

EXPLANATORY STATEMENT

National Health Act 1953

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

PB 66 of 2024

Purpose

The *National Health Legislation Amendment (Extension of Closing the Gap – PBS Co-payment Program) Instrument 2024* (Instrument) broadens access to the Closing the Gap (CTG) Pharmaceutical Benefits Scheme (PBS) Co-payment Program, as announced by the Australian Government as part of the 2024-25 Budget, so that it also applies to pharmaceutical benefits:

- supplied by approved hospital authorities for public hospitals; and
- that can only be supplied in accordance with the five special arrangements made under section 100 of the *National Health Act 1953* (Act) specified below.

In particular, the Instrument amends the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016* (CTG Special Arrangement) to:

- allow the provisions of the CTG Special Arrangement to be applied to pharmaceutical benefits that can only be supplied in accordance with another special arrangement under section 100 of the Act, in addition to pharmaceutical benefits that are generally available for supply under Part VII of the Act (to which the CTG Special Arrangement already applies);
- correct a drafting error relating to use of the manual system for making a claim for payment from the Commonwealth for the supply of a pharmaceutical benefit under the CTG Special Arrangement;
- repeal historic transitional arrangements relating to the supply of pharmaceutical benefits under the CTG Special Arrangement under Continued Dispensing arrangements; and
- enable approved hospital authorities for public hospitals to supply pharmaceutical benefits under the CTG Special Arrangement, in addition to approved pharmacists, approved medical practitioners and approved hospital authorities for private hospitals (to which the CTG Special Arrangement already applies).

In addition, this Instrument also makes consequential amendments to the following five special arrangements made under section 100 of the Act to enable specific provisions under the CTG Special Arrangement to apply to the supply of pharmaceutical benefits under those arrangements (namely, provisions that relate to patient co-payment reduction, payment by the Commonwealth, contributions to a patient's PBS safety net and making claims for payment):

- *National Health (Botulinum Toxin Program) Special Arrangement 2015* (Botox Special Arrangement);
- *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* (EFC Special Arrangement);
- *National Health (Growth Hormone Program) Special Arrangement 2015* (Growth Hormone Special Arrangement);
- *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (HSD Special Arrangement); and
- *National Health (IVF Program) Special Arrangement 2015* (IVF Special Arrangement).

The effect of these consequential amendments will be that supplies of pharmaceutical benefits made under each of these five section 100 special arrangements to CTG patients by CTG suppliers (who are

also eligible to supply under the relevant section 100 special arrangement) will attract the lower patient co-payment provided under the CTG Special Arrangement. In each case, any provisions for special patient contributions, such as mandatory brand price premiums, existing under each of the five section 100 special arrangements specified above, will apply to such supplies, instead of the special patient contribution provisions operating under the CTG Special Arrangement itself.

Background

CTG Special Arrangement

The CTG Special Arrangement supports affordable access to PBS medicines for eligible First Nations people and continues to benefit First Nations people who, in the opinion of their PBS prescriber or First Nations health practitioner:

- would experience setbacks in the prevention or ongoing management of a medical condition if the patient did not adhere to a course of treatment (involving a pharmaceutical benefit) for that medical condition; and
- is unlikely to adhere to the course of treatment without assistance under the CTG Special Arrangement.

The CTG Special Arrangement provides for a reduction of the usual PBS patient co-payment for First Nations 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. For a small number of PBS medicines, mandatory brand price premiums, which are special patient contributions, may still need to be paid by the patient. The amount of the PBS patient co-payment is indexed annually under the Act, and is published on the Department of Health and Aged Care's PBS website at www.pbs.gov.au.

Five section 100 special arrangements

Each of the five section 100 special arrangements specified above provides for the supply of specialised pharmaceutical benefits for the treatment of specific conditions to eligible patients, which because of their clinical use and other special features, have restrictions on how they can be prescribed and supplied.

The PBS Botulinum Toxin Program, which operates under the Botox Special Arrangement, helps eligible patients access PBS-subsidised botulinum toxin to assist in the treatment of conditions such as facial spasms, urinary incontinence, chronic migraine, and symptoms associated with cerebral palsy.

The PBS Efficient Funding of Chemotherapy (EFC) Program, which operates under the EFC Special Arrangement, provides access to chemotherapy medicines used for the treatment of cancer that are administered through infusion or injection at public or private hospitals. This program also provides for public hospitals to supply related benefits used to manage side-effects associated with chemotherapy medicines.

The PBS Growth Hormone Program, which operates under the Growth Hormone Special Arrangement, provides eligible paediatric and adult patients access to growth hormone medicines for relevant conditions such as growth hormone deficiency.

