



PB 66 of 2024

National Health Legislation Amendment (Extension of Closing the Gap – PBS Co-payment Program) Instrument 2024

I, David Laffan, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 19 June 2024

David Laffan
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
Department of Health and Aged Care

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1 Name

- (1) This instrument is the *National Health Legislation Amendment (Extension of Closing the Gap – PBS Co-payment Program) Instrument 2024*.
- (2) This instrument may also be cited as PB 66 of 2024.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information | | |
|--|---|--------------|
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table | The day after this instrument is registered. | 28 June 2024 |
| 2. Schedule 1 | 1 July 2024. | 1 July 2024 |
| 3. Schedule 2 | A single day to be fixed by the Secretary by notifiable instrument. However, if the provisions do not commence before 1 January 2025, they commence on that day. | |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

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

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Main Amendments

National Health (Botulinum Toxin Program) Special Arrangement 2015

1 Section 4

Insert:

CTG registered patient means a patient registered under subsection 10(2) of the CTG Special Arrangement.

CTG Special Arrangement means the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016*.

CTG supplier has the same meaning as in the CTG Special Arrangement.

2 At the end of subsection 13(1)

Add:

Note: However, see Part 9 in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

3 At the end of subsection 14(1)

Add:

Note: However, see Part 9 in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

4 At the end of subsection 22(1)

Add:

Note: However, see Part 9 in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

5 After Part 8

Insert:

Part 9—Supply to CTG registered patients by CTG suppliers

23 Application of this Part

This Part applies to a supply (the **relevant supply**) of a pharmaceutical benefit under this Special Arrangement if the relevant supply is made:

- (a) to an eligible patient who is a CTG registered patient; and
- (b) by an approved hospital authority who is a CTG supplier.

24 Application of the CTG Special Arrangement—co-payment and payment etc.

- (1) Despite sections 13, 14 and 22 of this Special Arrangement, subsections 11(1), (2), (3) and (4) (co-payment reduction etc.) and section 13 (payment by Commonwealth) of the CTG Special Arrangement apply in relation to the

relevant supply under this Special Arrangement with the modification set out in subsection (2) of this section.

- (2) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this Special Arrangement.
- (3) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement do not apply in relation to the relevant supply under this Special Arrangement.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this Special Arrangement are instead dealt with under section 25 of this Special Arrangement.

25 Claim for payment

- (1) If an approved hospital authority who is a CTG supplier wants to receive payment from the Commonwealth in relation to the relevant supply under this Special Arrangement, the approved hospital authority must make a claim for payment to the Chief Executive Medicare on behalf of the Secretary.
- (2) The claim must be made in accordance with the rules made under subsections 98AC(4) and 99AAA(8) of the Act with the modification set out in subsection (3) of this section.
- (3) A claim for payment made using the manual system referred to in section 99AAA of the Act must include an indicator that the patient is a CTG registered patient.

National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016

6 Subsection 5(2)

Omit “to a pharmaceutical benefit that can only be supplied under Part VII of the Act in accordance with another Special Arrangement under section 100 of the Act or”.

7 Section 5 (note)

Repeal the note, substitute:

- Note 1: See section 85AAA of the Act in relation to pharmaceutical benefits that can only be supplied under the prescriber bag provisions of the Act.
- Note 2: The modifications of the Act under this Special Arrangement relating to:
- (a) charges for the supply of a pharmaceutical benefit (section 11 of this Special Arrangement); and
 - (b) payments to a CTG supplier by the Commonwealth for the supply of a pharmaceutical benefit (section 13 of this Special Arrangement);
- may apply in relation to the supply of a pharmaceutical benefit under other Special Arrangements to a person who is registered under subsection 10(2) of this Special Arrangement.

8 Section 11 (at the end of the heading)

Add “etc.”.

9 Paragraph 14(2)(b)

Omit “unless made using the manual system,”, substitute “if made using the manual system referred to in section 99AAA of the Act—”.

10 Sections 16 and 17

Repeal the sections.

11 Division 2 of Part 2

Repeal the Division.

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024

12 Section 5

Insert:

CTG registered patient means a patient registered under subsection 10(2) of the CTG Special Arrangement.

