

## **EXPLANATORY STATEMENT**

### *National Health Act 1953*

#### *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension and Record Forms) Instrument 2020*

PB 101 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).

#### **Purpose**

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension and Record Forms) Instrument 2020* (the Amendment Instrument) amends the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Arrangement). This instrument amends the Arrangement by:

- extending the repeal date of this instrument from 30 September to 31 March 2021 (section 4);
- allowing waiver of the requirement for a signature for a pharmaceutical benefits prescription record, where an approved supplier's signature is normally required, but the record is not handwritten and it is not practicable for the patient to obtain the approved supplier's signature (section 5, 16 and 16A); and
- making minor changes to a number of definitions (section 6).

#### **Background**

As part of the COVID-19 National Health Plan, temporary Medicare Benefits Schedule (MBS) items allow doctors, nurses, midwives and mental health professionals to deliver services via telehealth. These arrangements are described in the *Health Insurance (Section 3C General Medical Services – COVID-19 Telehealth and Telephone Attendances) Determination 2020* (the 2020 3C Determination)

Given the current COVID-19 situation and extension of the MBS Telehealth measure, the arrangement will be extended from 30 September 2020 to 31 March 2021 to ensure that people who are confined to their home can still access necessary medicines.

The Arrangement sets out interim measures to provide a patient who is confined to home access to necessary medicines through “Image Based Prescription for Medicine Supply”

The Special Arrangement allows prescribers to provide a pharmacy with a digital image or copy of a patient’s prescription via fax, email or text message, enabling the pharmacy to dispense the required medicines, and deliver or post them to the patient.

The Arrangement is available to all patients who have had a telehealth or telephone attendance with their prescriber, as described in the 2020 3C Determination. It provides an option for a patient to easily access their medicines while self-isolating. However if a patient instead prefers to receive their paper prescription following a telehealth or telephone attendance, they may still collect their prescription in person or receive it by post and arrange supply of medicines separately in line with existing processes.

The Arrangement applies to all pharmaceutical benefits available for supply under Part VII of the Act, other than Schedule 8 and 4(D) medicines such as opioids and fentanyl except where they are specifically permitted under the relevant State or Territory law. These are high-risk medicines that may pose significant risks to the community, including through misuse or diversion. Urgent supply of these medicines can otherwise be provided under existing provisions in section 48 of the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Community pharmacies have also raised concerns surrounding the Pharmaceutical Benefits Scheme (PBS) requirement for patients (or their nominated agents) to sign the prescription as acknowledgement of receipt of supply of a pharmaceutical benefit in the current COVID-19 environment, due to potential contamination risks in the pharmacy where many people are using the same pen to sign for this purpose. Concerns have also been raised in this context with regards to the signature requirements where a record must be made of the supply of a pharmaceutical benefit and the cross-infection risk associated with obtaining signatures.

The Arrangement temporarily allows the supply of a pharmaceutical benefit without acknowledgement from the patient wherever it is impractical for them to sign the prescription (for example where the patient is concerned about transmission of COVID-19 by using the pharmacy pen) until the cessation of the MBS Telehealth measure under the COVID-19 National Health Plan.

Pharmacists are still expected to ask patients to acknowledge receipt of the pharmaceutical benefit where practical, however pharmacists are not required to sign on the patient’s behalf where it is not practical to do so (for example the pharmacist supplying medicine from an image based prescription). This measure should be used as an exception, not a rule, and pharmacists are required to use their professional judgement in these circumstances and implement localised processes for vulnerable patients.

A provision has also been added in *The National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension and Record Forms) Instrument 2020* to waive the requirement for an approved supplier to sign a pharmaceutical benefits prescription record, but only where the record is not handwritten and it is not practicable for the patient to obtain the approved supplier’s signature due to concerns relating to the transmission of COVID-19.

The Arrangement will be repealed at the beginning of 31 March 2021 in line with the MBS Telehealth measure.

## **Consultation**

The Department of Health (the Department) has consulted with State and Territory governments regarding the extension of the interim measure. States and Territories regulate the supply of medicines within their jurisdiction and are supportive of the extension of the Special Arrangement to manage the continuation of COVID-19 restrictions. Consultation has also occurred with clinical peak bodies such as the Pharmacy Guild, Pharmaceutical Society of Australia and the Royal Australian College of General Practice who are supportive of the continued arrangements in line with the extension to the MBS Telehealth Measure. The Department has also consulted with the Department of Veterans' Affairs to ensure inclusion of medicines dispensed under the Repatriation Pharmaceutical Benefits Schedule and Services Australia regarding the claiming of PBS benefits and acceptance of PBS Prescription Record Forms.

