

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024

PB 31 of 2024

Purpose and operation

This instrument ('2024 EFC Special Arrangement') replaces the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* ('2011 EFC Special Arrangement'), which sunsets on 1 April 2024.

The 2024 EFC Special Arrangement makes provision for prescribing and supplying chemotherapy medicines to eligible patients being treated for cancer, and for medicines associated with the side-effects of cancer and cancer treatment ('related pharmaceutical benefits'). It regulates how claims for payment for the supply of chemotherapy pharmaceutical benefits under the 2024 EFC Special Arrangement may be made, the amount of payment that the relevant supplier is entitled to receive from the Commonwealth, and the amount the patient may be required to pay for each supply. The 2024 EFC Special Arrangement achieves efficiency in payment for the supply of chemotherapy pharmaceutical benefits, by reimbursing suppliers for the combination of vials that most cost-effectively make up the required dose for the patient.

Arrangements under the 2024 EFC Special Arrangement are substantially similar to those under the 2011 EFC Special Arrangement. Redrafting has been undertaken where necessary to improve clarity and consistency. The changes also include updating or removing obsolete references and providing new definitions. The provisions have been rewritten, reordered, and renumbered using modern drafting principles and language.

Background

The Efficient Funding of Chemotherapy (EFC) program provides access to Pharmaceutical Benefits Scheme (PBS) medicines to eligible patients for the treatment of cancer or cancer-related conditions.

Chemotherapy pharmaceutical benefits

Under the 2024 EFC Special Arrangement, authorised prescribers (namely medical practitioners) will continue to prescribe chemotherapy drugs in doses tailored to the individual needs of patients, rather than needing to prescribe specific pharmaceutical benefits. Suppliers are to supply the prescribed doses of those drugs, with the supply being made from chemotherapy pharmaceutical benefits.

The Commonwealth will continue to pay suppliers for the most efficient combination of vials (or equivalent) of chemotherapy pharmaceutical benefits that most cost-effectively make up the required patient dose, regardless of the combination of chemotherapy pharmaceutical benefits that are actually supplied to the patient.

The 2024 EFC Special Arrangement maintains a low cost to patients, by providing that a patient co-payment will only be charged for an original supply of a dose of a chemotherapy drug, and not for a repeat supply.

The 2024 EFC Special Arrangement provides for the supply of chemotherapy pharmaceutical benefits to an eligible patient by:

- Approved pharmacists;
- Approved medical practitioners;
- Approved hospital authorities for a private hospital; or
- Approved hospital authorities for a public hospital participating in the Pharmaceutical Reform Arrangement (PRA).

In addition to the above, if an approved hospital authority is not a participating hospital authority, the hospital authority can supply a dose of a chemotherapy pharmaceutical benefit containing trastuzumab only and no other drug.

Where the supplier of a chemotherapy pharmaceutical benefit is a public hospital authority, the eligible patient must be a non-admitted patient, day admitted patient or a patient on discharge.

Related pharmaceutical benefits

The 2024 EFC Special Arrangement also provides for the supply of related pharmaceutical benefits that are supplied by an approved hospital authority for a public hospital that is participating in a PRA, on the basis of a prescription written when the person was receiving medical treatment at or from a public hospital as a non-admitted patient, day admitted patient or patient on discharge.

Updates made by the 2024 EFC Special Arrangement:

The key updates in the 2024 EFC Special Arrangement include:

- Amending the drafting, to refer to a ‘dose of a chemotherapy drug’ instead of an ‘infusion’. This drafting amendment better reflects that in practice, a separate prescription is written in respect of each dose of a chemotherapy drug, and that a separate claim for payment is made in respect of the supply of chemotherapy pharmaceutical benefits used to make up each dose;
- Simplifying drafting, including by the introduction of the concept of a ‘special arrangement supply’ that brings together the concepts of eligible patients, eligible suppliers and eligible supplies for different types of pharmaceutical benefits;
- Inclusion of a simplified outline in line with current drafting principles;
- Inclusion of an express requirement that chemotherapy medicines and related pharmaceutical benefits may only be prescribed under the 2024 EFC Special Arrangement for a person receiving treatment for cancer or a cancer-related condition;
- Inclusion of a simplified definition of an ‘authorised prescriber,’ being a medical practitioner, for both chemotherapy medicines and related pharmaceutical benefits;
- Improving and clarifying the method of calculating the dispensed price of a dose of a chemotherapy drug and related pharmaceutical benefit, including by expressly

incorporating reference to the ‘approved ex-manufacturer price’ of the pharmaceutical benefit as defined in section 84 of the *National Health Act 1953* (‘the Act’);

- Updating of the provisions relating to the amount contributing to a patient’s PBS safety net to refer to the concept of the ‘value for safety net’ of a supply, as used in section 84C of the Act;
- Simplifying drafting by removing separate references to Highly Specialised Drugs (HSD) hospital authorities, as HSD hospital authorities are approved hospital authorities. A note clarifies for readers that a reference to an approved supplier or an approved hospital authority includes a reference to an HSD hospital authority within the meaning of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*;
- Removal of redundant terms and concepts including the term ‘benefit card,’ which is no longer used, and removal of the provisions specifying the responsible person for a chemotherapy and related pharmaceutical benefit, given that this information is specified in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*;
- Simplifying the columns in the Schedules to minimise duplication and streamline their use including adding variation codes relating to the consideration of requests to authorise the writing of prescriptions for increased maximum quantity or number of units and/or maximum number of repeats, to align with the use of variation codes in the new *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*;
- Removal of expired transitional provisions for existing medication chart prescribing which related to the *National Health (Efficient Funding of Chemotherapy) Amendment (COVID-19 Simplified Prescribing) Special Arrangement 2020*;
- Providing that only section 6 and 7 of the *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017* apply to the special arrangement supply of doses of chemotherapy drugs.

Authority

Subsection 100(1) of the *National Health Act 1953* (‘Act’) enables the Minister to make special arrangements for the 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).

Section 85A of the Act enables the Minister to:

- Determine the maximum quantity of a pharmaceutical item that may be directed for supply on one occasion in a prescription for particular purposes;
- Determine the maximum number of times that a supply of a pharmaceutical benefit can be directed in a single prescription for particular purposes.

Under subsection 85(7) of the Act, the Minister may determine that a pharmaceutical benefit is a ‘relevant pharmaceutical benefit’ and the circumstances in which the pharmaceutical benefit may be prescribed.

Under subsection 99(4) of the Act, the Minister may determine the amount that approved hospital authorities may be paid by the Commonwealth for the supply of pharmaceutical benefits.

Commencement

This instrument commences on 1 April 2024.

Consultation

Key stakeholders participated in a targeted consultation process regarding the remaking of the 2024 EFC Special Arrangement in February 2024. The Department of Health and Aged Care (the Department) considered a targeted consultation approach was appropriate, given that the 2024 EFC Special Arrangement is not intended to result in substantive changes to the EFC program.

Stakeholders who were invited to comment on an exposure draft of the 2024 EFC Special Arrangement included but were not limited to Therapeutic Goods Administration (TGA)-licensed chemotherapy compounders, peak pharmacy organisations, state and territory health departments and Services Australia.

Stakeholders sought confirmation that the remuneration structure under the EFC program remained unchanged. Some stakeholders also queried why the terminology has changed from an ‘infusion’ to ‘dose of a chemotherapy drug’. Stakeholders also questioned whether the 2024 EFC Special Arrangement would result in substantive changes to the mark-ups for chemotherapy pharmaceutical benefits and raised queries regarding the introduction of the term ‘restricted drug’. The Department separately responded to these enquiries and reiterated that there are no changes to the EFC program arrangements, remuneration or broader policy parameters as a result of the remake of the EFC legislative instrument.

An ongoing and formal process of consultation in relation to matters relevant to the EFC program includes the involvement of interested parties through the membership of the Pharmaceutical Benefits Advisory Committee (PBAC).

The PBAC is an independent expert body established by section 100A of the Act. The PBAC makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. The recommendatory role of the PBAC ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

General

The 2024 EFC Special Arrangement is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the 2024 EFC Special Arrangement are set out in **Attachment A**.

The 2024 EFC Special Arrangement 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**.

The 2024 EFC Special Arrangement reflects changes made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* which also commences on 1 April 2024, and which affects the pharmaceutical benefits that may be supplied under the 2024 EFC Special Arrangement. Details of changes made to medicines listings, such as the deletion of listed drugs, the addition and deletion of brands of pharmaceutical benefits, and the alteration of circumstances in which a prescription may be written for a number of listed drugs is set out in **Attachment C**.

ATTACHMENT A

Details of the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024*

Part 1 Preliminary

Section 1 Name

This section provides that the name of the instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* ('2024 EFC Special Arrangement') and that it may also be cited as PB 31 of 2024.

Section 2 Commencement

This section provides that the 2024 EFC Special Arrangement commences on 1 April 2024.

Section 3 Authority

This section provides that the 2024 EFC Special Arrangement is made under sections 85, 85A, 99 and 100 of the *National Health Act 1953* ('Act').

Section 4 Simplified outline

This section provides that the 2024 EFC Special Arrangement makes a special arrangement for the supply of pharmaceutical benefits for the purposes of treatment for cancer and cancer-related conditions. It also provides a high-level summary of the key features of the 2024 EFC Special Arrangement.

Section 5 Definitions

Section 5 sets out definitions used in the 2024 EFC Special Arrangement. Key definitions include:

- Chemotherapy drug – a drug listed on the PBS (listed drug) that is mentioned in Part 1 of Schedule 1 to the 2024 EFC Special Arrangement;
- Chemotherapy pharmaceutical benefit – a pharmaceutical benefit mentioned in Part 1 of Schedule 1 to the 2024 EFC Special Arrangement. Chemotherapy pharmaceutical benefits are medicines used for the treatment of cancer that are administered through infusion or injection and require reconstitution or preparation for individual patients;
- Compounder – an entity that is responsible for the compounding of doses of chemotherapy drugs. Compounders can include pharmacies, hospitals, companies or other persons;
- Dose of a chemotherapy drug – a quantity of the drug for a single treatment of a patient that is made from one or more chemotherapy pharmaceutical benefits;
- Participating hospital authority – a PBS approved hospital authority for a public hospital that is participating in a Pharmaceutical Reform Arrangement ('PRAs'). Under PRAs, the Commonwealth has entered into bilateral agreements with all jurisdictions except New South Wales and the Australian Capital Territory to support the access of PBS medicines in the public hospital setting. The PRAs enable approved public hospitals to prescribe and dispense PBS-subsidised medicines, relevantly including chemotherapy drugs, to day-admitted patients, outpatients, and patients upon discharge;

- Related pharmaceutical benefit – a pharmaceutical benefit mentioned in Schedule 2 to the 2024 EFC Special Arrangement. Related pharmaceutical benefits are medicines associated with the side-effects of cancer and cancer treatment;
- Single unit ex-manufacturer price – the single unit ex-manufacturer price applies to a chemotherapy pharmaceutical benefit that is a PBS listed brand of a pharmaceutical item. It is the approved ex-manufacturer price (‘AEMP’) for the chemotherapy pharmaceutical benefit, divided by the pricing quantity for the benefit.

