EXPLANATORY STATEMENT

National Health Act 1953

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011

PB 79 of 2011

Purpose

This legislative instrument provides for a special arrangement under subsection 100(1) of the *National Health Act 1953* ("the Act") to achieve greater efficiency in payment for the supply of injected or infused chemotherapy medicines ("chemotherapy pharmaceutical benefits") to eligible patients being treated for cancer, to reflect the 2010 budget measure titled 'Revised arrangements for the efficient funding of chemotherapy drugs'. This special arrangement also relates to the supply of medicines associated with the side-effects of cancer and cancer treatment ("related pharmaceutical benefits") at certain public hospitals.

Subsection 100(1) of the Act enables the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

(a) who are living in isolated areas; or

(b) who are receiving treatment in circumstances in which generally available pharmaceutical benefits are inadequate for that treatment; or

(c) if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(3) provides that Part VII of the Act, and regulations and other legislative instruments made for the purposes of Part VII, have effect subject to a special arrangement made under subsection 100(1). A section 100 special arrangement may thus modify the operation of Part VII, the regulations and other relevant instruments made under Part VII.

This section 100 special arrangement

This Special Arrangement provides for the supply of both chemotherapy pharmaceutical benefits and related pharmaceutical benefits.

Chemotherapy pharmaceutical benefits

Under this Special Arrangement, prescribers will be required to write dose-specific prescriptions, without reference to forms, strengths or brands of a particular chemotherapy drug (infusion prescriptions or infusion medication charts).

The Commonwealth will then pay the supplier only for the combination of vials (or equivalent) of chemotherapy pharmaceutical benefits with that drug that most cost

effectively makes up the required patient dose, regardless of the combination of chemotherapy pharmaceutical benefits that were actually supplied to the patient. An algorithm has been created to help suppliers to work out the most cost effective combination of vials (or equivalent) to make up the patient's dose.

A range of new fees will be payable to the supplier per infusion to specifically acknowledge the resource intensive activity of preparing chemotherapy infusions. The fees differ per supplier and will be indexed annually from 1 July 2012.

This Special Arrangement also reduces the cost of cancer chemotherapy for patients by reducing the number of patient co-payments that would otherwise apply. A patient co-payment will only be charged on an original supply of an infusion and not on repeat supplies.

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

- approved pharmacist;
- approved medical practitioner;
- approved hospital authority for a private hospital; or
- an approved hospital authority for a public hospital that is participating in a Pharmaceutical Reform Arrangement within the meaning of the National Healthcare Agreement.

If the supplier is a hospital authority, a prescription in the form of an infusion medication chart may be used.

In addition to the above suppliers, a chemotherapy pharmaceutical benefit that includes trastuzumab may also be supplied by any public hospital authority (on an infusion prescription only).

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

This 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 Arrangement within the meaning of the National Healthcare Agreement; and
- to a non-admitted patient, day admitted patient or a patient on discharge.

This retains medication chart prescribing for these suppliers.

These medicines are also available to be supplied by other approved suppliers under general supply pursuant to the ordinary operation of the Act.

There will also be increased numbers of pharmaceutical benefits available for supply through streamlined authority arrangements when supplied under this Special Arrangement by a hospital authority.

Interim and transitionals

Chemotherapy pharmaceutical benefits will no longer be available under general supply from 1 December 2011. Instead they will only be able to be supplied under this Special Arrangement or another section 100 special arrangement.

The Chemotherapy Pharmaceutical Access Program (CPAP) and the Trastuzumab Program section 100 special arrangements will remain in force for supplies of pharmaceutical benefits by approved public hospital authorities that are participating in a Pharmaceutical Reform Arrangement (for CPAP) or by a public hospital authority approved under either the Act or the Highly Specialised Drugs Program (for Trastuzumab), and general supply will remain available for Bortezomib, until all public hospital authorities are able to transition to this Special Arrangement. This will allow more time for those public hospitals that are unable to transition to this Special Arrangement on 1 December 2011, due to software delays.

This Special Arrangement contains transitional provisions that, until the end of 31 March 2012, allow chemotherapy pharmaceutical benefits prescribed prior to 1 December 2011 to be supplied as if under general supply, as in effect on 30 November 2011. This will prevent the need for patients to obtain a new prescription that complies with this Special Arrangement in order to access, under this Special Arrangement, pharmaceutical benefits for which they already have a prescription.

A similar provision regarding prescriptions for Trastuzumab written prior to 1 December 2011 has been inserted into the section 100 special arrangement for the Trastuzumab program.

Consultation

An ongoing and formal process of consultation in relation to matters relevant to this instrument includes the involvement of interested parties through the membership of the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC is an independent expert body established by section 100A of the Act which 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. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. When recommending the listing of a medicine on the Pharmaceutical Benefits Scheme (PBS), PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies were consulted throughout the process for additions and changes to listings on the PBS and for the Special Arrangement. This includes consultation through the PBAC process, and agreement to final listing details.

Medical and pharmacy professional groups, key stakeholder groups representing oncologists and pharmacists, State and Territory health departments, as well as the Department of Human Services and the Medical Software Industry Association, were also consulted throughout the process of developing all legislative instruments under the Act necessary to implement the section 100 special arrangement for the Efficient Funding of Chemotherapy.

This Instrument

An item by item description of this Special Arrangement is contained in the Attachment.

This Special Arrangement commences on 1 December 2011.

This instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003.*

ATTACHMENT 1

ITEM BY ITEM DESCRIPTION OF THE *NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT 2011* (PB 79 OF 2011)

Part 1 General

Division 1 Preliminary

Section 1 Name of Special Arrangement

This section provides that the Special Arrangement is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* and that it may also be cited as PB 79 of 2011.

Section 2 Commencement

This section provides that the Special Arrangement commences on 1 December 2011.

Section 3 Definitions

A number of expressions are defined in section 3, including 'chemotherapy pharmaceutical benefit', 'chemotherapy drug', 'eligible patient', 'eligible public hospital patient', 'infusion', 'participating hospital authority' and 'related pharmaceutical benefit'.

A 'participating hospital authority' is a hospital authority for a public hospital that is:

- approved under section 94 of the Act; and
- participating in a Pharmaceutical Reform Arrangement within the meaning of the National Healthcare Agreement.

The National Healthcare Agreement is a schedule to the *Intergovernmental Agreement on Federal Financial Relations* ("IGA"), which in turn is referred to in the *Federal Financial Relations Act 2009*. This instrument refers to the National Healthcare Agreement as in force 1 July 2011. A copy of the IGA, and the National Healthcare Agreement, which is a schedule to the IGA, can be obtained at the Council of Australian Governments ("COAG") website at http://www.coag.gov.au.

Division 2 Pharmaceutical benefits

Section 4 Pharmaceutical benefits covered by this Special Arrangement

This section provides for the pharmaceutical benefits that are covered by the Special Arrangement.

The Special Arrangement covers the pharmaceutical benefits set out in:

- Part 1 of Schedule 1 to the Special Arrangement (these are chemotherapy pharmaceutical benefits); and

- Schedule 2 to the Special Arrangement (these are related pharmaceutical benefits)

Section 5 Application of Part VII of the Act

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

Subsection 5(1) provides that each pharmaceutical benefit supplied under the Special Arrangement is supplied under Part VII. This is the situation under the Act and the subsection confirms that this is not intended to be modified by the Special Arrangement.

The Note under subsection 5(1) explains that, under this Special Arrangement, the pharmaceutical benefits listed in Part 1 of Schedule 1 (chemotherapy pharmaceutical benefits) are supplied as an infusion made from one or more pharmaceutical benefits.

Subsection 5(2) confirms that the provisions of Part VII, and regulations and other instruments made for Part VII apply, subject to the Special Arrangement.

Section 6 Responsible person

This section provides for the responsible persons for the brands of pharmaceutical items covered by this Special Arrangement. The responsible persons have been determined by the Minister to be the responsible persons under section 84AF of the Act in another legislative instrument and are included in this Special Arrangement for transparency.

