

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (CHEMOTHERAPY PRESCRIBING) SPECIAL ARRANGEMENT 2020

PB 52 of 2020

Authority

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

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 (Chemotherapy Prescribing) Special Arrangement 2020* (this Special Arrangement), made under subsection 100(1) of the Act, is to make a special arrangement to make the supply of certain pharmaceutical benefits to patients who have been prescribed certain pharmaceutical benefits for the purposes of chemotherapy more efficient and convenient.

This Special Arrangement modifies arrangements for prescribing the supply of pharmaceutical benefits available for general supply, to enable them to be prescribed using a medication chart also used to prescribe the person an infusion or related chemotherapy benefit under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (the EFC Special Arrangement).

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

The EFC Special Arrangement is being amended 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.

This Special Arrangement will enable prescriptions for pharmaceutical benefits available for general supply to be written on a chemotherapy medication chart that is also being used to prescribe a chemotherapy infusion or related pharmaceutical benefit. This Special Arrangement will enable these prescriptions to be written via an electronic chemotherapy medication chart, without the requirement for the original paper prescription, to reduce contact with vulnerable patients.

A description of this Special Arrangement is contained in the Attachment.

Consultations

Chemotherapy Compounders have formed part of ongoing discussions in relation to this Special Arrangement and other amendments relating to the prescriptions and supply of chemotherapy medications, particularly as it may impact on vulnerable patients during the COVID-19 crisis. Consultation also occurred with Services Australia and with relevant areas within the Department of Health.

This Special Arrangement commences at the same time as the commencement of the *National Health (Efficient Funding of Chemotherapy) Amendment (COVID-19 Simplified Prescribing) Special Arrangement 2020*.

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

**DESCRIPTION OF NATIONAL HEALTH (CHEMOTHERAPY PRESCRIBING)
SPECIAL ARRANGEMENT 2020**

Section 1 - Name of Special Arrangement

This section provides that the title of this Special Arrangement is the *National Health (Chemotherapy Prescribing) Special Arrangement 2020* and that it may also be cited as PB 52 of 2020.

Section 2 - Commencement

This section provides that this Instrument to commence at the same time as the commencement of the *National Health (Efficient Funding of Chemotherapy) Amendment (COVID-19 Simplified Prescribing) Special Arrangement 2020*, but will not commence at all if that event does not occur.

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 – Simplified outline of this instrument

This section provides that this Instrument makes a special arrangement to make the supply of certain pharmaceutical benefits to patients who have been prescribed certain pharmaceutical benefits for the purposes of chemotherapy more efficient and convenient.

The instrument modifies arrangements for prescribing the supply of pharmaceutical benefits available for general supply, to enable them to be prescribed using a medication chart also used to prescribe the person an infusion or related chemotherapy benefit under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*.

A note to section 4 provides that subsection 100(3) of the Act provides that Part VII of the Act, and regulations or other instruments made for the purposes of Part VII, have effect subject to this Instrument.

Section 5 – Definitions

This section provides for definitions used in this Instrument.

A number of terms used in the this Instrument have the same meaning as in the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (the EFC Special Arrangement) including 'eligible private hospital patient', 'eligible public hospital patient', 'infusion' and 'related pharmaceutical benefit'. Under the EFC Special Arrangement, infusions are treatments that contain one or more chemotherapy pharmaceutical benefits listed in Part 1

of Schedule 1 of that instrument. Related pharmaceutical benefits are listed in Part 2 of Schedule 1 of the EFC Special Arrangement.

The definition of 'authorised prescriber' ensures that only those classes of persons able to prescribe a pharmaceutical benefit under the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* are able to prescribe the benefit under this Special Arrangement.

The reader is referred to section 8 of the Special Arrangement for the terms 'chemotherapy medication chart', 'chemotherapy medication chart prescription' and 'electronic chemotherapy medication chart prescription'.

Some terms used in this Instrument have the same meaning as in the Act.

Subsection 5(2) provides that in this Instrument, references to the supply of an infusion or a related pharmaceutical benefit refer to supply under the EFC Special Arrangement.

Section 6 – Pharmaceutical benefits covered by this Special Arrangement

This section provides that this Special Arrangement applies to a pharmaceutical benefit that is generally available for supply under Part VII of the Act.

Specific circumstances in which a pharmaceutical benefit is generally available for supply under Part VII of the Act are set out. This is where the pharmaceutical benefit does not contain a drug that is subject to a declaration under subsection 85(2A) of the Act (where it is only available under special arrangements), where it is not subject to a determination under paragraph 85(8)(a) of the Act (where there is a legislative instrument determining it can only be supplied under special arrangements) or where the Minister has determined that, in certain circumstances, it can only be supplied under special arrangements.

Section 6 also makes clear that this Special Arrangement does not apply 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.

Section 7 – Application of Part VII of the Act

This section provides that each pharmaceutical benefit supplied in accordance with this Special Arrangement is supplied under Part VII of the Act, which deals with supply of pharmaceutical benefits. This section also provides that a provision of Part VII, or of regulations or other instruments made for that Part, applies subject to this Special Arrangement.

Section 8 – Method of prescribing pharmaceutical benefits

Subsection 8(1) provides that an authorised prescriber for a pharmaceutical benefit may only write a prescription for a pharmaceutical benefit under this Special Arrangement (a 'chemotherapy medication chart prescription'):

- for an eligible public hospital patient, by completing a section of a medication chart that also directs the supply of an infusion or a related pharmaceutical benefit to the patient; or

- for an eligible private hospital patient, by completing a section of a medication chart that also directs the supply of an infusion to the patient.