The PBS Highly Specialised Drugs (HSD) Program, which operates under the HSD Special Arrangement, provides access to specialised medicines for the treatment of chronic conditions, some of which include HIV/AIDS, rheumatoid arthritis, hepatitis B and C and pulmonary arterial hypertension. These medicines, because of their clinical use or other special features, have restrictions on where they can be prescribed and supplied.

The PBS In-Vitro Fertilisation (IVF) Program, which operates under the IVF Special Arrangement, provides access to medicines for use in in-vitro fertilisation.

Pharmaceutical benefits provided under the Botox Special Arrangement can only be supplied through hospital authorities approved under section 94 of the Act, with those benefits to be administered by medical practitioners at those same approved hospital authorities, or by medical practitioners approved under section 92 of the Act, who are operating out of registered practice locations. Pharmaceutical benefits provided under the EFC Special Arrangement, Growth Hormone Special Arrangement, HSD Special Arrangement, and IVF Special Arrangement can more generally be supplied by pharmacists approved under section 90 of the Act, medical practitioners approved under section 92 of the Act, or hospital authorities approved under section 94 of the Act.

Authority

Section 100(1) of 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).

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII, have effect, subject to a special arrangement made under subsection 100(1).

Consultation

The Department of Health and Aged Care consulted with the National Indigenous Australians Agency, the National Aboriginal Community Controlled Health Organisation and the Pharmaceutical Benefits Advisory Committee regarding expansion of the CTG PBS Co-payment Program. There was consistent support for expanding coverage of the Program to all PBS medicines dispensed by community pharmacies, approved medical practitioners, and private and public hospitals.

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

Commencement

Sections 1 to 4 of this Instrument commence the day after this Instrument is registered.

Schedule 1 to this Instrument (which contains the amendments to the CTG Special Arrangement, other than the amendments to enable approved hospital authorities for public hospitals to supply pharmaceutical benefits under the CTG Special Arrangement, and the amendments to the other five special arrangements) commences on 1 July 2024.

Schedule 2 to this Instrument (which contains the amendments to the CTG Special Arrangement to enable approved hospital authorities for public hospitals to supply pharmaceutical benefits under the CTG Special Arrangement) commences on a date to be fixed by the Secretary by notifiable instrument, or 1 January 2025, whichever comes earlier.

Incorporation by reference

This Instrument incorporates by reference the following legislative instruments, or provisions of the following legislative instruments:

- *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016* – incorporated by reference within each of the five section 100 special arrangements specified above;
- *National Health (Supply of Pharmaceutical Benefits —Under Co-payment Data and Claims for Payment) Rules 2022* – incorporated by reference within the HSD Special Arrangement.

These instruments or relevant provisions of the instruments are incorporated as in force from time to time and the instruments can be accessed free of charge on the Federal Register of Legislation at www.legislation.gov.au.

General

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

Details of this Instrument are set out in **Attachment A**.

This Instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

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

Section 1 Name

This section provides that the name of the instrument is the *National Health Legislation Amendment (Extension of Closing the Gap – PBS Co-payment Program) Instrument 2024*, which may also be cited as PB 66 of 2024.

Section 2 Commencement

This section provides that:

- sections 1 to 4 of the instrument commence the day after the instrument is registered;
- Schedule 1 of the instrument commences on 1 July 2024; and
- Schedule 2 of the instrument commences on the earlier of 1 January 2025, or on a date prior to be fixed by the Secretary by notifiable instrument.

Section 3 Authority

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

Section 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 has effect according to its terms.

Schedule 1 – Main Amendments

The amendments in Schedule 1 involve amendments to the CTG Special Arrangement to expand its application to also include the supply of pharmaceutical benefits that can only be supplied under Part VII of the Act in accordance with another special arrangement under section 100 of the Act. In addition, Schedule 1 includes the consequential amendments to the Botox Special Arrangement, EFC Special Arrangement, Growth Hormone Special Arrangement, HSD Special Arrangement, and IVF Special Arrangement with respect to the supply of pharmaceutical benefits to CTG patients by CTG suppliers under those five section 100 special arrangements. These amendments relate to the patient co-payment reduction, payment by the Commonwealth, contributions to a patient's PBS safety net and making claims for payment.

The main effect of these consequential amendments will be that supplies of pharmaceutical benefits under each of the five section 100 special arrangements to CTG patients by CTG suppliers (who are also eligible to supply under the relevant section 100 special arrangement) will attract the lower patient co-payment provided under the CTG Special Arrangement.

National Health (Botulinum Toxin Program) Special Arrangement 2015

The changes to the *National Health (Botulinum Toxin Program) Special Arrangement 2015* (Botox Special Arrangement) are summarised below.

