

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) AMENDMENT (COVID-19 SIMPLIFIED PRESCRIBING) SPECIAL ARRANGEMENT 2020

PB 53 of 2020

Authority

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the adequate supply of pharmaceutical benefits. Subsection 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).

Purpose

The purpose of the *National Health (Efficient Funding of Chemotherapy) Amendment (COVID-19 Simplified Prescribing) Special Arrangement 2020* (the Instrument), made under subsection 100(1) of the Act, is to amend the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011) (the Special Arrangement) to make changes relating to the Efficient Funding of Chemotherapy (EFC).

The Special Arrangement achieves greater efficiency in payments through the Pharmaceutical Benefits Scheme (PBS) for the supply of injected or infused chemotherapy medicines ('chemotherapy pharmaceutical benefits') to eligible patients being treated in, at or from approved public and private hospitals. The Special Arrangement also relates to the supply of PBS medicines associated with the side-effects of cancer and cancer treatment ('related pharmaceutical benefits') at certain public hospitals.

Chemotherapy Compounders made initial contact with the Department raising concerns that timely access to chemotherapy medicines for vulnerable patients during the COVID-19 crisis may be at risk because of the current requirements for prescribing EFC medicines.

This Instrument amends the Special Arrangement to enable eligible public hospitals to use a 'chemotherapy medication chart' to write prescriptions for infusions and related pharmaceutical benefits, and private hospitals to use a chemotherapy medication chart to write prescriptions for infusions, without the requirement for the original paper prescriptions.

Minor updates have also been made to the Special Arrangement to ensure consistency with current practices and protocols and up to date terminology.

A description of this Instrument is contained in the Attachment.

Consultations

Chemotherapy Compounders were consulted in the development on the amendments to the Special Arrangements. Consultation also occurred with Services Australia and with relevant areas within the Department of Health.

This Instrument commences on the day after it is registered.

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

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) AMENDMENT (COVID-19 SIMPLIFIED PRESCRIBING) SPECIAL ARRANGEMENT 2020*

Section 1 Name of Instrument

This section provides that this Instrument is the *National Health (Efficient Funding of Chemotherapy) Amendment (COVID-19 Simplified Prescribing) Special Arrangement 2020* and that it may also be cited as PB 53 of 2020.

Section 2 Commencement

This section provides that this Instrument commences on the day after this instrument is registered.

Section 3 Authority

This section provides that this Instrument is made under subsection 100(1) of the *National Health Act 1953* (the Act).

Section 4 Schedules

This section provides that 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 concern, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 reflect changes in the prescribing of chemotherapy medicines, enabling prescribers to also use a chemotherapy medication chart prescription or an electronic chemotherapy medication chart prescription to prescribe chemotherapy medication and related benefits. Pharmacists are now able to use the chemotherapy medication chart or the electronic chemotherapy medication chart to dispense chemotherapy medicines without the need for duplication or a paper prescription. Minor updates have also been made to this Special Arrangement to ensure consistency and up to date terminology. These changes are summarised below.

Schedule 1 – Amendments

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011

Items 1-5 – Section 3

Item 1 renumbers existing section 3 as subsection 3(1), as a consequence of the insertion of new subsection 3(2) by item 5.

Item 2 inserts the following definitions into subsection 3(1):

chemotherapy medication chart prescription means a section of medication chart directing the supply of an infusion or a related pharmaceutical benefit.

electronic chemotherapy medication chart prescription means a chemotherapy medication chart directing the supply of an infusion or a related pharmaceutical benefit, prepared in an electronic medication chart system.

electronic medication chart system means a software system that is used for prescribing and recording the administration of medicines to persons receiving treatment in, at or from a public or private hospital.

Chemotherapy medication chart prescriptions are not required to be written on a form of medication chart approved for the purposes of section 41 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations).

Items 3 and 4 repeal the definition of ‘infusion medication chart prescription’ and ‘medication chart prescription’. These definitions are redundant with the introduction of the concept of a chemotherapy medication chart.

Item 5 adds a new subsection 3(2) which provides that a reference to a chemotherapy medication chart prescription in the Special Arrangement includes a reference to an electronic chemotherapy medication chart prescription.

Item 6 – Subsection 14(1)

Item 6 repeals and substitutes subsection 14(1). Subsection 14(1) deals with the methods of prescribing a chemotherapy pharmaceutical benefit in an infusion to reflect the two ways an authorised prescriber can prescribe a chemotherapy medication, being:

- by writing an infusion prescription, in accordance with section 40 of the Regulations as modified by the Special Arrangement; or
- by preparing a chemotherapy medication chart, that is, a section of a medication chart directing the supply of an infusion or a related pharmaceutical benefit, in accordance with section 41 of the Regulations as modified by the Special Arrangement.