CTG Special Arrangement means the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016*.

CTG supplier has the same meaning as in the CTG Special Arrangement.

13 At the end of paragraph 26(2)(c)

Add:

- (iv) if the claim is made using the manual system referred to in section 99AAA of the Act, the eligible patient is a CTG registered patient and the supplier is a CTG supplier—an indicator that the eligible patient is a CTG registered patient;

14 At the end of section 26

Add:

Supplies of related pharmaceutical benefits—CTG registered patients and suppliers

- (3) For a claim in relation to a special arrangement supply of a related pharmaceutical benefit, the requirements in the rules made by the Minister under subsections 98AC(4) and 99AAA(8) of the Act are modified as set out in subsection (4) of this section.
- (4) If:
 - (a) a claim is made using the manual system referred to in section 99AAA of the Act; and
 - (b) the supplier is a CTG supplier; and
 - (c) the eligible patient is a CTG registered patient;the claim must include an indicator that the eligible patient is a CTG registered patient.

15 Subsection 27(1)

Omit “An approved pharmacist”, substitute “Subject to section 40 of this instrument, an approved pharmacist”.

16 At the end of subsection 27(1)

Add:

Note: Section 40 of this instrument applies to an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to a CTG registered patient by a CTG supplier.

17 Subsection 28(1)

Omit “This section”, substitute “Subject to Part 5 of this instrument, this section”.

18 Subsection 28(1) (before the note)

Insert:

Note 1: Part 5 of this instrument applies to an original special arrangement supply of a dose of a chemotherapy drug, and to a special arrangement supply of a related pharmaceutical benefit, if the supply is made to a CTG registered patient by a CTG supplier.

19 Subsection 28(1) (note)

Omit “Note”, substitute “Note 2”.

20 Subsection 36(1)

Omit “This section”, substitute “Subject to section 40 of this instrument, this section”.

21 At the end of subsection 36(1)

Add:

Note: Section 40 of this instrument applies to an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to a CTG registered patient by a CTG supplier.

22 After subsection 36(3)

Insert:

(3A) In addition, if the supply is made to an eligible patient who is a CTG registered patient by a CTG supplier, no amount may be charged under subsections 11(1) to (3) of the CTG Special Arrangement for a repeated supply.

Note: See section 40 of this instrument in relation to the application of the CTG Special Arrangement.

23 Subsection 37(1)

Omit “This section”, substitute “Subject to section 40 of this instrument, this section”.

24 At the end of subsection 37(1)

Add:

Note: Section 40 of this instrument applies to an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to a CTG registered patient by a CTG supplier.

25 After subsection 37(3)

Insert:

- (3A) In addition, if the supply is made to an eligible patient who is a CTG registered patient by a CTG supplier, no amount may be charged under subsections 11(1) to (3) of the CTG Special Arrangement for a repeated supply.

Note: See section 40 of this instrument in relation to the application of the CTG Special Arrangement.

26 Subsection 39(2) (before the note)

Insert:

Note 1: However, see section 40 of this instrument for an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to a CTG registered patient by a CTG supplier.

27 Subsection 39(2) (note)

Omit “Note”, substitute “Note 2”.

28 After Part 4

Insert:

Part 5—Supply to CTG registered patients by CTG suppliers

40 Application of the CTG Special Arrangement—original special arrangement supply of a dose of a chemotherapy drug

- (1) This section applies to an original special arrangement supply (the *relevant supply*) of a dose of a chemotherapy drug under this instrument if the relevant supply is made:
 - (a) to an eligible patient who is a CTG registered patient; and
 - (b) by an approved pharmacist, an approved medical practitioner or an approved hospital authority who is a CTG supplier.
- (2) Despite paragraphs 27(1)(a) and 28(3)(a) and subsections 36(2), 37(2) and 39(2) of this instrument, subsections 11(1), (2), (3) and (4) (co-payment reduction etc.) and section 13 (payment by Commonwealth) of the CTG Special Arrangement apply in relation to the relevant supply under this instrument with the modification set out in subsection (3) of this section.
- (3) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this instrument.
- (4) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement do not apply in relation to the relevant supply under this instrument.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this instrument are instead dealt with under section 26 of this instrument.

