

## EXPLANATORY STATEMENT

### *National Health Act 1953*

#### *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2020 Measures No.1) Instrument 2020*

PB 77 of 2020

#### **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 (2020 Measures No.1) Instrument 2020* (the Amendment Instrument) amends the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (PB 97 of 2019) (the Arrangement). The instrument amends the Arrangement by:

- amending section 25 to clarify the scope of powers and functions able to be performed and exercised by a third party under section 25 of the Arrangement;
- adding section 26 to provide for internal review by the Department of Health (the Department) of decisions made by persons under section 25 of the Arrangement;
- adding section 27 to save any authorisations in force under section 25 immediately before the commencement of the Arrangement, and after commencement, as if they had been made under that section as amended by the Amending Instrument; and
- amending Schedule 1 to add Naloxone (Junalox ®), subsequent to its listing on the Pharmaceutical Benefits Scheme (PBS) from 1 July 2020; as an additional brand of PBS listed items which are able to be supplied free of charge and without prescription, to persons who are at risk of overdose, and those who may witness an overdose.

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 28 February 2021 in New South Wales (NSW), Western Australia (WA), and South Australia (SA).

The aim of the Pilot is to trial the supply of Naloxone 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.

Through the Pilot, Naloxone is able to be supplied free of charge and without a prescription from 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.

Section 25 of the Arrangement provides that the Secretary may authorise persons having suitable qualifications and experience to perform any of the Secretary's functions, or exercise any of the Secretary's powers, under the Arrangement on behalf of the Secretary. Authorisation may be given in the form of a contract entered into by the Secretary on behalf of the Department.

The Department has entered into a Contract for Services with Australian Healthcare Associates Pty Ltd (AHA), as a person with 'suitable qualifications and experience' to perform the functions and exercise powers under section 25 of Arrangement. Specifically, these functions include the receipt, management and processing of claims for payment to approved suppliers, requesting information from Authorised Alternative Suppliers, and collection and reporting of data to be used to evaluate the Pilot.

These amendments to the Arrangement address particular scrutiny concerns raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation (the Committee) in relation to the Arrangement. The Committee assesses delegated legislation against a set of scrutiny principles that focus on compliance with statutory requirements, the protection of individual rights and liberties, and principles of parliamentary oversight.

The Committee raised concerns about:

- the scope of power and source of legal authority for section 25 of the Arrangement; and
- whether Parliament intended for special arrangements under section 100 of the Act to enable the Secretary to authorise a private third party to perform all of the Secretary's functions and exercise all the powers under the Arrangement.

To address the Committee's concerns and to resolve the Committee's motion to disallow the Arrangement, the Department made an undertaking to amend the Arrangement to expressly:

- state the particular powers and functions the Secretary may authorise a third party to perform or execute under the Arrangement; and
- to provide for internal merits review by the Department of decisions made by a third party under the Arrangement. This will ensure fair treatment of all persons affected by decisions made by the third party under section 25 of the Arrangement. The addition of merits review will support a process by which the Department can reconsider, at an applicant's request, decisions of the third party in administering claims for payment, thus ensuring procedural fairness and accountability.

A provision-by provision description of the Amendments to the Arrangement is contained in the Attachment.

### **Consultation**

The Pilot operates in NSW, WA and SA and therefore the Department consulted the relevant State agencies: 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 implementing a process for internal merits review by the Department of decisions made by AHA in administering the Pilot; and the inclusion of the additional Naloxone brand (Junalox ®) to the Schedule of PBS listed items able to be supplied through the Pilot. The State agencies had no significant comment on the nature of the instrument.

The listing of the additional Naloxone brand (Junalox ®) is a result of a previous decision made by the Pharmaceutical Benefits Advisory Committee (PBAC) recommending the inclusion of Naloxone on the PBS. The add brand was listed on the PBS from 1 July 2020. PBAC is an independent expert body established by section 100A of the Act. PBAC makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. Members of PBAC are appointed by the Minister for Health following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have

qualifications and experience in a field relevant to the functions of PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC.

The Junalox ® brand shares similar characteristics with regard to form and strength of other listed brands about which PBAC has made positive recommendations and will support wider access to take home Naloxone under the Pilot.

In addition, the Department consulted the product sponsor about making Junalox ® available for free and without a prescription in the participating Pilot states and notes that the packaging and leaflet for Junalox ® have been specifically designed to be more accessible for people with no medical training. Junalox ® includes an *Opioid Overdose Action Plan* with clear instructions on how to administer the product. Inclusion of the action plan at the beginning of the leaflet ensures it is readily available and simple to use in an emergency.

As persons affected by the instrument, AHA 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](http://www.ppaonline.com.au/programs/trial-programs) are to be updated to include reference to the fees payable for supplies under the Pilot of Junalox ® and the availability of internal merits review.