Item 7 – Subsection 14(2)

Item 7 makes a technical change to subsection 14(2) to omit reference to “an infusion medication chart prescription” and replace with “a chemotherapy medication chart prescription directing the supply of an infusion”.

Item 8 – Subsection 14(3)

Item 8 repeals subsection 14(3), which required prescriptions for infusions containing trastuzumab or bortezomib to only be written using an infusion prescription. Following the amendments made in 2019 to enable streamlined prescribing for trastuzumab, and in 2018 for bortezomib, the requirement to only use an infusion prescription is now redundant and is being removed.

Item 9 – Subsection 14(4)

Item 9 repeals and replaces subsection 14(4) to provide that:

- where an infusion prescription is written in accordance with section 40 of the Regulations as modified by section 15, the prescription is taken to be written in accordance with section 40 of the Regulations; and

- where a chemotherapy medication chart prescription is written in accordance with section 41 of the Regulations as modified by section 16, the prescription is taken to be written in accordance with section 41 of the Regulations.

Item 9 is intended to provide that the requirement of the Regulations that a prescription be written in accordance with section 40 or section 41 is met for infusion prescriptions or chemotherapy medication chart prescriptions written in accordance with this Special Arrangement and replaces outdated terminology referring to validly written prescriptions.

Items 10 and 11 – Sections 15 and 16

Items 10 and 11 omit “infusion medication chart prescriptions” in the heading of the sections 15 and 16 and substitutes “chemotherapy medication chart prescription directing the supply of an infusion”.

Item 12 – Section 16

Item 12 repeals and replaces section 16 (including the note). Section 16 of the Special Arrangement modifies the requirements for writing medication chart prescriptions as set out in section 41 of the Regulations.

Subsection 16(2) makes clear that a medication chart used to write a chemotherapy medication chart prescription is not required to be in a form approved under the Regulations for standard PBS medication chart prescribing.

Subsections 16(3) and (4) provide that a chemotherapy medication chart prescription directing the supply of an infusion must include the following information:

- the name of each chemotherapy drug included in the infusion; and
- for each chemotherapy drug – the dose, the frequency of administration and the route of administration.

However, a completed section of a chemotherapy medication chart prescription does not need to include the form of the chemotherapy drug to be supplied.

Subsection 16(5) provides that section 41 of the Regulations applies as if references to a person receiving treatment in or at a hospital includes a reference to a person receiving treatment from a hospital. This adjustment reflects the existing definitions of eligible public hospital patient and eligible private hospital patient in the Special Arrangement.

Subsection 16(6) modifies the operation of the Regulations in relation to prescriptions written using chemotherapy medication chart prescriptions in an electronic medication chart system, being a software system that is used for prescription and recording the administration of medicines to persons receiving treatment at or from a public or private hospital. The modifications adjust requirements in the Regulations for prescribers to write certain information on prescriptions.

Item 13 – Paragraph 17(1)(b)

Item 13 makes a consequential change to omit “an infusion medication chart prescription” and substitutes with “a chemotherapy medication chart prescription” in paragraph 17(1)(b).

Item 14 – Subsection 17(2)

Item 14 repeals and substitutes a new subsection 17(2), which modifies the operation of section 30 of the Regulations. New subsection 17(2) expands the modification of section 30 to ensure that a

reference in section 30 to persons receiving treatment in or at a hospital includes reference to patients receiving treatment from a hospital, references to electronic prescriptions include reference to electronic chemotherapy medication chart prescriptions and references to compliance with subsection 41(2) of the Regulations includes reference to compliance with subsection 41(2) as modified by section 16 of the Special Arrangement.

Item 15 – Paragraph 17(3)(b)

Item 15 omits reference to “an infusion medication chart prescription” and substitutes with reference to “a chemotherapy medication chart prescription” in paragraph 17(3)(b).

Item 16 – Subsection 17(4)

Item 16 repeals and substitutes subsection 17(4) to expand the modifications of section 30 of the Regulations made by the Special Arrangement in relation to prescriptions for infusion benefits where the dose of number of repeats is greater than the maximum. These modifications ensure that reference in section 30 to persons receiving treatment in or at a hospital includes reference to patients receiving treatment from a hospital, references to electronic prescriptions include reference to electronic chemotherapy medication chart prescriptions and references to compliance with subsection 41(2) of the Regulations includes reference to compliance with subsection 41(2) as modified by section 16 of the Special Arrangement.

