

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (ACSS Eligible Supplies) Rules 2024

PB 108 of 2024

Purpose

The *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* (Principal Instrument) defines the procedures to be followed and sets out the details regarding the information required to be provided by approved suppliers when making claims for payment for supplies of pharmaceutical benefits, or providing information on supplies of pharmaceutical benefits where there is no claim to be made.

The purpose of the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (ACSS Eligible Supplies) Rules 2024* (Amending Instrument) is to amend the Principal Instrument to support arrangements for the processing and determination of claims by approved pharmacists for payment of the new Additional Community Supply Support payment (ACSS payment).

In July 2024, the *National Health Act 1953* (Act) was amended to give effect to the agreement between the Minister for Health and Aged Care (on behalf of the Commonwealth) and the Pharmacy Guild of Australia (Guild) made under the Eighth Community Pharmacy Agreement (8CPA) to introduce the new ACSS payment for eligible supplies made by approved pharmacists.

The 8CPA took effect on 1 July 2024 and will remain in effect until 30 June 2029. A copy of the 8CPA can be found on the Department of Health and Aged Care's website at: <https://www.health.gov.au/resources/publications/eighth-community-pharmacy-agreement>.

Supplies eligible for the ACSS payment and the amount of the payment are determined in the *National Health (Additional Community Supply Support Payment) Determination 2024* (ACSS Determination).

Claims for the ACSS payment will initially be processed manually by officers in Services Australia until a system solution is developed to enable those claims to be processed in the same manner, and on the same timetable, as general Commonwealth payments to approved suppliers for supplies of pharmaceutical benefits. A system solution is anticipated to be in place by 1 July 2025. Approved pharmacists will receive ACSS payments quarterly during the manual processing period.

The Amending Instrument amends the Principal Instrument to reflect that the procedures for processing and determining claims in respect of ACSS payments will differ from those for other claims, while the system solution is being developed.

Authority

The Amending Instrument is made under subsection 99AAA(8) of the Act.

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.

Background

The Pharmaceutical Benefits Scheme (PBS) operates under Part VII of the Act and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

Subsection 99AAA(8) of the Act provides that the Minister must, by legislative instrument, make rules defining the procedures to be followed by approved suppliers in making claims for payment, and specifying the information to be given to the Secretary by approved suppliers and procedures for giving this information, in relation to the supply of pharmaceutical benefits.

Subsection 99AAA(8) additionally provides that the Minister must, by legislative instrument, make rules defining the procedures to be followed by the Secretary in processing and determining claims by approved suppliers.

Consultation

There has been broad consultation with various stakeholders, including the clinical software industry and Services Australia, in relation to the content of the Amending Instrument. These industries welcome the Amending Instrument, noting that the Amending Instrument supports the submission of information by approved pharmacists to Services Australia about supplies that are ACSS eligible supplies,

As part of the 8CPA, the Guild and the Commonwealth agreed that manual processing of ACSS payments would be required initially, with a goal of automation of payments on or around 1 July 2025.

Commencement

This Amending Instrument commences on the day after it is registered.

General

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

Details of this Amending Instrument are outlined in **Attachment A**.

This Amending Instrument 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 (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (ACSS Eligible Supplies) Rules 2024

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (ACSS Eligible Supplies) Rules 2024* (Amending Instrument), which may also be cited as PB 108 of 2024.

Section 2 – Commencement

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

Section 3 – Authority

Section 3 provides that the Amending Instrument is made under subsection 99AAA(8) of the *National Health Act 1953* (Act).

Section 4 – Schedules

Section 4 provides that each instrument specified in a Schedule to the Amending Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in that Schedule has effect according to its terms. The Schedule amends the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* (Principal Instrument).

Schedule 1—Amendments

Item 1 – Subsection 5(1)

Item 1 inserts a definition of *non-ACSS payment* and accompanying note in subsection 5(1) of the Principal Instrument.

The term *non-ACSS payment* is defined as a payment, other than an ACSS payment, to an approved supplier under Part VII of the Act in relation to the supply of a pharmaceutical benefit.

The note to subsection 5(1) informs readers that Commonwealth payments to approved suppliers under Part VII of the Act that are not ACSS payments include payments under sections 93, 93AB and 99 of the Act.