Item 1 – Section 4

This item inserts definitions of *CTG registered patient*, *CTG Special Arrangement* and *CTG supplier* into section 4 of the Botox Special Arrangement.

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

A ‘CTG registered patient’ means a patient registered under subsection 10(2) of the CTG Special Arrangement and ‘CTG supplier’ has the same meaning as in the CTG Special Arrangement.

These definitions incorporate the CTG Special Arrangement as in force from time to time. A copy of the instrument is available free of charge on the Federal Register of Legislation at www.legislation.gov.au.

Items 2, 3 and 4 – At the end of subsections 13(1), 14(1) and 22(1)

These items insert notes at the end of subsections 13(1), 14(1) and 22(1) of the Botox Special Arrangement to direct readers to refer to the new Part 9 of the Botox Special Arrangement in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier. This is because the new Part 9 provides that sections 13, 14 and 22 of the Botox Special Arrangement, which relate to payment by the Commonwealth and patient contributions, do not apply to such supplies.

Item 5 – After Part 8

This item inserts a new **Part 9 —Supply to CTG registered patients by CTG suppliers** into the Botox Special Arrangement. Part 9 introduces new sections 23, 24 and 25 into the Botox Special Arrangement.

The new section 23 provides that Part 9 applies to the supply of a pharmaceutical benefit (relevant supply) under the Botox Special Arrangement to an eligible person who is a CTG registered patient by an approved hospital authority who is a CTG supplier. Until Schedule 2 of the instrument commences, approved hospital authorities for public hospitals are not CTG suppliers.

The new section 24 provides that subsections 11(1), (2), (3), and (4) (co-payment reduction etc.) and 13 (payment by Commonwealth) of the CTG Special Arrangement apply in relation to a relevant supply under the Botox Special Arrangement. This has the effect that:

- CTG registered patients who would normally pay the general PBS patient co-payment will pay the concessional PBS co-payment and concessional patients will receive their PBS medicines for free, without making a co-payment (subsections 11(2) and (3));
- the amount that would have accumulated towards the PBS Safety Net for the benefit of patients and their families is the same amount that would have accumulated if the CTG Special Arrangement had not applied (subsection 11(4)); and
- the Commonwealth will pay CTG approved suppliers the difference between the regular PBS co-payment and the reduced co-payment paid by the patient (section 13).

The special patient contribution provisions of the CTG Special Arrangement will not apply to relevant supplies under the Botox Special Arrangement.

Subsection 11(3E) of the CTG Special Arrangement, which relates to the charging of delivery fees by approved pharmacists and approved medical practitioners, does not apply as it is not

relevant to the Botox Special Arrangement (because only approved hospital authorities can supply pharmaceutical benefits under the Botox Special Arrangement).

The new section 25 provides that a claim for payment from the Commonwealth in relation to a relevant supply under the Botox Special Arrangement must be made in accordance with the rules made under subsections 98AC(4) and 99AAA(8) of the Act, except that claims made using the manual system must include an indicator that the patient is a CTG registered patient.

As noted for item 1, the CTG Special Arrangement is incorporated by reference as in force from time to time and can be accessed for free on the Federal Register of Legislation.

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

The initial changes to the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016* (CTG Special Arrangement) are summarised below.

Item 6 – Subsection 5(2)

This item amends subsection 5(2) of the CTG Special Arrangement to remove the restriction on its application to pharmaceutical benefits that can only be supplied under Part VII of the Act in accordance with another special arrangement under section 100 of the Act. This amendment allows the CTG Special Arrangement to be applied to pharmaceutical benefits that are supplied under the other five special arrangements made under section 100 of the Act referred to in the instrument (namely, the Botox Special Arrangement, EFC Special Arrangement, Growth Hormone Special Arrangement, HSD Special Arrangement, and the IVF Special Arrangement).

Item 7 – Section 5 (note)

This item amends the note at the end of section 5 of the CTG Special Arrangement to indicate that the provisions of the CTG Special Arrangement that modify the Act in relation to:

- charges for the supply of a pharmaceutical benefit; and
- payments to a CTG supplier by the Commonwealth for the supply of a pharmaceutical benefit;

may also apply to the supply of pharmaceutical benefits under other special arrangements to a person who is a CTG registered patient under subsection 10(2) of the CTG Special Arrangement.

Item 8 – Section 11 (at the end of the heading)

This item amends the heading of section 11 of the CTG Special Arrangement to describe its content more appropriately.

