

EXPLANATORY STATEMENT

National Health Act 1953

National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension for Receipt Requirements) Instrument 2023 (PB 33 of 2023)

Purpose

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension for Receipt Requirements) Instrument 2023* (the instrument) extends the modification of the application of regulation 57 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations) so that it would not be an offence if an approved supplier is unable to obtain written acknowledgement from a person receiving a benefit because it was not practical to do so.

This means that a person does not need to provide a signature on the prescription (including a repeat authorisation or deferred supply) if it is not practical to do so, and the supplier is not required to certify the date of supply and the reason it was not practical to do so.

The instrument the *National (COVID-19 Supply of Pharmaceutical Benefits Special Arrangement 2020)*, with these amendments, will now repeal on 1 April 2024.

The Government is focused on providing improved access to medicines for all Australians. The Minister for Health and Aged Care may make special arrangements to provide more convenient and efficient access to Pharmaceutical Benefits Scheme (PBS) medicines for patients. As such, this instrument relieves unnecessary administrative burden and accessibility issues for both patient and supplier. This is especially true for patients who:

- a) are not able to attend a pharmacy in person, or
- b) may be unwilling to sign due to potential transmission of disease, or
- c) are unable to read, write to, or understand the signed component of the prescription.

In such circumstances, the supplier (usually pharmacist) would sign on behalf of the patient.

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 has arranged to deliver the medicines to the patient's home). 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.

This instrument enables further transition to a digital workflow for pharmacies and reduces unnecessary administrative burden by removing the offence provision for suppliers for not certifying the reason why it was not practicable for a patient to provide a written acknowledgement of supply, allowing pharmacists to focus on clinical care. It improves access to prescription medicines across our community.

Authority

Subsection 100(1) of the National Health Act 1953 (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 who are living in isolated areas or are

receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment, amongst other circumstances. Section 100(1) states:

Special arrangements

(1) 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 pharmaceutical benefits (other than those to which subsection (1A) applies) are 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) of the Act.

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

The Special Arrangement commenced on 1 April 2023.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Under subsection 33(3) of the Acts Interpretation Act 1901, 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.

Background

The 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.

In the 2018-19 Budget, the Australian Government announced that it would support a national electronic prescribing system, contributing to PBS efficiency, compliance, drug safety and data collection. Further, creating an electronic prescribing framework that will provide an option for prescribers and their patients to have a fully electronic PBS prescription as an alternative to paper PBS prescriptions. The Government announced additional funding under the 2019-20 MYEFO COVID-19 Response Package – guaranteeing Medicare and access to medicines Budget measure to accelerate the implementation of electronic prescribing for PBS medicines.

The implementation of the now repealed *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement) was implemented 26 March 2020 as an interim arrangement to support the community to manage the risk of spread of infection during the COVID-19 emergency phase, while electronic prescribing capability was being implemented nationally. The Special Arrangement was amended in September 2020 to include an exemption for signatures by a patient and supplier at the time medicines are dispensed due to the potential contamination risks of COVID-19.

While most COVID-19 emergency arrangements have ceased, including the Special Arrangement, the exemption of signatures for receipt of pharmaceutical benefits by a patient and supplier is still required for reasons of convenience and efficiency, rather than to prevent COVID-19 transmission.

The Special Arrangement is a legislative instrument for the purposes of the *Legislation Act 2003*.

Commencement

This section provides that sections 1 to 4 and Schedule 1 in the instrument commences immediately after the instrument is registered, and Schedule 2 commences on 1 April 2023.

Consultation

There has been broad consultation with various stakeholders, including the Pharmacy Guild, and Services Australia. These industries welcome the Instrument,

Details of the amending instrument are set out in the **Attachment**.

ATTACHMENT

Details of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension for Receipt Requirements) Instrument 2023*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension for Receipt Requirements) Instrument 2023*. The instrument may also be cited as PB 33 of 2023.

Section 2 – Commencement

Section 2 provides that the Amending Instrument commences on 1 April 2023.

Section 3 – Authority

Section 3 provides that the Amending Instrument is made under section 100 of the *National Health Act 1953 (Act)*.

Section 4 – Schedules

Section 4 provides details on the operation of the new instrument and any other item in that Schedule has effect according to its terms.

Schedule 1 – Amendments

Item 1 Section 4

This item changes the repeal date from 2023 to 2024.

Schedule 2 – Amendments

Item 1- Section 5

This item amends the simplified outline of the instrument to explain that it modifies arrangements for supplies of pharmaceutical benefits in relation to written acknowledgment of receipt of the benefits

Item 2 Section 6

This item repeals the following definitions

- (a) definition of approved hospital authority;
- (b) definition of *CTS claim*;
- (c) definition of *Medicare/DVA copy*;
- (d) definition of *medication chart prescription*;
- (e) definition of *paper-based prescription*;
- (f) definition of *PBS prescriber*;
- (g) definition of *pharmacist/patient copy*;
- (h) definition of *relevant streamlined authority code*.

relevant streamlined authority code

Item 3 Section 6(3)

This item repeals Section 6(3).

Item 4 Division 2 or Part 2

This item repeals Division 2 Part 2.

Item 5 Division 3 or Part 2 (heading)

This item repeals the heading.

Item 6 Section 16A

This item repeals Section 16A.

Item 7 Section 18

This item repeals section 18 and replaces it with a revised section 18 and new section 19 which are application provisions that allow for the application of the Special Arrangement to supplies of pharmaceutical benefits made under the arrangement as they were in force immediately before the relevant repeal dates.

Statement of Compatibility with Human Rights

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

National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (General Co-payment) Rules 2022

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 Amending Instrument

The Pharmaceutical Benefits Scheme (PBS) provides Australians with timely, reliable and affordable access to necessary medicines. The PBS operates under Part VII of the *National Health Act 1953* (the Act), which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

The instrument temporarily allows the supply of a pharmaceutical benefit without acknowledgement from the patient, wherever it is impractical for them to sign the prescription.

Human rights implications

The Amending Instrument engages Articles 2 and 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), by supporting the right to health and assisting in realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The UN Committee on Economic Social and Cultural Rights (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

The Instrument does this by supporting the efficient operation and effective administration of the PBS scheme, which provides Australians with subsidised access to medicines.

Conclusion

This legislative instrument is compatible with human rights because it promotes the protection of human rights.

Minister Butler, Minister for Health and Aged Care