Section 7 Authorised prescriber

This section provides for the authorised prescribers for the pharmaceutical benefits covered by this Special Arrangement.

Subsection 7(1) provides that only a person who is an authorised prescriber for a chemotherapy pharmaceutical benefit may prescribe the supply of an infusion that includes the chemotherapy drug in that chemotherapy pharmaceutical benefit under this Special Arrangement. The authorised prescribers for each chemotherapy pharmaceutical benefit are listed in the column headed 'Authorised prescriber' in Part 1 of Schedule 1 to the Special Arrangement.

Subsection 7(2) provides that only a person who is an authorised prescriber for a related pharmaceutical benefit may prescribe the supply of a related pharmaceutical benefit under this Special Arrangement. The authorised prescribers for each related pharmaceutical benefit are listed in the column headed 'Authorised prescriber' in Schedule 2 to the Special Arrangement.

The authorised prescribers for both chemotherapy pharmaceutical benefits and related pharmaceutical benefits are the same as under the Act – this Special Arrangement does not modify who can prescribe a pharmaceutical benefit.

Section 8 Prescription circumstances

This section provides for the circumstances in which a chemotherapy pharmaceutical benefit or a related pharmaceutical benefit may be prescribed under this Special Arrangement.

Chemotherapy pharmaceutical benefits

- If there is at least one circumstance code mentioned in the column headed 'Circumstances' in Part 1 of Schedule 1 for a particular chemotherapy pharmaceutical benefit, the circumstances in Schedule 4 that correspond to that code are circumstances in which an infusion containing the chemotherapy drug in that chemotherapy pharmaceutical benefit may be prescribed;

- If each chemotherapy pharmaceutical benefit that has the same chemotherapy drug has at least one circumstance code mentioned in Part 1 of Schedule 1, an infusion containing that chemotherapy drug may only be prescribed in circumstances that correspond to a circumstance code.

This means that if there are two chemotherapy pharmaceutical benefits with Drug A, that have different circumstance codes, an infusion including Drug A may be prescribed for either circumstance.

Related pharmaceutical benefits

If there is at least one circumstance code mentioned in the column headed 'Circumstances' in Schedule 2 for a particular related pharmaceutical benefit:

- the circumstances in Schedule 4 that correspond to that code are circumstances in which that related pharmaceutical benefit may be prescribed; and

- the related pharmaceutical benefit may only be prescribed in circumstances that correspond to a circumstance code.

Section 9 Maximum amount – chemotherapy drug

This section provides for the maximum amount of a chemotherapy drug that an authorised prescriber may direct to be included in an infusion in one infusion prescription or infusion medication chart ("maximum amount").

The maximum amount for a particular chemotherapy drug is the number in the column headed 'Maximum amount' in Part 2 of Schedule 1 for that chemotherapy drug.

If there is at least one purpose code mentioned in the column headed 'Purposes' in Part 2 of Schedule 1 for a particular chemotherapy drug, the maximum amount of that chemotherapy drug is the maximum amount for the purpose in Schedule 4 that corresponds with that purpose code.

If there are no purpose codes mentioned in the column headed 'Purposes' in Part 2 of Schedule 1 for a particular chemotherapy drug, the maximum amount for that chemotherapy drug is the maximum amount for all purposes, other than a purpose for which a different maximum amount is mentioned for that same chemotherapy drug.

Section 9 is subject to section 17, which provides for variation to the maximum amount of a chemotherapy drug in some situations.

Section 10 Maximum quantity – related pharmaceutical benefit

This section provides for the maximum quantity or number of units of the pharmaceutical item in each related pharmaceutical benefit that may, in one prescription, be directed to be supplied on one occasion ("maximum quantity or number of units").

The maximum quantity or number of units for a particular related pharmaceutical benefit is the number in the column headed 'Maximum Quantity' in Schedule 2 for that related pharmaceutical benefit.

If there is at least one purpose code mentioned in the column headed 'Purposes' in Schedule 2 for a particular related pharmaceutical benefit, the maximum quantity or number of units for that related pharmaceutical benefit is the maximum quantity or number of units for the purpose in Schedule 4 that corresponds with that purpose code.

If there are no purpose codes mentioned in the column headed 'Purposes' in Schedule 2 for a particular related pharmaceutical benefit, the maximum quantity or number of units for that related pharmaceutical benefit is the maximum quantity or number of units for all purposes, other than a purpose for which a different maximum quantity or number of units is mentioned for that same related pharmaceutical benefit.

The maximum quantity or number of units have been determined by the Minister under paragraph 85A(2)(a) of the Act for each pharmaceutical item in each related pharmaceutical benefit in another legislative instrument and are included in this Special Arrangement for transparency.

Section 10 is subject to section 21, which provides for variation to the maximum quantity of a pharmaceutical item in a related pharmaceutical benefit in some situations.

Section 11 Maximum number of repeats – chemotherapy drug

This section provides for the maximum number of occasions an authorised prescriber may, in one infusion prescription or infusion medication chart, direct the supply of an infusion containing a chemotherapy drug covered by this Special Arrangement be repeated ("maximum number of repeats").

The maximum number of repeats for an infusion containing a particular chemotherapy drug is the number in the column headed 'Number of repeats' in Part 2 of Schedule 1 for that chemotherapy drug.

If there is at least one purpose code mentioned in the column headed 'Purposes' in Part 2 of Schedule 1 for a particular chemotherapy drug, the maximum number of repeats for an infusion with that chemotherapy drug is the maximum number for the purpose in Schedule 4 that corresponds with that purpose code.

If there are no purpose codes mentioned in the column headed 'Purposes' in Part 2 of Schedule 1 for a particular chemotherapy drug, the maximum number of repeats for an infusion with that chemotherapy drug is the maximum number of repeats for all purposes, other than a purpose for which a different maximum number of repeats is mentioned for that same chemotherapy drug.

If the infusion prescribed contains more than one chemotherapy drug, the maximum number of repeats for that infusion is the smallest maximum number of repeats that applies to one of the chemotherapy drugs that make up the infusion.

Section 11 is subject to section 17, which provides for variation to the maximum number of repeats of an infusion containing a particular chemotherapy drug in some situations.

Section 12 Maximum number of repeats – related pharmaceutical benefit

This section provides for the maximum number of occasions an authorised prescriber may, in one prescription or medication chart, direct the supply of a related pharmaceutical benefit covered by this Special Arrangement to be repeated ("maximum number of repeats").

The maximum number of repeats for a particular related pharmaceutical benefit is the number in the column headed 'Number of repeats' in Schedule 2 for that related pharmaceutical benefit.

If there is at least one purpose code mentioned in the column headed 'Purposes' in Schedule 2 for a particular related pharmaceutical benefit, the maximum number of repeats for that related pharmaceutical benefit is the maximum number of repeats for the purpose in Schedule 4 that corresponds with that purpose code.

If there are no purpose codes mentioned in the column headed 'Purposes' in Schedule 2 for a particular related pharmaceutical benefit, the maximum number of repeats for that related pharmaceutical benefit is the maximum number of repeats for all purposes, other than a purpose for which a different maximum number of repeats is mentioned for that same related pharmaceutical benefit.

The maximum number of repeats have been determined by the Minister under paragraph 85A(2)(b) for each pharmaceutical item in each related pharmaceutical benefit in another legislative instrument and are included in this Special Arrangement for transparency.

Section 12 is subject to section 21, which provides for variation to the maximum number of repeats for a related pharmaceutical benefit in some situations.

Section 13 Section 100 only supply

This section provides for matters relating to the section 100 only supply of the pharmaceutical benefits covered by this Special Arrangement. These matters have been determined by the Minister under relevant provisions of the Act in another legislative instrument and are included in the Special Arrangement for transparency. The matters concern:

- Section 100 only drugs declared under subsection 85(2A) of the Act;
- Section 100 only pharmaceutical benefits determined under paragraph 85(8)(a) of the Act; and
- Section 100 only circumstances for supply of a pharmaceutical benefit determined under paragraph 85(8)(b) of the Act.