Section 99 of the Act establishes entitlement to the general PBS payment for supply of a pharmaceutical benefit by an approved supplier. Payment under section 99 of the Act is determined by reference to the Commonwealth price of the pharmaceutical benefit for the purposes of supply by approved suppliers.

The new ACSS payment is paid outside of, and in addition to, the existing Commonwealth price based mechanism for Commonwealth payments in respect of supplies of pharmaceutical benefits.

Payment for prescriber bag supplies made under sections 93 and 93AB of the Act are made under regulations made for those sections.

Item 2 – Subsection 5(2)

Item 2 repeals and substitutes subsection 5(2) of the Principal Instrument. New subsection 5(2) provides that an expression used in the Principal Instrument that is defined for Part VII of the Act has the same meaning in the Amending Instrument as in Part VII of the Act, including the expressions *ACSS eligible supply* and *ACSS payment*.

Item 3 – Subsection 12(1)

Item 4 – Subsection 12(2) (note)

Item 5 – At the end of section 12

Items 3, 4 and 5 amend section 12 of the Principal Instrument. Section 12 is made for subparagraph 99AAA(8)(e)(i) of the Act.

Section 12(1) previously provided that the procedures to be followed by the Chief Executive Medicare in processing and determining claims by an approved supplier for payment relating to the supply of pharmaceutical benefits were established in subsection 12(2).

Subsection 12(2) relevantly requires the Chief Executive Medicare to institute reasonable checks to be satisfied that the approved supplier is entitled to be paid an amount in respect of the claim.

Item 5 adds a new subsection 12(3) to clarify that the Chief Executive Medicare is not required to determine an approved supplier's entitlement for an ACSS payment in respect of the supply of a benefit that is the subject of a claim at the same time as they determine entitlement to a non-ACSS payment for that supply. This reflects that claims for the ACSS payment will initially need to be processed manually until a system solution is developed to enable claims to be processed in the same manner and on the same timetable as non-ACSS payments. Delegates of the Chief Executive Medicare in Services Australia will therefore take longer to determine entitlement to ACSS payments.

Item 3 therefore amends subsection 12(1) by omitting reference to “subsection (2) defines” and substituting “subsections (2) and (3) define”, as a consequence of the addition of new subsection 12(3) made by item 5.

The note to subsection 12(2) previously informed readers that advance payments associated with claims made using the Claims Transmission System are permitted and made in accordance with subsection 99AB(1) of the Act.

Item 4 amends the note to subsection 12(2) to clarify that advance payments may be made in respect of amounts that may become payable specifically under section 99 of the Act. While claims for the ACSS payment rely on manual processing by officers in Services Australia, advance payments of amounts that may become payable under section 99AAAA as ACSS payments are not available.

Item 6 – Paragraph 13(2)(b)

Item 7 – At the end of section 13

Items 6 and 7 amend section 13 of the Principal Instrument. Section 13 is made for subparagraph 99AAA(8)(e)(ii) of the Act.

Section 13 establishes the procedures to be followed by the Chief Executive Medicare in making payments in respect of claims by an approved supplier. Paragraph 13(2)(b) previously required the Chief Executive Medicare to ensure that a statement of account is given to the approved supplier in respect of each claim for payment.

Item 6 repeals paragraph 13(2)(b) (not including the example) and substitutes new paragraphs 13(2)(b) and (c). These together require the Chief Executive Medicare to ensure:

- a statement of account including information about non-ACSS payments is given to an approved supplier in respect of each claim for payment; and
- for an approved supplier who is an approved pharmacist, a statement of account including information about ACSS payments covered by the statement of account to be given to the pharmacist.

Item 7 adds a new subsection 13(3) to clarify that a statement of account referred to in paragraph 13(2)(c) is not required to relate to a particular claim period and may include information about ACSS payments made in respect of supplies of pharmaceutical benefits made in different claim periods. A note to subsection 13(3) informs readers that approved pharmacists are the only approved suppliers who are entitled to ACSS payments.

The amendments to subsections 13(2) and 13(3) of the Principal Instrument reflect the need for there to be operational flexibility in respect of the timeframes in which statements of account including information about ACSS payments are given to approved pharmacists during the interim manual processing period.