Item 17 – Section 19

Item 17 repeals and substitutes section 19, which sets out how related pharmaceutical benefits may be prescribed. New section 19 provides that a related pharmaceutical benefit can be prescribed under this Special Arrangement by:

- writing a prescription for a related pharmaceutical benefit in accordance with section 40 of the Regulations; or
- writing a chemotherapy medication chart prescription for the related benefit in accordance with section 41 of the Regulations as modified by section 20.

The existing note to section 19, which clarifies for the reader that related pharmaceutical benefits can only be supplied under the Special Arrangement by a participating hospital authority to an eligible public hospital patient, is replaced.

Item 18 - After section 19

Item 18 inserts a new section 20 to modify requirements in the Regulations in respect of the prescribing of related pharmaceutical benefits.

Subsection 20(2) provides that prescriptions for related pharmaceutical benefits may be written under this Special Arrangement using a medication chart that is not in a form approved under the Regulations.

Subsection 20(3) modifies section 41 of the Regulations so that a reference in section 41 to a person receiving treatment in or at a hospital will include reference to a person receiving treatment from a hospital.

Subsection 20(4) modifies requirements in the Regulations to facilitate the use of an electronic chemotherapy medication chart prescription. In that case, the requirement for a prescriber to include a signature on the prescription does not apply, but the prescriber must electronically approve the

electronic chemotherapy medication chart prescription in the electronic medication chart system, and include the authority approval number (if any) for the prescription.

Item 19 – Subsection 22(1)

Item 19 omits reference to an “infusion medication chart prescription”, and inserts reference to a “chemotherapy medication chart prescription used to direct the supply of an infusion” in subsection 22(1).

Item 20 – Subsection 22(1)

Item 20 omits reference to ‘compliance with modified Written Authority Required procedures’ in subsection 22(1), as any chemotherapy medicines which require additional documentation as part of the Written Authority Required process now have this information included in the text of the PBS restriction and modified authority required procedures are no longer in use under the Special Arrangement.

Items 21 and 22 – Subsection 22(2)

Item 21 inserts the word “chemotherapy” so that a “medication chart prescription” is now a “chemotherapy medication chart prescription”. Section 22 of the Special Arrangement deals with authority required procedures for prescriptions for chemotherapy pharmaceutical benefits and related pharmaceutical benefits. Item 21 makes consequential changes to that the existing reference to a medication chart prescription for a related pharmaceutical benefit in section 22 becomes a reference to a “chemotherapy medication chart prescription”.

Item 22 omits reference to ‘compliance with modified Written Authority Required procedures’ paragraph 22(2)(c), as those modified procedures are no longer followed in obtaining authority approvals for any medicines under the Special Arrangement.

Item 23 – Subsection 22(3)

Item 23 repeals and replaces subsection 22(3) to modify the application of sections 11 to 15 of the of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* for prescriptions that would be authority prescriptions.

Subsection 22(4) provides that references in sections 11 to 15 to medication chart prescriptions include a reference to a chemotherapy medication chart prescription. This provides for authority procedures for paper-based chemotherapy medication chart prescriptions.

Subsections 22(6) to (7) deal with authority procedures for electronic chemotherapy medication chart prescriptions and provide that an authorised prescriber may submit a copy of an electronic chemotherapy medication chart prescription or details of the prescription to the Chief Executive Medicare, and specify what information must be provided where details of the prescription are submitted, to obtain the authority required.

Subsection 22 (8) to (10) set out how the Chief Executive Medicare may authorise an electronic chemotherapy medication chart prescription.

Item 24 – Subsection 22(4)

Item 24 repeals subsection 22(4), which dealt with modified authority required procedures, as these modified procedures are no longer followed.

Item 25 – Subsection 31(3)

Item 25 omits reference to “infusion medication chart prescription”, and inserts reference to “infusion directed to be supplied under a chemotherapy medication chart prescription” in subsection 31(3).

Item 26 – Section 34

Item 26 omits the sub-heading “Infusions” under subsection 34, as the section now deals with matters other than infusion prescriptions and the supply of infusions (see item 27).

Item 27 – Subsection 34(3)

Item 27 repeals and substitutes subsection 34(3), which modifies the application of subsections 45(2) to (7), section 47 and section 49 of the Regulations.