The letter 'D' in the 'Section 100 only' column in Part 1 of Schedule 1 or in Schedule 2 indicates that the drug is a section 100 only drug and that all pharmaceutical benefits that have that drug may only be supplied under this or another special arrangement under section 100.

The letters 'PB' in the 'Section 100 only' column in Part 1 of Schedule 1 or in Schedule 2 indicates that the pharmaceutical benefit is a section 100 only pharmaceutical benefit and that pharmaceutical benefit may only be supplied under this or another special arrangement under section 100. It is not available for general supply on the PBS.

The letter 'C' in the 'Section 100 only' column in Part 1 of Schedule 1 or in Schedule 2 indicates that the pharmaceutical benefit has a section 100 only circumstance and that pharmaceutical benefit may only be supplied in that circumstance under this or another special arrangement under section 100. It is not available for general supply on the PBS.

Part 2 Prescription

Division 1 Chemotherapy pharmaceutical benefits

Section 14 Methods of prescribing chemotherapy pharmaceutical benefit

Section 14 sets out the methods of prescribing a chemotherapy pharmaceutical benefit under this Special Arrangement.

Subsection 14(1) provides that an authorised prescriber may prescribe a chemotherapy pharmaceutical benefit by either:

- *for all eligible patients* – by writing an infusion prescription, for an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit; or

- *for eligible public hospital patients only* – by preparing an infusion medication chart for an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit.

An infusion prescription must be written in accordance with the ordinary requirements for writing a prescription in regulation 19 of the Regulations, as modified by section 15 of this Special Arrangement.

An infusion medication chart must be prepared in accordance with section 16 of this Special Arrangement.

Subsection 14(2) provides that chemotherapy pharmaceutical benefit containing either trastuzumab or bortezomib can only be prescribed in an infusion prescription – not in an infusion medication chart.

Subsection 14(3) provides that an infusion prescription written in accordance with section 15 of this Special Arrangement, or an infusion medication chart prepared in accordance with section 16 of the Special Arrangement, is taken to be a duly written prescription for regulation 19 of the Regulations. The purpose of this provision is to ensure that any provision of the Act, or an instrument made under the Act, that applies to a prescription written in accordance with regulation 19 also applies to an infusion prescription or an infusion medication chart under this Special Arrangement, unless the contrary is provided in this Special Arrangement.

Subsection 14(4) provides that paragraph 19(2)(a) of the Regulations does not apply to an infusion prescription or an infusion medication chart. Paragraph 19(2)(a) prevents a prescription from being a duly written prescription if there was another prescription written on the same day for the supply of the same pharmaceutical benefit (or an equivalent pharmaceutical benefit) for the same patient. This Special Arrangement overrides this provision as there is no restriction under this Special Arrangement regarding how soon a second infusion prescription or infusion medication chart may be written for an eligible patient.

Section 15 Information to be included in infusion prescription

Subsection 15(1) provides that this section modifies the requirements of regulation 19 of the Regulations in relation to infusion prescriptions. Regulation 19 deals with how a prescription must be written and what information must be included.

Subsection 15(2) sets out the information that is required to be provided in an infusion prescription.

Subsection 15(3) sets out the information that is not required to be provided in an infusion prescription.

The information relating to the quantity and number of repeats for a pharmaceutical benefit would ordinarily be required in a prescription written under Regulation 19, but is not required under this Special Arrangement.

The Note following subsection 15(3) explains that, due to section 33 of this Special Arrangement, if an authorised prescriber does include the information mentioned in subsection 15(3) in the prescription, the supplier is not required to follow it.

Section 16 Information to be included in infusion medication chart

This section sets out the information that is required to be included in an infusion medication chart for an eligible public hospital patient.

The note following this section explains that if certain information is included in the infusion medication chart, the supplier is not required to follow it. This is provided for in section 33 of this Special Arrangement.

Section 17 Dose or number of repeats greater than maximum amount

Section 17 applies if an authorised prescriber seeks to:

- prescribe a dose of a chemotherapy drug that is greater than the maximum amount of that chemotherapy drug that is permitted, under section 9, to be prescribed in a single infusion prescription or infusion medication chart; or

- direct that the supply of an infusion be repeated more times that the maximum number of repeats permitted, under section 11, for one or more of the chemotherapy drug included in the infusion

For infusion prescriptions – Paragraphs 17(1)(a) and 17(3)(a) provide that the prescription must be authorised in accordance with the procedures mentioned in Regulation 13 of the Regulations, as modified by subsection 17(2) or (4).

Subsection 17(2) has the effect that a reference in Regulation 13 to a determination in force under paragraph 85A(2)(a) of the Act for a pharmaceutical benefit is to be read as a reference to the maximum amount for the chemotherapy drug, as described in section 9 of this Special Arrangement.

Subsection 17(4) has the effect that a reference in Regulation 13 to a determination in force under paragraph 85A(2)(b) of the Act for a pharmaceutical benefit is to be read as a reference to the maximum number of repeats for the chemotherapy drug, as described in section 11 of this Special Arrangement.

This modification of regulation 13 is necessary as there are no maximum quantities or maximum number of repeats determined under paragraph 85A of the Act for chemotherapy pharmaceutical benefits. Instead, a maximum amount and the maximum number of repeats for a chemotherapy drug are determined under this Special Arrangement. This is because 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.

For infusion medication charts – Paragraphs 17(1)(b) and 17(3)(b) provide that the medication chart must be authorised in accordance with the procedures mentioned in section 28 of this Special Arrangement.

Section 18 Direction to vary dose of chemotherapy drug in infusion

This section allows an authorised prescriber to direct the supplier to vary the prescribed dose of a chemotherapy drug in an infusion, without writing a new infusion prescription or infusion medication chart.

Subsection 18(1) provides that an authorised prescriber may direct the supplier to vary the prescribed dose of a chemotherapy drug in an infusion without writing a new infusion prescription or infusion medication chart, as long as the new dose is between 90% and 110% (inclusive) of the original dose prescribed in the prescription or medication chart.

Subsection 18(2) provides that a new dose of a chemotherapy drug that has been directed under subsection 18(1) of this Special Arrangement does not require approval under section 17, even if it is above the maximum amount for that chemotherapy drug, as determined under section 9 of this Special Arrangement.

This means that an authorised prescriber can direct that the prescribed dose of a chemotherapy drug be increased above the maximum amount for that drug, as long as the increase from the dose on the original prescription is not more than 10%. In these circumstances, the authorised prescriber would not be required to obtain an approval for the increase under section 17 of this Special Arrangement.

However, if the authorised prescriber wanted to increase or decrease the prescribed dose of a chemotherapy drug by more than 10%, he or she would need to:

- write a new infusion prescription or infusion medication chart for the higher (or lower) dose; and
- obtain approval under section 17 of this Special Arrangement if the new dose is higher than the maximum amount for the chemotherapy drug.

A dose varied under this section may continue to be increased or decreased as long as the overall variation remains 10% or less of the original prescribed dose for that chemotherapy drug. If the authorised prescriber wishes to increase or decrease the prescribed dose over the 10% amount, he or she will need to write a new infusion prescription or infusion medication chart.

Subsection 18(3) sets out the information that the supplier must record on the infusion prescription or infusion medication chart if they receive a direction to vary a prescribed dose under this section.

Division 2 Related pharmaceutical benefits

Section 19 Methods of prescribing related pharmaceutical benefit

Section 19 sets out the methods of prescribing a related pharmaceutical benefit under this Special Arrangement.

Subsection 19(1) provides that an authorised prescriber may prescribe a related pharmaceutical benefit by either:

- writing a prescription in accordance with the ordinary requirements for writing a prescription in regulation 19 of the Regulations; or

- preparing a medication chart in accordance with section 20.

Subsection 19(2) provides that a medication chart prepared in accordance with section 20 of the Special Arrangement is taken to be a duly written prescription for regulation 19 of the Regulations. The purpose of this provision is to ensure that any provision of the Act, or an instrument made under the Act, that applies to a prescription written in accordance with regulation 19 also applies to a medication chart prescribing a related pharmaceutical benefit under this Special Arrangement, unless the contrary is provided in this Special Arrangement.

