

# EXPLANATORY STATEMENT

*National Health Act 1953*

## ***National Health (Additional Community Supply Support Payment) Determination 2024 PB 94 of 2024***

### **Authority**

Paragraph 98B(1)(b) of the *National Health Act 1953* (Act) provides that a function of the Pharmaceutical Benefits Remuneration Tribunal (Tribunal) is to determine, by legislative instrument:

- the kinds of supplies by approved pharmacists of pharmaceutical benefits (if any) that are Additional Community Supply Support (ACSS) eligible supplies; and
- the amount of the ACSS payment for any or all ACSS eligible supplies, or the manner in which that amount is to be worked out.

Subsection 98BAA(1A) of the Act requires that, where the Commonwealth and the Pharmacy Guild of Australia (Guild) have entered into an agreement relating to the kinds of supplies made by approved pharmacists that are ACSS eligible supplies, and the amount of the ACSS payment for ACSS eligible supplies, or the manner in which that amount is to be worked out, the Tribunal, when making a determination pursuant to paragraph 98B(1)(b) of the Act, is to give effect to the terms of that agreement, while the agreement is in force.

### **Purpose**

The *National Health (Additional Community Supply Support Payment) Determination 2024* (Determination) gives effect to the agreement between the Commonwealth and the Guild made under the Eighth Community Pharmacy Agreement (8CPA) for the purposes of subsection 98BAA(1A) of the Act.

The 8CPA took effect on 1 July 2024 and will remain in effect until 30 June 2029. It is made between the Minister for Health and Aged Care (on behalf of the Commonwealth) and the Guild. Under clause 4.1 of the 8CPA the components of the ACSS payment for PBS supplies made by approved pharmacists are:

- a \$4.79 payment for each Commonwealth subsidised supply of a ‘section 85 medicine’ with increased dispensing quantities; and
- a \$0.78 payment for each Commonwealth subsidised supply of a PBS prescription of a ‘section 85 medicine’.

Giving effect to the agreement in the 8CPA, the Determination provides that a supply by an approved pharmacist of a pharmaceutical benefit is an ACSS eligible supply, unless the supply is made in accordance with any of the following special arrangements made under section 100 of the Act:

- *National Health (Botulinum Toxin Program) Special Arrangement 2015* (Botox Special Arrangement);
- *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* (EFC Special Arrangement);

- *National Health (Growth Hormone Program) Special Arrangement 2015* (Growth Hormone Special Arrangement);
- *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (HSD Special Arrangement);
- *National Health (IVF Program) Special Arrangement 2015* (IVF Special Arrangement);
- *National Health (Take Home Naloxone) Special Arrangement 2019* (THN Special Arrangement).

Supplies of pharmaceutical benefits under these special arrangements are not supplies of section 85 medicines (i.e. general supply medicines).

The Determination further provides that the amount of the ACSS payment for ACSS eligible supplies is either:

- \$0.78 per supply; or
- where the supply is made on the basis of an increased maximum quantity prescription (also known as a 60-day prescription) and the full increased maximum quantity is supplied, or is a continued dispensing supply of the increased maximum quantity, an additional \$4.79 per supply is payable, making the total ACSS payment \$5.57.

### **Consultation**

The 8CPA includes an agreement between the Commonwealth and the Guild, for the purposes of subsection 98BAA(1A) of the Act, regarding the kinds of supplies that are ACSS eligible supplies, and the amount of the ACSS payment for ACSS eligible supplies. The Guild has been consulted in relation to the content of this Determination as it relates to that agreement. Services Australia has also been consulted in relation to implementation of the PBS payment systems changes managed by Services Australia, to support making ACSS payments to approved pharmacists, as provided for by this Determination.

### **Commencement**

This Determination commences on the day after it is registered.

### **General**

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

Details of this Determination are outlined in **Attachment A**.

This Determination is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

**Details of the *National Health (Additional Community Supply Support Payment) Determination 2024***

**Section 1 – Name**

Section 1 provides that the name of the Determination is the *National Health (Additional Community Supply Support Payment) Determination 2024*, which may also be cited as PB 94 of 2024.

**Section 2 – Commencement**

Section 2 provides that the Determination commences on the day after it is registered.

**Section 3 – Authority**

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

**Section 4 – Definitions**

Subsection 4(1) provides definitions for the terms *Act*, *increased maximum quantity*, *increased maximum quantity prescription* and *relevant purpose*.

*Act* is defined to mean the *National Health Act 1953*.

