

## EXPLANATORY STATEMENT

### *National Health Act 1953*

### *National Health Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only) Instrument 2020*

PB 109 of 2020

#### **Authority**

This legislative instrument is made pursuant to section 88 and subsection 100(2) of the *National Health Act 1953* (the Act).

Section 88 of the Act provides that the Minister may authorise by legislative instrument, the classes of authorised prescriber who may prescribe a pharmaceutical benefit. It also provides that the Minister can list pharmaceutical benefits without determining any authorised prescribers for the benefit.

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 Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only) Instrument 2020* (the instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) and the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) to allow for pharmaceutical benefits to be listed without an authorised prescriber from 1 November 2020 and therefore be listed for supply only.

Pharmaceutical benefits will be listed for supply only for a period of up to 12 months, after which time they will be fully de-listed from the PBS (available for neither prescribing nor supply).

The changes provide administrative clarity for the Department, Services Australia, Approved Pharmacists and software vendors who have been relying on manual workarounds prior to 1 November, to ensure that patients receive critical medicines regardless of the administrative circumstances of a pharmaceutical benefit.

These supply only arrangements ensure that patients will not be disadvantaged as existing valid prescriptions will remain valid after the pharmaceutical benefit is removed for prescribing purposes. This removes the need for a patient to consult with their prescriber about an existing prescription which has become invalid due to the delisting of the pharmaceutical benefit.

The arrangements will also allow manufacturers time to deplete remaining stock of the pharmaceutical benefit which reduces medicine wastage.

#### **Background**

Changes made to the Act in February 2018 provided for pharmaceutical benefits to be listed on the Pharmaceutical Benefits Scheme (PBS) for supply only, but not for prescribing.

This was achieved by extending the Minister's power already in place to determine authorised prescribers for a pharmaceutical benefit (such as optometrists, dental practitioners, and medical practitioners) to also be able to determine that a pharmaceutical benefit has no authorised prescribers applying to it (subsection 88(1EB)).

This change allows for a pharmaceutical benefit to be listed on the PBS, but with no authorised prescriber. In this way, the Minister could revoke any determination made under any of subsections

88(1) to 88(1E) in the event that the listing needs to be retained only for supply purposes. This has the effect of preventing any new prescriptions being written in relation to the specified listing, while still allowing the pharmaceutical benefit to remain listed on the PBS for supply of the benefit on the basis of a valid prescription written prior to the date the determination of authorised prescribers was revoked.

The powers conferred by the changes made to the Act in February 2018 have not been exercised to date but are scheduled to begin being exercised with effect from 1 November 2020. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) and the *National Health (Highly specialised drugs program) Special Arrangement 2010* consequently require amendment to support the implementation of this policy by describing the pharmaceutical benefits that are available on the PBS for supply purposes only.

### **Consultation**

The amendments made by this Instrument accord with changes made to the Act in February 2018. These changes were minor and mechanical in nature and were made to allow valid prescriptions written for a subsequently deleted pharmaceutical benefit to be dispensed after the deletion.

This change has been made in response to prior consultation with, and ongoing feedback from, PBS prescribing and dispensing Software Vendors, and Services Australia, who frequently undergo complicated and time consuming manual efforts to allow valid scripts to continue being supplied, and related claims to be paid, for pharmaceutical benefits that may no longer be prescribed under the Act.

It was considered that further consultation for this instrument was unnecessary due to the minor and mechanical nature of the change.

This instrument commences immediately after the commencement of the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 10)* and the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 9)*.

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

## **Details of the *National Health Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only) Instrument 2020***

### **1 Name**

This section provides that the name of this instrument is the *National Health Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only) Instrument 2020* and may also be cited as PB 109 of 2020.

### **2 Commencement**

This section provides that the instrument commences immediately after the commencement of the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 10)* and the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 9)*.

### **3 Authority**

This section states that this instrument is made under subsections 88 and 100(2) of the *National Health Act 1953*.

### **4 Schedules**

Section 4 provides that each instrument that is specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule has effect according to its terms.

## **Schedule 1—Amendments**

### Part 1 - Listing of pharmaceutical benefits

*National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)*

### **1 Section 9 (heading)**

This section repeals the name of the section, being ‘9 Authorised prescriber’. The name is replaced with the new name ‘9 Authorised prescribers—Part 1 of Schedule 1’.

### **2 Subsection 9(1A)**

This section makes changes to restrict authorised medical practitioners to write a prescription for pharmaceutical benefits listed only in Part 1 of Schedule 1.

### **3 Subsections 9(1), (2), (3), (4) and (5)**

This section makes changes to restrict authorised dental practitioners, authorised optometrists, authorised midwives and authorised nurse practitioners, to write a prescription for pharmaceutical benefits listed only in Part 1 of Schedule 1.

### **4 Schedule 1 (heading)**

This section repeals the name of schedule 1, being Schedule 1—Ready- prepared pharmaceutical benefits (sections 5 to 10, 16 to 18, 20, 21, 23 to 26). The name is replaced with the new name Schedule 1—Ready prepared pharmaceutical benefits Note: See sections 5 to 10, 16 to 18, 20, 21 and 23 to 26. Part 1—Ready prepared pharmaceutical benefits for prescription and supply.

## **5 At the end of the Schedule 1**

This section inserts a new part to Schedule 1 in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012). This part, Part 2—Ready prepared pharmaceutical benefits for supply only, lists pharmaceutical benefits which are not able to be prescribed and are therefore listed for supply only.

### Part 2 - Highly specialised drugs

*National Health (Highly specialised drugs program) Special Arrangement (PB 116 of 2010)*

## **6 At the end of Section 8**

This section inserts a new subsection which limits the power of Subsection 8(1) so that it does not apply to HSD pharmaceutical benefits mentioned in Part 2 of Schedule 1 to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (ready prepared pharmaceutical benefits for supply only).

## **Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011  
National Health Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only)  
Instrument 2020*

**(PB 109 of 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 *National Health Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only) Instrument 2020* (the amendment instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) and the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010). The amendment instrument introduces for the first time pharmaceutical benefits which are available on the Pharmaceutical Benefits Scheme for the purposes of supply only.

The *National Health Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only) Instrument 2020* (109 of 2020) modifies Schedule 1 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) to include Part 2, which lists pharmaceutical benefits which are available for the purposes of supply only. This allows for pharmaceutical benefits which have been removed from the PBS for prescribing purposes to be supplied to patients who still possess valid prescriptions.

PB 109 of 2020 also amends the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) to align it with the changes being made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) so that any pharmaceutical benefits listed in Schedule 1 Part 1 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* can also no longer be prescribed under the *National Health (Highly specialised drugs program) Special Arrangement 2010*.

### **Human rights implications**

This Disallowable Legislative Instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with 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 Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

### **Conclusion**

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

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