The Note under subsection 19(1) explains that a related pharmaceutical benefit can only be supplied this Special Arrangement by a participating hospital authority to an eligible public hospital patient.

Section 20 Information to be included in medication chart for related pharmaceutical benefit

This section sets out the information that is required to be included in a medication chart prescribing a related pharmaceutical benefit for an eligible public hospital patient.

Section 21 Quantity or number of repeats greater than maximum

Section 21 applies if an authorised prescriber seeks to:

- prescribe a related pharmaceutical benefit in a quantity or number of units greater than the maximum quantity or number of units of the related pharmaceutical benefit permitted to be directed to be supplied on one occasion by section 10 of this Special Arrangement; or

- direct that the supply of an related pharmaceutical benefit be repeated more times that the maximum number of repeats permitted under section 12 of this Special Arrangement.

For prescriptions – Paragraphs 21(1)(a) and 21(2)(a) have the effect that the prescription must be authorised in accordance with the procedures mentioned in regulation 13 of the Regulations.

For medication charts – Paragraphs 21(1)(b) and 21(2)(b) have the effect that the medication chart must be authorised in accordance with the procedures mentioned in section 28.

Division 3 Authority required procedures

Section 22 Authority required procedures to be followed

This section sets out matters relevant to prescriptions where authorisation from the Chief Executive Medicare is required because the supply of the infusion or related pharmaceutical benefit is prescribed in circumstances, mentioned in Schedule 4, which include one of the following statements:

- Compliance with Authority Required procedures;
- Compliance with Written Authority required procedures;
- Compliance with Telephone Authority Required procedures;
- Compliance with Written or Telephone Authority Required procedures; or
- Compliance with modified Written Authority Required procedures.

Subsection 22(3) makes it clear which authority procedure needs to be followed for each prescription, by setting out the following:

- If the circumstance includes the statement 'Compliance with Authority Required procedures', the prescription may be authorised in accordance with any of:
    - the Written Authority Required procedure;
    - the Telephone Authority Required procedure; or
    - the Electronic Authority Required procedure;

- If the circumstance includes the statement 'Compliance with Written Authority Required procedures', the prescription must be authorised in accordance with the Written Authority Required procedure;

- If the circumstance includes the statement 'Compliance with Telephone Authority Required procedures', the prescription must be authorised in accordance with the Telephone Authority Required procedure;

- If the circumstance includes the statement 'Compliance with Written or Telephone Authority Required procedures, the prescription may be authorised in accordance with either of:
    - the Written Authority Required procedure; or
    - the Telephone Authority Required procedure;

- If the circumstance includes the statement 'Compliance with modified Written Authority Required procedures', the prescription must be authorised in accordance with the modified Written Authority Required procedure;

Subsection 22(4) provides that if medication chart or an infusion medication chart requires authorisation, it must be authorised in accordance with the procedure in section 28.

Subsection 22(5) has the effect that if the circumstance requiring authorisation includes the words 'Streamlined Authority Code' followed by a number, a prescription or medication chart prescribing the supply of an infusion or related pharmaceutical benefit in that circumstance is taken to be authorised when the streamlined authority code is recorded on it.

Section 23 Written Authority Required procedure

This section sets out how a prescription is authorised in accordance with the Written Authority Required procedure mentioned in subsection 22(3) of this Special Arrangement.

Section 24 Modified Written Authority Required procedure

This section sets out how a prescription is authorised in accordance with the modified Written Authority Required procedure mentioned in subsection 22(3) of this Special Arrangement.

A prescription authorised in accordance with the modified Written Authority Required procedure is submitted to the Chief Executive Medicare and authorised in the same way as the Written Authority Required procedures, however the authorised prescriber must also comply with any additional requirements set out in the relevant circumstance for which the prescription is to be authorised.

These additional requirements generally involve the submission of additional documents with the prescription.

Section 25 Submission of prescription by agent permitted

This section applies to a prescription written under this Special Arrangement that is required to be authorised using either the Written Authority Required procedure (section 23) or the Modified Written Authority Required procedure (section 24).

A prescription that has been prepared and signed by an authorised prescriber is taken to have been submitted by that authorised prescriber if it is submitted by his or her agent.

Section 26 Telephone Authority Required procedure

This section sets out how a prescription is authorised in accordance with the Telephone Authority Required procedure mentioned in subsection 22(3) of this Special Arrangement.

Section 27 Electronic Authority Required procedure

This section sets out how a prescription is authorised in accordance with the Electronic Authority Required procedure mentioned in subsection 22(3) of this Special Arrangement.

Section 28 Medication chart authorisation

This section specifies how a prescription that is written on a medication chart is authorised.

In practice, this provision is only used to authorise medication charts that prescribe a quantity or number of repeats of a chemotherapy drug or related pharmaceutical benefit greater than is permitted under sections 9-12 of this Special Arrangement.

This is because all circumstances that apply to supply of a pharmaceutical benefit by a public hospital authority under this Special Arrangement contain a streamlined authority code. When the circumstance contains a streamlined authority code, paragraph 22(5)(c) provides that a medication chart prescribing an infusion or a related pharmaceutical benefit in that circumstance is taken to be authorised when the medication chart is prepared in accordance with paragraph 14(1)(b) (for infusion medication charts) or 19(1)(b) (for medication charts prescribing a related pharmaceutical benefit).

Section 29 Alternative if medication chart not authorised

This section applies where a pharmacist attempted to have a medication chart authorised under section 28, but the authorisation was refused or the computer system was unavailable.

In this situation, the authorisation may be sought by writing an authority prescription for the supply of the infusion or related pharmaceutical benefit and submitting that prescription to the Chief Executive Medicare in accordance with a procedure allowed by subsection 22(3) for the relevant circumstance for which authorisation of the prescription is required.

Part 3 Supply

Section 30 Entitlement to infusion or related pharmaceutical benefit

Section 30 provides that an eligible patient is entitled to receive an infusion or a related pharmaceutical benefit under this Special arrangement without payment or other consideration, other than a charge made under Part 5.

Section 31 Supply of infusion under this Special Arrangement

Section 31 sets out who may supply an infusion to an eligible patient under this Special Arrangement.

The following suppliers may supply an infusion under this Special Arrangement:

- an approved pharmacist;
- an approved medical practitioner;
- an approved hospital authority for a private hospital
- a public hospital authority (but only to an eligible public hospital patient).

However, if a public hospital authority is not a participating hospital authority:

- the hospital authority can only supply an infusion containing trastuzumab and no other chemotherapy drug; and

- the hospital authority cannot supply an infusion that was prescribed on an infusion medication chart.

A 'public hospital authority' is defined in section 4 of the Act as the governing body of a 'public hospital'.

All references to 'private hospital' or 'public hospital' mean a hospital in respect of which there is in force a statement under subsection 121-5(8) of the *Private Health Insurance Act 2007* that the hospital is a public hospital or a private hospital.

Section 32 Supply of related pharmaceutical benefits under this Special Arrangement

Section 32 provides that a related pharmaceutical benefit may only be supplied under this Special Arrangement by a participating hospital authority to an eligible public hospital patient.

A 'participating hospital authority' is defined in section 3 of the Special Arrangement as being an approved hospital authority for a public hospital that is participating in a Pharmaceutical Reform Arrangement within the meaning of the National Healthcare Agreement.

Section 33 Selection of chemotherapy pharmaceutical benefits to make infusion

This section deals with requirements for suppliers when presented with an infusion prescription or infusion medication chart prescribing the supply of an infusion for an eligible patient.

Under sections 15 and 16 of this Special Arrangement, the prescriber is not required to identify the following, in an infusion prescription or infusion medication chart:

- a particular form of a chemotherapy drug;
- a particular brand of a chemotherapy drug
- a particular manner of administration of a chemotherapy drug;
- the quantity or number of units of a particular chemotherapy pharmaceutical benefit to be supplied; or
- the number of repeats of a particular chemotherapy pharmaceutical benefit to be supplied.