The AEMP of a PBS listed brand of a pharmaceutical item is the price agreed between the Minister and the responsible person for the brand as the appropriate maximum price for the brand or, if no price agreement has been reached and the Minister has determined an appropriate maximum price for the brand, that determined price.

The pricing quantity of a chemotherapy pharmaceutical benefit is the smallest of any PBS determined pack quantity for a brand of the pharmaceutical item. For example, if a pack of 2 vials, a pack of 5 vials and a pack of 10 vials are all determined pack quantities of brands of a pharmaceutical item for PBS purposes, the pricing quantity for all the brands is a pack of 2 vials.

So for a PBS listed brand of a pharmaceutical item with an AEMP of \$500 and a pricing quantity of 2 vials, the single unit ex-manufacture price for the chemotherapy pharmaceutical benefit is \$250. This concept is required for the purposes of calculating the dispensed price for doses of chemotherapy drugs (see sections 31 - 34).

- TGA-licensed compounder – a compounder who holds a license issued under the *Therapeutic Goods Act 1989* that authorises the aseptic compounding of sterile chemotherapy drugs by the compounder. TGA-licensed compounders who compound a dose of a chemotherapy drug for the purposes of the 2024 EFC Special Arrangement are entitled to be paid a TGA-licensed compounding fee for the dose (see section 30).

Section 5 also sets out the amount of various fees that are components of the dispensed price for the supply of a dose of chemotherapy drug under Division 3 of Part 3 of the 2024 EFC Special Arrangement. These are:

- Diluent fee (an amount of \$5.77) and dispensing fee (an amount of \$8.37). These two fees are components of the dispensed price for supplies of doses of chemotherapy drugs made by an approved pharmacist, approved medical practitioner or approved hospital authority for a private hospital;
- Distribution fee - an amount of \$29.15. The distribution fee is a component of the dispensed price for supplies of doses of chemotherapy drugs made by an approved pharmacist or approved medical practitioner;
- Preparation fee – an amount of \$88.62. The preparation fee is a component of the dispensed price for supplies of doses of chemotherapy drugs made by an approved pharmacist, approved medical practitioner, approved hospital authority for a private hospital or approved hospital authority for a public hospital. A note to the definition of ‘preparation fee’ that appeared in the 2011 EFC Special Arrangement has been omitted from the 2024 EFC Special Arrangement. The note indicated that the preparation fee included a component of \$40 for compounding the dose of

chemotherapy drug, which was not indexed annually, and that where a TGA-licensed compounder compounded the dose they were entitled to an additional \$20 TGA-licensed compounder fee. These arrangements are not affected by the removal of the note and under the 2024 EFC Special Arrangement, where an approved supplier who is a TGA-licensed compounder supplies a dose of chemotherapy drug under the 2024 EFC Special Arrangement and compounds the dose, the preparation fee remains part of the determination of the dispensed price for the supply and the separate TGA-licensed compounder fee is also payable.

Section 5 also provides that a number of terms have the same meaning as in Part VII of the Act, including:

- Approved ex-manufacturer price;
- Approved hospital authority;
- Approved medical practitioner;
- Approved pharmacist;
- Listed drug;
- Pharmaceutical item;
- Pricing quantity.

Note 1 to section 5 also explains that a number of expressions used in the 2024 EFC Special Arrangement are defined in the Act, including ‘hospital’ and ‘public hospital’.

Note 2 explains that the expressions ‘eligible person’, ‘medical practitioner’, ‘private hospital’ and ‘specialist’ have the same meaning as the *Health Insurance Act 1973*, in accordance with subsection 4(1A) of the Act.

Note 3 explains that a reference to an ‘approved supplier’ or an ‘approved hospital authority’ includes a reference to an ‘Highly Specialised Drugs (HSD) hospital authority’ within the meaning of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*. A HSD hospital authority is a hospital authority approved under section 94 of the Act, or under the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*, to supply patients with pharmaceutical benefits that contain HSDs.

Section 6 Definition of *authorised prescriber*

Only authorised prescribers can prescribe a special arrangement supply of a dose of a chemotherapy drug or a related pharmaceutical benefit under the 2024 EFC Special Arrangement (see section 10).

Section 6 provides that a medical practitioner is an authorised prescriber for a chemotherapy drug and for a related pharmaceutical benefit. No other type of PBS prescriber is an authorised prescriber for the purposes of the special arrangement supply of a dose of a chemotherapy drug or a related pharmaceutical benefit.

Medical practitioners were also the only authorised prescribers for a chemotherapy drug and for a related pharmaceutical benefit under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (‘2011 EFC Special Arrangement’) (see subsection 3(1) of that special arrangement).

Section 7 Definition of *eligible patient*

This section defines an ‘eligible patient’ for a chemotherapy drug and for a related pharmaceutical benefit. A supply of a chemotherapy drug or related pharmaceutical benefit will not be a special arrangement supply for the purposes of the 2024 EFC Special Arrangement unless, among other things, it is made to an eligible patient for the chemotherapy drug or related pharmaceutical benefit.

Subsection 7(1) provides that a person is an eligible patient for a chemotherapy drug if:

- The person is, or is to be treated as an ‘eligible person’ for the purpose of the *Health Insurance Act 1973*; and
- The dose of the drug is or will be prescribed to the person for the purposes of treatment for cancer or a cancer-related condition.

Subsection 7(2) provides that a person is an eligible patient for a related pharmaceutical benefit if the person:

- Is, or is to be treated as an eligible person; and
- The benefit is or will be prescribed to the person for the purposes of treatment for cancer or a cancer related condition.

Under the 2011 EFC Special Arrangement, an eligible patient was defined as a person who was or was treated as an eligible person and who was receiving treatment from an authorised prescriber (i.e., a medical practitioner). Section 7 of the 2024 EFC Special Arrangement introduces the requirement that the chemotherapy drug or related pharmaceutical benefit must be prescribed to a person for the treatment of cancer or a cancer related condition in order for them to be an eligible patient. This amendment reflects the longstanding policy position, that chemotherapy medicines and related pharmaceutical benefits may only be prescribed and supplied to persons receiving treatment for cancer or a cancer-related condition under this instrument.

Section 8 Application of Act and instruments in relation to special arrangement supplies to patients receiving treatment from hospitals

Under standard PBS arrangements in section 94 of the Act, a hospital authority may only be approved in relation to the supply of pharmaceutical benefits to patients receiving treatment ‘in or at’ the hospital. However, under the EFC program patients who receive treatment from a hospital, for example non-admitted patients, are also eligible to receive special arrangement supplies of doses of chemotherapy drugs and related pharmaceutical benefits.

Subsection 8(1) enables this by providing that in the application of Part VII of the Act and regulations or other instruments made for the purposes of that Part, to special arrangement supplies, a reference to a person receiving treatment in or at an approved hospital is taken to include a reference to a person receiving treatment *from* an approved hospital.

Further, subsection 8(2) provides that in Part VII of the Act, and regulations or other instruments made for the purposes of that Part, a reference to an approved hospital authority supplying pharmaceutical benefits to patients receiving treatment in or at a hospital is taken to include a reference to an approved hospital authority supplying doses of chemotherapy drugs or related pharmaceutical benefits to patients receiving treatment from a hospital.

Section 9 Application of Act and instruments in relation to chemotherapy prescriptions and special arrangement supplies of doses of chemotherapy drugs

This instrument provides for medical practitioners to prescribe chemotherapy drugs in doses tailored to the needs of individual patients, rather than prescribing quantities of ‘ready for supply’ pharmaceutical benefits such as tablets. Suppliers are to supply the prescribed doses of those chemotherapy drugs, with the supply being made from chemotherapy pharmaceutical benefits.

This section therefore provides that subject to this instrument, a reference in Part VII of the Act or regulations or other instruments made for the purposes of that Part, to a prescription for the supply of a pharmaceutical benefit is taken to include a reference to a chemotherapy prescription (see section 11), and a reference to a supply of a pharmaceutical benefit is taken to include a special arrangement supply of a dose of a chemotherapy drug.

Part 2 Special arrangement supplies

Division 1 Preliminary

Section 10 Definition of *special arrangement supply*

This section defines a ‘special arrangement supply’ for the purposes of the 2024 EFC Special Arrangement. It sets out the circumstances in which a dose of a chemotherapy drug or a related pharmaceutical benefit can be supplied to a person under the 2024 EFC Special Arrangement.

A supply of a dose of a chemotherapy drug to a person is a special arrangement supply of the dose if the person is an eligible patient for the drug, and:

- The dose is supplied by an approved pharmacist, on the basis of a chemotherapy prescription written by an authorised prescriber for the drug in accordance with Division 2 (subsection 10(1)); or
- The dose is supplied by an approved medical practitioner, on the basis of a chemotherapy prescription written by an authorised prescriber for the drug in accordance with Division 2, and the prescription is not a medication chart prescription (subsection 10(2)); or
- The dose is supplied by an approved hospital authority of a private hospital, on the basis of a chemotherapy prescription written when the person was receiving medical treatment at or from a private hospital, by an authorised prescriber for the drug in accordance with Division 2 (subsection 10(3)); or
- The dose is supplied by a participating hospital authority, on the basis of a chemotherapy prescription written when the person was receiving medical treatment at or from a public hospital as a non-admitted patient, day admitted patient or patient on discharge, by an authorised prescriber for the drug in accordance with Division 2 (subsection 10(4)); or
- The supply is of a dose of the chemotherapy drug trastuzumab, supplied by an approved hospital authority of a public hospital that is not a participating hospital authority, on the basis of a prescription written when the person was receiving medical treatment at or from a public hospital as an non-admitted patient, day admitted patient or patient on discharge, by an authorised prescriber for the drug in

accordance with Division 2, and the prescription is not a medication chart prescription (subsection 10(5)).

Subsection 10(6) provides that a supply of a related pharmaceutical benefit to a person is a special arrangement supply of the benefit if:

- The person is an eligible patient for the benefit and the benefit is supplied by a participating hospital authority, on the basis of a prescription written:
 - when the person was receiving medical treatment at or from a public hospital as a non-admitted day patient, day admitted patient or patient on discharge; and
 - by an authorised prescriber for the benefit; and
 - if the benefit is a relevant pharmaceutical benefit for the purposes of section 88A of the Act, in circumstances determined by subsection 12(3) of the 2024 EFC Special Arrangement.

Pharmaceutical benefits may be determined as relevant pharmaceutical benefits under paragraph 85(7)(a) of the Act, for the purposes of section 88A of the Act. Relevant pharmaceutical benefits can only be prescribed in circumstances determined under paragraph 85(7)(b) of the Act. For the purposes of special arrangement supplies under the 2024 EFC Special Arrangement of related pharmaceutical benefits that are relevant pharmaceutical benefits, subsection 12(3) determines those related pharmaceutical benefits that are relevant pharmaceutical benefits and the circumstances in which a prescription for a special arrangement supply of the benefit may be written.

