

EXPLANATORY STATEMENT

National Health Act 1953

*National Health (Take Home Naloxone Pilot) Special Arrangement Amendment
(2021 Measures No.1) Instrument 2021*

PB 69 of 2021

Authority

Subsection 100(2) of the *National Health Act 1953* (the Act) provides that the Minister may vary or revoke an arrangement made under subsection 100(1) of the Act.

Subsection 100(1) of the Act enables the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to certain persons. These are persons who: live in isolated areas; or are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment; or if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII, have effect, subject to a special arrangement made under subsection 100(1).

Purpose

The *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2021 Measures No.1) Instrument 2021* (PB 69 of 2021) (the Amendment Instrument) amends the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (PB 97 of 2019) (the Arrangement) to continue the arrangements of the Take Home Naloxone Pilot Program (the Pilot) in 2021-22.

Background

In the 2021-22 Budget, the Australian Government provided \$3.9 million to ensure Naloxone continues to be available for people who are at risk of an opioid overdose or adverse reaction and their carers, friends and family members in Western Australia, New South Wales and South Australia for an additional year until 30 June 2022 (the Pilot). The Pilot first began in these States on 1 December 2019.

This additional year will support the three participating jurisdictions to maintain their now established Take Home Naloxone (THN) programs without a break in continuity of service for those accessing Naloxone in the community during 2021-22 while the Pilot evaluation is completed in the second half of 2021. The outcomes of the evaluation will inform future decisions about establishing a national THN program in Australia.

The continuation of the Pilot also provides further opportunity to continue to build awareness of the availability of Naloxone and further increase participation by community pharmacies and other access sites.

The Pilot program enables the supply of Naloxone free of charge to persons who are at risk of an opioid overdose, and persons who are likely to be able to assist such persons, outside of the normal Pharmaceutical Benefit Scheme supply regime. Under the Pilot, Naloxone can be supplied by hospitals, pharmacists, certain medical practitioners, and other authorised persons and organisations, such as needle and syringe programs, alcohol drug treatment centres, or correctional release programs.

In addition to the Pilot, Naloxone also continues to be available in all states and territories with a prescription or purchased over the counter from a pharmacy.

Consultation

The Pilot operates in NSW, WA and SA and therefore the Department of Health (the Department) consulted the relevant State agencies, namely New South Wales Ministry of Health, the Western Australian Mental Health Commission and South Australia Health, about the implementation of the

2021-22 Budget measure to extend the Pilot for an additional year from 30 June 2021 to 30 June 2022. The Department advised State agencies of the extension of the Pilot for an additional year of which states were supportive. The relevant State agencies are aware the Amendment Instrument would be required to effect this change.

Australian Healthcare Associates, as the Pilot administrator, were consulted to confirm their ability to implement the relevant administrative arrangements in 2021-22, including making updates to software solutions to support the amendments made by this Amendment Instrument. Specifically, guidelines and user guides to support the operation of the Pilot at www.ppaonline.com.au/programs/trial-programs are to be updated to reflect the revised Pilot timeframe and data requirements.

This Amendment Instrument commences the day after it is registered.

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

Details of this instrument are set out in the Attachment.

Details of the *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2021 Measures No.1) Instrument 2021***Section 1 Name**

This section provides that the name of the instrument is the *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2021 Measures No.1) Instrument 2021* (the Amendment Instrument) and may also be cited as PB 69 of 2021.

Section 2 Commencement

This section provides that the Amendment Instrument commences the day after the instrument is registered.

Section 3 Authority

This section provides that the Amendment Instrument is made under subsection 100(2) of the *National Health Act 1953*.

Section 4 Schedules

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

Schedule 1 – Amendments***National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019) (the Arrangement)*****1 Section 4**

This item amends section 4 of the Arrangement to replace the repeal date of the Arrangement from 1 September 2021 to 1 September 2022.

2 Section 5

This item amends section 5 of the Arrangement to change the date the special arrangement ends from 30 June 2021 to 30 June 2022. This amendment reflects the extension to the period in which Naloxone can be supplied in New South Wales, Western Australia, and South Australia under the Pilot.

3 Paragraph 7(1)(a)

This item amends paragraph 7(1)(a) of the Arrangement to extend the date from 1 July 2021 to 1 July 2022 before which supplies of Naloxone by approved hospital authorities, will be ‘special arrangement supplies’ (provided all other requirements are met).

