

EXPLANATORY STATEMENT

National Health Act 1953

National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Further Extension) Special Arrangement 2021

PB 106 of 2021

Authority

Subsection 100(1) of the *National Health Act 1953* (the Act) provides that the Minister may make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

- a) who are living in isolated areas: or
- b) who are receiving treatment in circumstances in which the supply of pharmaceutical benefits under general arrangements is inadequate for that treatment; or
- c) 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 a special arrangement made under subsection 100(1).

Purpose

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Further Extension) Special Arrangement 2021* (the Amendment Instrument) amends the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement). The Amendment Instrument extends the date of repeal of the Special Arrangement by three months so it is repealed at the start of 1 January 2022.

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 or telephone services. 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).

In support of the telehealth measure, and as an interim measure while electronic prescribing capability has been implemented nationally, the Special Arrangement was developed under the Act to provide a patient who is confined to their home access to Pharmaceutical Benefits Scheme (PBS) medicines through ‘Image Based Prescription for Medicine Supply’. Given the continuing risk of COVID-19 and associated lockdowns and restrictions, the Special Arrangement will again be extended from being repealed from 30 September 2021 to 1 January 2022.

The PBS is established under 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.

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

The Special Arrangement assists in protecting people most at-risk in the community from exposure to COVID-19. It is available to all patients who have had a telehealth or telephone attendance with their prescriber, as described in the 2020 3C Determination.

Division 2 of the Special Arrangement allows prescribers to provide a copy or a digital image of a patient's prescription as part of a telehealth or telephone attendance, as described in the 2020 3C Determination, to a pharmacy of the patient's choice via email, text message or fax, enabling the pharmacy to supply the required medicines, in the absence of a paper-based prescription (image based prescribing).

Division 3 of the Special Arrangement 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). This is because of potential contamination risks of people in the pharmacy using pens to sign for this purpose in the current COVID-19 environment.

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 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.

Division 3 also removes 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 Special Arrangement will be repealed at the start of 1 January 2022.

Consultation

The Department of Health (the Department) has consulted with State and Territory governments through the Electronic Prescribing Working Group (EPWG) regarding this third extension of the interim measure. Given the severity of the current COVID-19 outbreak across a number of jurisdictions, States and Territories have since indicated a preference for the Special Arrangement to continue, to assist with continuation of COVID-19 restrictions.

The Department also consulted with clinical peak bodies including the Pharmacy Guild, Pharmaceutical Society of Australia, Royal Australian College of General Practitioners and the Australian Medical Association. These groups acknowledged the benefits of prescribers and pharmacists adopting electronic prescribing as the preferred option for remote medicines supply. However, due to the severity of the current COVID-19 outbreak they are also supportive of the continued arrangements.

The Australian Digital Health Agency, the Department of Veterans' Affairs and Services Australia have been informed of this extension. The Department is communicating the extension of the Special Arrangement on its website and through direct communications to Australian Medical Association, Pharmaceutical Society of Australia, Australian College of Rural and Remote Medicine, Royal Australian College of General Practitioners, Rural Doctors of Australia, Society of Hospital Pharmacists of Australia, Medicines Australia, the Australian Dental Association, the Australian Indigenous Doctor's Association and State and Territory governments through the EPWG. All State and Territory representatives have advised they will amend any state or territory legislation as required.

This instrument commences on the day after registration.

This 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 (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Further Extension) Special Arrangement 2021*

Section 1 Name

This section provides that the name of the instrument is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Further Extension) Special Arrangement 2021*.

The instrument can also be cited as PB 106 of 2021.

Section 2 Commencement

This section provides that the instrument commences on the day after registration.

Section 3 Authority

This section provides that the 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 a 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 (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020

Item 1 – Section 4

This item extends the date of repeal of the instrument by three months, so it is repealed on 1 January 2022.

Item 2 – After Section 17

This item adds section 18 which is a transitional provision that provides a pharmaceutical benefit can be supplied in accordance with this Special Arrangement after the repeal date of the Special Arrangement if the prescription for the pharmaceutical benefit is dated before the repeal date. This allows for supply in circumstances such as on first presentation of a prescription dated before the repeal date but not supplied before that date, repeat authorisation prescriptions, and deferred supply prescriptions.

Statement of Compatibility with Human Rights

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

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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

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Further Extension) Special Arrangement 2021* (the Amendment Instrument) amends the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*. The Amendment Instrument extends the date of repeal of the Special Arrangement by three months, so it is repealed at the start of 1 January 2022. Given the current COVID-19 situation and continuation of the COVID-19 restrictions, the Special Arrangement will be extended from being repealed on 30 September 2021 to 1 January 2022.

The amendment continues support for the supply of pharmaceutical benefits to patients who have had a telehealth or telephone attendance more convenient and effective. It clarifies arrangements for the supply of a pharmaceutical benefit through image based prescribing by including a transitional provision which allows for supply in accordance with the Special Arrangement for prescriptions that are dated before the Special Arrangement is repealed.

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 Disallowable Legislative Instrument 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 Disallowable Legislative Instrument is compatible with human rights because it promotes the protection of human rights.