The new definition of a ‘special arrangement supply’ has been introduced to streamline drafting and improve consistency of drafting across special arrangements made under section 100 of the Act. The new definition centralises concepts that existed in various sections in the 2011 EFC Special Arrangement, such as in the now redundant definitions of ‘eligible public hospital patient’ and ‘eligible private hospital patient’. It is not intended to change the existing operation of the EFC arrangements such as the chemotherapy benefits or related pharmaceutical benefits which can be prescribed to a patient or which types of approved suppliers can supply which types of chemotherapy benefits or related pharmaceutical benefits.

Division 2—Prescribing doses of chemotherapy drugs and related pharmaceutical benefits

Section 11 Prescribing chemotherapy drugs

This section provides that subject to Division 2, an authorised prescriber for a chemotherapy drug is authorised to write a prescription (a ‘chemotherapy prescription’) for the special arrangement supply of the dose of the drug. Such a prescription is referred to for the purposes of the 2024 EFC Special Arrangement as a ‘chemotherapy prescription’.

Subsection 11(2) clarifies that the section applies in addition to authorisations to write prescriptions under section 88 of the Act. This means that if the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (or another special arrangement) authorises a person under section 88 of the Act to prescribe a chemotherapy drug, but if the person is not an authorised prescriber as defined in section 6 of 2024 EFC Special Arrangement, they are not authorised to write a chemotherapy prescription for a dose of the drug for the purposes of the 2024 EFC Special Arrangement.

Section 12 Prescription circumstances—general

This section sets out when a prescription for a dose of a chemotherapy drug or a related pharmaceutical benefit may only be written in particular circumstances, and what those circumstances are. Section 13 of the 2024 EFC Special Arrangement separately sets out when the writing of a prescription for a dose of a chemotherapy drug or related pharmaceutical benefit must be authorised by the Chief Executive Medicare.

Chemotherapy drugs

Subsection 12(1) provides that a chemotherapy drug is a ‘restricted drug’ if there is one or more circumstances codes (the letter C followed by a number) mentioned in the column of the table in Part 1 of Schedule 1 headed ‘Circumstances’ (‘Schedule 1 circumstance column’) in relation to each chemotherapy pharmaceutical benefit that has the chemotherapy drug. Accordingly, if there is no circumstances code mentioned in the Schedule 1 circumstances column for any of the chemotherapy pharmaceutical benefits that have the chemotherapy drug, it is not a restricted drug. The note to subsection 12(1) clarifies that it is irrelevant for the purposes of subsection 12(1) whether the circumstances codes for different pharmaceutical benefits having the drug are the same or are different.

Subsection 12(2) provides that a chemotherapy prescription for a dose of a restricted drug may only be written in circumstances mentioned in the column of the table in Part 1 of Schedule 3 headed “Circumstances and Purposes” (circumstances and purposes column’) in relation to any of the circumstances codes that relate to chemotherapy pharmaceutical benefits that have the drug.

Related pharmaceutical benefits

Paragraph 85(7)(a) of the Act provides that the Minister may, by legislative instrument, determine that a particular pharmaceutical benefit is to be a relevant pharmaceutical benefit for the purposes of section 88A of the Act. Where a pharmaceutical benefit is determined to be a relevant pharmaceutical benefit for the purposes of section 88A of the Act, the writing of a prescription for the supply of the benefit is authorised under Part VII of the Act only in circumstances specified in the determination under subsection 85(7)(b) of the Act.

Subsection 12(3) of the 2024 EFC Special Arrangement provides that for the purposes of paragraphs 85(7)(a) and (b) of the Act, if a circumstances code is mentioned in the column of the table in Schedule 2 headed “Circumstances” in relation to a related pharmaceutical benefit, the pharmaceutical benefit is a relevant pharmaceutical benefit for the purposes of section 88A of the Act. The circumstances mentioned in the circumstances and purposes column in relation to the circumstances code are the circumstances in which a prescription for a special arrangement supply of a related pharmaceutical benefit may be written.

Application of this section

Subsection 12(4) provides that this section applies in addition to section 13 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (‘Listing Instrument’). Section 13 of the Listing Instrument outlines the circumstances in which a prescription can be written by an authorised prescriber for the supply of the ready-prepared pharmaceutical benefits listed in Schedule 1 to that instrument. This means that for the purposes of the 2024 EFC Special Arrangement, it is not sufficient for writing a prescription for the special arrangement supply of a restricted drug or related pharmaceutical benefit that is a relevant pharmaceutical benefit that writing the prescription would be allowable under the Listing Instrument. The

prescription must be written in at least one of the applicable circumstances under the 2024 EFC Special Arrangement.

Section 12 corresponds to section 8 of the 2011 EFC Special Arrangement.

Section 13 Prescription circumstances—authority required procedures

This section sets out the circumstances in which an authorised prescriber must follow certain procedures (called “authority required procedures”) to receive authorisation from the Chief Executive Medicare to write a prescription for the supply of a dose of a restricted drug or a related pharmaceutical benefit.

Authority required procedures apply to a chemotherapy prescription for a dose of a restricted drug if the circumstances mentioned in Part 1 of Schedule 3 that apply to the writing of the prescription include:

- Compliance with Authority Required procedures; or
- Compliance with Written Authority Required procedures.

Authority required procedures apply to a prescription for a special arrangement supply of a related pharmaceutical benefit if the circumstances mentioned in Part 1 of Schedule 3 (if any) in which the prescription is written include:

- Compliance with Authority Required procedures; or
- Compliance with Written Authority Required procedures.

Subsection 13(3) provides that the authority required procedures set out in section 19 of the Listing Instrument apply as if a reference to Part 1 of Schedule 4 to the Listing Instrument were a reference to Part 1 of Schedule 3 of the 2024 EFC Special Arrangement and a reference to an authorised prescriber were a reference to an authorised prescriber within the meaning of the 2024 EFC Special Arrangement (i.e. a medical practitioner).

Section 13 corresponds to section 22 of the 2011 EFC Special Arrangement. Drafting has been simplified as a consequence of the simplification of drafting of authority required procedures in the Listing Instrument.

Section 14 Maximum amount—chemotherapy drug

Subsection 14(1) provides that the section determines the maximum amount of a chemotherapy drug that an authorised prescriber may, in one chemotherapy prescription, direct to be supplied in a dose of the drug (“maximum amount”).

Regular arrangements for the PBS enable the determination of the maximum quantity or number of units (“maximum quantity”) of a pharmaceutical item that may be directed for supply in a prescription, rather than the maximum amount. This maximum quantity may be, for example, 50 x 10 mg tablets, with a 10 mg tablet being the relevant form of the pharmaceutical benefit. However, chemotherapy pharmaceutical benefits are prescribed under this Special Arrangement by reference to a dose of the chemotherapy drug that is in the chemotherapy pharmaceutical benefit.

This instrument therefore refers to a “maximum amount,” to reflect the maximum amount of the chemotherapy drug that an authorised prescriber may, in one chemotherapy prescription, direct to be supplied in a dose of a drug. This is also consistent with the 2011 EFC Special Arrangement which also referred to a maximum amount of a chemotherapy drug rather than a

maximum quantity (noting that a maximum amount is not substitutable with a maximum quantity).

Subsection 14(2) provides that if only one amount is mentioned in the column of the table in Part 2 of Schedule 1 headed “Maximum Amount” (“maximum amount column”) in relation to a chemotherapy drug, that amount is the maximum amount of the chemotherapy drug that may be directed to be supplied in a dose of the drug for all purposes.

Subsection 14(3) provides that if more than one amount is mentioned in the maximum amount column in relation to a chemotherapy drug, then if a purposes code (i.e. the letter P followed by a number) is mentioned in the column of the table headed “Purposes” in relation to the amount, that amount is the maximum amount of the chemotherapy drug that may be directed to be supplied in a dose of the drug for the purposes mentioned in the table in Part 1 of Schedule 3 for that purposes code. If no purposes code is mentioned that amount is the maximum amount that may be directed to be supplied in a dose of the drug for all purposes other than purposes for which a different amount is mentioned for that same chemotherapy drug.

Section 14 corresponds to section 9 of the 2011 EFC Special Arrangement.

Section 15 Maximum quantity (number of units)—related pharmaceutical benefit

Subsection 15(1) provides that section 15 determines the maximum number of units of the pharmaceutical item in a related pharmaceutical benefit that may, in one prescription for a special arrangement supply of the benefit, be directed to be supplied to a patient on any one occasion (“maximum quantity”).

Subsection 15(2) provides that if only one number of units is mentioned in the column of the table in Schedule 2 headed “Maximum Quantity” (“maximum quantity column”) in relation to brands of the pharmaceutical item, that number of units is the maximum number of units of the pharmaceutical item that may be directed to be supplied on any one occasion in a prescription for all purposes.

Subsection 15(3) deals with where more than one number of units is mentioned in the maximum quantity column in relation to brands of the pharmaceutical item. Where this is the case, then if a purposes code is mentioned in the column of the table headed “Purposes” in relation to that number of units, that number is the maximum number of units of the pharmaceutical item that may be directed to be supplied on any one occasion in a prescription for the particular purposes mentioned in the table in Part 1 of Schedule 3 for that purposes code.

However, if no purposes code is mentioned in the column in relation to a number of units, that number is the maximum number of units that may be directed to be supplied on any one occasion in a prescription for all purposes, other than purposes for which a different number of units is mentioned for the pharmaceutical item.

Related pharmaceutical benefits available for special arrangement supply under 2024 EFC Special Arrangement may also be available for general supply. This means that the Listing Instrument may also make provision for the maximum number of units of the pharmaceutical item in a related pharmaceutical benefit that may be directed to be supplied to a patient on any one occasion in a prescription.

Subsection 15(4) provides that to the extent section 15 provides for a matter not provided for in the Listing Instrument, the section applies in addition to the Listing Instrument.

Subsection 15(5) provides that to the extent section 15 provides differently for a matter that also provided for in the Listing Instrument, section 15 applies despite the Listing Instrument.

Section 15 corresponds to section 10 of the 2011 EFC Special Arrangement.

Section 16 Maximum number of repeats—chemotherapy drug

Subsection 16(1) provides that section 16 determines the maximum number of occasions an authorised prescriber may, in one chemotherapy prescription, direct that a special arrangement supply of a dose of a chemotherapy drug be repeated (“maximum number of repeats”).

Subsection 16(2) provides that if only one number is mentioned in the column of the table in Part 2 of Schedule 1 headed “Number of Repeats” (“repeats column”) in relation to the chemotherapy drug, that number is the maximum number of repeats for all purposes.

Subsection 16(3) deals with where more than one number is mentioned in the repeats column in relation to the chemotherapy drug. Where this is the case, if a purposes code is mentioned in the column of the table headed “Purposes” in relation to the number, for the purposes mentioned in the table in Part 1 of Schedule 3 for that purposes code, that number is the maximum number of times the supply may be directed in a single prescription. If no purposes code is mentioned in the column in relation to a number of repeats, that number is the maximum number of repeats for all purposes other than purposes for which a different number of repeats is mentioned for that chemotherapy drug.

Section 16 corresponds to section 11 of the 2011 EFC Special Arrangement.

Section 17 Maximum number of repeats—related pharmaceutical benefit

Subsection 17(1) provides that section 17 determines the maximum number of occasions an authorised prescriber may, in one prescription, direct that a special arrangement supply of a related pharmaceutical benefit be repeated (“maximum number of repeats”), for the purposes of paragraph 85A(2)(b) of the Act.