Item 9 – Paragraph 14(2)(b)

This item corrects an existing drafting error in paragraph 14(2)(b) of the CTG Special Arrangement. That paragraph currently provides that claims for payment from the Commonwealth must include an indicator that the claim is being made for the supply of a pharmaceutical benefit under the CTG Special Arrangement, *unless* the claim is made using the manual system. The amendment provides that *only* claims made using the manual system need to include that indicator.

Item 10 – Sections 16 and 17

This item repeals transitional arrangements in sections 16 and 17 of the CTG Special Arrangement relating to now historic amendments made by the *National Health (Closing the Gap – PBS Co-payment Program) Amendment Special Arrangement 2021*.

Item 11 – Division 2 of Part 2

This item repeals Division 2 of Part 2 of the CTG Special Arrangement pertaining to historic transitional arrangements regarding the supply of pharmaceutical benefits under Continued Dispensing arrangements.

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024

The changes to the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* (EFC Special Arrangement) are summarised below.

The references to an ‘original special arrangement supply of a dose of a chemotherapy drug’ are to an initial special arrangement supply of a dose of a chemotherapy drug listed in Schedule 1 of the EFC Special Arrangement. These are medicines used for the treatment of cancer that are administered through infusion or injection.

The references to a ‘special arrangement supply of a related pharmaceutical benefit’ are to an initial or repeated special arrangement supply of a pharmaceutical benefit listed in Schedule 2 of the EFC Special Arrangement. These are medicines used to manage side effects associated with a chemotherapy drug.

The terms ‘dose’ and ‘special arrangement supply’ are defined in sections 5 and 10 of the EFC Special Arrangement respectively.

Item 12 – Section 5

This item inserts definitions of *CTG registered patient*, *CTG Special Arrangement* and *CTG supplier* into section 5 of the EFC Special Arrangement. These definitions are the same as those being introduced into the Botox Special Arrangement.

These definitions incorporate the CTG Special Arrangement as in force from time to time. A copy of the instrument is available free of charge on the Federal Register of Legislation at www.legislation.gov.au.

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

This item inserts a new subparagraph 26(2)(c)(iv) into the EFC Special Arrangement. The new subparagraph provides that a claim for payment made using the manual system in relation to a special arrangement supply of a dose of a chemotherapy drug under the EFC Special Arrangement, where the eligible patient is a CTG registered patient and the supplier is a CTG supplier, must include an indicator that the patient is a CTG registered patient.

Item 14 – At the end of section 26

This item inserts new subsections 26(3) and (4) into the EFC Special Arrangement. The new subsections provide that a claim or giving of information in relation to a special arrangement supply of a related pharmaceutical benefit made using the manual system where the eligible patient is a CTG registered patient, and the supplier is a CTG supplier, must include an indicator that the eligible patient is a CTG registered patient.

Items 15 and 16 – Subsection 27(1) and at the end of subsection 27(1)

These items amend subsection 27(1) of the EFC Special Arrangement, to refer to the new section 40. The effect is that the new section 40, rather than subsection 27(1), sets out the entitlement of approved pharmacists and approved medical practitioners who are CTG suppliers to payment from the Commonwealth in relation to *original* special arrangement supplies of a dose of a chemotherapy drug to a CTG registered patient under the EFC Special Arrangement. Subsection 27(1) of the EFC Special Arrangement will continue to apply in relation to repeated special arrangement supplies by approved pharmacists and approved medical practitioners of a dose of a chemotherapy drug.

Items 17, 18 and 19 – Subsection 28(1), subsection 28(1) (before the note) and subsection 28(1) (note)

Items 17 and 18 amend subsection 28(1) of the EFC Special Arrangement to refer to a new Part 5 of the EFC Special Arrangement. The effect is that the new Part 5, rather than subsection 28(1), sets out the entitlement of approved hospital authorities who are CTG suppliers to payment from the Commonwealth in relation to original special arrangement supplies of a dose of a chemotherapy drug, and to a special arrangement supplies of a related pharmaceutical benefit to a CTG registered patient under the EFC Special Arrangement. Paragraph 28(3)(b) of the EFC Special Arrangement will continue to apply in relation to repeated special arrangement supplies by approved hospital authorities of a dose of a chemotherapy drug.

Item 19 is a minor consequential amendment as a result of the insertion of an additional note under subsection 28(1) introduced by Item 18.

Item 20 – Subsection 36(1)

This item amends subsection 36(1) of the EFC Special Arrangement to make that subsection subject to the new section 40 of the EFC Special Arrangement. The effect is that the new section 40, rather than subsection 36(1), sets out the amount of patient co-payment that an approved pharmacist or approved medical practitioner who is a CTG supplier can charge CTG registered patients for original special arrangement supplies of a dose of chemotherapy drug.

