

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Highly Specialised Drugs Program) Special Arrangement 2021

PB 27 of 2021

Authority

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of certain highly specialised drugs to patients receiving treatment at or from public or private hospitals having access to appropriate specialised facilities.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1) of the Act.

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).

Along with section 100 of the Act, this instrument is also made under sections 85 (Pharmaceutical benefits), 85A (Determinations of forms of pharmaceutical benefits or pharmaceutical items with respect to classes of persons), 88 (Prescribing of pharmaceutical benefits) and 99 (Payment for supply of benefits) of the Act.

Purpose

The *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021) (the instrument) revokes and remakes the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) (the Special Arrangement 2010).

The provisions in this instrument retain substantially similar content to that of the Special Arrangement 2010, 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. The changes also include updating obsolete references and providing definitions for terms used, but not defined in the Special Arrangement 2010. The provisions have been rewritten, reordered, and renumbered using modern drafting principles and language.

Background

The Highly Specialised Drugs (HSD) program provides access to specialised Pharmaceutical Benefits Scheme (PBS) medicines to eligible patients, for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied.

The relevant medicines under the HSD program are referred to throughout this arrangement as “HSD pharmaceutical benefits”. The HSD pharmaceutical benefits covered by this arrangement are set out in Schedule 1 to this instrument. Each HSD pharmaceutical benefit is a brand of a highly specialised drug in a specified form and with a specified manner of administration.

There are three categories of HSD pharmaceutical benefits – those that have a “Complex Authority Required Drug” (CAR drugs), those that have a “Non-Complex Authority Required Drug” (Non-CAR drugs) and those that are “Community Access”. The list of CAR drugs is set out in the definitions section (section 6) of this instrument. HSD pharmaceutical benefits that have a CAR drug require a higher level of authorisation to prescribe in certain circumstances. A non-CAR drug is any highly specialised drug that is not a CAR drug. Community access medicines are also set out in section 6 of this instrument.

Under this arrangement, HSD pharmaceutical benefits may be supplied by hospital authorities for public and private hospitals to an eligible patient receiving treatment in, at or from a public or private hospital. If the eligible patient is receiving treatment in, at or from a private hospital, the HSD pharmaceutical benefits may also be supplied by an approved pharmacist. An approved pharmacist may also supply an HSD pharmaceutical benefit to an eligible patient receiving treatment at or from a public hospital if the HSD pharmaceutical benefit has a CAR drug. HSD pharmaceutical benefits that

are community access medicines may be supplied by approved suppliers. A prescription for an HSD pharmaceutical benefit written by an authorised prescriber in a public hospital cannot be supplied by a private hospital and vice versa.

The prescribing of HSD pharmaceutical benefits is in most cases limited to practitioners who have undertaken particular training or are affiliated with a specialised hospital unit. To better align existing HSD program arrangements with current clinical practice and models of care, hospital affiliation is not required for prescribers of community access medicines. Authorised nurse practitioners are authorised prescribers for HSD pharmaceutical benefits used for the treatment of HIV, hepatitis B and hepatitis C.

This instrument provides for matters relating to the prescribing and supplying of HSD pharmaceutical benefits to eligible patients. The instrument also specifies how claims for payment for the supply of HSD pharmaceutical benefits may be made, the amount of reimbursement 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 of a HSD pharmaceutical benefit.

The key updates provided for in the instrument are:

- provides simplified wording throughout,
- provides only for where overarching PBS legislation has been modified. The instrument avoids repetition of provisions or positions made available in other legislation e.g. prescribing methods and claims rules,
- substitutes definitions of affiliated specialist medical practitioner (now ‘affiliated’) and eligible patient in line with current policy. The definitions provide clarity for prescribers in both the private and public hospital settings and further clarify the policy intent in view of previously raised enquiries from stakeholders,
- improves and clarifies reference to the community access arrangements that were introduced in 2015,
- clarifies intent through revising the provision for approval of hospital authorities without an onsite dispensary that are otherwise unable to seek approval under section 94 of the Act. In the instrument the provision for approval of hospital authorities without an onsite dispensary is provided as a modified section 94 approval for the purposes of supplying HSD pharmaceutical benefits only. In practice, the application process for a hospital authority remains the same,
- amends the current sections relating to quantity and repeat exceptions for Written Authority Required prescriptions to provide the information in a table format in Schedule 2 of the instrument which will provide clarity and increased useability, and
- simplifies the columns in the Schedules to minimise duplication and streamline their use.

The instrument also relies on subsection 33(3) of the *Acts Interpretation Act 1901*, where the instrument repeals or amends another instrument and there is no express power in the enabling legislation to do so.