Subsection 17(2) provides that if only one number is mentioned in the column of the table in Schedule 2 headed “Number of Repeats” (“repeats column”) in relation to the related pharmaceutical benefit, that number is the maximum number of repeats for all purposes.

Subsection 17(3) deals with where more than one number is mentioned in the repeats column in relation to the related pharmaceutical benefit. Where this is the case, if a purposes code is mentioned in the column of the table headed “Purposes” in relation to the number, for the purposes mentioned in the table in Part 1 of Schedule 3 for that purposes code, that number is the maximum number of times the supply may be directed in a single prescription. If no purposes code is mentioned in the repeats column in relation to a number of repeats, that number is the maximum number of repeats for all purposes other than purposes for which a different number of repeats is mentioned for the related pharmaceutical benefit.

Related pharmaceutical benefits available for special arrangement supply under the 2024 EFC Special Arrangement may also be available for general supply. This means that the Listing Instrument may also make provision for the maximum number of times a single prescription may direct the supply of the pharmaceutical benefit to a patient.

Subsection 17(4) provides that to the extent section 17 provides for a matter not provided for in the Listing Instrument, it applies in addition to the Listing Instrument.

Subsection 17(5) provides that to the extent section 17 makes a different provision for a matter provided for in the Listing Instrument, section 17 applies despite the Listing Instrument.

Section 17 corresponds to section 12 of the 2011 EFC Special Arrangement.

Section 18 Variation of maximum amount or quantity or maximum number of repeats

Modified application of section 30 of the Regulations for chemotherapy prescriptions

Section 18 deals with situations where an authorised prescriber seeks to:

- Prescribe a dose of a chemotherapy drug that is greater than the maximum amount, as determined by section 14 of the 2024 EFC Special Arrangement; or
- Direct in one chemotherapy prescription that the supply of a dose of a chemotherapy drug be repeated more times than the maximum number of repeats permitted by section 16 of the 2024 EFC Special Arrangement.

Subsection 18(1) modifies the application of section 30 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (“the Regulations”). Section 30 of the Regulations provides for the Minister (in practice delegates at Services Australia) to authorise the variation of maximum quantities determined for paragraph 85A(2)(a) of the Act and maximum numbers of repeats determined for paragraph 85A(2)(b) of the Act in particular cases. It provides for details of a proposed prescription that would be written for more than the maximum quantity or maximum number of repeats to be submitted to the Minister and, where the Minister varies the application of the determination made under paragraph 85A(2)(a) and/or paragraph 85A(2)(b), the Minister to allot an ‘authority number’ to the prescription and inform the practitioner of the number.

Subsection 18(1) provides that section 30 of the Regulations applies in relation to a chemotherapy prescription as if:

- A reference to a determination under paragraph 85A(2)(a) of the Act were a reference to a determination of the maximum amount of a chemotherapy drug by section 14 of this instrument; and
- A reference to a determination under paragraph 85A(2)(b) of the Act were a reference to a determination by section 16 of this instrument.

The effect of subsection 18(1) is that where an authorised prescriber is seeking to write a chemotherapy prescription for more than the maximum amount or maximum number of repeats, they must follow the processes applying under section 30 of the Regulations.

Section 30 of the Regulations is being amended from 1 April 2024 to streamline processes for prescribers seeking authorisation of variation to maximum quantities or maximum number of repeats. New section 104 in Part 9 of the Regulations establishes transitional arrangements that provide that, for prescriptions written before 1 July 2024, prescribers may submit prescriptions for authorisation, and prescriptions may be authorised, in accordance with section 30 of the Regulations as in force immediately before 1 April 2024. These transitional arrangements will also apply to chemotherapy prescriptions written before 1 July 2024.

Rules for related pharmaceutical benefits

Subsections 18(2) to (4) deal with rules that must be applied by the Minister (or delegates in Services Australia) when considering requests to authorise the variation of the application of the usual maximum quantities and/or maximum number of repeats in relation to a prescription for a special arrangement supply of a related pharmaceutical benefit.

Subsection 18(2) provides that for the purposes of subsection 85A(3A) of the Act, section 18 determines such rules.

Subsection 18(3) provides that if the column of the table in Schedule 2 headed “Variations” (“variations column”) includes a variation code (i.e. the letter V followed by a number) in relation to a maximum quantity, the rules mentioned in the column of the table in Part 2 of Schedule 3 headed “Variation Rules” (“variation rules column”) in relation to the variation code must be applied when deciding whether to authorise a variation of that maximum (to the extent that those rules relate to the number of units).

Subsection 18(4) provides that if the variations column includes a variation code in relation to a maximum number of repeats, the rules mentioned in the variation rules column in relation to the variation code must be applied when deciding whether to authorise a variation of that maximum (to the extent that those rules relate to the number of repeats). The note to subsection 18(4) clarifies that rules may relate to the maximum number of units, the maximum number of repeats or both.

Variation codes and variation rules were not included in the 2011 EFC Special Arrangement. The capacity to specify variations rules has been added to more accurately reflect that binding rules about the variation of maximum quantities of related pharmaceutical benefits that can be prescribed for supply on one occasion, or the maximum number of repeats are not part of the general circumstances for writing a prescription determined for subsection 85(7) of the Act. These variation rules can now be identified in a separate Part 2 of Schedule 3 to the 2024 EFC Special Arrangement.

Application of this section

Subsection 18(5) provides that to the extent section 18 provides for a matter not provided for in the Listing Instrument, it applies in addition to the Listing Instrument.

Subsection 18(6) provides that to the extent section 18 makes a different provision for a matter provided for in the Listing Instrument, it applies despite the Listing Instrument.

Section 18 corresponds to section 17 of the 2011 EFC Special Arrangement.

Section 19 Writing chemotherapy prescriptions that are not medication chart prescriptions

Subsection 19(1) provides that the section applies to chemotherapy prescriptions that are not medication chart prescriptions.

Subsection 19(2) provides that the prescription must include the name of the chemotherapy drug directed to be supplied, the dose of the drug and, if supply of the dose is to be repeated, the number of times it is to be repeated.

The ordinary requirements for writing PBS prescriptions are set out in the Regulations. Subsection 19(3) modifies the application of the Regulations in relation to chemotherapy prescriptions that are not medication chart prescriptions. It provides that the following provisions of the Regulations do not apply to these prescriptions:

- Paragraph 40(1)(d) and subsection 40(2A) – these provisions would ordinarily require the prescription to identify the pharmaceutical benefit being prescribed and detail how this requirement can be met. However, section 23 of the 2024 EFC Special Arrangement provides that when making a special arrangement supply of a dose of chemotherapy drug, approved suppliers may disregard any direction in the prescription about a particular listed brand of a pharmaceutical item or form of the chemotherapy drug. Accordingly, requiring prescriptions to identify particular pharmaceutical benefits (including by brand or form) is redundant;
- Paragraph 40(1)(e) - would ordinarily require the prescription to state the quantity of the pharmaceutical benefit to be supplied and the number of repeats (where applicable). Under section 23 of the 2024 EFC Special Arrangement, approved suppliers may also disregard any direction in the prescription about the supply of a quantity or number or repeats of a particular chemotherapy pharmaceutical benefit particular. Accordingly, requiring this to be included in prescriptions for a dose of chemotherapy drug is redundant;
- Paragraph 40(3)(a)) – would ordinarily prevent a prescriber from writing a prescription for a pharmaceutical benefit where, on the same day, they have written another prescription for the same benefit, another brand of the same pharmaceutical item or a pharmaceutical benefit that is Schedule equivalent. However, as a single dose of a chemotherapy drug for a patient may comprise multiple vials of one or more brands of a chemotherapy pharmaceutical benefit, prescribers may need to prescribe the supply of multiple benefits at the one time;
- Paragraph 40(1)(j) and section 49 – section 49 would ordinarily allow a prescriber to direct a supply on one occasion of more than the maximum quantity, in place of repeated supplies. Authorised prescribers are not permitted to make such a direction for special arrangement supplies of doses of chemotherapy drugs. Paragraph 40(1)(j) details information that must be included in the prescription where the prescriber makes such a direction.

The note to subsection 19(3) clarifies that if the prescription includes directions about particular pharmaceutical benefits to be supplied to a patient, an approved supplier is not required to follow the prescriber’s directions.

Section 19 corresponds to section 15 and subsection 14(5) of the 2011 EFC Special Arrangement.

Section 20 Writing medication chart prescriptions

For general PBS supply, a chart used to write a prescription must comply with applicable form and/or information requirements set out in subsections 41(4), 41(5) and 41(6) of the Regulations to be a valid medication chart, and thus the prescription be a valid medication chart prescription. Section 41 of the Regulations also sets out information that a medication chart prescription must include.

Section 20 sets out the requirements for using a chart to write a chemotherapy prescription or a prescription for a special arrangement supply of a related pharmaceutical benefit, including by modifying the application of section 41 of the Regulations.

Chart is not required to be in approved form

Subsection 20(1) provides that a chart used to write a chemotherapy prescription or a prescription for a special arrangement supply of a related pharmaceutical benefit is not required to be in a form approved under paragraph 41(5)(a) of the Regulations or meet the information requirements approved under paragraph 41(5)(b) of the Regulations. The chart is taken to be a medication chart for the purposes of the Regulations, despite paragraphs 41(4)(a) and (b) of the Regulations.

No application to persons receiving treatment in or at residential care services

Subsection 20(2) provides that subparagraph 41(1)(a)(i) of the Regulations does not apply to a medication chart prescription that is a chemotherapy prescription or a prescription for a special arrangement supply of a related pharmaceutical benefit. Subparagraph 41(1)(a)(i) would ordinarily allow a medication chart prescription to be written for a person who is receiving treatment in residential aged care. As persons receiving treatment in residential aged care are not eligible patients for the purposes of the 2024 EFC Special Arrangement, medication chart prescriptions cannot be written for them.

Modified application of section 41 of the Regulations—electronic medication chart prescriptions

Subsection 20(3) provides that for an electronic medication chart prescription that is a chemotherapy prescription or a prescription for the special arrangement supply of a related pharmaceutical benefit, paragraph 41(2)(c) of the Regulations does not apply, which would ordinarily require the prescriber to sign the prescription. However, the authorised prescriber must approve the prescription in the electronic system used to write the prescription. Subsection 20(3) also provides that paragraph 104(3)(b) of the Regulations does not apply. Paragraph 104(3)(b) of the Regulations is part of transitional arrangements relating to applications for authorisation to write a prescription for increased maximum quantity and/or maximum number of repeats, where the prescription is written before 1 July 2024. Paragraph 104(3)(b) of the Regulations would otherwise remove the requirement for a prescriber to write certain authority numbers allotted by the Chief Executive Medicare on a medication chart prescription.

Modifications for chemotherapy drugs only

Subsection 20(4) provides that a medication chart prescription that is a chemotherapy prescription must include the name of the chemotherapy drug directed to be supplied, the dose of the chemotherapy drug directed to be supplied, the frequency of administration and route of administration of the dose, and the date of the prescription.

