

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (Program Extension) Instrument 2021

PB 9 of 2021

Authority

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

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 *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment Program Extension Instrument 2021* (the Amendment Instrument) amends the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (PB 97 of 2019) (the Arrangement) to extend the Take Home Naloxone Pilot Program (The Pilot) by 4 months. The Pilot enables the trial of 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 PBS 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.

Consultation

The Pilot operates in NSW, WA and SA and therefore the Department consulted the relevant State agencies, namely New South Wales Ministry of Health, the Western Australian Mental Health Commission and South Australia Health, regarding the amendments to the Arrangement. In particular, the Department advised the State agencies of the amendments to extend the date of cessation of the Pilot. The State agencies had no significant comment on the nature of the instrument.

Australian Healthcare Associates, as the Pilot administrator, were consulted to confirm their ability to implement the relevant administrative arrangements, including making updates to software solutions to support the amendments made by this 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 include reference to the revised Pilot timeframe.

This Amendment Instrument commences the day after it is registered on the Federal Register of Legislation.

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 (Program Extension) 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 (Program Extension) Instrument 2021* and may also be cited as PB 9 of 2021.

Section 2 Commencement

This section provides that the Arrangement commences the day after the instrument is registered on the Federal Register of Legislation.

Section 3 Authority

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

Section 4 Schedules

This section provides that changes are made to the Arrangement as specified in the Schedule contained in this instrument.

Schedule 1 - Amendments

Section 4

Section 4 is amended to update the repeal date of the Arrangement to 1 September 2021.

Section 5

Section 5 is amended by substituting the reference to 28 February 2021 with a reference to 30 June 2021, reflecting the extension to the period in which Naloxone can be supplied in New South Wales, Western Australia, and South Australia under the Pilot.

Paragraphs 7(1)(a), 7(3)(a) and 7(4)(a)

Subparagraph 7(2)(a)(i)

These provisions are amended by substituting references to 1 March 2021 with reference to 1 July 2021. This extends the date before which supplies of Naloxone by approved hospital authorities, approved medical practitioners, approved pharmacists and authorised alternative suppliers will be 'special arrangement supplies' (provided all other requirements are met).

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 (Program Extension) Instrument 2021 (PB 9 of 2021)

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

Pursuant to subsection 100(2) of the *National Health Act 1952* (the Act), this 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 PBS subsidised Take Home Naloxone Pilot (the Pilot), which commenced 1 December 2019, and will operate to 30 June 2021 in New South Wales (NSW), Western Australia (WA), and South Australia (SA). The Pilot is part of the 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 this instrument amend and 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 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 2021.

Human rights implications

This instrument engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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 Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

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