

EXPLANATORY STATEMENT

National Health Act 1953

*National Health (Take Home Naloxone Pilot) Special Arrangement Amendment
(2022 Measures No.1) Instrument 2022*

PB 60 of 2022

Authority

The Pharmaceutical Benefits Scheme (PBS) is established under the *National Health Act 1953* (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 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(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).

Purpose

The *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2022 Measures No.1) Instrument 2022* (PB 60 of 2022) (the Amendment Instrument) amends the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (PB 97 of 2019) (the Arrangement) to expand the Take Home Naloxone (THN) program initially piloted in New South Wales, South Australia and Western Australia nationally, commencing 1 July 2022.

Commencing 1 July 2022, the expanded national THN program enables the supply of naloxone free of charge and without a prescription 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 program, naloxone can be supplied by hospitals, pharmacists, certain medical practitioners, and other authorised organisations, such as needle and syringe programs, alcohol drug treatment centres, or correctional release programs.

The Amendment Instrument sets out that from 1 July 2022, Section 90 (s90) and Section 94 (s94) approved pharmacies as well as Section 92 (s92) approved medical practitioners in all states and territories will be able to participate in the national THN program.

The Amendment Instrument also sets out that in Tasmania, Victoria, Queensland, Northern Territory, and the Australian Capital Territory, Special Arrangement supply of naloxone by authorised alternative suppliers (i.e. state and territory authorised sites such as alcohol and drug treatment centres and needle and syringe programs) will commence from 1 November 2022. This recognises the consultation required with these jurisdictions who are newly participating in the program and also the updates required to the administrative claiming and payment system to support participation by authorised alternative suppliers in these jurisdictions. However, as noted above naloxone will be available at no cost to the individual and without a prescription from community pharmacies, hospital-based pharmacies and approved medical practitioners nationally from 1 July 2022.

The Amendment Instrument sets out the minimum data to be provided with a claim for payment.

Background

Naloxone is a drug that can temporarily reverse the effects of an opioid overdose or adverse reaction. The 2022-23 Federal Budget included \$19.6 million (over 4 years) to deliver the THN program nationally following the evidence-based evaluation of the THN pilot program. Under the THN program, naloxone is available in all Australian states and territories, to people who are at risk of, or who may witness an opioid overdose or adverse reaction.

In addition to the national THN program, naloxone continues to be available in all states and territories with a prescription or over the counter from a pharmacy for a fee.

Consultation

The Department of Health and Aged Care (the Department) made the Amendment Instrument available to all state and territory health departments, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia (SHPA) and Australian Healthcare Associates (as the THN program administrator) for comment. Two responses were received, one from NSW Health and the other from SHPA, neither making significant comment on the nature of the Amendment Instrument itself. SHPA welcomed the national initiative to support the funding of naloxone to members of the community who are most at risk of opioid-related harms and overdose and further discussions with the Department on enabling participation by hospitals. NSW Health noted the importance of implementing the findings from the THN pilot evaluation to improve supply arrangements and access to naloxone from non-pharmacy sites. There will be ongoing consultation with key stakeholders to support access to naloxone at a national level.

The Department has consulted with New South Wales, South Australia, and Western Australia who participated in the THN pilot program to support transition to the national THN program from 1 July 2022. No concerns were raised with regard to transition to the national program. The Department is also working with Tasmania, Victoria, Queensland, Northern Territory, and the Australian Capital Territory on the implementation of the expanded THN program to support engagement and participation. States and territories are supportive of the roll out of the THN program at a national level to improve access to this life-saving medicine.

Australian Healthcare Associates, as the THN program administrator, were consulted to confirm their ability to implement the relevant administrative arrangements in 2022-23, including making updates to software solutions to support the amendments made by this Amendment Instrument. Specifically, program rules and user guides to support the operation of the program at www.ppaonline.com.au/programs/trial-programs are updated to reflect the program requirements and communications materials have been distributed to all pharmacies.

This Amendment Instrument commences on 1 July 2022.

The Act specifies no conditions that need to be satisfied before the power to make the instrument is exercised.

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

A provision-by-provision description of the instrument is contained in the [Attachment](#).

Details of the *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2022 Measures No.1) Instrument 2022*

Section 1 Name

This section provides that the name of the instrument is the *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2022 Measures No.1) Instrument 2022* (the Amendment Instrument) and may also be cited as PB 60 of 2022.

Section 2 Commencement

This section provides that the Amendment Instrument commences on 1 July 2022.

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)

Item 1 - Subsection 1(1)

This item amends subsection 1(1) of the Arrangement to remove the word “*Pilot*”. This reflects the completion of the pilot THN program phase to be expanded to a national, ongoing-THN program.

Item 2 - Section 4

This item repeals section 4 of the Arrangement. This repeal section is no longer required as the THN program is ongoing.

Items 3 and 4 - Section 5

These items amend section 5 of the Arrangement to remove references in the simplified outline of the Arrangement to the Pilot and the dates of the Pilot, and supplies in participating states. This reflects expansion from a Pilot program to a national, ongoing THN program.