Subsection 20(5) provides that subparagraphs 41(2)(a)(i), (ii) and (iii) and subsection 41(2A) of the Regulations do not apply in relation to the writing of a medication chart prescription that is a chemotherapy prescription. Subparagraph 41(2)(a)(i), along with subsection 41(2A), would ordinarily require a medication chart prescription to include particulars identifying the pharmaceutical benefit and describe how this requirement can be met. Subparagraphs 41(2)(a)(ii) and (iii) would ordinarily require a medication chart prescription to include the date the pharmaceutical benefit was prescribed and its dose, frequency of administration and route of administration.

The note to subsection 20(5) states that if the prescription does include directions about particular pharmaceutical benefits to be supplied, an approved supplier is not required to follow the prescriber's directions (see subsection 23(8)).

Section 20 corresponds to section 16 and subsection 14(5) of the 2011 EFC Special Arrangement.

Section 21 Direction to vary prescribed dose of chemotherapy drug

Subsection 21(1) provides that an authorised prescriber who has written a chemotherapy prescription for a chemotherapy drug may direct an approved supplier to increase or decrease the dose to be supplied, without writing a new prescription, if the new dose is between 90% to 110% of the dose that was originally prescribed.

Subsection 21(2) provides that a new dose that has been directed under subsection 21(1) that is greater than the maximum amount for the chemotherapy drug determined by section 14 of the 2024 EFC Special Arrangement does not require approval under section 30 of the Regulations (as modified by section 18(1) of the 2024 EFC Special Arrangement).

This means that if the authorised prescriber wanted to increase or decrease the prescribed dose of a chemotherapy drug by more than 10%, they would need to:

- Write a new chemotherapy prescription for the higher (or lower) dose; and
- Obtain authorisation from Services Australia, if the new dose is higher than the maximum amount for the chemotherapy drug.

Subsection 21(3) provides that if an approved supplier receives a direction in accordance with subsection 21(1), the supplier must record the following on the chemotherapy prescription:

- The new dose of the chemotherapy drug;
- The name of the authorised prescriber who gave the direction to vary the dose;
- The means by which the supplier received the direction (e.g., by phone or by fax); and
- The date and time the supplier received the direction.

Subsection 21(4) provides that if an approved supplier records the information outlined in subsection 21(3) on a chemotherapy prescription, the prescription is taken to be varied accordingly.

Section 21 corresponds to section 18 of the 2011 EFC Special Arrangement.

Division 3—Supplying doses of chemotherapy drugs and related pharmaceutical benefits

Section 22 Entitlement to receive special arrangement supplies

Under section 86 of the Act, eligible persons receiving treatment including medical treatment by a medical practitioner are ordinarily entitled to be supplied pharmaceutical benefits without the payment or provision of money or other consideration other than a charge made in accordance with section 87 of the Act. Part 4 of the 2024 EFC Special Arrangement modifies the amounts that patients may be charged in respect of supplies under the special arrangement.

Subsection 22(1) of the 2024 EFC Special Arrangement provides that a person is entitled to receive a special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit without payment or other consideration, other than a charge made under Part 4 of the 2024 EFC Special Arrangement, if the person is an eligible patient for the chemotherapy drug or related pharmaceutical benefit.

Section 89 of the Act contemplates that a person may be entitled to receive a pharmaceutical benefit without a prescription in certain circumstances including under ‘prescriber bag’ arrangements or as a ‘continued dispensing’ supply.

Subsection 22(2) of the 2024 EFC Special Arrangement provides that a person is not entitled to receive a special arrangement supply of a dose of a chemotherapy drug unless it is supplied by an approved supplier on presentation of a chemotherapy prescription, written in accordance with Division 2.

Subsection 22(3) provides that section 22 has effect in addition to sections 86 and 89 of the Act.

Section 22 has been included in the 2024 EFC Special Arrangement to clarify the interaction of sections 86 and 89 of the Act with supplies of doses of chemotherapy drugs and related pharmaceutical benefits.

Section 23 Special arrangement supplies of doses of chemotherapy drugs

Subsection 23(1) provides that subject to section 23, an approved supplier may make a special arrangement supply of a dose of a chemotherapy drug on presentation of a chemotherapy prescription for the dose.

Subsection 23(2) provides that the supply of the dose must be made from chemotherapy pharmaceutical benefits. A dose of a chemotherapy drug administered to a patient may need to be made up of multiple vials (or other forms) to make up the full dose prescribed for the patient. Subsection 23(2) requires that each of the vials or other form used to make up the dose is a chemotherapy pharmaceutical benefit.

Rules for approved pharmacists modified

In many circumstances, where a dose of a chemotherapy drug is supplied by an approved pharmacist, the dose is compounded at an off-site compounding site, and then transported straight from that compounding site to the location where the dose is administered to the patient. As such, in many circumstances, the dose of the chemotherapy drug is never physically at the premises that an approved pharmacist is approved to supply pharmaceutical benefits at or from. For the avoidance of doubt subsection 23(3) therefore provides that, despite sections 89 and 90 of the Act, an approved pharmacist may make the supply of the dose other than at or from the premises in respect of which the pharmacist is for the time being approved.

Subsection 23(4) provides that the *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017* (Conditions for Approval Determination), other than sections 6 and 7, does not apply to the supply of the dose. All approved pharmacists are subject to the Conditions for Approval Determination. Sections 6 and 7 of the Conditions for Approval Determination determine conditions focussing on the professionalism of the pharmacist and their interactions with patients which remain applicable for special arrangement supplies of doses of chemotherapy drugs. However, the Conditions for Approval Determination also deals with matters such as ‘prescribing steps’ that must be completed at the approved premises for the approved pharmacist and a prohibition on an approved pharmacist making a claim for Commonwealth payment where the pharmaceutical benefit was not supplied at or from the approved premises for the approved pharmacist. The unique nature of compounding, dispensing and supplying doses of chemotherapy drugs mean that these provisions of the Conditions for Approval Determination are impractical to apply.

Method of administration and circumstances must be complied with

Subsection 23(5) provides that if the prescription directs the dose of the chemotherapy drug to be administered by a particular method, the supply of the dose must be able to be administered by that method. Subsection 23(6) provides that subsection 23(5) applies regardless of whether the method directed by the prescription is also a manner of administration for a chemotherapy pharmaceutical benefit that has the chemotherapy drug.

Subsection 23(7) provides that if the prescription was authorised in circumstances mentioned in Part 1 of Schedule 3 in relation to the chemotherapy drug, the supply of the dose must be made only from chemotherapy pharmaceutical benefits for which the circumstances code for those circumstances is mentioned in the column in Part 1 of Schedule 1 headed “Circumstances”.

For example, if there are two chemotherapy pharmaceutical benefits that have Drug A but which have different circumstances codes, a dose of Drug A may be prescribed for either circumstance. However, when the dose is supplied, only the chemotherapy pharmaceutical benefit that has the relevant circumstance code for the circumstances for which the prescription was written may be used to make up the dose of Drug A.

Directions as to form, brand, quantity of benefits and number of repeats of benefits may be disregarded

Subsection 23(8) provides that an approved supplier may disregard any directions as to the following that are included in the prescription:

- The form of the chemotherapy drug to be supplied;
- The listed brand of a pharmaceutical item to be supplied;
- The quantity or number of units of a particular chemotherapy pharmaceutical benefit to be supplied;
- The number of times the supply of a particular chemotherapy pharmaceutical benefit is to be repeated.

A note to subsection 23(8) clarifies that the above matters are not required to be included in chemotherapy prescriptions, in accordance with sections 19 and 20.

Section 23 corresponds to section 33 of the 2011 EFC Special Arrangement.

Section 24 Rules not applicable to special arrangement supplies of chemotherapy drugs

Early supply of pharmaceutical benefit not applicable

Subsection 24(1) provides that a special arrangement supply of a dose of a chemotherapy drug is not an early supply of a specified pharmaceutical benefit.

Under section 84AAA of the Act, the Minister may determine an early supply period for a pharmaceutical item. For those pharmaceutical items with an early supply period, the minimum early supply period is 20 days.

Where a pharmaceutical benefit is supplied to a patient within 20 or 50 days, as applicable, following the supply of the same pharmaceutical benefit, another brand of the same pharmaceutical item or a pharmaceutical benefit that is Schedule equivalent, patient charges for the supply do not count towards meeting the patient’s PBS safety net threshold. Many

patients will require multiple doses of a chemotherapy drug within a 20-day period, 15 so it is appropriate to exclude doses of chemotherapy drugs from early supply rules.

Restrictions on frequency of repeated supplies not applicable

Subsection 24(2) provides that subsections 51(2) to (4) of the Regulations do not apply to a special arrangement supply of a dose of a chemotherapy drug. The note to subsection 24(2) states that the effect of those subsections of the Regulations is to restrict how soon a repeat supply of a pharmaceutical benefit may be made, and that there is no restriction on how soon a repeat supply of a chemotherapy drug may be made under the 2024 EFC Special Arrangement.

Deferred supply authorisations not applicable

Subsection 24(3) provides that subsection 53 of the Regulations does not apply in relation to a special arrangement supply of a dose of a chemotherapy drug. Regulation 53 deals with deferred supplies. Where a single prescription contains a direction to supply more than one pharmaceutical benefit, where requested the approved supplier may defer the supply of one or more of the pharmaceutical benefits in the prescription.

Section 24 corresponds to subsections 34(1) and (2) and subsection 34(3B) of the 2011 EFC Special Arrangement.

Section 25 Modified rules for special arrangement supplies on the basis of an electronic medication chart prescription

Section 25 modifies the application of several provisions of the Regulations in relation to a special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit made by an approved supplier on the basis of an electronic medication chart prescription.

It provides that:

- Paragraph 45(2)(c) of the Regulations does not apply. That provision would ordinarily require the approved supplier to write their name and approval number, an identification number for the supply and date of supply; and
- The approved supplier must verify the supply and the date of supply in the electronic system used to write the prescription; and
- Section 61 of the Regulations, which sets out requirements for approved suppliers to retain certain documents associated with a supply made on the basis of a medication chart prescription, applies as if the reference to the details referred to in paragraph 45(2)(c) of the Regulations includes a reference to the verification required by paragraph (b) of this section.

Section 25 corresponds to subsection 34(3C) of the 2011 EFC Special Arrangement.

Part 3 — Claims, information and payment

Division 1—Claims for payment and giving information

Section 26 Modified requirements for claims or giving information

Under co-payment data

The Minister may make rules under subsection 99AAA(8) of the Act dealing with the making of claims for payment for supplying pharmaceutical benefits including information that must be provided in a claim. The Minister may also make rules under subsection 98AC(4) of the Act about information that must be given by an approved supplier in relation to an ‘under co-payment supply’. Under co-payment supplies are, in essence, supplies where the Commonwealth price for the supply is equal to or less than the applicable patient co-payment and, as a result, the Commonwealth does not pay suppliers in relation to the supply. The current rules for both subsection 99AAA(8) and 98AC(4) are the *National Health (Supply of Pharmaceutical Benefits – Under Co-payment Data and Claims for Payment) Rules 2022* (‘the Rules’).

