

EXPLANATORY STATEMENT

National Health Act 1953

National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020 and National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020.

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.

Section 100 of 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 circumstance which pharmaceutical benefits 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.

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 at *Health Insurance (Section 3C General Medical Services –COVID-19 Telehealth and Telephone Attendances) Determination 2020*.

In support of the Telehealth measure the Australian Government is fast tracking the implementation of Electronic Prescribing to help protect people most at-risk in the community from exposure to COVID-19. Under this measure, Electronic Prescribing is being fast tracked to 80 percent of general practices and community pharmacies with expected commencement by May 2020. The rapid spread of COVID-19 has made it clear that the community, including health professionals, are in need of an interim solution to ensure people who are confined to their home can access necessary medicines prior to the implementation of Fast Track Electronic Prescribing.

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and the *National Health (COVID-19 Supply of Pharmaceutical Benefits Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020* (collectively the Special Arrangement) has been developed under Section 100 of the Act to provide an interim measure to provide a patient who is confined to home access to necessary medicine 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 Special Arrangement is available to all patients who have had a telehealth or telephone attendance with their prescriber, as described in the *Health Insurance (Section 3C General Medical Services –COVID-19 Telehealth and Telephone Attendances) Determination 2020*. 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-based 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 Special 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 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*.

Community pharmacies have also raised concerns surrounding the PBS requirement for patients (or a nominated agent) to sign the prescription to acknowledge receipt of supply of a pharmaceutical benefit due to potential contamination risks of people in the pharmacy using pens to sign for this purpose in the current COVID-19 environment.

The Special Arrangement temporarily allows the supply of a pharmaceutical benefit without acknowledgement from the patient wherever it is impractical for them to sign the prescription (e.g. 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 do so (e.g. 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 on 30 September 2020 in line with the Telehealth measure. There is provision to extend the Special Arrangement instrument if the Telehealth measure is extended past 30 September 2020.

The Department of Health (the Department) has consulted with clinical peak bodies and industry regarding the requirement for an interim measure prior to the implementation of Fast Track Electronic Prescribing. The Department has informed the Department of Veterans' Affairs, Services Australia and state and territory governments through the Electronic Prescribing Working Group (EPWG) about the Special Arrangement including its amendment.

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

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

The Special Arrangement commenced on 26 March 2020 and its amendment commenced on 8 April 2020.

Authority: Section 100 under the *National Health Act 1953*

Details of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020*.

Part 1 – Preliminary

Section 1 – Name

This section provides that the title of the instrument is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020*.

Section 2 – Commencement

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

Section 3 – Authority

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

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, meaning the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* is amended by this instrument the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020*.

Schedule 1 – Amendments to *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*

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, in that it makes the supply of pharmaceutical benefits to patients who have had a telehealth or telephone attendance more convenient and effective.

Section 2 – Subsection 6(1)

This section inserts definitions for additional terms used in the Special Arrangement.

Section 3 – Subsection 6(1) (definition of *patient at risk of COVID-19 virus*)

This section repeals the definition of *patient at risk of COVID-19 virus*.

Section 4 – Subsection 6(1) (definition of *phone attendance*)

This section repeals the definition of *phone attendance* and inserts a new definition to correspond with the latest definition included in the Telehealth measure, and inserts a new definition for *Poisons Standard* relating to the *Therapeutic Goods Act 1989*.

Section 5 – Subsection 6(1) (definition of *telehealth attendance*)

This section repeals the definition of *telehealth attendance* and inserts a new definition to correspond with the latest definition included in the Telehealth measure.

Section 6 – Subsection 6(2)

This section repeals subsection 6(2) of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and insert a new subsections 6(2) to provide updated definitions for references used in the Special Arrangement.

It also inserts subsection 6(3) which provides a definition for a reference to a digital image of a prescription to include a reference to a digital image of the prescription that indicates subsection 40(1), (2) and (2A) of the Regulations have been complied with.

Section 7 – Subsection 7(1)

This section repeals subsection 7(1) of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and inserts a new subsection 7(1) to provide for pharmaceutical benefits covered by the Special Arrangement.

Subsections 7(1)(a) and (b) refer to Division 2 of the Special Arrangement and provide that all pharmaceutical benefits available for supply under Part VII of the Act are available to be supplied under the Special Arrangement, unless they are medicines referred to in Schedule 8 or Schedule 4(D) of the Poisons Standard and they may not be supplied on the basis of a digital image of a prescription or a copy of a prescription under the relevant State or Territory law where the pharmaceutical benefit would be supplied.

