

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019

Authority

Paragraph 98C(1) of the *National Health Act 1953* (the Act) provides that the Minister may, by legislative instrument, make determinations on two matters.

Under subparagraph 98C(1)(a), the Minister may 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 medical practitioners for the supply of pharmaceutical benefits. The current Determination is the *Commonwealth Price (Pharmaceutical Benefits Supplied By Approved Medical Practitioners) Determination 2010* (the 98C(1)(a) Determination). It provides that the Commonwealth price for a pharmaceutical benefit that is supplied by a medical practitioner is the price determined under the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*.

Under subparagraph 98C(1)(b), the Minister may determine the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners. The current Determination is the *Determination – Conditions (PB 119 of 2008) (Federal Register of Legislation No. F2019C00881)* (the 98C(1)(b) Determination), which sets out the conditions subject to which these payments will be made.

In addition to the power to make this instrument under paragraph 98C(1) of the Act, subsection 33(3) of the *Acts Interpretation Act 1901* provides that 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.

Purpose

The subparagraph 98C(1)(b) and the 98C(1)(a) Determinations that are currently in force are scheduled to sunset on 1 April 2020 and 1 October 2020, respectively.

The purpose of the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019* (the Principal Determination) is to remake and improve the operations of these existing Determinations before they sunset, by merging them into one Determination. The Principal Determination will:

- outline 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 medical practitioners for the supply of pharmaceutical benefits; and
- outline the conditions subject to which payments to medical practitioners and approved pharmacists will be made.

This will improve the overall clarity and operation of the relevant Determinations and ensure that the Principal Determination reflects current drafting practices.

This remake does not alter the manner in which the Commonwealth price is currently calculated for the supply of PBS by approved medical practitioners or the conditions subject to which the relevant payments will be made.

The *Legislation Act 2003* provides that all legislative instruments, other than exempt instruments, progressively sunset according to the timetable in section 50 of that Act. Sunsetting legislative instruments generally cease to have effect after 10 years unless their operation is extended such as by remaking the instrument.

The Principal Determination commences on 1 February 2020.

The Principal Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

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

Background

Part VII of the Act is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Paragraph 85(1) provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits. Paragraph 98C(1)(a) of the Act provides that the Minister may, from time to time, 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 medical practitioners for the supply of pharmaceutical benefits. Paragraph 98C(1)(b) of the Act provides that the Minister may, from time to time, determine the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

Consultation

The Department of Health undertook consultation with a number of stakeholders, including the Pharmacy Guild of Australia, Services Australia and state and territory departments of health. The consultation period commenced on 15 November 2019 and closed on 29 November 2019. No material objections were raised in relation to this Principal Determination.

ATTACHMENT 1**Provision by provision description of the National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019****Part 1 – Preliminary****Section 1 Name**

This section provides for the Principal Determination to be referred to as the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019*. This section also provides that the Determination, in the alternative to its long name, may be cited as PB 114 of 2019.

Section 2 Commencement

This section provides that the Principal Determination commences 1 February 2020.

Section 3 Authority

This section provides that Principal Determination is made under subsection 98C(1) of the *National Health Act 1953*.

Section 4 Schedule 6

This section provides that each instrument that is specified in Schedule 6 to this instrument is amended or repealed as set out in the applicable items in that Schedule, and any other item in that Schedule has effect according to its terms.

Section 5 Simplified outline of this instrument

This section contains an outline of how the Principal Determination operates. It states that the Commonwealth price for pharmaceutical benefits supplied by an approved medical practitioner is worked out in the same way as the Commonwealth price for those benefits supplied by an approved pharmacist.

This section also states that the Commonwealth will pay an approved medical practitioner or an approved pharmacist for the supply of a pharmaceutical benefit only if certain conditions are met. The first is that payment will be made only for supply of a brand of a pharmaceutical benefit as specified in a determination under subsection 85(6). The second is that where a pharmaceutical benefit is specified in Schedule 4 of the Principal Determination, payment will be made for the supply of that benefit only if it is supplied in a complete pack. Schedule 4 lists pharmaceutical benefits that must be supplied in complete packs by an approved medical practitioner or an approved pharmacist for them to be paid by the Commonwealth for the supply.

This section explains that Schedules 1, 2, 3 and 5 list pharmaceutical benefits and ingredients of pharmaceutical benefits for which particular rules apply for working out the Commonwealth price. These schedules apply to benefits being supplied by an approved medical practitioner or an approved pharmacist.

Section 6 Definitions

This section contains defined terms used in the Principal Determination. The definition of ‘extemporaneously-prepared pharmaceutical benefit’ has the same meaning as incorporated in *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015* (PB 64 of 2015) as in force from time to time.