Subsection 26(1) provides that a reference in the Rules to under co-payment data is taken to include a reference to information relating to the special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit where the amount payable to the supplier under Division 2 of Part 3 is nil. This modification is required because Commonwealth payments for the supply of doses of chemotherapy drug or related pharmaceutical benefits is calculated with reference to a dispensed price rather than the Commonwealth price.

Supplies of doses of chemotherapy drugs

Subsection 26(2) provides that for a claim or giving of information in relation to a special arrangement supply of a chemotherapy drug, the requirements in the Rules are modified as follows:

- A reference to a pharmaceutical benefit includes a reference to a dose of a chemotherapy drug;
- A reference to an authority prescription includes a reference to an authority prescription within the meaning of the 2024 EFC Special Arrangement;
- The claim or information must include an identifying code for the chemotherapy drug, the dose of the drug supplied, and the compounder ID of the site at which the compounder compounded the dose of the drug;
- The supplier is not required to include in the claim or information the PBS/Repatriation Pharmaceutical Benefits Scheme (RPBS) Item Code for the supplied pharmaceutical benefit, the brand of the supplied pharmaceutical item, whether or not section 49 of the Regulations applies and whether or not immediate supply was necessary.

The note to subsection 26(2) states that a special arrangement supply of a dose of a chemotherapy drug is taken to be a supply of a pharmaceutical benefit.

Section 26 corresponds to sections 37 and 38 of the 2011 EFC Special Arrangement.

Division 2—Payment of claims

Section 27 Payment of approved pharmacists and approved medical practitioners for supplies of doses of chemotherapy drugs

This section sets out the amount that an approved pharmacist or an approved medical practitioner who makes a claim for the supply of a dose of a chemotherapy drug to a patient under the 2024 EFC Special Arrangement is entitled to be paid by the Commonwealth. Entitlement to payment is subject to section 99AAA of the Act and any conditions determined under section 98C of the Act relating to payments to approved pharmacists and approved medical practitioners.

Paragraph 27(1)(a) provides that for an original supply, an approved pharmacist or an approved medical practitioner is entitled to be paid the amount, if any, by which the dispensed price for the dose exceeds the amount that the approved pharmacist or approved medical practitioner was required to charge the patient under subsection 36(2) of the 2024 EFC Special Arrangement. The dispensed price for a dose of a chemotherapy drug supplied by an approved pharmacist or approved medical practitioner is determined under section 31 of the 2024 EFC Special Arrangement.

Paragraph 27(1)(b) provides that for a repeat supply, an approved pharmacist or an approved medical practitioner is entitled to be paid the dispensed price for the dose. Approved pharmacists and approved medical practitioners may not charge patient contributions for a repeat supply of a dose of chemotherapy drug (see section 36).

Subsection 27(2) provides that subsection 27(1) applies despite subsections 99(2) and (2AA) of the Act. The amount of Commonwealth payment for supplies of pharmaceutical benefits would ordinarily be calculated in accordance with subsections 99(2) and (2AA) of the Act.

Subsection 27(3) provides that paragraph 99(3)(b) of the Act does not apply to a special arrangement supply of a dose of a chemotherapy drug by an approved pharmacist. Paragraph 99(3)(b) would ordinarily prevent Commonwealth payments being made for the supply of a pharmaceutical benefit by an approved pharmacist if the supply was not made at or from premises in respect of which the pharmacist is not approved.

Section 27 corresponds to sections 41 and 41A of the 2011 EFC Special Arrangement.

Section 28 Payment of approved hospital authorities for supplies

Subsection 28(1) provides that the section determines, for the purposes of subsection 99(4) of the Act, the amount payable to an approved hospital authority in respect of a special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit. The note to subsection 28(1) clarifies that under the 2024 EFC Special Arrangement, subsection 99(4) of the Act applies as if it includes a reference to patients receiving treatment from a hospital. Subsection 99(4) ordinarily limits Commonwealth payment to approved hospital authorities for the supply of pharmaceutical benefits to supplies made to patients receiving treatment in or at a hospital approved for the approved hospital authority. However, under the 2024 EFC Special Arrangement approved, hospital authorities can also make special arrangement supplies to patients receiving treatment from the hospital.

Subsection 28(2) provides that the section also applies despite the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied by Public Hospitals) Determination 2017* and the *National Health (Commonwealth Price - Pharmaceutical benefits supplied by private hospitals) Determination 2020*. Those instruments ordinarily

provide for the amount of Commonwealth payment to an approved hospital authority for public and private hospitals, respectively, for supplying pharmaceutical benefits.

Subsection 28(3) provides that the amount payable to an approved hospital authority in respect of a special arrangement supply of a dose of a chemotherapy drug to a patient is:

- For an original supply, the amount, if any, by which the dispensed price for the dose exceeds the amount that the hospital authority was entitled to charge the patient under subsection 37(2) for the supply; and
- For a repeat supply, the dispensed price for the dose.

Approved hospital authorities may not charge patient contributions for a repeat supply of a dose of chemotherapy drug (see section 37).

Subsection 28(4) provides that for a special arrangement supply of a related pharmaceutical benefit, the amount payable to a participating hospital authority is the amount, if any, by which the dispensed price for the supply exceeds the amount the patient could have been required to pay in accordance with subsection 87(2) of the Act if the patient had obtained the related pharmaceutical benefit from an approved pharmacist. Only an approved hospital authority that is also a participating hospital authority (i.e. is an approved hospital authority for a public hospital that is participating in a Pharmaceutical Reform Arrangement) may supply related pharmaceutical benefits under the 2024 EFC Special Arrangement.

The note to subsection 28(4) clarifies for readers that subsection 87(5) of the Act enables the participating hospital authority to charge the patient the amount mentioned in subsection 87(2) of the Act.

Section 28 corresponds to sections 42 and 43 of the 2011 EFC Special Arrangement.

Section 29 No separate entitlement to payment for supplies of diluent

This section provides that if an approved supplier adds a pharmaceutical benefit to the supply of a dose of a chemotherapy drug as a diluent, no amount is payable by the Commonwealth for supply of that pharmaceutical benefit, despite section 99 of the Act. It is irrelevant whether the pharmaceutical benefit added as a diluent is a related pharmaceutical benefit.

Section 29 corresponds to section 46 of the 2011 EFC Special Arrangement.

Section 30 Payment to TGA-licensed compounders

This section provides that if a TGA-licensed compounder compounds a dose of a chemotherapy drug for a special arrangement supply of the dose, the compounder is entitled to be paid a TGA-licensed compounding fee by the Commonwealth for compounding the dose. The TGA-licensed compounding fee is \$20 (see section 5).

Where an approved supplier who is a TGA-licensed compounder supplies a dose of chemotherapy drug for a special arrangement supply under the 2024 EFC Special Arrangement and compounds the dose, they are entitled to the TGA-licensed compounding fee in addition to any amount they are entitled to under section 27 or 28 of the 2024 EFC Special Arrangement.

The note to section 30 reflects that information about the compounder is required to be included in the claim by the supplier of the chemotherapy drug or in information about the supply, in accordance with subsection 26(2).

Section 30 corresponds to section 46B of the 2011 EFC Special Arrangement. Subsection 46B(2) of the 2011 EFC Special Arrangement provided that a TGA-licensed compounding was only entitled to one TGA-licensed compounding fee for compounding a dose of chemotherapy drug for an infusion for an individual patient. An equivalent of subsection 46B(2) has not been included in section 30 as it was considered unnecessary. However, this does not indicate an intention that TGA-licensed will be entitled to more than one TGA-licensed compounding fee for compounding a dose of a chemotherapy drug for a patient.

Division 3—Dispensed price for dose of chemotherapy drug

Section 31 Dispensed price for doses supplied by approved pharmacists and approved medical practitioners

Section 31 sets out how the dispensed price for a dose of chemotherapy drug supplied by an approved pharmacist or approved medical practitioner is calculated.

Subsection 31(1) provides that for a dose of a chemotherapy drug supplied by an approved pharmacist or approved medical practitioner, the dispensed price is the sum of the following amounts:

- The base price for the dose, which is worked out under subsection 31(2);
- The distribution fee (\$29.15 – see section 5);
- The dispensing fee (\$8.37 – see section 5);
- The preparation fee (\$88.62 – see section 5); and
- The diluent fee (\$5.77 – see section 5).

Subsection 31(2) provides that the base price for a dose of a chemotherapy drug supplied by an approved pharmacist or approved medical practitioner is the lowest sum of ‘reference prices’ for a chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that make up an amount of the chemotherapy drug that is equal to or greater than the dose.

The reference price of a chemotherapy pharmaceutical benefit is defined in subsection 31(4) as the sum of the single unit ex-manufacturer price for the chemotherapy pharmaceutical benefit (see section 5) and the mark-up for the benefit calculated under section 32. The reference price and single unit ex-manufacturer price are both rounded to the nearest cent, with a half cent rounded up.

As mentioned above in relation to section 5, the single unit ex-manufacturer price for a chemotherapy pharmaceutical benefit is the AEMP for the benefit, divided by its pricing quantity.

The note to subsection 31(2) states that if there is more than one chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that contains enough of the drug to make up the dose, the base price is determined by the lowest priced benefit or combination of benefits.

The base price is therefore the most cost-effective combination of vials required to make up the required dose. Approved suppliers are paid by the Commonwealth for the combination of vials that most cost effectively make up the required patient dose, regardless of the combination of vials that is actually dispensed to the patient. The algorithm originally introduced by the Department as part of the 2011 changes to the EFC program continues to

assist suppliers to work out the most cost-effective combination of vials to make up the patient’s prescribed dose.

Subsection 31(3) explains that a combination of chemotherapy pharmaceutical benefits includes a quantity of 2 or more of the same chemotherapy pharmaceutical benefit. The example following this subsection also makes this clear by explaining that two of the same chemotherapy pharmaceutical benefit, each of which contains 50mg of a drug, could be used in combination to make up an amount of 100mg of the drug. The reference price for each 50mg of the drug would be added together to calculate the price of the combination.

Section 31 corresponds to section 47 of the 2011 EFC Special Arrangement.

Section 32 Mark-up for a chemotherapy pharmaceutical benefit

This section sets out how to calculate the mark-up for a chemotherapy pharmaceutical benefit. The mark-up forms part of the reference price for a dose of a chemotherapy drug supplied by an approved pharmacist or an approved medical practitioner (see paragraph 31(4)(b)).

Subsection 32(1) provides that the mark-up for a chemotherapy pharmaceutical benefit is the mark-up for maximum units, divided by the maximum units of pharmaceutical benefit.

‘Maximum units of pharmaceutical benefit’ is defined as the whole number of units of the chemotherapy pharmaceutical benefit required to make up the maximum amount of the chemotherapy drug in the benefit that is determined by section 14. For example, if the maximum amount of the chemotherapy drug is 1000mg and the form of a chemotherapy pharmaceutical benefit with that drug is 600 mg solution concentrate, the whole number units of that pharmaceutical benefit required to make up the maximum amount is 2.

‘Mark-up for maximum units’ is defined as:

- If the chemotherapy pharmaceutical benefit does not have the drug trastuzumab – the amount worked out under subsection 32(2); and
- If the chemotherapy pharmaceutical benefit has the drug trastuzumab - the amount worked out under subsection 32(3).