*increased maximum quantity* of a pharmaceutical benefit is defined to mean the maximum quantity or number of units (maximum quantity) of the benefit, or the pharmaceutical item in the benefit, that may, in one prescription, be directed to be supplied on any one occasion, for a relevant purpose, under a determination of the Minister under paragraph 85A(2)(a) of the Act.

These maximum quantities are determined in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (Listing Instrument). Where a pharmaceutical benefit includes a pharmaceutical item, maximum quantities are determined at the level of the pharmaceutical item. Otherwise, maximum quantities are determined at the level of the pharmaceutical benefit.

Where a pharmaceutical benefit has an increased maximum quantity determined, that maximum quantity is currently equivalent to two months' supply of the benefit. Increased maximum quantities give effect to the Australian Government policy that commenced implementation on 1 September 2023 and is also known as the '60-day prescribing' policy.

*increased maximum quantity prescription* means a prescription directing, for a relevant purpose, the supply on any one occasion of the increased maximum quantity of a pharmaceutical benefit.

*relevant purpose* for a pharmaceutical benefit means a purpose mentioned in Schedule 4 to the Listing Instrument for a purposes code specified in Schedule 1 to the Listing Instrument

for the benefit, where that purpose includes the phrase “The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient”. This phrase is included in all purposes determined under paragraph 85A(2)(a) for which an increased maximum quantity of a pharmaceutical benefit can be prescribed for supply to a patient on the one occasion. The reference to the Listing Instrument is to that instrument as in force from time to time. The Listing Instrument is a legislative instrument and can be accessed free of charge on the Federal Register of Legislation at [www.legislation.gov.au](http://www.legislation.gov.au).

Subsection 4(2) provides that an expression used in the Determination and in Part VII of the Act has the same meaning in the Determination as in Part VII. A note to subsection 4(2) provides examples of such expressions.

## **Section 5 – ACSS eligible supplies**

Section 5 specifies which supplies made by approved pharmacists are ACSS eligible supplies, for the purposes of subparagraph 98B(1)(b)(i) of the Act.

It provides that a supply of a pharmaceutical benefit by an approved pharmacist is an ACSS eligible supply, unless the supply is made in accordance with any of the following special arrangements:

- Botox Special Arrangement;
- EFC Special Arrangement;
- Growth Hormone Special Arrangement;
- HSD Special Arrangement;
- IVF Special Arrangement;
- THN Special Arrangement.

Supplies of pharmaceutical benefits made under these special arrangements are not section 85 / general supplies.

The provision of pharmaceutical benefits by approved pharmacists to approved medical practitioners and authorised nurse practitioners, for the purpose of the approved medical practitioner or authorised nurse practitioner supplying the benefit to patients under prescriber bag arrangements, are also not section 85 / general supplies and not eligible for an ACSS payment under the 8CPA. Payments for prescriber bag supplies are exclusively dealt with under sections 93, 93AA and 93AB of the Act and therefore do not need to be expressly excluded from the terms of the Determination.

## **Section 6 – Amount of ACSS Payment**

Section 6 specifies the amount of the ACSS payment for ACSS eligible supplies and is made for the purposes of subparagraph 98B(1)(b)(ii) of the Act.

Paragraph 6(1)(a) provides that, where paragraph 6(1)(b) does not apply, the amount of ACSS payment for each ACSS eligible supply is \$0.78. Paragraph 6(1)(a) applies where an ACSS eligible supply does not involve the supply of an increased maximum quantity of the pharmaceutical benefit.

Paragraph 6(1)(b) provides that if either subsection 6(2) or (3) applies to the supply, the amount of the ACSS payment is the sum of \$0.78 and \$4.79.

The note to subsection 6(1) informs readers that:

- an approved pharmacist who wants to receive an ACSS payment must make a claim for the payment under section 99AAA of the Act; and
- entitlement to the ACSS payment is subject to any applicable conditions determined under section 98C of the Act, and the conditions set out in section 98AAB of the Act.

Subsection 6(2) sets out circumstances in which an approved pharmacist will be entitled to the additional \$4.79 component of the ACSS payment, where the pharmaceutical benefit is supplied on the basis of a prescription. The subsection applies to an ACSS eligible supply of a pharmaceutical benefit if both the following apply:

- the supply is made upon an increased maximum quantity prescription directing the supply of the benefit, or another pharmaceutical benefit that is Schedule equivalent to the benefit; and
- the supply is of the increased maximum quantity of the benefit.