Statement of Compatibility with Human Rights

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

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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 Amending Instrument

The purpose of the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (ACSS Eligible Supplies) Rules 2024* (Amending Instrument) is to make consequential amendments to the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* (Principal Instrument).

These amendments relate to procedures for processing and determining claims in respect of the new Additional Community Supply Support (ACSS) payment for eligible supplies of pharmaceutical benefits, and the procedures for making the ACSS payment in respect of those claims.

The new ACSS payment to approved pharmacists was agreed under the Eighth Community Pharmacy Agreement (8CPA) between the Minister for Health and Aged Care (on behalf of the Commonwealth) and the Pharmacy Guild of Australia (Guild). The *National Health Act 1953* (Act) was amended in July 2024 to include new section 99AAAA that creates an entitlement to the ACSS payment for eligible supplies.

The *National Health (Additional Community Supply Support Payment) Determination 2024*, which commenced in October 2024, determines supplies eligible for the new ACSS payment and the amount of the payment, giving effect to the agreement in the 8CPA.

Relevantly for the purposes of the Amending Instrument, entitlement to the ACSS payment operates outside the standard mechanism for paying approved pharmacists in relation to the supply of pharmaceutical benefits, found in section 99 of the Act. As a consequence, Services Australia is required to develop a new system to automate ACSS payments to approved pharmacists. It was agreed in the 8CPA that an initial period of manual processing of ACSS payments would be required, with a goal of Services Australia implementing automated ACSS payments on or around 1 July 2025.

The Amending Instrument makes minor changes to the Principal Instrument to reflect that during this interim period of manual processing of claims, processing payments for ACSS-eligible supplies will not be on the same timetable as automated processing of claims for

payment under section 99 of the Act. Approved pharmacists will receive ACSS payments on a quarterly basis during the manual processing period.

Human rights implications

The Amending Instrument engages Articles 2, 7, 9, 12 and 17 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR). It supports the rights to health and social security and assisting in realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. It also supports the right to just and favourable conditions at work, specifically to fair wages. It does not impose any further limitations on the right to privacy.

The Pharmaceutical Benefits Scheme (PBS) established under Part VII of the Act assists with the advancement of the rights to health and social security by providing Commonwealth subsidised access to necessary and cost-effective medicines for Australians.

The new ACSS payment will positively affect an individual's rights to health, social security, and favourable conditions of work by supporting the continued supply of Commonwealth subsidised pharmaceutical benefits by approved pharmacists. This will further support patient access to PBS medicines through community pharmacies and will provide 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 patients.

The Amending Instrument makes clear that during the interim period where claims for ACSS payments are processed manually by officers in Services Australia, the timetable for making payments for ACSS entitlements under section 99AAAA of the Act for a supply will differ from the timetable for making payments for Commonwealth price-based entitlements under section 99 of the Act for the same supply. Manual processing is necessary to ensure that approved pharmacists can start receiving the new ACSS payment while a system solution is developed.

The need for initial manual payment arrangements was recognised by the Commonwealth and the Guild in the 8CPA.

The Amending Instrument does not affect patient entitlement to the subsidised supply of pharmaceutical benefits under the PBS. This includes in relation to which pharmaceutical benefits may be supplied to the patient under the PBS, the amount a patient may be required to pay for a PBS supply and the amount of patient co-payment that will count towards their PBS safety-net.

The Amending Instrument also does not affect the procedures that must be followed by approved pharmacists in submitting claims for payment for supplies of pharmaceutical benefits to Services Australia or the information that must be given as part of the claim. Approved pharmacists are not required to submit a separate claim to receive an ACSS payment (where eligible) in addition to a claim for payment under section 99 of the Act. No additional personal information about patients or pharmacists is required to be supplied to Services Australia in order for an approved pharmacist to make a claim for the new ACSS payment.

The Amending Instrument therefore does not impose any additional limitation on the right to privacy contained in Article 17 of the International Covenant on Civil and Political Rights (ICCPR). Personal information required by the Principal Instrument to be submitted to Services Australia for the purposes of making PBS claims is collected and disclosed in accordance with the *Privacy Act 1988* and the secrecy provisions in the Act.

Conclusion

This legislative instrument is compatible with human rights because it promotes the protection of human rights to health and social security, and favourable conditions of work as outlined above.

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