

## EXPLANATORY STATEMENT

*National Health Act 1953*

*National Health (Closing the Gap – PBS Co-payment Program) Amendment  
Special Arrangement 2021*

### **Authority**

Section 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons who live in isolated areas or are receiving treatment in circumstances in which general supply pharmaceutical benefits are inadequate for that treatment, or if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Section 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 (Closing the Gap – PBS Co-payment Program) Amendment Special Arrangement 2021* (Amendment Instrument) amends the *National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangement 2016* (Special Arrangement). The Amendment Instrument makes changes associated with reforms to the Closing the Gap (CTG) Pharmaceutical Benefits Scheme (PBS) Co-payment Program.

These amendments resulted from changes to enhance the CTG PBS Co-payment Program announced through the Seventh Community Pharmacy Agreement (7CPA) in June 2020.

The Special Arrangement assists eligible Aboriginal and Torres Strait Islander people to access PBS medicines with a reduced patient co-payment.

The Special Arrangement continues to benefit Aboriginal and Torres Strait Islander people who in the opinion of the PBS prescriber or Aboriginal and Torres Strait Islander Health Practitioner:

- would experience setbacks in the prevention or ongoing management of a condition if the patient did not adhere to a course of treatment involving a pharmaceutical benefit; and
- would be unlikely to adhere to the course of treatment without assistance from this Special Arrangement.

The Special Arrangement continues to provide for a reduction of the usual PBS co-payment for Aboriginal and Torres Strait Islander people registered for the CTG PBS Co-payment Program. Those patients who would normally pay the general rate will receive their PBS medicines at the concessional rate and concessional patients will receive their PBS medicines without making a patient co-payment. Mandatory price brand premiums, which are special patient contributions, for a small number of PBS medicines may still need to be paid by the patient. The amount of the PBS co-payment is indexed annually under the Act, and appears on the Department of Health website at: [Pharmaceutical Benefits Scheme \(PBS\) | Fees & Patient Contributions](#)

The amendments to the Special Arrangement are:

- any PBS prescriber or Aboriginal and Torres Strait Islander health practitioner registered with Medicare as a provider can register an eligible Aboriginal or Torres Strait Islander person for

- the CTG PBS Co-payment Program. As is currently the case, a person can only be registered where the person has provided consent to receive supplies under the Program;
- any Aboriginal or Torres Strait Islander person can be registered for the CTG PBS Co-payment Program, regardless of their chronic disease status and where they live in Australia;
  - PBS prescriptions for eligible medicines will no longer need to be annotated with 'CTG' by the prescriber to be eligible for the reduced co-payment.
  - Correction of a drafting error to give effect to the long-standing policy of the CTG PBS Co-payment Program that suppliers can charge, in addition to reduced co-payments, special patient contributions and, in the case of approved pharmacists and approved medical practitioners, delivery charges.

### **Consultation**

Thirty five stakeholder groups covering clinical and pharmaceutical health professionals, peak bodies, State and Territory health departments and consumer groups were consulted during the development of the reforms to the CTG PBS Co-payment Program. This included two rounds of consultations and a targeted workshop. There was overwhelming support for reforms to the Program that would make it easier for Aboriginal and Torres Strait Islander people to register for the Program, regardless of their chronic disease status and wherever they live in Australia and to expand the range of health care professionals who can issue eligible prescriptions.

The Department of Health consulted with Services Australia and the Department of Veterans' Affairs in regards to development of the instrument. Comments from Services Australia have been accepted and implemented into the instrument and the Department of Veterans' Affairs had no changes.

Engagement with Services Australia, Medical Software Industry Association (MSIA) and pharmacy software providers has occurred to assist with implementation of necessary software and system changes.

The Department of Health and Services Australia have developed respective communications material to advise consumers, PBS prescribers, Aboriginal and Torres Strait Islander Health Practitioners, approved pharmacists and approved hospital authorities of the changes made by this instrument. These materials have been developed in consultation with key stakeholder groups.

This instrument commences on 1 July 2021.

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 (Closing the Gap – PBS Co-payment Program) Amendment Special Arrangement 2021***

**Section 1 Name**

This section provides that the name of the instrument is the *National Health (Closing the Gap – PBS Co-payment Program) Amendment Special Arrangement 2021* and may also be cited as PB 71 of 2021.

**Section 2 Commencement**

This section provides that the instrument commences on 1 July 2021.

**Section 3 Authority**

This section provides that the instrument is made under subsection 100(2) of the *National Health Act 1953*.

**Section 4 Schedules**

Schedule 1 – Amendments

**Item 1 – before Section 1**

Item 1 creates a new Part 1 of the Special Arrangement, as a consequence of amendments made by item 39 which inserts a Part 2 dealing with transitional matters.

**Item 2- Section 1**

Section 1 is amended to update the name of the Special Arrangement to reflect that it is no longer restricted to supplies to patients with chronic disease.