Item 21 – At the end of subsection 36(1)

This item inserts a note at the end of subsection 36(1) of the EFC Special Arrangement to refer to a new section 40 applying to an original special arrangement supply of a dose of a chemotherapy drug to a CTG registered patient by a CTG supplier.

Item 22 – After subsection 36(3)

This item inserts a new subsection 36(3A) after subsection 36(3) of the EFC Special Arrangement which provides that no amount may be charged under subsections 11(1) to (3) of the CTG Special Arrangement (co-payment reduction etc.) for a repeated supply under the EFC Special Arrangement if the supply is made to an eligible patient who is a CTG registered patient by a CTG supplier. This has the effect that CTG registered patients will not be charged a co-payment for repeated supplies of doses of chemotherapy drugs by approved pharmacists and approved medical practitioners under the EFC Special Arrangement.

As noted for item 12, the CTG Special Arrangement is incorporated by reference as in force from time to time and can be accessed for free on the Federal Register of Legislation.

Item 23 – Subsection 37(1)

This item amends subsection 37(1) of the EFC Special Arrangement to make that subsection subject to the new section 40 of the EFC Special Arrangement. This will have the same effect

as item 20 but in relation to original special arrangement supplies of doses of a chemotherapy drug by approved hospital authorities that are CTG suppliers to CTG registered patients.

Item 24 – At the end of subsection 37(1)

This item inserts a note at the end of subsection 37(1) of the EFC Special Arrangement to refer to the new section 40 applying to an original special arrangement supply of a dose of a chemotherapy drug to a CTG registered patient by a CTG supplier.

Item 25 – After subsection 37(3)

This item inserts a new subsection 37(3A) after subsection 37(3) of the EFC Special Arrangement which provides that no amount may be charged under subsections 11(1) to (3) of the CTG Special Arrangement (co-payment reduction etc.) for a repeated supply under the EFC Special Arrangement if the supply is made to an eligible patient who is a CTG registered patient by a CTG supplier. This has the effect that CTG registered patients will not be charged a co-payment for repeated supplies of doses of chemotherapy drugs by approved hospital authorities under the EFC Special Arrangement.

As noted for item 12, the CTG Special Arrangement is incorporated by reference as in force from time to time and can be accessed for free on the Federal Register of Legislation.

Items 26 and 27 – Subsection 39(2) (before the note) and subsection 39(2) (note)

Item 26 inserts a new note before the existing note at the end of subsection 39(2) of the EFC Special Arrangement to refer to the new section 40 relating to an original special arrangement supply of a dose of a chemotherapy drug to a CTG registered patient by a CTG supplier.

Item 27 is a minor consequential amendment as a result of the insertion of the additional note under subsection 39(2).

Item 28 – After Part 4

This item inserts a new **Part 5 —Supply to CTG registered patients by CTG suppliers** into the EFC Special Arrangement. Part 5 introduces new sections 40 and 41 into the EFC Special Arrangement.

The new section 40 provides that subsections 11(1), (2), (3), and (4) (co-payment reduction etc.) and 13 (payment by Commonwealth) of the CTG Special Arrangement apply under the EFC Special arrangement in relation to an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to an eligible patient who is a CTG registered patient by an approved supplier who is a CTG supplier. Until Schedule 2 commences, approved hospital authorities for public hospitals are not CTG suppliers.

The new section 41 provides that subsections 11(1), (2), (3), and (4) (co-payment reduction etc.) and 13 (payment by Commonwealth) of the CTG Special Arrangement apply under the EFC Special arrangement in relation to a special arrangement supply of a related pharmaceutical benefit if the supply is made to an eligible patient who is a CTG registered patient by an approved hospital authority who is a CTG supplier. Until Schedule 2 commences, approved hospital authorities for public hospitals are not CTG suppliers.

These sections have the same effect in relation to ‘original special arrangement supplies of a dose of a chemotherapy drug’ and ‘special arrangement supplies of related pharmaceutical benefits’ as the new section 24 of the Botox Special Arrangement (inserted by item 5) has in relation to relevant supplies under that special arrangement. As with the Botox Special Arrangement:

- the special patient contribution provisions of the CTG Special Arrangement will not apply to these supplies; and
- subsection 11(3E) of the CTG Special Arrangement, which relates to the charging of delivery fees by approved pharmacists and approved medical practitioners, does not apply under the EFC Special Arrangement. The EFC Special Arrangement does not allow for approved pharmacists and approved medical practitioners to charge delivery fees under subsection 87(4) of the Act.

As noted for item 12, the CTG Special Arrangement is incorporated by reference as in force from time to time and can be accessed for free on the Federal Register of Legislation.