Form and brand of a chemotherapy drug

Subsections 33(1) and (2) have the effect that if an authorised prescriber does direct, in the infusion prescription or infusion medication chart, a particular form or brand of a chemotherapy drug to be supplied, the supplier may disregard the direction and may use chemotherapy pharmaceutical benefits with the same drug but a different form and/or brand to make the infusion.

Method of administering chemotherapy drug

Subsections 33(3) provides that where an authorised prescriber directs, in the infusion prescription or infusion medication chart, a particular method of administering a chemotherapy drug, supply of the infusion to the patient must be consistent with that method.

Subsection 33(4) provides that this is the case regardless of whether the method of administering the chemotherapy drug identified in the prescription/medication chart is also a manner of administration for a chemotherapy pharmaceutical benefit that has that chemotherapy drug, as determined under subsection 85(5) of the Act.

Where infusion prescription/infusion medication chart specifies the supply of a quantity or number of repeats of a particular chemotherapy pharmaceutical benefit

Subsections 33(5) and 33(6) provide that if an authorised prescriber does direct, in an infusion prescription or infusion medication chart, that a quantity or number of units or a number of repeats of a particular chemotherapy pharmaceutical benefit be supplied, the supplier may disregard that direction.

Circumstances

Subsection 33(7) provides that if an infusion prescription or infusion medication chart prescribes the supply of an infusion in circumstances mentioned in Schedule 4, the supplier may only make up the infusion using chemotherapy pharmaceutical benefits for which the circumstance code that corresponds to those circumstances is mentioned in Part 1 of Schedule 1.

For example:

- If there are two chemotherapy pharmaceutical benefits with Drug A, that have different circumstance codes, an infusion including Drug A may be prescribed for either circumstance (see subsection 8(2) of this Special Arrangement);

- Subsection 33(7) of this Special Arrangement will then operate so that when the infusion is supplied, only the chemotherapy pharmaceutical benefit that has the relevant circumstance code for the circumstance for which the prescription was written, may be used to make up the dose of Drug A in the infusion.

Section 34 Modified application of Act and Regulations

This section modifies the Act and Regulations for supplies made under this Special Arrangement.

Infusions

Subsection 34(1) provides that the supply of an infusion under this Special Arrangement cannot be an early supply of a specified pharmaceutical benefit under subsection 84AAA(1) of the Act.

The effect of this modification is that flow-on consequences under the Act for an early supply, including safety net consequences, do not apply to the supply of an infusion under this Special Arrangement.

Subsection 34(2) provides that subregulations 25(2), 25(3) and 25(4) of the Regulations do not apply to the supply of an infusion under this Special Arrangement. The effect of this modification is to override restrictions in the Regulations regarding how soon a repeat supply may be made. Under this Special Arrangement there is no restriction on how soon a repeat supply of an infusion may be made.

The restrictions in subregulations 25(2), 25(3) and 25(4) still apply to the supply of a related pharmaceutical benefit under this Special Arrangement.

Subsection 34(3) provides that regulations 24 and 26A do not apply to the supply of an infusion under this Special Arrangement. These regulations deal with supply of the original and all repeats at one time (regulation 24) and deferred supply (regulation 26A), which are both considered inappropriate for the supply of an infusion.

Both regulations 24 and 26A still apply for the supply of a related pharmaceutical benefit under this Special Arrangement.

Subsection 34(4) provides that a reference in the regulations to the supply of a pharmaceutical benefit is taken to include the supply of an infusion under this Special Arrangement. The effect of this provision is to ensure that it is clear that all regulations that are not being modified apply to the supply of an infusion under this Special Arrangement. A supply of an infusion is still the supply of one or more pharmaceutical benefits under Part VII of the Act.

Medication charts

Subsection 34(5) has the effect that regulations 22 and 31 do not apply to the supply of an infusion or related pharmaceutical benefit under this Special Arrangement if the infusion or related pharmaceutical benefit was prescribed in a medication chart.

These regulations deal with the supply of pharmaceutical benefit before the surrender of a prescription (regulation 22) and acknowledgement by the patient of the receipt of a pharmaceutical benefit (regulation 31) and are being overridden because they are considered to be inappropriate where a medication chart is used.

Section 35 Medication charts – acknowledging receipt of infusion or related pharmaceutical benefit

Section 35 sets out a specific rule to replace regulation 31 where the supply of an infusion or a related pharmaceutical benefit is prescribed in a medication chart.

Subsection 35(1) provides that if the supply of an infusion is prescribed under the Special Arrangement by an authorised prescriber preparing an infusion medication chart, the patient's treating medical practitioner, or a person employed or engaged by

the participating hospital authority, must record the date that the infusion was supplied to the patient on the medication chart.

Similarly, subsection 35(2) provides that if the supply of a related pharmaceutical benefit is prescribed under the Special Arrangement by an authorised prescriber preparing a medication chart, the patient's treating medical practitioner, or a person employed or engaged by the participating hospital authority, must record the date that the infusion was supplied to the patient on the medication chart.

Part 4 Claims and payment

Division 1 Claims for payment

Section 36 How claims to be made

This section deals with how suppliers may make a claim for the supply of an infusion or a related pharmaceutical benefit under this Special Arrangement.

Subsection 36(1) provides that an approved supplier or an HSD hospital authority may make a claim for payment for the supply of an infusion or a related pharmaceutical benefit by making a claim in accordance with section 99AAA of the Act, and the rules made by the Minister under subsection 99AAA(8) of the Act ("the claim rules"), as modified by this Division.

An approved supplier is defined in subsection 84(1) of the Act as covering an approved pharmacist (approved under section 90 of the Act), an approved medical practitioner (approved under section 92 of the Act) or an approved hospital authority (approved under section 94 of the Act).

Subsection 36(2) provides that the State or Territory responsible for a non-approved public hospital authority that supplies an infusion containing only trastuzumab under this Special Arrangement may make a claim for payment for that supply by making an 'off-line' claim for payment in accordance with section 40 of this Special Arrangement.

Section 37 Modified references for claim by HSD hospital authority

Section 37 modifies the claim rules to deal with supplies of infusions made by HSD hospital authorities. These modifications are necessary in order for HSD hospital authorities to be treated the same way as hospital authorities approved under section 94 of the Act.

Paragraph 37(a) provides that a reference in the claim rules to an 'approved supplier' or an 'approved hospital authority' includes a reference to an HSD hospital authority.

Paragraph 37(b) provides that a reference in the claim rules to a number allotted to an approval under regulation 8A includes a reference to a number allotted to an approval under section 52 of the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010*.

Section 38 Modified requirements for supply from medication chart

Subsection 38(1) provides that this section modifies the claim rules for supplies of infusions that were prescribed in an infusion medication chart and for supplies of related pharmaceutical benefits that were prescribed in a medication chart.

Subsection 38(2) modifies the claim rules by providing that:

- the participating hospital authority is not required to supply the medication chart with the claim; and
- the participating hospital authority is required to keep an electronic version of the information supplied with the claim for 1 year from the day that the infusion or related pharmaceutical benefit is supplied; and
- on request, the participating hospital authority must give the Chief Executive Medicare a copy of the medication chart and the information supplied with the claim

Section 39 Modified requirements for supply of infusion

This section modifies the claim rules for the supply of infusions by providing that:

- a reference in the claim rules to 'pharmaceutical benefit' includes a reference to an infusion; and
- a reference in the claim rules to an 'authority prescription' includes a reference to an authority prescription within the meaning of this Special Arrangement; and
- the claim must include the following additional information that does not appear in the claim rules:
    - a drug code for each chemotherapy drug supplied in the infusion. This is the drug code that is published by the Department of Health and Ageing on the *Schedule of Pharmaceutical Benefits*, and is available at www.pbs.gov.au
    - the dose of each chemotherapy drug supplied in the infusion; and
    - for an authority prescription, the authority approval number or streamlined authority code relevant to each circumstance requiring authorisation for which the infusion is prescribed.
- the claim does not need to include the following information that would otherwise have been required by the claim rules:
    - the PBS/RPBS Item code for any pharmaceutical benefit supplied; and
    - the brand of any supplied pharmaceutical item.