**Items 3 – 15 - Section 4**

Items 7 – 12 and item 14 repeal a number of definitions no longer applicable as a result of the repeal of subsection 7(3), which required a person prescribing benefits under the Special Arrangement to be a member of certain general practices or Indigenous Health Services, or a specialist treating a registered patient referred by a prescriber who was a member of such a general practice or Indigenous Health Service.

Item 5 adds additional definitions such as “CTG registering practitioner” and “CTG supplier”. A CTG supplier is an approved pharmacist, approved medical practitioner or approved hospital authority for a private hospital. A CTG registering practitioner is a PBS prescriber or a registered Aboriginal and Torres Strait Islander health practitioner registered with Medicare as a provider. Item 5 also adds the additional definition of “early supply of a specialised pharmaceutical benefit” which has the same meaning as in section 84AAA of the Act.

Item 13 updates an outdated reference to the *National Health (Pharmaceutical Benefits) Regulations 1960* to the *National Health (Pharmaceutical Benefits) Regulations 2017*.

**Item 16 - Subsection 7(3)**

Through the Seventh Community Pharmacy Agreement (7CPA), the Australian Government committed to make changes to the CTG PBS Co-payment Program to enable and empower

Aboriginal and Torres Strait Islander people to live healthy full lives by increasing access to affordable PBS medicines. This change allows any PBS prescriber to issue a PBS prescription including hospital scripts for eligible Aboriginal and Torres Strait Islander people registered for the CTG PBS Co-payment Program.

Subsection 7(3) is repealed to remove the requirement that a prescription can only be written under the Special Arrangement by a PBS prescriber who is a member of certain types of general practices or Indigenous Health Services, or a specialist treating a registered patient referred by a prescriber who was a member of such general practices or Indigenous Health Services.

**Item 17 – Subsection 7(4)**

Item 17 repeals subsection 7(4). It required a person prescribing a pharmaceutical benefit under the Special Arrangement to annotate the prescription as such.

**Item 18 - Section 8**

Section 8 is repealed as it was for the purposes of subsection 7(3) which has been repealed by item 16.

**Item 19 - Section 9**

Section 9 is repealed as it was for the purposes of subsection 7(3) which has been repealed by item 16.

**Items 20 – 28 - Section 10**

Items 20 – 28 amend section 10 of the Special Arrangement, which deals with the registration of patients to access benefits under the Arrangement.

The Australian Government is committed to providing access to more affordable PBS medicines for Aboriginal and Torres Strait Islander people. Through the 7CPA, the Australian Government committed to make changes to the CTG PBS Co-payment Program to enable and empower Aboriginal and Torres Strait Islander people to live healthy full lives by increasing access to affordable PBS medicines.

Item 20 repeals subsection 10(1), and item 21 alters references in subsection 10(2) from ‘the practitioner’ to ‘A CTG registering practitioner’. These changes have the effect that any PBS prescriber or a registered Aboriginal and Torres Strait Islander health practitioner registered with Medicare as a provider can register a person. Previously, only a general practitioner who was a member, employee or contractor of certain types of general practices mentioned in section 8 or a medical practitioner who was a member, employee or contractor of an Indigenous Health Service could register a patient. Item 24 makes a consequential change to paragraph 10(2)(d).

Items 26 and 27 amend subsection 10(3) to remove the requirement that a person must have an existing chronic disease, or be at risk of developing a chronic disease, to be registered to receive benefits for reduced co-payment under the Special Arrangement.

Items 25 and 28 make changes to the method of registration. Item 25 repeals the requirement in paragraph 10(2)(e) that an approved form be used to register a person. New subsections 10(4) and 10(5), added by item 28, provide that a practitioner must use Services Australia’s Health Professional Online Service (HPOS) to register a person except where, for reasons beyond the practitioner’s control, the practitioner does not have access to functioning IT systems is unable to access HPOS. In those circumstances, a registration may be made by telephone to Services Australia.

Items 22 and 23 are technical changes to remove gendered language and improve drafting.

### **Item 29 – After Section 10**

New section 10A is added to specify who may supply a pharmaceutical benefit under the Special Arrangement, being an approved pharmacist, approved medical practitioner or approved hospital authority for a private hospital. This amendment formally recognises that approved hospital authorities for public hospitals do not supply benefits under the Special Arrangement.

### **Items 30 – 41 - Sections 11 to 14**

Sections 11 to 14 are amended to replace all references to “an approved supplier” with a “CTG supplier”, as a consequence of the recognition that approved hospital authorities for public hospitals do not supply benefits under the Special Arrangement.

Item 34 adds provisions that correct a drafting error regarding the charging of special patient contributions, and charges by approved pharmacists and approved medical practitioners for delivery at or to a place other than a pharmacist’s approved premises, or the medical practitioner’s place of practice.

These charges have historically been applied under the CTG PBS Co-payment Program. However, the drafting of section 11 lacked clarity for suppliers about what charges, in addition to reduced co-payments, were allowable. Special patient contributions are only payable for a limited number of pharmaceutical benefits, including to reflect ‘brand premiums’.