Details of this instrument are set out in the Attachment.

This Amendment Instrument has been prepared by the Office of Parliamentary Counsel.

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 the *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2020 Measures No.1) Instrument 2020***

**Section 1 Name**

This section provides that the name of the instrument is the *National Health (Take Home Naloxone Pilot) Special Arrangement (2020 Measures No. 1) Instrument 2020* and may also be cited as PB 77 of 2020.

**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 1 Subsection 25(1)**

Subsection 25(1) is repealed and substituted with a new subsection 25(1) which expressly states the powers and functions that third party administrators exercise and perform in paragraphs 25(1)(a) to (d).

Subsection 25(1) provides the Secretary may authorise a third party, with suitable qualifications and experience, to perform any of the Secretary's functions or exercise any of the Secretary's powers under the Arrangement. This authorisation must be in writing.

The words 'persons having suitable qualifications and experience' in this respect is considered to constitute person(s) who have a specified skill or type of experience or knowledge that makes the person(s) suitable to perform the activities, functions and authorised powers. This may include but not be limited to formal education/qualifications, experience in a specific field, skills and personal qualities. In relation to this program it is a provider who can conduct the administrative services of the pilot program, specifically manage claims for payment, collect data and undertake reporting functions. Suitable qualifications and experience would need to be substantiated through demonstrated achievement of the same or similar relevant work and would be assessed by the department through a formal selection process (for example a procurement process conducted in accordance with the *Commonwealth Procurement Rules, April 2019* and the *Public Governance, Performance and Accountability Act*).

Subsection 25(1) provides the Secretary may authorise a third party to perform the following functions and exercise the following powers:

- receiving notices related to those defined as an 'authorised alternative supplier' and 'excluded approved supplier' under section 4 (paragraph 25(1)(a));
- receiving claims for payment, with the required information in accordance with section 20 and subsection 21(4) (paragraph 25(1)(b));

- determining the amount payable for a claim made under Part 2 of the Arrangement, and making any payment related to the claim in accordance with section 22 (paragraph 25(1)(c)); and
- requesting in writing, an authorised alternative supplier to provide information mentioned in subsections 20(b) and (c) in relation to any special arrangement supply of a designated pharmaceutical benefit made by the supplier (paragraph 25(1)(d)).

## **Section 2 At the end of Part 2 (Section 26)**

This section inserts a new section 26 to provide that a person who is affected by a decision of a person who is authorised under section 25 may apply for review of the decision by the Secretary. An application must be in writing and made within 28 days after the day of the decision first came to the notice of the applicant, or a longer period if the Secretary allows for it (subsection 26(2)).

On receiving an application for the review of decision, the Secretary must review the decision and affirm, vary or set aside the decision. If the decision is **affirmed**, the decision remains unchanged; if the decision is **varied**, the decision is changed or altered in some way; and if the decision is **set aside**, a new decision is made in substitution (subsection 26(3)).

A decision by the Secretary takes effect on the day specified in the decision on review or where a day is not specified, on the day the decision on review was made (subsection 26(4)). After making a decision the Secretary must give the applicant written notice of the terms of the decision and reasons for decision (subsection 26(5)).

## **Section 3 After Part 2 (insert Part 3)**

This section inserts a new Part (Part 3) and section 27 to save the authorisation of AHA under section 25 which was in force immediately before the commencement of the Amending Instrument, and gives effect to provide the authorisation to continue to be in force on and after the commencement of the Amending Instrument.

## **Section 4 Clause 1 of Schedule 1 (after table item 2)**

Schedule 1 sets out the designated pharmaceutical benefits as defined in section 6 and 15, for the purposes of the Arrangement. The table in Clause 1 sets out the item, drug, form, manner of administration, brand, and maximum quantity for each designated pharmaceutical benefit. This section adds a new Naloxone brand, Junalox ® which was listed on the PBS from 1 July 2020. The addition of Junalox ® will further reduce barriers to accessing Naloxone in the participating Pilot States by making another Naloxone brand available, free of charge and without prescription, to persons who at risk of overdose, and those who may witness an overdose.

# 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 (2020 Measures No. 1) Instrument 2020***

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 28 February 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 address particular scrutiny concerns raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation (the Committee) in relation to the Arrangement. To address the Committee's concerns and resolve the Committee's motion to disallow the Arrangement, the Department made an undertaking to amend the Arrangement to:

- state the particular powers and functions the Secretary may authorise a third party to perform or execute under the Arrangement; and
- provide for internal merits review by the Department of decisions made by an authorised third party in administering the Arrangement. This will ensure fair treatment of all persons affected by a decision, support transparency in decision-making and enhance the openness and accountability of decisions.

The instrument also adds another brand of Naloxone (Junalox ®), to the Schedule of Pharmaceutical Benefits Scheme (PBS) listed items available for supply under the Arrangement.

### **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.