Part 2 – Commonwealth price for pharmaceutical benefits supplied by approved medical practitioners

Section 7 Commonwealth price for pharmaceutical benefits supplied by approved medical practitioners

This section provides that the Commonwealth price for pharmaceutical benefits supplied by approved medical practitioners is to be ascertained in the same manner as the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015* (as in force from time to time) as if the pharmaceutical benefit was supplied by an approved pharmacist.

The *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015* identifies certain rules which refer to certain schedules in the Principal Determination. Specifically, Schedules 1, 2, 3 and 5 of the Principal Determination identify the pharmaceutical benefits and ingredients in relation to which particular rules, as outlined in the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015*, for ascertaining the Commonwealth price apply.

Part 3 – Conditions on payments for pharmaceutical benefits supplied by approved pharmacists and approved medical practitioners

Section 8 Scope of this Part

This section explains that Part 3 sets out the conditions subject to which payments will be made by the Commonwealth for the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

Section 9 Condition on payment for supply of certain pharmaceutical items

This section provides that where a determination under subsection 85(6) of the Act is in force for a brand of a pharmaceutical item, payments will be made by the Commonwealth in respect of the supply of the drug or preparation only if that brand is supplied. Subsection 85(6) provides that the Minister may, by legislative instrument, determine a brand of pharmaceutical item.

Section 10 Payment for supply of certain pharmaceutical benefits in complete packs

This section provides that payments will be made by the Commonwealth in respect of the supply of a listed drug in a form described in columns 1 and 2 of an item of Schedule 4 only where the quantity supplied is the quantity contained in a unit of the size described in column 2 of the item. This applies even if the prescription for the supply is for supply of a lesser quantity.

Schedules

Schedules in the Principal Determination reflect the order and content in the 98C(1)(a) Determination.

Schedule 1 Ready-prepared pharmaceutical benefits that are mixtures of ready-prepared ingredients

Schedule 1 identifies the ready-prepared pharmaceutical benefits that comprises the mixture of ready-prepared ingredients which the rules for ascertaining the Commonwealth price, as outlined in the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015*, apply to.

Schedule 2 Unstable or sterile ingredients used for extemporaneously-prepared pharmaceutical benefits

Schedule 2 identifies the unstable or sterile ingredients used for extemporaneously-prepared pharmaceutical benefits which the rules for ascertaining the Commonwealth price, as outlined in the

Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015, apply to.

Schedule 3 Pharmaceutical benefits for which a dangerous drug fee applies

Schedule 3 identifies the pharmaceutical benefits for which a dangerous drug fee applies. This relates to the rules for ascertaining the Commonwealth price, as outlined in the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015*.

Schedule 4 Pharmaceutical benefits to be supplied as complete packs only

Schedule 4 identifies the listed drugs for which payments will be made by the Commonwealth in respect of their supply only if they are supplied as complete packs. This relates to section 10 of the Principal Determination, which states that payments will be made by the Commonwealth in respect of the supply of a listed drug in this Schedule only if the quantity supplied reflects the quantity contained in a unit of the size described in column 2 of this Schedule.

Schedule 5 Standard formula preparations

Schedule 5 identifies the extemporaneously-prepared pharmaceutical benefits which are standard formula preparations for the purposes of ascertaining the Commonwealth price, as outlined in the rules contained in the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015*. Column 3 of schedule 5 refers to the following relevant Pharmaceutical Reference Standards: Australian Pharmaceutical Formulary (APF); British Pharmacopoeia (BP); British Pharmaceutical Codex (BPC) and Queensland Hospital Formulary (QHF). These standards are incorporated as in force at the time of commencement of this Determination and are available on a subscription basis only. The Standards are a specialised scientific tool used by practitioners, who will have subscription access to the Standards they use. Any changes to the standard after the commencement of this Determination will not be incorporated or applied by this Determination.

Schedule 6 Repeals

Schedule 6 repeals both the *Commonwealth Price (Pharmaceutical Benefits Supplied By Approved Medical Practitioners) Determination 2010* and the *Determination – Conditions (PB 119 of 2008) (Federal Register of Legislation No. F2019C00881)*.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011
National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) 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 subsection 98C(1) of the *National Health Act 1953* (the Act), is to remake and improve the operation of the current legislative instruments made under this subsection to preserve its effect beyond its sunset date (scheduled to sunset on 1 April and 1 October 2020).

Human rights implications

The Principal Determination engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The Principal Determination 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 and supportive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for PBS support effective administration of the scheme. The Principal Determination 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.

Conclusion

The Principal Determination is compatible with human rights, as they apply to Australia, as it supports the right to health.

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