Subsection 32(2) and 32(3) sets out how to work out the mark-up for maximum units for a chemotherapy pharmaceutical benefit as follows:

Maximum units ex-manufacturer price for pharmaceutical benefit that does not have trastuzumab	Mark-up for maximum units
Less than \$100	\$4.62
At least \$100 but not more than \$2,000	\$4.62 plus 5% of the amount by which the maximum units ex-manufacture price exceeds \$100
More than \$2,000	\$99.62

Maximum units ex-manufacturer price for pharmaceutical benefit that has trastuzumab	Mark-up for maximum units
Not more than \$40	10% of the maximum units ex-manufacturer price
More than \$40 but not more than \$100	\$4
More than \$100 but not more than \$1,000	4% of the maximum units ex-manufacturer price
More than \$1,000	\$40

Subsection 32(4) provides that the ‘maximum units ex-manufacturer price’ of a chemotherapy pharmaceutical benefit that is a listed brand of a pharmaceutical item is its AEMP divided by the pricing quantity, multiplied by the maximum units of pharmaceutical benefit.

Section 32 corresponds to sections 48 and 49 of the 2011 EFC Special Arrangement. The method of calculating the mark-up for a chemotherapy pharmaceutical benefit that does not have trastuzumab has been updated. Under the 2011 EFC Special Arrangement, the mark-up was calculated by reference to the administration, handling and infrastructure fee (‘AHI fee’) in the *Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020*. The AHI fee is calculated by reference to maximum quantities.

However, in accordance with section 14 of the 2024 EFC Special Arrangement chemotherapy drugs have maximum amounts rather than maximum quantities. Drafting has therefore been updated to accurately reflect particular arrangements for chemotherapy drugs. This is not intended to affect the amount of mark-up included in the dispensed price for supplies made by approved pharmacists and approved medical practitioners.

Section 33 Dispensed price if dose is supplied by approved private hospital authority

Subsection 33(1) provides that for a dose of a chemotherapy drug supplied by an approved hospital authority of a private hospital, the dispensed price is the sum of the following amounts:

- The base price for the dose, which is worked out under subsection 33(2);
- For a drug other than trastuzumab – the distribution fee;
- The dispensing fee;
- The preparation fee; and
- The diluent fee.

Subsection 33(2) sets out that the base price of a chemotherapy drug is the lowest sum of reference prices for a chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that make up an amount of the drug that is equal to or greater than the dose. The reference price for the purposes of section 33 is defined in subsection 33(4) as the sum, rounded to the nearest cent and with a half cent being rounded up, of:

- The single unit ex-manufacturer price for the chemotherapy pharmaceutical benefit, rounded to the nearest cent (with a half cent being rounded up); and
- 1.4% of the single unit ex-manufacturer price for the chemotherapy pharmaceutical benefit.

The note to subsection 33(2) states that if there is more than one chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that contains enough of the drug to make up the dose, the base price is determined by the lowest priced benefit or combination of benefits.

Subsection 33(3) provides that a combination of chemotherapy pharmaceutical benefits includes a quantity of 2 or more of the same chemotherapy pharmaceutical benefit.

Section 33 corresponds to section 50 of the 2011 EFC Special Arrangement.

Section 34 Dispensed price if dose is supplied by approved public hospital authority

Subsection 34(1) provides that for a dose of a chemotherapy drug supplied by an approved hospital authority of a public hospital, the dispensed price is the sum of:

- The base price for the dose, as worked out under subsection 34(2); and
- The preparation fee (\$88.62- see section 5).

Subsection 34(2) provides that the base price for a dose of a chemotherapy drug is the lowest sum of reference prices for a chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits, that make up an amount of the drug equal to or greater than the dose. The reference price of a chemotherapy pharmaceutical benefit for the purposes of section 34 is defined in subsection 34(4) as the single unit ex-manufacturer price for the chemotherapy pharmaceutical benefit, rounded to the nearest cent, with a half cent being rounded up.

Subsection 34(3) provides that a combination of chemotherapy pharmaceutical benefits includes a quantity of 2 or more of the same chemotherapy pharmaceutical benefit.

Section 34 corresponds to section 51 of the 2011 EFC Special Arrangement.

Division 4—Dispensed price for related pharmaceutical benefit

Section 35 Dispensed price for supply of related pharmaceutical benefit

Subsection 35(1) provides that the dispensed price for a related pharmaceutical benefit that is a listed brand of a pharmaceutical item is as follows:

- If the quantity of the benefit supplied is equal to a multiple of a pack quantity of the benefit, the sum of the Approved Ex-Manufacturer Price (AEMP) or the Proportional Ex-Manufacturer Price (PEMP) (as applicable) for each pack quantity;
- If the quantity of the benefit supplied is less than a pack quantity of the benefit (a ‘broken quantity’), the amount worked out in accordance with subsection 35(2);
- If neither of the above paragraphs applies to the quantity of the benefit supplied (i.e., if the quantity supplied is more than a pack quantity but is not equal to a multiple of a pack quantity), the sum of the AEMP or PEMP (as applicable) for each pack quantity, and the amount calculated in accordance with subsection 35(2) for the remainder of the quantity that is a broken quantity.

Subsection 35(2) sets out how to work out the amount for a broken quantity. It provides that the amount for a broken quantity is worked out by dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places, and applying that percentage to the AEMP or PEMP (as applicable) for the pack quantity.

Subsection 35(3) provides that the dispensed price under subsection (1) is rounded to the nearest cent (with a half cent being rounded up).

Section 35 corresponds to sections 52 and 53 of the 2011 EFC Special Arrangement.

Part 4—Patient contributions

Section 36 Supplies of doses of chemotherapy drugs by approved pharmacists and approved medical practitioners

Section 37 Supplies of doses of chemotherapy drugs by approved hospital authorities

Section 36 and 37 set out amounts that an approved pharmacist or approved medical practitioner (section 36) and an approved hospital authority (section 37) must or may charge an eligible patient for a special arrangement supply of a dose of a chemotherapy drug.

For an original special arrangement supply of a dose of a chemotherapy drug made by an approved pharmacist or approved medical practitioner, the approved pharmacist or approved medical practitioner must charge the patient an amount that is equivalent to the amount that may be charged under subsection 87(2) of the Act for the supply of a pharmaceutical benefit to the patient. Subsection 87(2) of the Act sets out the basic co-payments that an approved pharmacist or approved medical practitioner may charge a patient, excluding special patient contribution (if any), delivery fees or out of hours fees (subsection 36(2)).

For an original special arrangement supply of a dose of a chemotherapy drug made by an approved hospital authority, they may charge the patient an amount not exceeding the amount that the patient could have been required to pay under subsection 87(2) of the Act, if the patient had obtained a pharmaceutical benefit from an approved pharmacist (subsection 37(2)).

Notes to subsections 36(2) and 37(2) clarify that this is a single amount for the supply of the dose, and not a separate amount for supply of each chemotherapy pharmaceutical benefit used to make the dose. In other words, if 4 vials, each a chemotherapy pharmaceutical benefit, are required to make up a single dose of chemotherapy drug for a patient, they may only be charged one patient co-payment.

Subsections 36(3) and 37(3) both provide that no amount can be charged to the patient for a repeated supply of a dose of a chemotherapy drug.

Subsections 36(4) and 37(4) both deal with the charging of special patient contributions for special arrangement supplies of doses of chemotherapy drugs.

Subsection 85B(2) of the Act enables the Minister to set a ‘determined price’ for a listed brand of a pharmaceutical item, which becomes its AEMP, where the Minister and the responsible person for the pharmaceutical benefit cannot agree on an agreed price as its AEMP. Where the Minister sets a determined price for a listed brand of pharmaceutical item, a higher ‘claimed price’ will also be set for the listed brand under subsection 85B(3). Determined and claimed prices are set in the Listing Instrument.

Where a listed brand of pharmaceutical item has a determined price, patients will ordinarily be required to pay a special patient contribution for the supply of the brand. Subsection 85B(5) provides that the special patient contribution is, in essence, the difference between what would have been the Commonwealth price for the quantity of the brand supplied if the Commonwealth price was based on the claimed price, and the Commonwealth price based on the determined price.

Commonwealth payments for supply of doses of chemotherapy drugs and related pharmaceutical benefits under the 2024 EFC Special Arrangement are based on the dispensed price for the dose or related pharmaceutical benefit rather than the Commonwealth price (see sections 27 and 31 to 35).

Paragraphs 36(4)(a) and 37(4)(a) provide that if a determination under subsection 85B(3) of the Act is in force in relation to a chemotherapy pharmaceutical benefit used to make a dose of chemotherapy drug, the approved pharmacist, approved medical practitioner or approved hospital authority (as appropriate) may charge a special patient contribution in accordance with the Act, for the supply of the benefit.

Paragraphs 36(4)(b) and 37(4)(b) provide that subsection 85B(5) of the Act applies as if a reference to the Commonwealth price for a quantity or number of units of a listed brand of a pharmaceutical item were a reference to the dispensed price for a dose of a chemotherapy drug made using a quantity or number of units of a listed brand of a pharmaceutical item.

Section 36 corresponds to section 54 of the 2011 EFC Special Arrangement. Section 37 corresponds to section 55 of the 2011 EFC Special Arrangement.

Section 38 Supplies of related pharmaceutical benefits—special patient contribution

Section 38 relates to special patient contributions for related pharmaceutical benefits.

Section 38 of the 2024 EFC Special Arrangement provides that if a determination under subsection 85B(3) of the Act is in force in relation to a related pharmaceutical benefit (i.e. it has a claimed price), subsection 85B(5) of the Act applies to a special arrangement supply of the related pharmaceutical benefit as if a reference to the Commonwealth price were a reference to the dispensed price.

Special patient contributions for supplies made under the 2011 EFC Special Arrangement were dealt with in section 58 of that instrument, which required specifying pharmaceutical benefits with a special patient contribution in Schedule 5 of the 2011 EFC Special Arrangement, along with amounts enabling the calculation of the special patient contribution in accordance with section 58. Section 38 of the 2024 EFC Special Arrangement will enable a special patient contribution to be calculated for any related pharmaceutical benefit that has a claimed price without needing to amend the instrument.

Section 39 Application of safety net provisions

Section 84C of the Act sets out when amounts paid by patients for the supply of pharmaceutical benefit will contribute towards meeting their PBS safety net or their family PBS safety net threshold. It also sets out the amount that will contribute, known as the ‘value for safety net purposes’.

Under subsection 84C of the Act, amounts paid in respect of a supply of a pharmaceutical benefit made by an approved pharmacist do not ordinarily contribute to meeting the PBS safety net threshold unless the supply was made at or from premises in respect of which the pharmacist is for the time being approved. Subsection 39(1) provides that subparagraph 84C(4)(a)(i) of the Act applies to a special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit as if the words “at or from premises in respect of which the pharmacist is for the time being approved” were omitted. This is to ensure that if a dose of chemotherapy drug is compounded for an approved pharmacist at premises other than their approved premises and supplied to the patient from there, patient contributions will still count towards their PBS safety net.