Section 8 – Section 9

This section repeals section 9 of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and inserts a new section 9 relating to supplies to which the Special Arrangement applies.

Subsection 9(1)(a), (b) and (c) refer to Division 2 of the Special Arrangement - *Requirements for supply of pharmaceutical benefit - paper-based prescriptions* and state that the Special Arrangement applies to the supply of a pharmaceutical benefit based on a paper-based prescription (excluding medication chart prescription) written as a result of a telehealth or phone attendance prior to the commencement of this Special Arrangement but after the provision for the new telehealth arrangements, providing the prescription is for an eligible item under the Telehealth measure as specified in the general medical services table or in the *Health Insurance (Section 3C General Medical Services – COVID-19 Telehealth and Telephone Attendances) Determination 2020*.

Subsections 9(2)(a) and (b) provide that Division 2 of the Special Arrangement does not apply to the supply of a pharmaceutical benefit if the prescription must be in writing under the relevant State or Territory law in the area where the supply would be made.

Subsection 9(3) refers to Division 3 of the Special Arrangement – *Requirements for receipt of a pharmaceutical benefit - all prescriptions* and states that this Special Arrangement applies to the supply of a pharmaceutical benefit made by an approved supplier, meaning the provision for the patient or the approved supplier to acknowledge the receipt of the pharmaceutical benefit has been removed.

Subsection 9(4) provides the definition of *item* in this section to include an item relating to a service specified under subsection 3C(1) of the *Health Insurance Act 1973* and notes that subsection 3C(1) enables the Minister to determine that a health service not already specified in the general medical services table is to be treated as a professional or medical service and that the health service should be treated as if there were an item in that table.

Section 9 – Section 10

This section repeals section 10 of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and inserts a new section 10 – *Modified application of section 44 of the Regulations - supplies on first presentation of prescription*, which provides for the modified application of section 44 of the Regulations to allow supply of a pharmaceutical benefit based on the provisions in this Special Arrangement.

Subsection 10(1) states that section 44 of the Regulations are modified to provide for the supply of a pharmaceutical benefit based on the provision in this Special Arrangement.

Subsection 10(2) states that an approved pharmacist or an approved medical practitioner may supply a pharmaceutical benefit to a person on the first presentation of a prescription if the PBS prescriber has given the approved pharmacist or medical practitioner a digital image of the prescription or a copy of the prescription, noting that a paper-based prescription includes both the pharmacist/patient copy and the Medicare/DVA copy of the prescription.

Subsection 10(3) states that an approved hospital authority may supply a pharmaceutical benefit to a person on the first presentation of a prescription if the PBS prescriber has given the approved hospital authority dispenser a digital image of the prescription or a copy of the prescription.

Subsection 10(4) states that if the prescription is or would be an authority prescription, the approved supplier may supply the pharmaceutical benefit only if:

- Under Subsections (3)(a)(i) and (ii) the pharmaceutical benefit prescribed has a relevant streamlined authority code and the PBS prescriber informs the supplier of that code or the digital image displays that code, or
- Under Subsection (3)(b)(i) and (ii) the Minister or Chief Executive Medicare has notified the PBS prescriber that each relevant authorisation will be given and the PBS prescriber informs the approved pharmacist, approved medical practitioner or approved hospital authority dispenser of that notification prior to the pharmaceutical benefit being supplied.

Section 10 – Section 11

This section repeals section 11 of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and inserts a new section 11, section 12, section 13, section 14 and section 15.

Section 11 provides for the modified application of section 51 of the Regulations relating to repeated supplies of pharmaceutical benefits.

Subsection 11(1) provides that for the supply of a pharmaceutical benefit from a digital image or copy of a prescription, this section modifies section 51 of the Regulations relating to repeated supplies of a pharmaceutical benefit being provided to a patient sooner than 20 or 4 days after the last supply of that same or equivalent pharmaceutical benefit if the supplier of the benefit reasonably believes that the previous supply was destroyed, lost or stolen, or that the supply of the benefit is immediately necessary for the treatment of the person, which requires the approved supplier to write the words “immediate supply necessary” and sign the Medicare/DVA copy of the prescription.

Subsections 11(2)(a) and (b) provide that in the circumstances where the supplier reasonably believes that the previous supply of the pharmaceutical benefit was destroyed, lost or stolen, or that the supply of the benefit is immediately necessary for the treatment of the person, the supplier meets the requirements of paragraph 51(4)(b) or 51(4)(c) of the Regulations if they write the words “immediate supply necessary” and sign the copy of the prescription, the digital image of the prescription or a print out of the digital image of the prescription.