National Health (Growth Hormone Program) Special Arrangement 2015

The changes to the *National Health (Growth Hormone Program) Special Arrangement 2015* (Growth Hormone Special Arrangement) are summarised below.

Item 29 – Subsection 4(1)

This item inserts definitions of ***CTG registered patient***, ***CTG Special Arrangement*** and ***CTG supplier*** into subsection 4(1) of the Growth Hormone Special Arrangement. These definitions are the same as those being introduced into the Botox Special Arrangement.

These definitions incorporate the CTG Special Arrangement as in force from time to time. A copy of the instrument is available free of charge on the Federal Register of Legislation at www.legislation.gov.au.

Items 30, 31 and 32 – At the end of subsections 14(1), 15(1) and 23(1)

These items insert notes at the end of subsections 14(1), 15(1) and 23(1) of the Growth Hormone Special Arrangement to direct readers to refer to the new Part 6A of the Growth Hormone Special Arrangement in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier under this Special Arrangement. This is because the new Part 6A provides that sections 14, 15 and 23 of the Growth Hormone Special Arrangement that relate to payment by the Commonwealth and patient contributions do not apply to such supplies.

Item 33 – After Part 6

Inserts a new **Part 6A —Supply to CTG registered patients by CTG suppliers** into the Growth Hormone Special Arrangement. Part 6A introduces new sections 23A, 23B and 23C into the Growth Hormone Special Arrangement.

The new section 23A provides that Part 6A applies to the supply of a pharmaceutical benefit (relevant supply) under the Growth Hormone Special Arrangement to a CTG registered patient by an approved supplier who is a CTG supplier. Until Schedule 2 commences, approved hospital authorities for public hospitals are not CTG suppliers.

The new section 23B provides that 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 a relevant supply under the Growth Hormone Special Arrangement. This has the same effect as the new section 24 of the Botox Special Arrangement (inserted by item 5) has in relation to relevant supplies under that special arrangement, except that application of subsections 11(1), (2), (3) and (4) of the CTG Special Arrangement will not prevent CTG suppliers who are approved pharmacists and approved medical practitioners from

charging delivery fees in accordance with subsection 87(4) of the Act (by reason of the application of subsection 11(3E)).

The special patient contribution provisions of the CTG Special Arrangement will not apply to relevant supplies under the Growth Hormone Special Arrangement.

The new section 23C provides that a claim for payment from the Commonwealth in relation to a relevant supply under the Growth Hormone Special Arrangement must be made in accordance with the rules made under subsections 98AC(4) and 99AAA(8) of the Act, except that claims made using the manual system must include an indicator that the patient is a CTG registered patient.

As noted for item 29, the CTG Special Arrangement is incorporated by reference as in force from time to time and can be accessed for free on the Federal Register of Legislation.

National Health (Highly Specialised Drugs Program) Special Arrangement 2021

The changes to the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (HSD Special Arrangement) are summarised below.

Item 34 – Section 6

This item inserts definitions of ***CTG registered patient***, ***CTG Special Arrangement*** and ***CTG supplier*** into section 6 of the HSD Special Arrangement. These definitions are the same as those being introduced into the Botox Special Arrangement.

These definitions incorporate the CTG Special Arrangement as in force from time to time. A copy of the instrument is available free of charge on the Federal Register of Legislation at www.legislation.gov.au.

Items 35, 36, 37, 38 and 39 – Subsection 28(1) (note), at the end of subsection 28(1), at the end of subsection 30(1), subsection 31(1) (note), at the end of subsection 31(1)

These items insert and make adjustments to notes at the end of subsections 28(1), 30(1) and 31(1) of the HSD Special Arrangement to direct readers to refer to the new Part 3A of the HSD Special Arrangement in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier. This is because the new Part 3A provides that sections 28, 30 and 31 of the HSD Special Arrangement that relate to payment by the Commonwealth do not apply to such supplies.

Item 40 – After Part 3

This item inserts a new **Part 3A —Supply to CTG registered patients by CTG suppliers** into the HSD Special Arrangement. Part 3A introduces new sections 34A and 34B into the HSD Special Arrangement.

The new section 34A provides that Part 3A applies to the supply of a pharmaceutical benefit (relevant supply) under the HSD Special Arrangement to an eligible patient who is a CTG registered patient by an approved supplier who is a CTG supplier. Until Schedule 2 commences, approved hospital authorities for public hospitals are not CTG suppliers.

The new section 34B provides that 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 a relevant supply under the HSD Special Arrangement. This has the same

effect as the new section 23B of the Growth Hormone Special Arrangement (inserted by item 33) has in relation to relevant supplies under that special arrangement.