Subsection 34(3) provides that in subsections 45(2) to (7) of the Special Arrangement, references to persons receiving treatment in or at a hospital includes reference to patients who may be receiving treatment from a hospital. This reflects the existing definitions of 'eligible public hospital patient' and 'eligible private hospital patient' in the Special Arrangement.

Subsections 34(3A) and (3B) reflect existing subsection 34(3) and ensure that the requirements in sections 49 and 53 of the Regulations do not apply in relation to the writing of an infusion prescription or the supply of an infusion on the basis of an infusion prescription, respectively.

New subsection 34(3C) appropriately modifies requirements in the Regulations for electronic chemotherapy medication chart prescriptions, including that the supplier must verify in the electronic medication chart prescription that the benefit has been supplied.

Item 28 - Subsection 37(1)

Item 28 inserts a new paragraph 37(1)(ab) in subsection 37(1) which states “a reference to a medication chart prescription includes a reference to a chemotherapy medication chart prescription”.

Item 29 and 30 - Section 48

Items 29 and 30 corrects minor error in drafting errors in section 48. Item 28 omits in section 48 the word “divided by” and substitute it with the mathematical symbol “÷”. Item 30 omits the words “*mark-up for maximum multiple*” and substitutes them with all italicised and bold words “***mark-up for maximum multiple***”.

Item 31 – Part 5A – Record Keeping Requirements

Item 31 inserts a new “Part 5A – Record keeping” which sets out the record-keeping requirements for chemotherapy medication chart prescriptions.

Subsection 59A(1) provides that an approved supplier or public hospital authority who has supplied an infusion or a related pharmaceutical benefit under the Special Arrangement on the basis of a chemotherapy medication chart prescription must keep the chemotherapy medication chart, or a copy, including details required by subsection 45(2) of the Regulations or the electronic verification required by subsection 34(3C) of this Special Arrangement. This must be kept for a period of at least 2 years from the date the pharmaceutical benefit is supplied, which time-period reflects existing requirements in the Regulations.

The record-keeping requirements in relation to the supply of an infusion or a related pharmaceutical benefit on the basis of an infusion prescription are captured by section 59 of the Regulations. A note has been included to this effect.

Item 32 – Section 60

Item 32 repeals section 60, a spent transitional provision, and inserts new transitional provisions.

Section 60 ensures that the Special Arrangement as in force immediately before the amendments made by the Instrument continues to apply to the prescribing of chemotherapy pharmaceutical benefits or related pharmaceutical benefits using the same chart that was used to prescribe benefits under the Special Arrangement prior to the commencement of this Instrument. This ensures that existing medication charts commenced before the amendments take effect can continue to be used to prescribe medicines to patients during their period of validity.

It also ensures that the Special Arrangement as in force immediately before the amendments made by the Instrument continues to apply to the supply of a chemotherapy pharmaceutical benefit or a related pharmaceutical benefit made on the basis of an existing prescription written before the commencement of this Instrument and claims, payment and provisions of under co-payment data in relation to such a supply.

Item 33 - Amendments of listed provisions

Item 33 omits the words “infusion medication chart prescription” and “infusion medication chart prescriptions” and substitutes them with “chemotherapy medication chart prescription” or “chemotherapy medication chart prescriptions” in a number of provisions in the Special Arrangement.

Statement of Compatibility with Human Rights

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

National Health (Efficient Funding of Chemotherapy) Amendment (COVID-19 Simplified Prescribing) Special Arrangement 2020

(PB 53 of 2020)

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(1) of the *National Health Act 1953* (the Act), is to amend the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011) (the Special Arrangement) to make changes relating to the Efficient Funding of Chemotherapy.

The Special Arrangement achieves greater efficiency in payment for the supply of injected or infused chemotherapy medicines ('chemotherapy pharmaceutical benefits') to eligible patients being treated for cancer, to reflect the 2010 Budget measure titled 'Revised arrangements for the efficient funding of chemotherapy drugs'. The Special Arrangement also relates to the supply of medicines associated with the side-effects of cancer and cancer treatment ('related pharmaceutical benefits') at certain public hospitals.

This Instrument amends the Special Arrangement to allow prescriptions for both infused chemotherapy medicines and related pharmaceutical benefits to be written using a 'chemotherapy medication chart'. Chemotherapy medication charts are not required to be in one of the standard approved forms for medication charts used to write PBS prescriptions.

Human Rights Implications

This Legislative Instrument engages Article 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 the advancement of this human right by providing for subsidised access by patients to essential medicines. This Legislative Instrument makes the supply of certain pharmaceutical benefits to patients receiving chemotherapy more efficient and convenient, and reduces contact with vulnerable patients.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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