This enables prescriptions for pharmaceutical benefits to be written under this Special Arrangement by the completion of part of a medication chart that directs the supply of an infusion or related pharmaceutical benefit (in accordance with the EFC Special Arrangement) and, as provided for in subsection 8(2), a medication chart used to write a chemotherapy medication chart prescription is not required to be in a form approved under the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations).

Subsection 8(3) makes provision for prescriptions written using chemotherapy medication chart prescriptions in an electronic medication chart system, being a software system that is used for prescribing and recording the administration of medicines to persons receiving treatment at or from a public or private hospital.

For these 'electronic chemotherapy medication chart prescriptions', the requirement for including a signature under the Regulations does not apply, but the authorised 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. Electronic chemotherapy medication chart prescriptions are not required to meet the requirements in the Regulations for other electronic prescriptions.

Subsection 8(4) provides that a prescription written in accordance with this section is taken to be written in accordance with section 41 of the Regulations, so the requirement of the Regulations that a prescription be written in accordance with section 40 or section 41 of the Regulations is met for prescriptions written in accordance with this Special Arrangement. The subsection also provides that references in Parts 4 and 5 of the Regulations, which deal with the prescription and supply of pharmaceutical benefits, apply as if a reference to a medication chart prescription in the Regulations (being a prescription on an approved form of medication chart) includes a reference to a chemotherapy medication chart prescription.

The Special Arrangement makes it easier and more convenient to prescribe a general supply pharmaceutical benefit to a patient who is also being prescribed an infusion or related pharmaceutical benefit under the EFC Special Arrangement using the same medication chart. Facilitating the use of electronic medication chart prescribing for these patients without the need to comply with the requirements of the Regulations will also assist in reducing the need for paper prescribing.

Section 9 – Authority required procedures for electronic chemotherapy medication charts

Section 9 of this Special Arrangement modifies the application of sections 11 to 15 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* for prescriptions that would be authority prescriptions.

Subsection 9(2) 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 9(4) to (5) 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. Subsections 9(6) to (8) set out how the Chief Executive Medicare may authorise the electronic chemotherapy medication chart prescription, and requires the Chief Executive Medicare to tell the authorised prescriber the approval number allotted to the prescription, which the authorised prescriber must enter into the prescription.

Section 10 – Supply of pharmaceuticals under this Special Arrangement

This section sets out who may supply a pharmaceutical benefit under this Special Arrangement, being a participating hospital authority to an eligible public hospital patient, an approved hospital authority for a private hospital to an eligible private hospital patient, or an approved pharmacist to an eligible public hospital patient or eligible private hospital patient. Subsection 10(2) provides that a participating hospital authority may not supply a related pharmaceutical benefit under this Special Arrangement. Participating hospital authorities may supply related pharmaceutical benefits under the EFC Special Arrangement.

Subsection 10(3) provides for modifications to the application of subsections 45(2) to (7), section 47 and section 49 of the Regulations. The modifications ensure that references to medication chart prescriptions are to be read as including chemotherapy medication chart prescriptions and reference to persons receiving treatment in or at a hospital includes reference to chemotherapy patients who may be receiving treatment from a hospital, but not in or at that hospital. The requirements in those sections relating to written signatures are appropriately modified for electronic chemotherapy medication chart prescriptions.

Subsection 10(4) provides that section 53 of the Regulations which relates to deferred supply authorisations does not apply to a supply of a pharmaceutical benefit under this Instrument.

Section 11 – Electronic chemotherapy medication chart prescription records

This section sets out the record-keeping requirements for electronic chemotherapy medication chart prescriptions.

Subsection 11(1) provides that an approved hospital authority or approved pharmacist who has supplied a pharmaceutical benefit under this Special Arrangement must keep the chemotherapy medication chart, or a copy, including details required by section 45(2) of the Regulations or the electronic verification required by section 10 of this Special Arrangement. This must be kept for a period of at least 2 years from the date the pharmaceutical benefit is supplied. This ensures documentation and evidence is available if required.

Section 12 – Modified application of legislative instruments

This section ensures that references to medication chart prescriptions in certain other legislative instruments are read as including references to a chemotherapy medication chart prescription or an electronic chemotherapy medication chart prescription as set out in this Special Arrangement.

Statement of Compatibility with Human Rights

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

National Health (Chemotherapy Prescribing) Special Arrangement 2020

(PB 52 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 Legislative Instrument is a special arrangement made under subsection 100(1) of the *National Health Act 1953* (the Act). Its purpose is to make the supply of certain pharmaceutical benefits to patients who are also being prescribed pharmaceutical benefits for the purposes of chemotherapy under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* more efficient and convenient.

This Legislative Instrument modifies arrangements for prescribing the supply of pharmaceutical benefits available for general supply, to enable them to be prescribed using a medication chart also used to prescribe the person an infusion or related chemotherapy benefit under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*.

This Instrument will enable prescription of pharmaceutical benefits and related pharmaceutical benefits via chemotherapy medication chart prescriptions normally used for infused chemotherapy medicines. This Instrument will also enable prescriptions for chemotherapy medicines via electronic chemotherapy medication chart prescriptions, without the requirement for the original paper prescription, to reduce contact with vulnerable patients.

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 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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