The special patient contribution provisions of the CTG Special Arrangement will not apply to relevant supplies under the HSD Special Arrangement.

As noted for item 34, the CTG Special Arrangement is incorporated by reference as in force from time to time and can be accessed for free on the Federal Register of Legislation.

Item 41 – At the end of Part 4

This item inserts a new section 35A at the end of Part 4 of the HSD Special Arrangement which provides that manual claims for payment made under the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* in relation to a special arrangement supplies of an HSD pharmaceutical benefit by approved suppliers who are CTG suppliers to eligible patients who are CTG registered patients must include an indicator that the eligible patient is a CTG registered patient.

The *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* is incorporated by reference as in force from time to time and can be accessed free of charge on the Federal Register of Legislation.

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

This item inserts a note at the end of subsections 37(1) and 37(2) of the HSD Special Arrangement to direct readers to the new Part 3A of the HSD Special Arrangement in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier. This is because the new Part 3A provides that section 37 of the HSD Special Arrangement that relates to the patient PBS safety net does not apply to such supplies.

National Health (IVF Program) Special Arrangement 2015

The changes to the *National Health (IVF Program) Special Arrangement 2015* (IVF Special Arrangement) are summarised below.

Item 43 – Section 4

This item inserts definitions of *CTG registered patient*, *CTG Special Arrangement* and *CTG supplier* into section 4 of the IVF Special Arrangement. These definitions are the same as those being introduced into the Botox Special Arrangement.

These definitions incorporate the CTG Special Arrangement as in force from time to time. A copy of the instrument is available free of charge on the Federal Register of Legislation at www.legislation.gov.au.

Items 44, 45, and 48 – At the end of subsections 8(1), 9(1) and 17(1)

These items insert notes at the end of subsections 8(1), 9(1) and 17(1) of the IVF Special Arrangement to direct readers to refer to the new Part 5A of the IVF Special Arrangement in relation to the supply of a pharmaceutical benefit to a CTG registered patient by a CTG supplier. This is because the new Part 5A provides that sections 8, 9 and 17 of the IVF Special Arrangement relating to payment by the Commonwealth and patient contributions do not apply to such supplies.

Item 46 – Subsection 17(1)

This item replaces the reference to ‘approved hospital authority for a public or a private hospital’ with ‘approved hospital authority’, as all approved hospital authorities are either for a public hospital or a private hospital.

Item 47 – Subsection 17(1)

This item replaces the reference to ‘eligible patient’ with ‘patient’, as ‘eligible patient’ is not otherwise defined in the IVF Special Arrangement or the Act.

Item 49 – Subsection 17(2)

This item amends subsection 17(2) of the IVF Special Arrangement to enable an approved pharmacist or approved medical practitioner to charge patient contributions equivalent to the amount that may be charged under section 87 of the Act in relation to supplies of pharmaceutical benefits under the IVF Special Arrangement. Subsection 17(2) of the IVF Special Arrangement currently only allows an approved hospital authority to charge patient contributions for supplies of pharmaceutical benefits under the IVF Special Arrangement.

Item 50 – After Part 5

This item inserts a new **Part 5A —Supply to CTG registered patients by CTG suppliers** into the IVF Special Arrangement. Part 5A introduces new sections 17A and 17B into the IVF Special Arrangement.

The new section 17A provides that Part 5A applies to the supply of a pharmaceutical benefit (relevant supply) under the IVF Special Arrangement to a CTG registered patient by an approved supplier who is a CTG supplier. Until Schedule 2 commences, approved hospital authorities for public hospitals are not CTG suppliers.

The new section 17B provides that 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 a relevant supply under the IVF Special Arrangement. This has the same effect as the new section 23B of the Growth Hormone Special Arrangement (inserted by item 33) has in relation to relevant supplies under that special arrangement.

The special patient contribution provisions of the CTG Special Arrangement will not apply to relevant supplies under the IVF Special Arrangement.

As noted for item 43, the CTG Special Arrangement is incorporated by reference as in force from time to time and can be accessed for free on the Federal Register of Legislation.

Item 51 – At the end of subsection 19(2)

This item inserts a new paragraph 19(2)(b) into the IVF Special Arrangement which provides that a claim for payment made using the manual system by an approved supplier who is a CTG supplier, in relation to a supply to a patient who is a CTG registered patient, must include an indicator that the patient is a CTG registered patient.

Schedule 2 – Approved hospital authorities

The amendments in Schedule 2 involve amendments to the CTG Special Arrangement to additionally enable approved hospital authorities for public hospitals to supply pharmaceutical benefits under the CTG Special Arrangement.

