agreement). These fees recognised the clinical input from pharmacy when dispensing PBS medicines.

The Sixth Agreement removes the previous six tiered pharmacy mark-up and replaces it with the new three tiered administration, handling and infrastructure fee (AHI). The AHI provides a simpler, more transparent, set fee paid on a per prescription basis. The AHI will de-link pharmacy remuneration from the price of medicines and aim 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 fees for RPPBs and EPPBs and the Dangerous Drug fees will all be indexed annually for the period of the Sixth Agreement, beginning 1 July 2016. Under the Sixth Agreement, this indexation will shift from the Wage Cost Index-9 (WCI-9), which was utilised under the Fifth Agreement, to the Consumer Price Index (CPI).

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

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	\$3.49 per dispense
	For a pack quantity of a listed brand with a price to pharmacists from \$180.00 to \$2,089.71	\$3.49, plus 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	\$70.00 per dispense
Dispensing fee (for RPPBs)	\$6.93 per dispense	
Dispensing fee (for EPPBs)	Dispensing fee for RPPBs, plus \$2.04 per dispense	
Dangerous Drug free (for (RPPBs)	\$2.91 per dangerous drug dispensed	

This Determination pursuant to paragraph 98B(1)(a) of the Act (the Determination) will commence on 1 July 2015 and will remain in effect until revoked by the Tribunal. This Determination revokes the previous Determination made on 17 June 2010 which gave effect to the terms of the Fifth Agreement concerning the Commonwealth price for pharmaceutical benefits.

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

Consultation

This Determination has been prepared in consultation with the Pharmacy Guild of Australia, an organisation representing a majority of approved pharmacists. The Pharmacy Guild of Australia is a party to the Sixth Agreement and supports this Determination.

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

COMMONWEALTH PRICE (PHARMACEUTICAL BENEFITS SUPPLIED BY APPROVED PHARMACISTS) DETERMINATION 2015

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 2015. It may be cited as PB 64 of 2015.

Section 2 – Commencement

This Section provides that the Determination commences on 1 July 2015.

Section 3 – Revocation

This Section revokes, as of 1 July 2015, the previous Determination made on 17 June 2010.

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 prescribes that the equivalent of a repeat supply of pharmaceutical benefits is to be supplied on one occasion.

Section 10 – Drugs and medicinal preparations to which a subsection 85(6) determination applies

This Section provides that, where there is a determination in effect under subsection 85(6) of the Act for the supply of a brand or brands of a drug or medicinal preparation as a

pharmaceutical benefit, the Commonwealth will only make a payment for the supply of a brand or brands of that drug or medicinal preparation mentioned in that determination.

Part 2- Ready-Prepared Pharmaceutical Benefits

Section 11 - 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 13 (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 14:
- either a ready-prepared dispensing fee or an extemporaneously-prepared dispensing fee; and
- a dangerous drug fee, where applicable.

Section 12- 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 13 – 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 14 – 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 15 – 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 quantity in a standard or non-standard pack (see Section 11).

Section 16 – Ready-prepared pharmaceutical benefits—limit on Commonwealth price

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

Section 17 – Pharmaceutical benefits mentioned in a determination under paragraph 98C(1)(b) of the Act

This section provides that, where a lesser quantity of a pharmaceutical benefit which is specified in Schedule 4 to the determination made under Section 98C(1)(b) of the Act 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 18 – Definition

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

Section 19 – Extemporaneously-prepared pharmaceutical benefits—Commonwealth price

This section provides that, subject to Section 31, 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 20 to 22;
- the applicable container fee calculated in accordance with Section 26; and
- an extemporaneously-prepared dispensing fee.

Section 20 - 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 21 and, where applicable, a mark-up for wastage, worked out in accordance with Appendix A.

Section 21 – 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 22 – 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 23 – 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 24 – 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 25—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 26 – 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 27 – 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 can hold at least double the quantity supplied.

Section 28 – 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 29 – 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 30 – 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.

$Section \ 31-Extemporaneously-prepared \ pharmaceutical \ benefit-mon-standard \ formula \ preparations$

This section provides the manner for calculating the Commonwealth price of extemporaneously-prepared pharmaceutical benefits which are not standard formula preparations and are specified in the Fourth Schedule to the determinations made under sections 85, 85A and 88 of the Act. The two exceptions to this are for exceptional prescriptions or where the pharmacist makes an election as described in Section 32.

Section 32 - Calculation of Commonwealth price under section 19

This section describes when the Commonwealth price for extemporaneously-prepared pharmaceutical benefits can be calculated using the methodologies under Section 19 or Section 31.

Section 33 - 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 19, even where a pharmacist has not made an election as described in Section 32.

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 Section 19. The pharmaceutical benefits are divided into the following categories:

- Table 1 Basic wholesale price for agreed purchase quantity less than \$180.00
- Table 2 Basic wholesale price for agreed purchase quantity \$180.00 to \$2,089.71
- Table 3 Basic wholesale price for agreed purchase quantity more than \$2,089.71

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 Section 19.

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 19.



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 2015

PB 64 of 2015

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 17 June 2010. 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 Sixth Community Pharmacy Agreement.

The Commonwealth price is calculated in accordance with the Sixth Community Pharmacy Agreement (the Sixth Agreement) between the Commonwealth and the Pharmacy Guild of Australia. The Tribunal makes this determination to give effect to the terms of the Agreement with respect to the calculation of the Commonwealth price and the application of an agreed annual consumer wage 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 Sixth Community Pharmacy Agreement).

Conclusion

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

Jonathan Hamberger
Chairperson
Pharmaceutical Benefits Remuneration Tribunal