Section 40 Off-line claim by State or Territory

This section sets out the manner in which an off-line claim for payment may be made by the State or Territory responsible for a non-approved hospital authority that supplies an infusion containing only trastuzumab.

Section 40 provides that the State or Territory responsible for the hospital makes an off-line claim by lodging a claim with the Human Services Department. The claim must be made within a specified time and contain the specified information.

Each State or Territory must only make 1 claim per calendar month. That claim should cover all infusions supplied under this Special Arrangement by non-approved public hospital authorities within the relevant State or Territory for which an off-line claim is to be made.

Division 2 Payment of claim

Section 41 Payment of approved pharmacist or approved medical practitioner for supply of infusion

This section sets out the amount that an approved pharmacist or an approved medical practitioner who makes a claim for the supply of an infusion under this Special Arrangement is entitled to be paid by the Commonwealth for that supply.

Under this Special Arrangement, an approved pharmacist or an approved medical practitioner is entitled to be paid the dispensed price for the supply of the infusion less the co-payment that they were required, under subsection 54(2) of this Special Arrangement, to charge the patient.

Section 42 Payment for approved hospital authority or HSD hospital authority for supply of infusion

This section sets out the amount that an approved hospital authority or an HSD hospital authority that makes a claim for the supply of an infusion under this Special Arrangement is entitled to be paid by the Commonwealth for that supply.

Under this Special Arrangement, an approved hospital authority or an HSD hospital authority is entitled to be paid the dispensed price for the supply of the infusion less the co-payment that it may, under subsection 55(2) of this Special Arrangement, charge the patient.

Section 43 Payment of participating hospital authority for supply of related pharmaceutical benefit

This section sets out the amount that a participating hospital authority that makes a claim for the supply of a related pharmaceutical benefit under this Special Arrangement is entitled to be paid by the Commonwealth for that supply.

Under this Special Arrangement, a participating hospital authority is entitled to be paid the dispensed price for the supply of the related pharmaceutical benefit less the co-payment that it may, under subsection 57(2) of this Special Arrangement, charge the patient.

Section 44 Payment of State or Territory for supply of trastuzumab by non-approved public hospital authorities

This section sets out the amount that a State or Territory that makes an off-line claim for the supply, by a non-approved public hospital in that State or Territory, of an infusion containing trastuzumab under this Special Arrangement is entitled to be paid by the Commonwealth for that supply.

Under this Special Arrangement, the State or Territory is entitled to be paid 99.2% of the dispensed price for the dose of trastuzumab.

Section 45 Method of working out dispensed price

This section sets out how to work out the dispensed price for the supply of an infusion and the dispensed price for the supply of a related pharmaceutical benefit.

Subsection 45(1) provides that the dispensed price for the supply of an infusion is worked out by adding together the dispensed prices for each dose of a chemotherapy drug included in the infusion.

If the supply is a repeat supply, the dispensed price for the infusion also includes an amount equivalent to the applicable patient co-payment under subsection 87(2) of the Act. This is because, under this Special Arrangement, the patient pays the applicable co-payment on the original supply and the Commonwealth pays it on all repeat supplies.

Subsection 45(2) provides that the dispensed price for a chemotherapy drug is worked out under Division 3.

Subsection 45(3) provides that the dispensed price for the supply of a related pharmaceutical benefit is worked out under Division 4.

Subsection 45(4) provides that a dispensed price worked out under Division 3 (for the dose of a chemotherapy drug) or under Division 4 (for the supply of a related pharmaceutical benefit) is rounded to the nearest cent.

Section 46 No separate entitlement to payment for supply of diluent

This section prevents a supplier from claiming, under general supply, for a pharmaceutical benefit used in an infusion as a diluent.

This is because, under this Special Arrangement, the supplier recovers the cost of a diluent by receiving a ‘diluent fee’ from the Commonwealth as part of the dispensed price for the dose of each chemotherapy drug supplied in the infusion.

Division 3 Dispensed price of chemotherapy drug

Section 47 Dispensed price if drug is in infusion supplied by approved pharmacist or approved medical practitioner

This section sets out how to calculate the dispensed price of a chemotherapy drug in an infusion where the infusion is supplied by an approved pharmacist or an approved medical practitioner under this Special Arrangement.

Subsection 47(1) provides that the dispensed price for a dose of a chemotherapy drug in an infusion supplied by an approved pharmacist or approved medical practitioner is the sum of the:

- base price for the dose (worked out under subsection 47(2));
- distribution fee ($24);
- dispensing fee ($6.42);
- preparation fee ($40); and
- diluent fee ($4.75).

The amount of each fee is set out in section 3 of this Special Arrangement and will be indexed annually from 1 July 2012.

Subsection 47(2) sets out what the base price is for a dose of a chemotherapy drug supplied under this Special Arrangement. 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 chemotherapy drug that is equal to or greater than the dose.

The base price is the most cost effective combination of vials required to make up the required patient dose. The purpose of this provision is so that suppliers are only paid for the combination of vials that most cost effectively makes up the required patient dose, regardless of the combination of vials that is actually dispensed to the patient. An algorithm has been created to help suppliers work out the most cost effective combination of vials to make up the patient's prescribed dose. This algorithm is being incorporated into dispensing software programs for suppliers.

Subsection 47(3) explains that that the reference in subsection 47(2) to a 'combination of chemotherapy pharmaceutical benefits' includes a quantity of 2 or more of the same pharmaceutical benefit. The example following this subsection also makes this clear by explaining that if the form of a chemotherapy pharmaceutical benefit contained 50 mg of a chemotherapy drug, a quantity of two of that pharmaceutical benefit could be used as 'a combination of chemotherapy pharmaceutical benefits' to make up a dose of 100 mg of the drug.

The note following subsection 47(3) further clarifies that a quantity of 1 of a chemotherapy pharmaceutical benefit is the amount of the drug that is represented by the form of that chemotherapy pharmaceutical benefit. The form of a chemotherapy pharmaceutical benefit has been determined under subsection 85(3) of the Act and is mentioned in Part 1 of Schedule 1 of this Special Arrangement. A quantity of 1 will often in practice equate to 1 vial, but will also work if there is no vial.

Subsection 47(4) explains the term 'reference price for a chemotherapy pharmaceutical benefit' that is used in subsection 47(2) to calculate the base price for a dose of a chemotherapy drug. The reference price for a chemotherapy pharmaceutical benefit is the sum (rounded to the nearest cent) of the:

- ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit, rounded to the nearest cent; and
- mark up for the chemotherapy pharmaceutical benefit.

For chemotherapy pharmaceutical benefits that do not have the drug trastuzumab, the mark up is worked out in accordance with section 48. For chemotherapy pharmaceutical benefits that have the drug trastuzumab, the mark up is worked out in accordance with section 49.

The note following this subsection explains that the reference price and the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit are for the amount of the drug mentioned in the form of the chemotherapy pharmaceutical benefit in Part 1 of Schedule 1.

The note also makes it clear that these prices are not necessarily for the same quantity of the chemotherapy pharmaceutical benefit as is found in the manufacturer's pack. The example following subsection 47(4) makes this clear by explaining that if the form of a chemotherapy pharmaceutical benefit is 'Injection 500 mg in 10 mL' and a manufacturer's pack contains 3 lots of 'Injection 500 mg in 10 mL', the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit is obtained by dividing the ex-manufacturer price for the manufacturer's pack by 3.

Section 48 Mark-up for chemotherapy pharmaceutical benefit that does not have trastuzumab

This section provides how to calculate the mark up for a chemotherapy pharmaceutical benefit that does not have trastuzumab. The mark up forms part of the reference price for the chemotherapy pharmaceutical benefit when an infusion is supplied by an approved pharmacist or an approved medical practitioner (see subparagraph 47(4)(b)(i)).

Subsection 48(1) defines the 'maximum multiple of pharmaceutical benefit' as the whole number of multiples of the form of the chemotherapy pharmaceutical benefit that is required to make up the maximum amount of the chemotherapy drug in the chemotherapy pharmaceutical benefit.

