

## EXPLANATORY STATEMENT

*Issued by the Authority of the Minister for Health and Aged Care*

*Coronavirus Economic Response Package Omnibus (Measures No. 2) Act 2020*

### ***Coronavirus Economic Response Package (Modifications—National Health (Pharmaceutical Benefits Scheme)) Determination 2020***

#### **Authority**

Subitem 1(2) of Schedule 5 to the *Coronavirus Economic Response Package Omnibus (Measures No. 2) Act 2020* (the CERPO Act) provides that a responsible Minister for an affected provision may, by legislative instrument, determine that the affected provision does not apply in relation to a period specified in the determination.

#### **Purpose**

The *Coronavirus Economic Response Package (Modifications—National Health (Pharmaceutical Benefits Scheme)) Determination 2020* (the Determination) temporarily, during COVID-19:

- disappplies the requirement in paragraph 84DA(3)(c) of the *National Health Act 1953* (the NH Act) that an applicant (or the applicant's agent) shall sign an application made to an approved supplier for a Safety Net Concession Card, where it is not practicable due to concerns relating to transmission of COVID-19; and
- disappplies the requirement in paragraph 84E(3)(c) of the NH Act that an applicant (or the applicant's agent) shall sign an application made to an approved supplier for a Pharmaceutical Benefits Entitlement Card, where it is not practicable due to concerns relating to transmission of COVID-19.

The temporary disapplication of signature requirements in paragraph 84DA(3)(c) and paragraph 84E(3)(c) of the NH Act by the Determination aligns with the disapplication of similar requirements in the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement). This creates consistency of signature requirements and reduces the likelihood of misinterpretation by approved suppliers, which, the Department has been notified by Services Australia who process and pay the claims, has been occurring in almost half the applications received.

The Determination has retrospective effect from 8 April 2020, which is permissible under subitem 1(3) of Schedule 5 to the CERPO Act. This date aligns with the commencement date of the Special Arrangement, to ensure any applications submitted during this period without signature due to concerns relating to transmission of COVID-19 satisfy requirements.

The retrospective effect of the Determination is intended to assist individuals by allowing Services Australia to process unsigned applications made within the relevant period, ensuring that the affected patients can continue to receive subsidised prescription drugs without experiencing disadvantage as a result of concerns with the transmission of COVID-19. The Determination will further assist pharmacies to remain compliant with subsection 84DA(3) and subsection 84E(3) of the Act when submitting an otherwise eligible application to Services Australia on behalf of an applicant.

The Determination permits Approved Pharmacists to issue Safety Net Concession Cards and Pharmaceutical Benefits Entitlement Cards, and allows Services Australia to process and pay claims by those suppliers, where the applications are lodged without an applicant signature.

The Determination ensures that patients can continue to receive subsidised prescription drugs during COVID-19. The Determination will improve consistency of Pharmaceutical Benefits Scheme (PBS)

signature requirements during COVID-19, and ensure pharmacies remain compliant with paragraph 84DA(3) and paragraph 84E(3) of the NH Act when submitting claims and applications to Services Australia.

Whilst the requirement for signatures on PBS Safety Net card applications is a long-standing compliance provision, the temporary relaxation of this requirement is considered to have an acceptably low risk, having regard for the respective risks of COVID-19 transmission versus the Commonwealth's other effective controls and compliance processes designed to prevent or identify fraudulent claiming on the PBS.

## **Background**

Under the NH Act, patients may choose to maintain records of how much they spend on pharmaceuticals in a calendar year. Patients may obtain a PBS/RPBS Safety Net prescription record form and application for a Safety Net card form (PB240) (PRF) from Services Australia for the purposes of collecting these records and making an application for a PBS safety net card once their eligible out-of-pocket expenses on PBS prescriptions has equalled or exceeded the relevant statutory threshold amount. There are two types of PBS safety net card:

- a. the Pharmaceutical Benefits Entitlement Card, which may be issued by an Approved Pharmacist to an eligible concessional patient who may then receive PBS prescriptions free of charge for the remainder of the calendar year in which the card was issued; and
- b. the Safety Net Concession Card, which may be issued by an Approved Pharmacist to an eligible non-concessional (general) patient who may then obtain PBS prescriptions paying only the concessional co-payment amount for the remainder of the calendar year in which the card was issued.

A payment of \$10.27 (as per the 2020 amount) may be claimed by Approved Pharmacists for each PBS Safety Net card they issue, by completing and signing a *Safety Net — claim for payment form*, and submitting the form to Services Australia no later than one month after the card is issued. Each claim must be supported by a corresponding patient PBS Safety Net card application.

Paragraphs 84DA(3)(c) and 84E(3)(c) of the Act require that applications, respectively, for a Safety Net Concession Card or Pharmaceutical Benefits Entitlement Card must be signed by the person making the application, or by the person's agent.

## **Consultation**

Services Australia notified the Department of Health regarding receipt of a large number of unsigned applications due to concerns about the risk of transmission of COVID-19, estimated to be almost half of all applications received. The increase in non-compliant applications is considered to be due to a misunderstanding of the extent of the operation of the Special Arrangement which disapplies signature requirements for other provisions of the NH Act.

The Department also consulted with Services Australia during drafting of the Determination and sought comment on the provisions. Services Australia responded that it was satisfied the Determination would clarify and align the signature requirements with the Special Arrangement. Services Australia will notify approved suppliers of the temporary disapplication of the requirement for patient signatures.