Where two pharmaceutical benefits are Schedule equivalent, approved pharmacists can undertake ‘brand substitution’ at the point of dispensing. In other words, even if a prescription directs the supply of pharmaceutical benefit A, the approved pharmacist can dispense pharmaceutical benefit B that is Schedule equivalent to benefit A.

Subsection 6(2) requires both that the prescription on which the supply is made directs an increased maximum quantity of the pharmaceutical benefit (or Schedule equivalent benefit) be dispensed to the patient on the one occasion and the supplied amount is that increased maximum quantity. If stock shortages prevent an approved pharmacist from physically providing a patient with their full supply on a particular day (for example if the PBS supply amount is 2 packets of tablets and the approved pharmacist only has one packet on hand and needs to provide the second packet to the patient when stock becomes available) the approved pharmacist would still be considered to have supplied the increased maximum quantity.

Subsection 6(3) sets out circumstances in which an approved pharmacist will be entitled to the additional \$4.79 component of the ACSS payment, where the pharmaceutical benefit is supplied on the basis of a ‘continued dispensing’ supply without a prescription.

Continued dispensing arrangements are authorised under section 89A of the Act, which enables the Minister to determine pharmaceutical benefits that may be supplied by approved pharmacists without prescription and the circumstances in which this may occur. Under continued dispensing arrangements, an approved pharmacist may supply patients with certain pharmaceutical benefits without a prescription where, among other things, the approved pharmacist is satisfied that:

- the immediately preceding supply of the pharmaceutical benefit (or a Schedule equivalent benefit) to the patient was on the basis of a PBS prescription;
- the patient has been taking the pharmaceutical benefit regularly for an uninterrupted period and in that time has been assessed by a PBS prescriber as continuing to need the pharmaceutical benefit; and

- the patient has not already received a continued dispensing supply of the pharmaceutical benefit in the previous 12 months.

Subsection 6(3) applies to an ACSS eligible supply of a pharmaceutical benefit if:

- the supply is made in accordance with section 89A of the Act;
- the immediately preceding supply to the person of the benefit, or of another pharmaceutical benefit that is Schedule equivalent to the benefit, was made upon an increased maximum quantity prescription directing the supply of the benefit, or another pharmaceutical benefit that is Schedule equivalent to the benefit; and
- both the ACSS eligible supply, and immediately preceding supply are of the increased maximum quantity of the relevant pharmaceutical benefit.

## Statement of Compatibility with Human Rights

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

National Health (Additional Community Supply Support Payment) Determination 2024

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This disallowable 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 the *National Health (Additional Community Supply Support Payment) Determination 2024* (Instrument), made under paragraph 98B(1)(b) of the *National Health Act 1953* (Act), is for the Pharmaceutical Benefits Remuneration Tribunal (Tribunal) to determine the kinds of supplies by approved pharmacists of pharmaceutical benefits that are Additional Community Supply Support (ACSS) eligible supplies and the amount of the ACSS payment for any or all such supplies.

The basis for the ACSS payment is an agreement under the Eighth Community Pharmacy Agreement (8CPA) between the Commonwealth and the Pharmacy Guild of Australia to establish a payment to approved pharmacists, in addition to the Commonwealth price, to provide the necessary level of support for the dispensing of Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) medicines, including for increased dispensing quantities, to ensure continued access to these medicines while providing cheaper medicines to patients.

The Instrument specifies ACSS eligible supplies and the amount of the ACSS payment for supplies of pharmaceutical benefits under the PBS.

### Human rights implications

This Instrument engages Articles 2, 7, 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The legislative instrument assists with the provision of 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 social security, and the enjoyment of the highest attainable standard of physical and mental health.

The 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. Subsection 98BAA(1A) of the Act requires that, where the Commonwealth and the Guild have entered into an agreement relating to the kinds of supplies made by approved pharmacists that are ACSS eligible supplies, and the amount of the ACSS payment for such supplies, or the manner in which that amount is to be worked out, the Tribunal must give effect to the terms of that agreement in making its determination under paragraph 98B(1)(b), while the agreement remains in force. The 8CPA, which commenced on 1 July 2024 and will continue until 30 June 2029, includes such an agreement.

The new ACSS payment included in the 8CPA provides a means through which the Commonwealth is able to provide the necessary level of financial support to community pharmacies for the dispensing of PBS medicines, without increasing the costs of medicines for some patients.

### **Conclusion**

This Instrument is compatible with human rights because it promotes the protection of human rights to health and social security, and favourable work conditions.

**Judith Wright**

**Chairperson**

**Pharmaceutical Benefits Remuneration Tribunal**