4 Subparagraph 7(2)(a)(i)

This item amends subparagraph 7(2)(a)(i) of the Arrangement to extend the date from 1 July 2021 to 1 July 2022 before which supplies of Naloxone by approved medical practitioners, will be ‘special arrangement supplies’ (provided all other requirements are met).

5 Paragraph 7(3)(a) and 4(a)

These items amend paragraphs 7(3)(a) and 4(a) of the Arrangement to extend the date from 1 July 2021 to 1 July 2022 before which supplies of Naloxone by approved pharmacists and

authorised alternative suppliers, will be ‘special arrangement supplies’ (provided all other requirements are met).

6 Subparagraph 20(b)(iv)

This item amends subparagraph 20(b)(iv) of the Arrangement to conclude the paragraph at ‘supplied.’, given subsequent subparagraphs 20(b)(v) and (vi) are repealed.

7 Subparagraphs 20(b)(v) and (vi)

These items amend subparagraphs 20(b)(v) and (vi) of the Arrangement by repealing them, as they no longer apply after 30 June 2021. These subparagraphs relate to information that must be provided in a claim for payment by an approved supplier in relation to a special arrangement supply of a designated pharmaceutical benefit, in the context of the evaluation of the Pilot.

A claim for payment, as defined in the Arrangement, by an approved supplier in relation to a special arrangement supply of a designated pharmaceutical benefit must continue to be in accordance with subparagraphs 20(a) and (b)(i), (ii), (iii) and (iv).

8 Paragraph 20(c)

This item amends paragraph 20(c) of the Arrangement by repealing it. This paragraph is no longer required as it relates to a person to whom the benefit was supplied, as mentioned in subparagraph 20(b)(vi), which is repealed.

While data collection requirements for the evaluation will cease on 30 June 2021 to ensure completion of the final evaluation report in the second half of 2021, the Department of Health will continue to receive and monitor supply claim data on a monthly basis through the Pilot administrator.

9 At the end of Part 3

This item adds a new provision to the end of Part 3 of the Arrangement. This ensures amendments to section 20 of the Arrangement made by the Amendment Instrument apply in relation to a claim for payment made on or after 1 July 2021 in respect of a special arrangement supply of a designated pharmaceutical benefit made before, on or after 1 July 2021.

Statement of Compatibility with Human Rights

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

National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2021 Measures No.1) Instrument 2021

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 Disallowable Legislative Instrument

Pursuant to subsection 100(2) of the *National Health Act 1953* (the Act), the *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2021 Measures No. 1) Instrument 2021* (the Amendment Instrument) amends the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (PB 97 of 2019) (the Arrangement).

The Arrangement is established under section 100(1) of the Act to support the Pharmaceutical Benefits Scheme (PBS) subsidised Take Home Naloxone Pilot (the Pilot), which commenced on 1 December 2019, and will operate to 30 June 2022 (once the Amendment Instrument commences) in New South Wales, Western Australia, and South Australia. The Pilot is part of the Australian Government's commitment to reducing adverse health, social and economic consequences of drug use through the National Drug Strategy.

The aim of the Pilot is to trial the supply of Naloxone (for opioid overdose reversal) to persons who are at risk of an opioid overdose, and persons who are likely to be able to assist such persons. The Pilot allows for Naloxone to be supplied free of charge and without prescription by hospitals, pharmacists, certain medical practitioners, and other authorised persons and organisations, such as needle and syringe programs, alcohol drug treatment centres, or correctional release programs who have registered to participate.

The Pilot, in conjunction with the various take home Naloxone programs currently operating in the States, provides an opportunity to increase access to Naloxone to a wider population at risk of overdose. It will provide critical evidence and information necessary for the consideration of a national roll out.

The amendments made by the Amendment Instrument extend both the repeal date of the Arrangement and the end date for supplies to be made under the Pilot. The Arrangement will now be repealed at the start of 1 September 2022 instead of 1 September 2021. Under the Pilot a supply of a designated pharmaceutical benefit is a special arrangement supply of the benefit if the benefit is supplied on or after 1 December 2019 and before 1 July 2022.

Human rights implications

This instrument engages Article 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with 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.

This instrument assists with the advancement of this right by ensuring access to PBS subsidised Naloxone through a variety of settings in participating states, free of charge, to persons at risk of or likely to witness an opioid overdose.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights because it maintains the protection of human rights to health.

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