The Department consulted the Attorney-General's Department as the responsible agency for the CERPO Act to determine the appropriateness of creating a Determination under Schedule 5.

The Office of Best Practice Regulation was consulted and has advised that the proposal is unlikely to have a more than minor regulatory impact, noting it is a temporary streamlining measure, and that the Department considers the risks to be acceptable (OBPR ID 43221).

The Determination commences on the day after it is registered.

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

A provision-by-provision description of the Determination is contained in the Attachment.

**Details of the *Coronavirus Economic Response Package (Modifications—National Health (Pharmaceutical Benefits Scheme)) Determination 2020***

**Section 1 Name**

Section 1 provides that the name of the instrument is the *Coronavirus Economic Response Package (Modifications—National Health (Pharmaceutical Benefits Scheme)) Determination 2020*.

**Section 2 Commencement**

Section 2 provides that the instrument commences on the day after it is registered.

**Section 3 Authority**

Section 3 provides that the instrument is made under subitem 1(2) of Schedule 5 to the *Coronavirus Economic Response Package Omnibus (Measures No. 2) Act 2020*.

**Section 4 Modifications**

Section 4 provides that each modification of a provision of the *National Health Act 1953* as set out in a Schedule to this instrument is determined for the purposes of subitem 1(2) of Schedule 5 to the *Coronavirus Economic Response Package Omnibus (Measures No. 2) Act 2020*.

**Schedule 1—Modifications of the National Health Act 1953**

**Item 1 Definitions**

This item provides that the relevant period that applies in relation to Items in the Schedule starts on 8 April 2020 and ends on the day on which item 1 of Schedule 5 to the *Coronavirus Economic Response Package Omnibus (Measures No. 2) Act 2020* is repealed.

**Item 2 Disapplication of paragraph 84DA(3)(c)**

This item disapplies the requirement for the person or the person's agent to sign an application for a Safety Net Concession Card where the application is made or processed during the relevant period.

**Item 3 Disapplication of paragraph 84E(3)(c)**

This item disapplies the requirement for the person or the person's agent to sign an application for a Pharmaceutical Benefits Entitlement Card where the application is made or processed during the relevant period.

## Statement of Compatibility with Human Rights

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

### ***National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2020***

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 purpose of this legislative instrument, made under subitem 1(2) of Schedule 5 to the *Coronavirus Economic Response Package Omnibus (Measures No. 2) Act 2020*, is to temporarily disapply the requirement for the signature of a person or the person's agent on an application for a Safety Net Concession Card or a Pharmaceutical Benefits Entitlement Card

The *Coronavirus Economic Response Package (Modifications—National Health (Pharmaceutical Benefits Scheme)) Determination 2020* temporarily, during COVID-19:

- disapplies the requirement in paragraph 84DA(3)(c) of the *National Health Act 1953* (the Act) that an applicant (or the applicant's agent) shall sign an application made to an approved supplier for a Safety Net Concession Card, where it is not practicable due to concerns relating to transmission of COVID-19; and
- disapplies the requirement in paragraph 84E(3)(c) of the Act that an applicant (or the applicant's agent) shall sign an application made to an approved supplier for a Pharmaceutical Benefits Entitlement Card, where it is not practicable due to concerns relating to transmission of COVID-19.

The temporary disapplication of signature requirements in paragraph 84DA(3)(c) and paragraph 84E(3)(c) of the NH Act by the Determination aligns with the disapplication of similar requirements in the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement). This creates consistency of signature requirements and reduces the likelihood of misinterpretation by approved suppliers, which, the Department has been notified by Services Australia who process and pay the claims, has been occurring in almost half the applications received.

The Determination has retrospective effect from 8 April 2020, which is permissible under subitem 1(3) of Schedule 5 to the CERPO Act. This date aligns with the commencement date of the Special Arrangement, to ensure any applications submitted during this period without signature due to concerns relating to transmission of COVID-19 satisfy requirements.

The retrospective effect of the Determination is intended to assist individuals by allowing Services Australia to process unsigned applications made within the relevant period, ensuring that the affected patients can continue to receive subsidised prescription drugs without experiencing disadvantage as a result of concerns with the transmission of COVID-19. The Determination will further assist pharmacies to remain compliant with paragraph 84DA(3) and paragraph 84E(3) of the Act when submitting an otherwise eligible application to Services Australia on behalf of an applicant.

The Determination permits Approved Pharmacists to legally issue Safety Net Concession Cards and Pharmaceutical Benefits Entitlement Cards, and allows Services Australia to process and pay claims by those suppliers, where the applications are lodged without an applicant signature.

The Determination ensures that patients can continue to receive subsidised prescription drugs without experiencing disadvantage due to the operation of compliance mechanisms that could militate against

community safety during COVID-19. The Determination will improve consistency of Pharmaceutical Benefits Scheme (PBS) signature requirements during COVID-19, and provide appropriate assistance to pharmacies to remain compliant with paragraph 84DA(3) and paragraph 84E(3) of the Act when submitting otherwise eligible claims and applications to Services Australia.

### **Human rights implications**

The Determination engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to health. The Determination 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 PBS is a benefit scheme which assists with providing subsidised access for people to medicines. This is a positive and supportive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the scheme. The Determination 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.

### **Conclusion**

The Determination is compatible with human rights, as they apply to Australia because it promotes the protection of human rights to the extent that the modification of signature requirements enables patients with concerns about transmission of COVID-19 to continue to receive subsidised access to PBS listed medicines.

**The Hon Greg Hunt MP**  
**Minister for Health and Aged Care**