

## **EXPLANATORY STATEMENT**

*National Health Act 1953*

### ***National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension for Receipt Requirements and Hospital Supplies) Instrument 2022***

**PB 32 of 2022**

#### **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 these 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) Special Arrangement 2020 Amendment (Extension for receipt Requirements and Hospital Supplies) Instrument 2022* (the Amendment Instrument) amends the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement). The Amendment Instrument extends the repeal date of the Special Arrangement by 12 months, so it is repealed at the start of 1 April 2023.

The Amendment Instrument changes the application of Division 2 by:

- Limiting this Division to apply to the supply of a pharmaceutical benefit by approved hospital authorities, as defined by section 94 of the Act, which includes both public and private hospitals.
- Removing the restriction on the supply of pharmaceutical benefits referred to in Schedule 8 to the Poisons Standard or referred to in both Schedule 4 and Appendix D to the Poisons Standard, unless specifically prohibited by State and Territory legislation.
- Removing the restriction to supplies of a pharmaceutical benefit written because of a telehealth attendance or a phone attendance.
- Removing the requirement for a supply to be based on a paper-based prescription written as the result of a telehealth attendance or phone attendance provided on or after 20 March 2020 to which specific items apply.

The Amendment Instrument retains the existing application of Division 3 of the Special Arrangement, which sets out exemptions to the requirements for written acknowledgement of receipt of pharmaceutical benefits and signatures for records of supplies of pharmaceutical

benefits on pharmaceutical benefits prescription record forms, i.e., safety net concession cards.

## **Background**

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.

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 this measure was only intended as an interim arrangement to support the community during COVID-19 while electronic prescribing capability was being implemented nationally. The Special Arrangement was developed under the Act to provide a patient who is confined to their home access to PBS medicines. However, the Special Arrangement must now be phased out due to the associated increased risk of fraudulent behaviour.

Most stakeholders are now supportive in their views about the cessation of image-based prescribing in the community setting from 31 March 2022, noting the widespread access to electronic prescribing. However, the Department of Health acknowledges that electronic prescribing capabilities are not available for most hospitals who treat and care for patients most at risk from COVID-19 and will most likely not be available until 2023.

Therefore, the Department has made the decision to extend image-based prescribing to approved hospital authorities only until 31 March 2023. This means that the supply of PBS benefits with image-based prescribing is no longer limited to those written because of a telehealth attendance or a phone attendance. The Special Arrangement was once limited to the supply of PBS benefits written for patients who have been confined to their homes. To support vulnerable and unwell Australians who require specialist hospital care and specialised medicines from hospital pharmacies, the Department removed this limitation to offer this arrangement to the those who have been treated in a hospital setting instead.

Urgent supply of these medicines can otherwise be provided under existing provisions in section 48 of the *National Health (Pharmaceutical Benefits) Regulations 2017*.

The Department has also continued to extend the powers that provide an exemption for signatures by a patient and supplier at the time medicines are dispensed. 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. Division 3 of the Special Arrangement now 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).

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.

The Special Arrangement will be repealed at the start of 1 April 2023.

## **Consultation**

The Department of Health (the Department) has consulted with State and Territory governments through the Electronic Prescribing Working Group (EPWG) regarding the fifth extension of this interim measure. States and Territories indicated a preference for the Special Arrangement to cease from 1 April 2022. All state and territory representatives have advised they will amend any state or territory legislation as required.

The Department also consulted with clinical peak bodies including the:

- Pharmacy Guild of Australia,
- Pharmaceutical Society of Australia,
- Royal Australian College of General Practitioners,
- Australian Medical Association, and
- Society of Hospital Pharmacists of Australia

Some of those groups acknowledged the benefits of prescribers and pharmacists adopting electronic prescribing as the preferred option for remote medicines supply. However, due to the delay by software vendors to implement electronic prescribing in hospitals, they have requested the extension of the Special Arrangement for approved hospital authorities.

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
- Australian Dental Association
- Australian Indigenous Doctors' Association
- Medical Software Industry Association

This instrument commences on the day after registration, except for Schedule 2 which commences on 1 April 2022. 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) Special Arrangement Amendment (Extension for Receipt Requirements and Hospital Supplies) Instrument 2022*.

**Section 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 for Receipt Requirements and Hospital Supplies) Instrument 2022*. It may also be cited as PB 32 of 2022.

**Section 2 Commencement**

This section provides that the instrument commences on the day after registration, except for Schedule 2 which commences on 1 April 2022.

**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 to *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* commencing day after registration**

This section defines when the changes to the repeal date will occur. In this case it is the day after the instrument has been registered and amends the year of the repeal date to 2023 within section 4 and subsection 18(1).

**Schedule 2—Amendments to *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* commencing 1 April 2022**

**Section 1 – Section 5 (including note)**

This section repeals section 5 of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and substitutes a new section that provides a simplified outline of the Special Arrangement.

**Sections 2 to 4 – Subsection 6(1)**

These sections remove and add definitions used in the Special Arrangement to remove ambiguity with the provisions that reference components to paper prescriptions.

### **Sections 5 and 6 – Subsection 6(2)**

These sections remove references to the *Health Insurance (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021*, and *Therapeutic Goods Act 1989*.

### **Section 7 – Divisions 1 and 2 of Part 2**

This section amends the application of the Special Arrangement by limiting the supply of pharmaceutical benefits to those provided by approved hospital authorities based on paper-prescriptions. It also amends how the Special Arrangement modifies the application of section 44, section 51, section 52, and section 53 of the Regulations.