41 Application of the CTG Special Arrangement—special arrangement supply of a related pharmaceutical benefit

- (1) This section applies to a special arrangement supply (the *relevant supply*) of a related pharmaceutical benefit under this instrument if the relevant supply is made:
 - (a) to an eligible patient who is a CTG registered patient; and
 - (b) by a participating hospital authority who is a CTG supplier.
- (2) Subsections 11(1), (2), (3) and (4) (co-payment reduction etc.) of the CTG Special Arrangement apply in relation to the relevant supply under this instrument with the modification set out in subsection (5) of this section.
- (3) Subsection (2) applies despite subsection 87(5) of the Act.
- (4) In addition, despite subsection 28(4) of this instrument, section 13 (payment by Commonwealth) of the CTG Special Arrangement applies in relation to the relevant supply under this instrument with the modification set out in subsection (5) of this section.
- (5) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this instrument.
- (6) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement do not apply in relation to the relevant supply under this instrument.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this instrument are instead dealt with under section 26 of this instrument.

National Health (Growth Hormone Program) Special Arrangement 2015

29 Subsection 4(1)

Insert:

CTG registered patient means a patient registered under subsection 10(2) of the CTG Special Arrangement.

CTG Special Arrangement means the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016*.

CTG supplier has the same meaning as in the CTG Special Arrangement.

30 At the end of subsection 14(1)

Add:

Note: However, see Part 6A in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

31 At the end of subsection 15(1)

Add:

Note: However, see Part 6A in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

32 At the end of subsection 23(1)

Add:

Note: However, see Part 6A in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

33 After Part 6

Insert:

Part 6A—Supply to CTG registered patients by CTG suppliers

23A Application of this Part

This Part applies to a supply (the *relevant supply*) of a pharmaceutical benefit under this Special Arrangement if the relevant supply is made:

- (a) to a patient who is a CTG registered patient; and
- (b) by an approved pharmacist, an approved medical practitioner or an approved hospital authority who is a CTG supplier.

23B Application of the CTG Special Arrangement—co-payment and payment etc.

- (1) Despite sections 14, 15, and 23 of this Special Arrangement, subsections 11(1), (2), (3), (3E) and (4) (co-payment reduction etc.) and section 13 (payment by Commonwealth) of the CTG Special Arrangement apply in relation to the relevant supply under this Special Arrangement with the modification set out in subsection (2) of this section.
- (2) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this Special Arrangement.
- (3) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement do not apply in relation to the relevant supply under this Special Arrangement.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this Special Arrangement are instead dealt with under section 23C of this Special Arrangement.

23C Claim for payment

- (1) If an approved pharmacist, an approved medical practitioner or an approved hospital authority who is a CTG supplier, wants to receive payment from the Commonwealth in relation to the relevant supply under this Special Arrangement, the pharmacist, medical practitioner or hospital authority must make a claim for payment to the Chief Executive Medicare on behalf of the Secretary.

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- (2) The claim must be made in accordance with the rules made under subsections 98AC(4) and 99AAA(8) of the Act with the modification set out in subsection (3) of this section.
- (3) A claim for payment made using the manual system referred to in section 99AAA of the Act must include an indicator that the patient is a CTG registered patient.

National Health (Highly Specialised Drugs Program) Special Arrangement 2021

34 Section 6

Insert:

CTG registered patient means a patient registered under subsection 10(2) of the CTG Special Arrangement.

CTG Special Arrangement means the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016*.

CTG supplier has the same meaning as in the CTG Special Arrangement.

35 Subsection 28(1) (note)

Omit “Note”, substitute “Note 1”.

36 At the end of subsection 28(1)

Add:

Note 2: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

37 At the end of subsection 30(1)

Add:

Note: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

38 Subsection 31(1) (note)

Omit “Note”, substitute “Note 1”.