Items 5, 6, 7, 8 and 9 - Section 6

These items amend section 6 of the Arrangement, to reflect the program moving from only being a pilot in some states to being a national program. The definitions of ‘*authorised alternative supplier*’ and ‘*excluded approved supplier*’ are amended to remove the word ‘participating’ before the word ‘jurisdiction’ and a new definition of ‘*jurisdiction*’ is inserted to mean a State or Territory. The definition of ‘*participating jurisdiction*’ is repealed, as all states and territories can participate, and it is therefore no longer required. A new definition of ‘*Territory*’ is also inserted to have the same meaning as in Part VII of the Act, meaning it includes internal and external Territories to which the Act applies.

Item 10 - Paragraphs 7(1)(a) and (b)

This item repeals subparagraphs 7(1)(a) and (b) of the Arrangement as they no longer apply after 30 June 2022. This item also inserts new paragraphs that specify the dates where naloxone will be considered a special arrangement supply by approved hospital authorities in particular States and Territories, reflecting when those States and Territories started participating in the program.

Item 11 - Paragraph 7(2)(a)

This item amends the paragraph 7(2)(a) of the Arrangement to insert new paragraphs that specify the dates where naloxone will be considered a special arrangement supply by approved medical practitioners in particular States and Territories, reflecting when those States and Territories started participating in the program.

Item 12 - Subparagraphs 7(2)(a)(i) and (ii)

This item repeals subparagraphs 7(2)(a)(i) and (ii) as they no longer apply after 30 June 2022.

Item 13 - Paragraphs 7(3)(a) and (b)

This item repeals subparagraphs 7(3)(a) and (b) of the Arrangement, as they no longer apply after 30 June 2022 and inserts new paragraphs that specify the dates where naloxone will be considered a special arrangement supply by approved pharmacists, in particular States and Territories, reflecting when those States and Territories started participating in the program.

Item 14 - Paragraphs 7(4)(a) and (b)

This item repeals paragraphs 7(4)(a) and 4(b) of the Arrangement, as they no longer apply after 30 June 2022 and inserts new paragraphs that specify the dates where naloxone will be considered a special arrangement supply by authorised alternative suppliers, in particular States and Territories, reflecting when those States and Territories started participating in the program.

In Tasmania, Victoria, Queensland, Northern Territory, and the Australian Capital Territory special arrangement supply by authorised alternative suppliers will commence from 1 November 2022. This recognises the system and policy development necessary to support authorised alternative suppliers, which may include administrative and/or legislative amendments for individual States or Territories.

Item 15 - Paragraph 7(5)(a)

This item amends paragraph 7(5)(a) of the Arrangement to omit 'participating' before the word 'jurisdiction' and substitute with an 'a' to reflect that all States and Territories can participate in the national, ongoing THN program.

Item 16 – At the end of section 20

This item adds new provisions to section 20 of the Arrangement, (v), (c)(i) and (ii) and specifies additional 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. With client consent, de-identified information regarding whether a person has previously received a supply of naloxone under the program and the reason for receiving a further supply will be recorded. This will support ongoing program monitoring by the Department of Health and Aged Care.

Privacy risks associated with the collection of the data are minor, as there is only a minor risk of the individual who supplied the naloxone being re-identified. Accordingly, the department's collection and use of information (insofar as it includes any personal information) will be in accordance with the *Privacy Act 1988*.

Item 17 - Subsection 21(1)

This item amends subsection 21(1) to specify requirements for entitlement to payment for authorised alternative suppliers.

Item 18 - At the end of Part 3

This item adds a new section 29 to the end of Part 3 of the Arrangement, being an application provision to ensure 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 2022 in respect of a special arrangement supply of a designated pharmaceutical benefit made on or after that date.

Item 19 – Clause 1 of Schedule 1 (table item 2A)

This item repeals the pharmaceutical benefit specified in item 2A of the table, being naloxone with the brand Junalox, as is has been delisted from the Pharmaceutical Benefits Scheme.

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 (2022 Measures No.1) Instrument 2022

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 (2022 Measures No. 1) Instrument 2022* (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 Program, which will commence from 1 July 2022 (once the Amendment Instrument commences) in all Australian States and Territories. The Program supports a commitment to reducing adverse health, social and economic consequences of drug use through the National Drug Strategy.

The aim of the program is to supply 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 program allows for naloxone to be supplied (at no cost to the individual and without the need to obtain a 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 program provides an opportunity to increase access to naloxone to a wider population at risk of overdose.

The amendments made by the Amendment Instrument extend the program to all Australian States and Territories. Under the program a supply of a designated pharmaceutical benefit is a special arrangement supply of the benefit if the benefit is supplied on or after 1 July 2022.

Human rights implications

The Disallowable Legislative Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct

its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

Analysis

The Disallowable Legislative Instrument advances the right to health and the right to social security by ensuring access to naloxone through a variety of settings in all Australian States and Territories, to persons at risk of or likely to witness an opioid overdose through the Pharmaceutical Benefits Scheme. The Disallowable Legislative Instrument ensures more ready and equitable access to the naloxone for eligible people by making the medicine available at no cost to the individual and without the need for a prescription.

Broadly, the PBS is a benefits scheme which assists with advancement of this human right by providing subsidised access to medicines for people in the community. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Sponsors are private entities that make their own decisions regarding their products and cannot be compelled by the Government to continue to list a product on the PBS. The delisting of a brand, in this case Junalox from the THN program, will not adversely affect members of the public as they will be able to obtain other equivalent brands. Consequently, the delisting of Junalox in this instrument does not result in an unmet clinical need.

Conclusion

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

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