The introduction of a waiver of the requirement for a pharmaceutical benefits prescription record to be signed addresses concerns raised by the Pharmaceutical Society of Australia and Services Australia regarding pharmacists being able to maintain appropriate COVID-19 risk management practices in pharmacies. Services Australia was consulted on the text of the provision to extend the temporary waiver of signature requirements.

Details of this instrument are set out in the Attachment.

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 purpose of the *Legislation Act 2003*.

**Details of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension and Record Forms) Instrument 2020***

**Part 1 – Preliminary**

**1 Name**

This section provides that the name of the instrument is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension and Record Forms) Instrument 2020* and may also be cited as PB 101 of 2020.

**2 Commencement**

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

**3 Authority**

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

**4 Schedules**

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

**Schedule 1 – Amendments**

**Item 1 - Section 4**

This section amends the repeal date of the instrument to extend it to 31 March 2021

**Item 2 - Section 5**

This section inserts a provision for the supply of pharmaceutical benefits in relation to written acknowledgement of receipt of pharmaceutical benefits and signature for records of supplies of pharmaceutical benefits on pharmaceutical benefits prescription forms.

**Item 3 to Item 8 - Subsection 6(1)**

This section amends a number of definitions to omit references to section 5 and section 6 inserts the definition of ‘PBS prescriber’ and repeals the definition of ‘commencement day’.

**Item 9 - Section 16**

This section amends the heading to include receipt of pharmaceutical benefits and omits reference to specific divisions in the instrument.

Section 16A (At the end of Division 3, Part 2)

This section inserts a new section 16A to provide that the requirement in subsection 84D (7) of the Act for a record of supply of a pharmaceutical benefit to be signed by an approved pharmacist or medical practitioner, does not apply in circumstances where the record is not a handwritten record and where it is not practicable for the approved pharmacist or medical practitioner to sign the record due to concerns relating to the transmission of COVID-19. Records of supplies of pharmaceutical benefits are necessary to substantiate patients' eligibility to be issued a PBS safety net concession card or a pharmaceutical benefits entitlement card when their, or their family's, total eligible out-of-pocket expense for PBS prescriptions in the calendar year has equalled or exceeded the relevant statutory threshold amount.

## Statement of Compatibility with Human Rights

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

### *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension and Record Forms) Instrument 2020*

#### **PB 101 of 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 1953* (the Act), the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension and Record Forms) Instrument 2020* (the Amendment Instrument) amends the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Arrangement).

The Arrangement sets out interim measures to provide a patient who is confined to home access to necessary medicine through “Image Based Prescription for Medicine Supply”. The Arrangement allows prescribers to provide a pharmacy with a digital image or copy of a patient’s prescription via fax, email or text message, enabling the pharmacy to dispense the required medicines, and deliver or post them to the patient.

Given the current COVID-19 situation and extension of the MBS Telehealth measure, the previous repeal date of 30 September 2020 in the Arrangement requires extending to 31 March 2021 to ensure that people who are confined to their home can still access necessary medicines.

The Amendment Instrument modifies arrangements for the supply of a pharmaceutical benefit on a paper prescription by temporarily allowing the option for an approved supplier to supply from a digital image or copy of the prescription received from the Pharmaceutical Benefits Schedule (PBS) prescriber before the presentation of the prescription. If a patient instead prefers to receive their paper prescription and arrange supply of medicines themselves following a telehealth or telephone attendance, they may still collect their prescription in person or receive it by post and arrange supply of medicines separately, in line with existing processes.

The Amendment Instrument also removes the need for a person in receipt of a pharmaceutical benefit to acknowledge the receipt of the pharmaceutical benefit upon supply. It also waives requirements of an approved pharmacist or medical practitioner to sign a record of supply of a pharmaceutical benefit for the purpose of the PBS Safety Net where the record is not a handwritten record and where it is not practicable for the approved pharmacist or medical practitioner to sign the record due to concerns relating to the transmission of COVID-19.

## **Human Rights Implications**

Broadly, the PBS is a benefits scheme which assists with providing subsidised access to medicines for people in the community. It engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), as it is a positive step towards attaining the highest standard of health for all Australians, and it assists in 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. The Arrangement is compatible with Articles 2 and 12 of the ICESCR as it contributes to the efficient operation and effective administration of the scheme.

## **Conclusion**

The Legislative Instrument is compatible with human rights as it does not raise any human rights issues or impinge on any applicable rights or freedoms.