39 At the end of subsection 31(1)

Add:

Note 2: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

40 After Part 3

Insert:

Part 3A—Supply to CTG registered patients by CTG suppliers

34A Application of this Part

This Part applies to a special arrangement supply (the *relevant supply*) of an HSD pharmaceutical benefit under this Special Arrangement if the relevant supply is made:

- (a) to an eligible patient who is a CTG registered patient; and
- (b) by an approved supplier who is a CTG supplier.

34B Application of the CTG Special Arrangement—co-payment and payment etc.

- (1) Despite sections 28, 30, 31 and 37 of this Special Arrangement, subsections 11(1), (2), (3), (3E) and (4) (co-payment reduction etc.) and section 13 (payment by Commonwealth) of the CTG Special Arrangement apply in relation to the relevant supply under this Special Arrangement with the modification set out in subsection (2) of this section.
- (2) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this Special Arrangement.
- (3) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement to not apply in relation to the relevant supply under this Special Arrangement.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this Special Arrangement are instead dealt with under Part 4 of this Special Arrangement.

41 At the end of Part 4

Add:

35A Claim for payment if an eligible patient is a CTG registered patient

If:

- (a) a claim for payment for a special arrangement supply of an HSD pharmaceutical benefit made under the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* is made using the manual system referred to in section 99AAA of the Act; and
- (b) the claim is made:
 - (i) by an approved supplier who is a CTG supplier; and
 - (ii) in relation to a special arrangement supply of an HSD pharmaceutical benefit to an eligible patient who is a CTG registered patient;

the claim must include an indicator that the eligible patient is a CTG registered patient.

42 At the end of subsections 37(1) and (2)

Add:

Note: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

National Health (IVF Program) Special Arrangement 2015**43 Section 4**

Insert:

CTG registered patient means a patient registered under subsection 10(2) of the CTG Special Arrangement.

CTG Special Arrangement means the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016*.

CTG supplier has the same meaning as in the CTG Special Arrangement.

44 At the end of subsection 8(1)

Add:

Note: However, see Part 5A in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

45 At the end of subsection 9(1)

Add:

Note: However, see Part 5A in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

46 Subsection 17(1)

Omit “for a public or a private hospital”.

47 Subsection 17(1)

Omit “an eligible patient”, substitute “a patient”.

48 At the end of subsection 17(1)

Add:

Note: However, see Part 5A in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier.

49 Subsection 17(2)

Omit “The approved hospital authority”, substitute “The approved pharmacist, approved medical practitioner or approved hospital authority”.

50 After Part 5

Insert:

Part 5A—Supply to CTG registered patients by CTG suppliers

17A Application of this Part

This Part applies to a supply (the *relevant supply*) of a pharmaceutical benefit under this Special Arrangement if the relevant supply is made:

- (a) to a patient who is a CTG registered patient; and
- (b) by an approved pharmacist, an approved medical practitioner or an approved hospital authority who is a CTG supplier.

17B Application of the CTG Special Arrangement—co-payment and payment etc.

- (1) Despite sections 8, 9 and 17 of this Special Arrangement, subsections 11(1), (2), (3), (3E) and (4) (co-payment reduction etc.) and section 13 (payment by Commonwealth) of the CTG Special Arrangement apply in relation to the relevant supply under this Special Arrangement with the modification set out in subsection (2) of this section.
- (2) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this Special Arrangement.
- (3) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement do not apply in relation to the relevant supply under this Special Arrangement.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this Special Arrangement are instead dealt with under section 19 of this Special Arrangement.

51 At the end of subsection 19(2)

Add:

- ; (b) must include an indicator that the patient is a CTG registered patient if:
- (i) the claim is made by an approved pharmacist, an approved medical practitioner or an approved hospital authority who is a CTG supplier in relation to a patient who is a CTG registered patient; and
 - (ii) the claim is made using the manual system referred to in section 99AAA of the Act.

Schedule 2—Approved hospital authorities

National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016

1 Section 4 (definition of CTG supplier)

Omit “for a private hospital”.

2 Section 4 (note at the end)

Before:

- approved medical practitioner

insert:

- approved hospital authority

3 Section 4 (note at the end)

Omit:

- private hospital

4 Paragraph 10A(1)(c)

Omit “for a private hospital”.

5 Paragraph 11(3C)(a)

Omit “for a private hospital”.