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

Items 1, 4 and 5 – Section 4 (definition of CTG supplier), paragraph 10A(1)(c), paragraph 11(3C)(a)

These items amend references to ‘approved hospital authority for a private hospital’ to ‘approved hospital authority’, the effect of which is to extend the application of the CTG Special Arrangement to include supplies made by approved hospital authorities for both private and public hospitals.

Items 2 and 3 – Section 4 (note at the end)

These items amend the list of words and expressions in the note at the end of section 4 of the CTG Special Arrangement to include the term ‘approved hospital authority’ and remove the term ‘private hospital’. This has the same effect as items 1, 4 and 5 which is to extend the application of the CTG Special Arrangement to include supplies made by approved hospital authorities for both private and public hospitals.

Statement of Compatibility with Human Rights

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

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

PB 66 of 2024

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 *National Health Legislation Amendment (Extension of Closing the Gap – PBS Co-payment Program) Instrument 2024* (Instrument) broadens access to the Closing the Gap (CTG) Pharmaceutical Benefits Scheme (PBS) Co-payment Program, as announced by the Australian Government as part of the 2024-25 Budget, so that it also applies to pharmaceutical benefits:

- supplied by approved hospital authorities for public hospitals; and
- that can only be supplied in accordance with the five special arrangements made under section 100 of the *National Health Act 1953* (Act) specified below.

In particular, the Instrument amends the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016* (CTG Special Arrangement) to:

- allow the provisions of the CTG Special Arrangement to be applied to pharmaceutical benefits that can only be supplied in accordance with another special arrangement under section 100 of the Act, in addition to pharmaceutical benefits that are generally available for supply under Part VII of the Act (to which the CTG Special Arrangement already applies);
- correct a drafting error relating to use of the manual system for making a claim for payment from the Commonwealth for the supply of a pharmaceutical benefit under the CTG Special Arrangement;
- repeal historic transitional arrangements relating to the supply of pharmaceutical benefits under the CTG Special Arrangement under Continued Dispensing arrangements; and
- enable approved hospital authorities for public hospitals to supply pharmaceutical benefits under the CTG Special Arrangement, in addition to approved pharmacists, approved medical practitioners or approved hospital authorities for private hospitals (to which the CTG Special Arrangement already applies).

In addition, this Instrument also makes consequential amendments to the following five special arrangements made under section 100 of the Act to enable specific provisions under the CTG Special Arrangement to apply to the supply of pharmaceutical benefits under those arrangements (namely, provisions that relate to patient co-payment reduction, payment by the Commonwealth, contributions to a patient's PBS safety net and making claims for payment):

- *National Health (Botulinum Toxin Program) Special Arrangement 2015*;
- *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024*;
- *National Health (Growth Hormone Program) Special Arrangement 2015*;

- *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*; and
- *National Health (IVF Program) Special Arrangement 2015*.

The effect of these consequential amendments will be that supplies of pharmaceutical benefits under each of these five section 100 special arrangements to CTG patients by CTG suppliers (who are also eligible to supply under the relevant section 100 special arrangement) will attract the lower patient co-payment provided under the CTG Special Arrangement. In each case the special patient contribution provisions of the CTG Special Arrangement will *not* apply to such supplies under any of the five section 100 special arrangements specified above.

Human rights implications

This instrument engages with 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 PBS is a benefit scheme which assists with advancement of these rights by providing for subsidised access to medicines. This instrument ensures ready and equitable access to an increased number of PBS medicines for eligible First Nations people by expanding the application of relevant provisions under the CTG Special Arrangement beyond pharmaceutical benefits that are generally available for supply under Part VII of the Act to those supplied under the five special arrangements mentioned above. Amongst other things, this means that the reduced patient co-payment under the CTG Special Arrangement will apply to relevant supplies under the other five special arrangements. This ensures ready and equitable access to an increased number of PBS medicines with a reduced PBS patient co-payment for eligible First Nations people. The Instrument also advances the rights under Articles 2 and 12 of the ICESCR by expanding the definition of CTG supplier under the CTG Special Arrangement to also include approved hospital authorities for public hospitals. This ultimately allows for more types of supplies of pharmaceutical benefits to be captured as CTG supplies under the CTG Special Arrangement, therefore creating more avenues for access to affordable medicines for First Nations people. This Instrument ensures that necessary amendments to the CTG Special Arrangement, and each of the five section 100 special arrangements specified above, are made concurrently.

Conclusion

The Instrument is compatible with human rights because, by expanding the application of the CTG Special Arrangement to include pharmaceutical benefits supplied under five section 100 special arrangements and supplies by approved hospital authorities for public hospitals, it recognises and advances the right to the enjoyment of the highest attainable standard of physical and mental health.

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