This section specifically repeals the existing Divisions 1 and 2 and substitutes them with a new sections 9-15.

Subsection 9(1) limits Division 2 of the Special Arrangement to apply to the supply of a pharmaceutical benefit by approved hospital authorities based on a paper-based prescription. There is a note to remind the reader that for a hospital authority to be approved under section 94 of the Act in respect of a hospital, the dispensing of drugs and medicinal preparations at that hospital must be performed by, or under the direct supervision of a medical practitioner or pharmacist in the hospital.

Subsection 9(2) defines the restrictions on the supply of a pharmaceutical benefit under this Special Arrangement. Specifically, the Special Arrangement does not allow the supply of pharmaceutical benefits for:

- medication charts, and
- when a State or Territory law prohibits the supply for certain drugs and medicinal purposes.

Subsection 9(2) also includes a note to remind the reader that section 45 of the Regulations provides for the supply of a pharmaceutical benefit on basis of a medication chart prescription.

New section 10 modifies section 44 of the Regulations when a patient presents their first prescription where authority is required.

Subsection 10(1) states that section 44 of the Regulations is modified to allow digital images (such as a photo or scan) or copies of prescriptions (e.g., provided by email or fax) to be accepted in place of the actual prescription.

Subsection 10(2) states adds the requirements, for authority prescriptions, that the requirements in subsection 48(2) of the Regulations are to apply, with the modification that the digital image can display the code.

New section 11 modifies section 51 of the Regulations for situations where the supply of the benefits is for repeat supplies of pharmaceutical benefits, and the words “immediate supply necessary” are instead written on the digital image or copy of the authority prescription.

New section 12 modifies the application of section 52 of the Regulations to apply to repeat authorisations, where instead the repeat authorisation is attached the digital image of copy of the prescription, where possible.

New section 13 modifies the application of section 53 of the Regulations and defers the supply of pharmaceutical benefits when the prescription is a digital image or copy of the prescription, and the words “original supply deferred” are written on the digital image or on a print-out of the digital image.

Subsection 13(3) also requires approved hospital authorities to retain the deferred supply authorisation and the print-out of the digital image or copy of the prescription as applicable.

New section 14 outlines the record keeping requirements of documents for approved hospital authorities, where documents like the digital image, print-out or copy of the prescription, repeat authorisation or deferred authorisation, must be kept for at least 2 years from the date of supply.

New section 15 outlines the record keeping requirements for prescribers, where they must also retain records for at least 2 years from the date of prescription.

### **Section 8 Division 3 (heading)**

This amends the heading, so it aligns with the clauses in this Division.

### **Section 9 to Section 11 – Section 16 to Section 17A**

These amendments remove redundant numbering of the provisions.

### **Section 12 – After section 17A**

This section inserts section 17B – Continued application of Special Arrangement as in force before 1 April 2022.

This section states that the provisions in the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* prior to its amendment on 1 April 2022 continue to apply for the supply of a pharmaceutical benefit that was made on a digital image of a prescription or copy of a prescription after 1 April 2022 and before the commencement of the amendment.

## 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 for Receipt Requirements and Hospital Supplies) Instrument 2022***

#### **PB 32 of 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**

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension for Receipt Requirements and Hospital Supplies) Instrument 2022* (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 12 months, so it is repealed on 1 April 2023.

The Amendment Instrument offers a Special Arrangement for supplying a pharmaceutical benefit, in particular circumstances. Specifically, the Special Arrangement supports the supply of pharmaceutical benefits to patients who receive treatment in or at a hospital that does not have access to legally conformant software that offers electronic prescribing capabilities.

It clarifies arrangements for the supply of a pharmaceutical benefit through image-based prescribing by approved hospital authorities to enable vulnerable and unwell Australians who require specialist hospital care and specialised medicines from hospital pharmacies to continue to be supported by image-based prescribing.

The Amendment Instrument changes the application of Division 2 by:

- Limiting this Division to apply to the supply of a pharmaceutical benefit by approved hospital authorities, as defined by section 94 of the Act, which includes both public and private hospitals.
- Removing the restriction on the supply of pharmaceutical benefits referred to in Schedule 8 to the Poisons Standard or referred to in both Schedule 4 and Appendix D to the Poisons Standard because hospital patients are often prescribed medicines and drugs listed in these schedules. However, the Special Arrangement retains the power that prohibits the supply of a pharmaceutical benefits as defined by State and Territory legislation to manage the risks with supply of these drugs and medications, and to support and better align with the requirements defined by each State and Territory.
- Removing the restriction to supplies of a pharmaceutical benefit written because of a telehealth attendance or a phone attendance because hospital patients receive treatment beyond the kind provided in *Health Insurance (Section 3C General*



*Medical Services – Telehealth and Telephone Attendances) Determination 2021 (3C Determination).*

- Removing the requirement for a supply to be based on a paper-based prescription written as the result of a telehealth attendance or phone attendance provided on or after 20 March 2020 to which specific items apply. This change has been made to support patients have received healthcare in or at a hospital and have received treatment unrelated to those listed in the 3C Determination.

The Amendment Instrument retains the existing application of Division 3 of the Special Arrangement, which sets out exemptions to the requirements for written acknowledgement of receipt of pharmaceutical benefits and signatures for records of supplies of pharmaceutical benefits on pharmaceutical benefits prescription record forms, i.e., safety net concession cards, to help offer protection to vulnerable patients from contracting COVID-19 due to potential contamination risks of people in the pharmacy using pens to sign for this purpose.

### **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. The PBS 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, including the right to access to healthcare.