Items 36 and 39 add a reference to subsection 99(2AA) of the Act into subsections 13(2) and 13(4), respectively, which deal with amounts payable by the Commonwealth under the Special Arrangement. To mirror the addition of clear drafting to allow the charging of a special patient contribution, subsections 13(2) and 13(4) have been amended to deal with situations where the Commonwealth is responsible for paying a special patient contribution rather than a patient. Where this is the case, subsections 13(2) and 13(4) now clearly provide for an approved pharmacist or approved medical practitioner to be paid an amount equal to the special patient contribution where they are so entitled under section 99(2AA) of the Act.

### **Item 42 – After Section 14**

Item 42 adds a Part 2 to the Special Arrangement, which establishes a number of transitional arrangements as a consequence of the changes to the operation of the CTG PBS Co-payment Program.

New section 15 sets out the following definitions:

- transition time – the time section 15 takes effect;
- old Special Arrangement – the Special Arrangement as in force immediately before the transition time;
- new Special Arrangement – the Special Arrangement, as amended by the Amendment Instrument.

New section 16 provides that the old Special Arrangement continues to apply in relation to the supply of a pharmaceutical benefit made before the transition time.

New section 17 provides that a pharmaceutical benefit that was prescribed for supply in accordance with the requirements of the old Special Arrangement, may be supplied from the transition time as if it had been prescribed in accordance with the requirements of the new Special Arrangement.

New section 18 provides that a person who was registered under the old Special Arrangement to receive supplies under the Special Arrangement is taken to be registered under section 10 of the new Special Arrangement. This is for the avoidance of doubt, to ensure that changes to registration criteria and processes do not affect existing registrations.

## Statement of Compatibility with Human Rights

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

### **National Health (Closing the Gap – PBS Co-payment Program) Amendment Special Arrangement 2021**

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 Legislative Instrument**

The purpose of this Legislative Instrument, made under subsection 100(2) of the Act, is to amend the *National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangement 2016* (the Special Arrangement) to make changes associated with amendments to the Closing the Gap (CTG) PBS Co-payment Program.

The cost of medicines is a significant barrier to improving access to medicines for Aboriginal and Torres Strait Islander people. The Special Arrangement continues to provide, for the benefit of eligible Aboriginal and Torres Strait Islander people, for a reduction in the PBS co-payment for concessional patients to nil, or if the full PBS co-payment would otherwise apply, a reduction to the concessional PBS co-payment. The co-payment amount (prior to reduction) continues to count towards the PBS Safety Net.

The key changes to the Special Arrangement made by the Legislative Instrument are:

- any PBS prescriber or a registered Aboriginal and Torres Strait Islander health practitioner registered with Medicare as a provider can register an eligible Aboriginal or Torres Strait Islander person for the CTG PBS Co-payment Program implemented through the Special Arrangement. Previously, only a general practitioner who was a member, employee or contractor of certain types of general practices, or a medical practitioner who was a member, employee or contractor of an Indigenous Health Service, could register a patient. As is currently the case, a person can only be registered where the person has provided consent to receive supplies under the Program;
- any Aboriginal or Torres Strait Islander person can be registered for the CTG PBS Co-payment Program, regardless of their chronic disease status and where they live in Australia. Previously, a person must have had an existing chronic disease, or have been at risk of developing a chronic disease;
  - the requirement that a prescription can only be written under the Special Arrangement by a PBS prescriber who is a member of certain types of general practices or Indigenous Health Services, or a specialist treating a registered patient referred by a prescriber who was a member of such general practices or Indigenous Health Services, has been removed.
- correction of a drafting error to give clear effect to the policy intent of the CTG PBS Co-payment Program to allow CTG suppliers to charge special patient contributions and delivery charges in addition to the reduced co-payment specified in the Special Arrangement.

The Legislative Instrument also updates processes for registering a person for access to reduced co-payment supplies of pharmaceutical benefits under the Special Arrangement, to promote use of

Services Australia's Health Professional Online System (HPOS). HPOS is widely used by health professionals in engaging with Services Australia. However, an exception to the requirement is provided where, for reasons beyond the registering practitioner's control, they do not have functioning IT systems or cannot access the HPOS system.

The Legislative Instrument includes transitional arrangements to ensure that the changes it makes do not affect existing patient registrations, and that existing prescriptions remain effective.

### **Human rights implications**

This Legislative Instrument engages the following rights:

- Article 12 of the *International Covenant on Economic, Social and Cultural Rights*
- 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 PBS assists with advancement of these human rights by providing for subsidised access to medicines. This Legislative Instrument ensures more ready and equitable access to PBS medicines for eligible Aboriginal and Torres Strait Islander peoples and is part of the Australian Government's Closing the Gap reform agenda.

### **Conclusion**

The Legislative Instrument is compatible with human rights because it promotes the protection of human rights.