Subsection 39(2) provides that the value for safety net purposes for an original special arrangement supply of a dose of a chemotherapy drug to a person is the amount paid by the person for the supply of the dose under subsection 36(2) or 37(2) of the 2024 EFC Special Arrangement. The note to this subsection clarifies that a special arrangement supply of a dose of a chemotherapy drug is taken to be a supply of a pharmaceutical benefit (see subsection 9(2)).

Subsection 39(3) provides that the value for safety net purposes for a repeated special arrangement supply of a dose of a chemotherapy drug to a person is zero. The note to this subsection states that a person must not be charged a patient co-payment for a repeat supply but may be charged a special patient contribution if applicable (see sections 36 and 37).

Subsection 39(4) provides that section 39 applies despite section 17A of the Regulations, which deals with the value for safety net purposes.

To summarise, therefore, the amount paid by the patient for an original supply of a dose of a chemotherapy drug under subsection 36(2) or 37(2) counts towards their PBS safety net threshold. In addition, any amount a participating hospital authority charges the patient for the supply of a related pharmaceutical benefit in accordance with subsection 87(2) of the Act counts towards their PBS safety net threshold. However, any amount paid by the patient as a special patient contribution will not count towards their PBS safety net threshold.

Section 39 corresponds to section 59 of the 2011 EFC Special Arrangement. While the patient contributions that do (or do not) count towards meeting the PBS safety net threshold are unchanged from the 2011 EFC Special Arrangement, drafting has been updated to use the concept of the value for safety net.

Schedule 1—Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1—Chemotherapy pharmaceutical benefits

Part 1 of Schedule 1 provides for a table, which sets out the chemotherapy pharmaceutical benefits and chemotherapy drugs covered by the 2024 EFC Special Arrangement. Each listed drug specified in the table is a chemotherapy drug, and each pharmaceutical benefit specified in the table is a chemotherapy pharmaceutical benefit.

The table also outlines any applicable circumstances code(s) for a chemotherapy pharmaceutical benefit in the column of the table headed “Circumstances”.

The note to Part 1 of Schedule 1 outlines that the drugs mentioned in the table have been declared by the Minister under subsection 85(2) of the Act. The forms, manners of administrations and brands mentioned in the table have been determined by the Minister under subsections 85(3), (5) and (6) of the Act, respectively. These declarations and determinations have been made in the Listing Instrument.

Part 2—Maximum amounts and number of repeats for chemotherapy drugs

Part 2 of Schedule 1 provides for a table which sets out, for each chemotherapy drug, the maximum amount of the drug that may be directed to be supplied on any one occasion and the maximum number of occasions that, in one chemotherapy prescription, supply of a dose of the drug may be directed to be repeated.

Where these maximums are for particular purposes, there is a purpose code in the column headed “Purposes” in the table. The detail for these codes and the purposes that are represented by those codes are set out in Part 1 of Schedule 3.

Schedule 2—Related pharmaceutical benefits

Schedule 2 provides for a table which sets out the related pharmaceutical benefits covered by the 2024 EFC Special Arrangement.

The table in Schedule 2 also specifies circumstances, purposes, maximum quantities and maximum repeats for related pharmaceutical benefits.

The note to Schedule 2 outlines that the drugs mentioned in the table have been declared by the Minister under subsection 85(2) of the Act. The forms, manners of administration and brands mentioned in the table have been determined by the Minister under subsections 85(3), (5) and (6) respectively. These declarations and determinations have been made in the Listing Instrument.

Schedule 3—Circumstances, purposes and variations

Part 1—Circumstances and purposes

Part 1 of Schedule 3 provides for a table which sets out the detail of circumstances for circumstances codes (for the purposes of sections 12 and 23), and purposes for purposes codes (for the purposes of sections 14 to 17).

In addition, for the purposes of section 13, this table sets out information relating to how authorisation is obtained, when the circumstances for writing a prescription include an authorisation requirement.

Part 2—Variation rules

Part 2 of Schedule 3 provides for a table which sets out variation rules for variation codes, for the purposes of section 18.

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) Special Arrangement 2024

(PB 31 of 2024)

This Disallowable 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 Disallowable Legislative Instrument

The *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* ('2024 EFC Special Arrangement') replaces the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* ('2011 EFC Special Arrangement'), which sunsets on 1 April 2024. It relates to the supply of chemotherapy medicines ('chemotherapy pharmaceutical benefits') to eligible patients being treated for cancer, and to the supply of medicines associated with the side-effects of cancer and cancer treatment ('related pharmaceutical benefits') at certain public hospitals.

The 2024 EFC Special Arrangement makes provision for prescribing and supplying chemotherapy pharmaceutical benefits and related pharmaceutical benefits to eligible patients being treated for cancer. The 2024 EFC Special Arrangement regulates how claims for payment for the supply of such pharmaceutical benefits may be made, the amount of payment that the relevant supplier is entitled to receive from the Commonwealth for each supply, and the amount the patient may be required to pay for each supply. The 2024 EFC Special Arrangement achieves efficiency in payment for the supply of chemotherapy pharmaceutical benefits, by reimbursing suppliers for the combination of vials that most cost-effectively make up the required dose for the patient.

The provisions in the 2024 EFC Special Arrangement retain substantially similar content to that of the 2011 EFC Special Arrangement, with redrafting where necessary to ensure provisions are clear, consistent and ordered in a logical manner. A number of minor updates clarify the policy intent of existing provisions and reflect current practice.

Background

Under the 2024 EFC Special Arrangement, authorised prescribers (namely, medical practitioners) will continue to prescribe chemotherapy drugs in doses tailored to the individual needs of patients, rather than prescribing specific pharmaceutical benefits. Suppliers are to supply the prescribed doses of those drugs, with the supply being made from chemotherapy pharmaceutical benefits.

The Commonwealth will continue to pay suppliers for the most efficient combination of vials (or equivalent) of chemotherapy pharmaceutical benefits the most cost effectively make up the required patient dose, regardless of the combination of chemotherapy pharmaceutical benefits that were actually supplied to the patient.

The 2024 EFC Special Arrangement continues to reduce costs for patients, by providing that a patient co-payment will only be charged in relation to an original supply of a dose of a chemotherapy drug, and not for a repeat supply.

The 2024 EFC Special Arrangement also provides for the supply of related pharmaceutical benefits that are supplied by an approved hospital authority for a public hospital that is participating in a Pharmaceutical Reform Agreement (PRA), on the basis of a prescription written when the person was receiving medical treatment at or from a public hospital as a non-admitted patient, day admitted patient or patient on discharge.

Human rights implications

The 2024 EFC Special Arrangement 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 advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based. The 2024 EFC Special Arrangement assists with the advancement of these rights by ensuring continued access to PBS subsidised pharmaceutical benefits for the treatment of cancer or cancer-related conditions.

The 2024 EFC Special Arrangement:

- Does not affect how much patients are required to pay for the supply of chemotherapy medicines and related pharmaceutical benefits, including that they do not pay any patient contribution for repeats of doses of chemotherapy drugs;
- Does not affect the amount that the patient co-payment counts towards their PBS Safety Net;
- Does not delist any drugs or brands of drugs which would result in unmet clinical needs;
- Adds a new provision, to expressly provide that only medical practitioners are authorised prescribers for the purposes of this instrument. Medical practitioners were also the only class of prescribers who could prescribe medicines under the 2011 EFC Special Arrangement, so the insertion of this clarifying provision into the 2024 EFC Special Arrangement will not result in any practical change;
- Provides for an express requirement that chemotherapy medicines and related pharmaceutical benefits may only be prescribed for a person receiving treatment for cancer or a cancer-related condition. This restriction is appropriate and proportionate, noting that the long-standing policy intention has been that EFC medicines should only be prescribed for the purposes of treatment for cancer or cancer-related conditions. Further, a large proportion of chemotherapy drugs are already, in effect, legally restricted to being prescribed for the purposes of cancer or cancer-related conditions, in accordance with relevant determinations made under 85(7) of the *National Health Act 1953*, which provide that the only circumstances for which such drugs may be prescribed are for the treatment of cancer or cancer-related conditions. Where PBAC considers it appropriate, medicines included in the 2024 EFC Special Arrangement are also available for general supply on the PBS for other conditions.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights as it promotes the rights to health and social security. If a decision were taken to not remake the 2011 EFC Special Arrangement, patient access would be negatively impacted. Chemotherapy medicines and related pharmaceutical benefits for the treatment and cancer or cancer-related conditions would not be available through PBS subsidised access, resulting in a significantly greater cost to patients.

Consequently, the decision to replace the 2011 EFC Special Arrangement with the 2024 EFC Special Arrangement promotes the rights to health and social security by ensuring continued access to PBS subsidised Efficient Funding of Chemotherapy (EFC) medicines.

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

SUMMARY OF CHANGES TO THE *EFFICIENT FUNDING OF CHEMOTHERAPY PROGRAM* MADE BY THE 2024 EFC SPECIAL ARRANGEMENT

The 2024 EFC Special Arrangement reflects changes made by the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* ('Listing Instrument'), which commences on the same day (1 April 2024), and which affects the pharmaceutical benefits that may be supplied under the 2024 EFC Special Arrangement.

The Listing Instrument determines the pharmaceutical benefits that are on the PBS through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. The PBS is a benefit scheme which provides for subsidised access by patients to medicines.

As compared with the 2011 EFC Special Arrangement as of 31 March 2024, and in order to reflect the changes made by the Listing Instrument, the 2024 EFC Special Arrangement provides for:

- The deletion of the listed drug tropisetron;
- The addition of a brand of the listed drug fosaprepitant,
- The deletion of a brand of the listed drug vinorelbine; and
- The alteration of circumstances in which a prescription may be written for the listed drugs avelumab, cemiplimab, durvalumab, pembrolizumab and tebentafusp.

The detail regarding these amendments are provided for in the table below.

In respect of the deletion of the listed drug tropisetron (Tropisetron-AFT), the sponsor made a request for this drug to be delisted from the PBS Schedule.

Subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug.

In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs.

In respect of the deletion of the drug tropisetron from the PBS Schedule, the PBAC noted the low number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised that the delisting of this drug would not result in an unmet clinical need.

In respect of the deletion of a brand of the listed drug vinorelbine, affected patients will be able to access equivalent brands of this drug, at the same cost. Consequently, this will not result in an unmet clinical need.

Drugs Deleted

Listed Drug

Tropisetron

Brands Added

Listed Drug

Form

Fosaprepitant Powder for I.V. infusion 150 mg (*FOSAPREPITANT MEDSURGE*)

Brands Deleted

Listed Drug

Form

Vinorelbine Solution for I.V. infusion 10 mg (as tartrate) in 1 mL (*Navelbine*)

Alteration of Circumstances in Which a Prescription May be Written

Avelumab

Cemiplimab

Durvalumab

Pembrolizumab

Tebentafusp

Documents Incorporated by Reference

Listed Drug

Document incorporated

Document access

Tebentafusp

Approved Product Information/Australian Product Information/TGA-approved Product Information.

The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*.

This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.

TGA-approved Product Information is available for download for free from the TGA website:

<https://www.tga.gov.au/product-information-0>