Section 12 provides for the modified application of section 52 of the Regulations relating to repeat authorisations.

Subsection 12(1) states that this section modifies section 52 of the Regulations relating to requirements for repeat authorisations of a pharmaceutical benefit.

Subsections 12(2)(a) and (b) provide that this section applies if an approved supplier provides a person with a pharmaceutical benefit from a digital image of a prescription or a copy of a prescription that contains a direction to repeat the supply the benefit, or from a copy of a prescription or print out of a digital image to which is attached a deferred supply authorisation or repeat authorisation that contains a direction to supply the benefit more than once, if there are repeats remaining on the prescription at the time of supply.

Subsections 12(3)(a) and (b) provide that paragraph 52(3)(a)(iii) of the Regulations, requiring the approved supplier to attach the repeat authorisation to the pharmacist/patient copy of the paper-based prescription and give the repeat authorisation and pharmacist/patient copy to the person to whom the pharmaceutical benefit is supplied, is taken to be met if the approved supplier attaches the repeat authorisation to a print out of the digital image of the prescription or copy of the prescription and retains the repeat authorisation and print out of the digital image of the prescription or the copy of the prescription for subsequent supply rather than give it to the person.

Section 13 provides for the modified application of section 53 of the Regulations relating to deferred supply.

Subsections 13(1) and (2)(a) and (b) provide that this section modifies section 53 of the Regulations relating to the requirements for deferred supply authorisations of a pharmaceutical benefit, allowing an approved supplier to defer the supply of one or more pharmaceutical benefits on a digital image of a prescription or a copy of a prescription when supplying one or more pharmaceutical benefits on the digital image or copy of that prescription.

Subsections 13(3)(a), (b) and (c) provide that paragraph 53(3)(c) of the Regulations, requiring the approved supplier to mark on the pharmacist/patient copy and the Medicare/DVA copy of the prescription the words “original supply deferred” and attach the deferred supply authorisation to the

pharmacist/patient copy and give the authorisation and pharmacist/patient copy to the person for whom the prescription is written, is taken to be met if the approved supplier writes the words “original supply deferred” on the copy of the prescription, digital image of the prescription or print out of the digital image of the prescription and attaches the deferred supply authorisation to a print out of the digital image of the prescription or the copy of the prescription and retains the deferred supply authorisation and print out of the digital image of the prescription or copy of the prescription for supply at a later time.

Subsection 13(4) states that if the supplier is retaining the deferred supply authorisation attached to the print out of the digital image of the prescription, the print out of the digital image of the prescription must include the words “original supply deferred”.

Section 14 states for supply made on the basis of a digital image of a prescription or a copy of a prescription for a pharmaceutical benefit given to the supplier by a PBS prescriber, or supply made on the basis of a deferred supply authorisation or repeat supply authorisation prepared in relation to a pharmaceutical benefit included in a digital image of a prescription or copy of a paper-based prescription, an approved supplier must retain either the digital image, print out of the digital image, copy of the prescription, repeat authorisation or deferred supply authorisation under the circumstances referred to in the tables for a period of 2 years from the date of supply

Section 15 provides that for a PBS prescriber who has written a prescription and given an approved supplier the digital image of the prescription or copy of the prescription for supply, the PBS prescriber must retain the prescription or a copy of the prescription for a period of at least 2 years from the date of prescription.

Section 11 – Section 12

This section renumbers section 12 of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* as section 16.

Section 12 – At the end of the instrument

This section inserts *Part 3 – Application, savings and transitional provisions* at the end of the Special Arrangement and inserts section 13 – Continued application of Special Arrangement as in force before commencement of the amendment.

This section states that the provisions in the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* prior to its amendment 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 26 March 2020 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 2020 and *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020*.

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and its amendment *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020* are 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

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* and its amendment *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020* (collectively the Special Arrangement) make a special arrangement to make the supply of pharmaceutical benefits to patients who have had a telehealth or telephone attendance more convenient and effective.

The Special Arrangement 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 PBS prescriber before the presentation of the prescription. If a patient instead prefers to receive their paper-based 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 instruments also remove the need for a person in receipt of a pharmaceutical benefit to acknowledge the receipt of the pharmaceutical benefit upon supply.

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 Special Arrangement is compatible with Articles 2 and 12 of the ICESCR as it contributes to the efficient operation and effective administration of the scheme.

The Section 100 Special Arrangement is made under the *National Health Act 1953*.

Conclusion

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

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