The maximum amount of the chemotherapy drug is the amount determined under section 9 of this Special Arrangement and mentioned in the column headed 'Maximum amount' in Part 2 of Schedule 1 for that chemotherapy drug.

Subsection 48(1) also defines the 'mark-up for maximum multiple' as the amount worked out in accordance with subsection 48(2). This is the mark up for the maximum multiple of the chemotherapy pharmaceutical benefit.

The mark up for a chemotherapy pharmaceutical benefit that does not have trastuzumab is calculated by:

- taking the ex-manufacturer price for the maximum multiple of the chemotherapy pharmaceutical benefit;

- applying that ex-manufacturer price to the table in subsection 48(2) to get the mark up for that maximum multiple of the chemotherapy pharmaceutical benefit; and

- dividing the mark up for the maximum multiple of the chemotherapy pharmaceutical benefit by the maximum multiple of the chemotherapy pharmaceutical benefit.

Section 49 Mark-up for chemotherapy pharmaceutical benefit that has trastuzumab

This section provides for how to calculate the mark up for a chemotherapy pharmaceutical benefit that has trastuzumab. The mark up forms part of the reference price for the chemotherapy pharmaceutical benefit when an infusion is supplied by an approved pharmacist or an approved medical practitioner (see subparagraph 47(4)(b)(ii)).

The only difference between calculating the mark up for a chemotherapy pharmaceutical benefit that has trastuzumab and calculating the mark up for a chemotherapy pharmaceutical benefit that does not have trastuzumab is the values in the mark up table in subsection 49(2). The process for calculating the mark up is the same.

Section 50 Dispensed price if drug is in infusion supplied by approved private hospital authority

This section sets out how to calculate the dispensed price of a chemotherapy drug in an infusion where the infusion is supplied by an approved hospital authority of a private hospital under this Special Arrangement.

Subsection 50(1) provides that the dispensed price for a dose of a chemotherapy drug in an infusion supplied by an approved hospital authority of a private hospital is the sum of the:

- base price for the dose (worked out under subsection 50(2));
- distribution fee (unless the drug is trastuzumab, for which there is not distribution fee)($24);
- dispensing fee ($6.42);
- preparation fee ($40); and
- diluent fee ($4.75).

The amount of each fee is set out in section 3 of this Special Arrangement and will be indexed annually from 1 July 2012.

The base price differs from the base price worked out under section 47 for supply by an approved pharmacist or approved medical practitioner in that instead of the reference price for a chemotherapy pharmaceutical benefit including a mark up worked out under section 48 or 49, the reference price includes a private hospital mark up. The private hospital mark up is 1.4% of the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit, as provided by paragraph 50(4)(b).

Section 51 Dispensed price if drug is in infusion supplied by public hospital authority

This section sets out how to calculate the dispensed price of a chemotherapy drug in an infusion where the infusion is supplied by a public hospital authority under this Special Arrangement. This section covers an approved hospital authority for a public hospital, an HSD hospital authority and a non-approved hospital authority.

Subsection 51(1) provides that the dispensed price for a dose of a chemotherapy drug in an infusion supplied by a public hospital authority is the sum of the:

- base price for the dose (worked out under subsection 51(2)); and
- preparation fee ($40).

The amount of the preparation fee is set out in section 3 of this Special Arrangement and will be indexed annually from 1 July 2012.

The base price differs from the base price for other suppliers in that there is no mark up included in the reference price for a chemotherapy pharmaceutical benefit.

Division 4 Dispensed price of related pharmaceutical benefit

Section 52 Dispensed price for supply of related pharmaceutical benefit

Section 52 provides that the dispensed price for a related pharmaceutical benefit supplied by a participating hospital authority is as follows:

- if the quantity of the related pharmaceutical benefit that is supplied is equal to the quantity contained in the manufacturer's pack – the ex-manufacturer price for the pack;

- if the quantity of the related pharmaceutical benefit that is supplied is less than the quantity contained in the manufacturer's pack – the amount worked out under section 53;

- if the quantity of the related pharmaceutical benefit that is suppled is more than the quantity contained in the manufacturer's pack – the sum of:

    - the ex-manufacturer price for each complete pack contained in the quantity supplied; and

- the amount calculated in accordance with section 52 for the quantity left over.

Subsection 52(2) provides that if there are 2 or more related pharmaceutical benefits that are the same pharmaceutical item but with different brands, the dispensed price for the supply of all related pharmaceutical benefits with that pharmaceutical item is to be based on the ex-manufacturer price of the related pharmaceutical benefit that has the lowest dispensed price.

Section 53 Quantity less than manufacturer's pack

This section sets out how to calculate the dispensed price where the quantity of a related pharmaceutical benefit that is supplied is less than the quantity contained in the manufacturer's pack.

This method is also used when calculating the dispensed price when a quantity of a related pharmaceutical benefit that is supplied is more than the quantity contained in the manufacturer's pack (section 52 above).

Part 5 Patient Contributions

Section 54 Supply of infusion by approved pharmacist or approved medical practitioner

Section 54 provides for the amount that an approved pharmacist or an approved medical practitioner may or must charge an eligible patient for the supply of an infusion containing under this Special Arrangement.

For the original supply of an infusion, an approved pharmacist or an approved medical practitioner must charge an eligible patient:

- an amount equivalent to the ordinary applicable patient co-payment for that patient, set by subsection 87(2) of the Act; and

- if a chemotherapy pharmaceutical benefit supplied in the infusion is a pharmaceutical benefit mentioned in Schedule 5 of this Special Arrangement, may also charge a special patient contribution calculated in accordance with section 58.

The patient co-payment cannot be charged for a repeat supply. For repeat supplies, the Commonwealth will cover the patient co-payment as part of the dispensed price for the supply of the infusion (see section 45).

The note under subsection 54(2) clarifies that only one patient co-payment is payable per infusion supplied, regardless of the number of chemotherapy pharmaceutical benefits used to make the infusion.

The note under subsection 54(4) clarifies that a separate special patient contribution may be charged for each Schedule 5 pharmaceutical benefit supplied in the infusion.

Section 55 Supply of infusion by approved hospital authority or HSD hospital authority

Section 55 provides for the amount that an approved hospital authority or an HSD hospital authority may charge an eligible patient for the supply of an infusion under this Special Arrangement.

For the original supply of an infusion, an approved hospital authority or an HSD hospital authority may charge an eligible patient:

- an amount not exceeding the ordinary applicable patient co-payment for that patient, set by subsection 87(2) of the Act; and

- if a chemotherapy pharmaceutical benefit supplied in the infusion is a pharmaceutical benefit mentioned in Schedule 5 of this Special Arrangement, a special patient contribution calculated in accordance with section 58.

The patient co-payment cannot be charged for a repeat supply. For repeat supplies, the Commonwealth will cover the patient co-payment as part of the dispensed price for the supply of the infusion (see section 45).

The note under subsection 55(2) clarifies that only one patient co-payment is payable per infusion supplied, regardless of the number of chemotherapy pharmaceutical benefits used to make the infusion.

The note under subsection 55(4) clarifies that a separate special patient contribution may be charged for each Schedule 5 pharmaceutical benefit supplied in the infusion.

Section 56 Supply of infusion by non-approved public hospital authority

Section 56 provides for the amount that a non-approved public hospital authority may charge an eligible patient for the supply of an infusion containing trastuzumab under this Special Arrangement.

For the original supply of an infusion, a non-approved public hospital authority may charge an eligible patient:

- a patient co-payment, which is the relevant amount specified as the maximum value of a supply of out-patient medication in the determination made under subsection 84BA(2) of the Act, as in force on the date of the supply of the infusion; and

- if a chemotherapy pharmaceutical benefit supplied in the infusion is a pharmaceutical benefit mentioned in Schedule 5 of this Special Arrangement, a special patient contribution calculated in accordance with section 58.

The patient co-payment cannot be charged for a repeat supply. For repeat supplies, the Commonwealth will cover the patient co-payment as part of the dispensed price for the supply of the infusion (see section 45).

The note under subsection 56(2) clarifies that only one patient co-payment is payable per infusion supplied, regardless of the number of chemotherapy pharmaceutical benefits used to make the infusion.

The note under subsection 56(4) clarifies that a separate special patient contribution may be charged for each Schedule 5 pharmaceutical benefit supplied in the infusion.

Section 57 Supply of related pharmaceutical benefit by participating hospital authority

Section 57 provides for the amount that a participating hospital authority may charge an eligible patient for the supply of a related pharmaceutical benefit under this Special Arrangement.

A participating hospital authority may charge an eligible patient:

- an amount not exceeding the ordinary applicable patient co-payment for that patient, set by subsection 87(2) of the Act; and

- if the related pharmaceutical benefit supplied is a pharmaceutical benefit mentioned in Schedule 5 of this Special Arrangement, a special patient contribution calculated in accordance with section 58.

A pharmaceutical benefit mentioned in Schedule 5 is a pharmaceutical benefit for which there is a special patient contribution under the Act.

Section 58 Special patient contribution for Schedule 5 pharmaceutical benefit

This section provides how to calculate the special patient contribution for pharmaceutical benefits mentioned in Schedule 5 of this Special Arrangement. This amount is similar to the amount of the special patient contribution under the Act, except that it is calculated on the basis of the ex-manufacturer price of the pharmaceutical benefit (rather than on the basis of the Commonwealth price of the pharmaceutical benefit).

Section 59 Amounts taken into account for eligibility for concession and entitlement cards

This section provides that any payment made under subsections 54(2), 55(2), 56(2) and 57(2) will count towards the patient's PBS safety net record for the purpose of determining whether he or she is eligible to be issued with a concession card or an entitlement card.

The amounts that count towards the patient's safety net are applicable patient co-payments paid for the supply of an infusion or a related pharmaceutical benefit. Any amount paid as a special patient contribution for the supply of a Schedule 5 pharmaceutical benefit will not count towards a patient's safety net record.

Part 6 Transitional

Section 60 Prescriptions for general supply

This section provides for transitional arrangements that deal with prescriptions for chemotherapy pharmaceutical benefits written under the general supply provisions of the Act prior to 1 December 2011, but for which no supply of a chemotherapy pharmaceutical benefit has been made to a patient prior to the commencement of this Special Arrangement.

All chemotherapy pharmaceutical benefits except those with bortezomib will only be available to be supplied under a section 100 special arrangement from 1 December 2011.

To ensure that patients who have prescriptions already written for these pharmaceutical benefits under general supply prior to 1 December 2011 are not disadvantaged, subsection 60(2) provides that the chemotherapy pharmaceutical benefit prescribed may be supplied as if it continued to be available for general supply on the Pharmaceutical Benefits Scheme, in accordance with the Act and with any instruments made under the Act that applied to the pharmaceutical benefit, as in force on 30 November 2011.

Subsection 60(3) has the effect that despite subsection 60(2), if the prescribed pharmaceutical benefit is no longer listed on the Pharmaceutical Benefits Scheme on the date of the proposed supply, it cannot be supplied to the patient. However, a substitute pharmaceutical benefit (i.e. a pharmaceutical benefit that was marked as schedule equivalent to the prescribed pharmaceutical benefit immediately prior to its delisting) may be supplied if the requirements of paragraphs 103(2A)(a), (c) and (d) are met.

This transitional provision ceases on 1 April 2012.

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Part 1 of Schedule 1 sets out the chemotherapy pharmaceutical benefits covered by this Special Arrangement and a number of related matters. Some of the matters have been declared or determined in other legislative instruments and are included in this Special Arrangement for reasons of transparency.

The pharmaceutical benefits covered by this Special Arrangement have been determined in this Special Arrangement (section 4) even though the declarations and determinations which define those medicines as pharmaceutical benefits have been made in another instrument.

The matters dealt with in the various columns in Part 1 of Schedule 1, the relevant provisions of the Act and the corresponding sections of the Special Arrangement are set out in the table below.

Column in Part 1 of Schedule 1	Provision of the Act	Section of the Special Arrangement
Listed Drug	Subsection 85(2)	Section 4
Form	Subsection 85(3)	Section 4
Manner of Administration	Subsection 85(5)	Section 4
Brand	Subsection 85(6)	Section 4
Responsible person	Subsection 84AF(1)	Section 6
Authorised prescriber	Section 88	Section 7
Circumstances	Subsection 85(7)	Section 8
Section 100 only	Subsection 85(2A), paragraph 85(8)(a), paragraph 85(8)(b)	Section 13

Part 2 Chemotherapy drugs and related information

Part 2 of Schedule 1 sets out the maximum amounts and number of repeats for which chemotherapy drugs can be prescribed under this Special Arrangement. Part 2 of Schedule 1 also lists the purpose codes representing the purposes for which these maximums can be prescribed under this Special Arrangement.

This information is separated from the information relating to chemotherapy pharmaceutical benefits in Part 1 of Schedule 1 because it is operates at the level of the chemotherapy drug.

Schedule 2 Related pharmaceutical benefits

Schedule 2 sets out the related pharmaceutical benefits covered by this Special Arrangement and a number of related matters. Some of the matters have been declared or determined in other legislative instruments and are included in this Special Arrangement for reasons of transparency.

The pharmaceutical benefits covered by this Special Arrangement have been determined in this Special Arrangement (section 4) even though the declarations and determinations which define those medicines as pharmaceutical benefits have been made in another instrument.

The matters dealt with in the various columns in Schedule 2, the relevant provisions of the Act and the corresponding sections of the Special Arrangement are set out in the table below.

Column in Part 1 of Schedule 1	Provision of the Act	Section of the Special Arrangement
Listed Drug	Subsection 85(2)	Section 4
Form	Subsection 85(3)	Section 4
Manner of Administration	Subsection 85(5)	Section 4
Brand	Subsection 85(6)	Section 4
Responsible person	Subsection 84AF(1)	Section 6
Authorised prescriber	Section 88	Section 7
Circumstances	Subsection 85(7)	Section 8

Maximum Quantity	Paragraph 85A(2)(a)	Section 10
Number of repeats	Paragraph 85A(2)(b)	Section 12
Section 100 only	Subsection 85(2A), paragraph 85(8)(a), paragraph 85(8)(b)	Section 13

Schedule 3 Responsible person codes

This Schedule relates to section 6 of the Special Arrangement. The responsible person for each brand of a pharmaceutical item is identified in the column headed 'Responsible Person' in Part 1 of Schedule 1 (for chemotherapy pharmaceutical benefits) or in Schedule 2 (for related pharmaceutical benefits) by a two letter code. Schedule 3 sets out the name of the responsible person and their ABN, if any, for each code.

Schedule 4 Circumstances and purposes codes

This Schedule relates to sections 8-12 of this Special Arrangement.

The prescription circumstances mentioned in section 8 are identified in the column headed 'Circumstances' in Part 1 of Schedule 1 (for chemotherapy pharmaceutical benefits) or in Schedule 2 (for related pharmaceutical benefits) by a circumstance code. These codes and the circumstances that are represented by those codes are set out in Schedule 4.

The maximum amounts and number of repeats for chemotherapy drugs, mentioned in sections 9 and 11 respectively, of this Special Arrangement, are set out in the respective columns in Part 2 of Schedule 1. Where these maximums are for particular purposes, there is a purpose code in the column headed 'Purposes' in Part 2 of Schedule 1. These codes and the purposes that are represented by those codes are set out in Schedule 4.

The maximum quantities and number of repeats for related pharmaceutical benefits mentioned in sections 10 and 12, respectively, of this Special Arrangement are set out in the respective columns in Schedule 2. Where these maximums are for particular purposes, there is a purpose code in the column headed 'Purposes' in Schedule 2. These codes and the purposes that are represented by those codes are set out in Schedule 4.

Schedule 5 Patient contributions

This Schedule specifies the pharmaceutical benefits for which a special patient contribution is payable in accordance with sections 54-58 of this Special Arrangement.