Consultation

Key stakeholders participated in a targeted consultation process about the remaking of the instrument in February 2021. There were no significant concerns raised during this process about the instrument. Stakeholders sought confirmation that the remuneration structure remains unchanged however, no amendment to the instrument was necessary. Although the instrument has been updated, the Department of Health considered a targeted consultation approach was appropriate given the practical implementation of HSD policy parameters for the HSD program have not been changed.

Stakeholders invited to comment on the exposure draft included peak prescriber and pharmacy organisations, medical and disease specific colleges, peak Aboriginal and Torres Strait Islander health organisations, consumer representative and advocacy organisations, state and territory health departments, and Services Australia.

An ongoing and formal process of consultation in relation to matters relevant to the HSD program 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. 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. 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.

Details of this instrument are set out in the **Attachment**.

This instrument commences 1 April 2021.

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

Details of the *National Health (Highly specialised drugs program) Special Arrangement 2021***Part 1 Preliminary****Division 1 General****Section 1 Name**

This section provides that the name of the instrument is the *National Health (Highly specialised drugs program) Special Arrangement 2021* (the instrument) and may also be cited as PB 27 of 2021.

Section 2 Commencement

This section provides that the instrument commences on 1 April 2021.

Section 3 Authority

This section provides that the instrument is made under sections 85, 85A, 88, 99 and 100 of the *National Health Act 1953* (the Act).

Section 4 Schedules

This section provides that each instrument specified in the schedules is amended or repealed as set out in the schedules and that any other item in the schedules has effect according to its terms.

Section 5 Simplified outline of this instrument

This section explains the purpose of the instrument, and summarises its key features, including outlining the restrictions to the prescribing and supply of these benefits and payments for supplies of these benefits.

The note to section 5 makes clear that Part VII of the Act, and regulations or other instruments made for the purposes of that Part, have effect subject to this instrument (see subsection 100(3) of the Act).

The simplified outline is included to assist readers to understand the substantive provisions, and is not intended to be comprehensive. It is intended that readers should rely on the substantive provisions of the instrument.

Section 6 Definitions

A number of expressions used in the instrument are defined in section 6.

Note 1 to section 6 explains that the expressions Chief Executive Medicare, hospital and public hospital have the same meaning as in the Act.

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

The definition of ‘affiliated’ replaces the previous definition of ‘affiliated specialist medical practitioner’ to provide clarity, and means a specialist is affiliated with a hospital if they are either a staff specialist of the hospital or a visiting or consulting specialist of the hospital.

The previous definition from the *National Health (Highly specialised drugs program) Special Arrangement 2010 (PB 116 of 2010)* (the Special Arrangement 2010) for ‘eligible medical practitioner’ has been incorporated into the definition of ‘authorised prescriber’ in section 7.

The previous definition from the Special Arrangement 2010 for ‘under co-payment data’ has been moved to section 35.

The definition of ‘community access medication’ has been added to clarify what Highly Specialised Drugs (HSD) pharmaceutical benefits are able to be prescribed and supplied under community access arrangements. The community access arrangements are provided in section 8 and section 13.

Section 7 Definition of *authorised prescriber*

This section provides a definition of who is an *authorised prescriber* for HSD pharmaceutical benefits covered by this instrument. The definition was previously defined in Section 4A of the Special Arrangement 2010. It incorporates the definitions of ‘affiliated specialist medical practitioner’ and ‘eligible medical practitioner’, of the Special Arrangement 2010.

Specialists affiliated with hospitals

Subsection 7(1) provides that a specialist is an authorised prescriber for an HSD pharmaceutical benefit for a patient receiving treatment in, at or from a hospital if the specialist is affiliated with the hospital.

Medical practitioners—with the agreement of specialists

Subsection 7(2) provides that a medical practitioner is an authorised prescriber for an HSD pharmaceutical benefit for a patient receiving treatment in, at or from a hospital if the benefit is for continuing treatment for the patient, the treatment is being managed by a specialist, it is impractical for the patient to obtain a prescription for the benefit from the specialist, and the specialist has agreed to the prescribing of the benefit to the patient by the medical practitioner. This definition clarifies and acknowledges current clinical practise where a patient may be receiving treatment from more than one hospital. For example, a patient may be receiving treatment from a specialist at a hospital in a capital city and also be receiving treatment from a hospital in a rural area.

Medical practitioners—if authorised by Commonwealth and State authorities

Subsection 7(3) provides that a medical practitioner is an authorised prescriber for an HSD pharmaceutical benefit for a patient if the benefit is for continuing treatment for the patient, the medical practitioner is authorised by an authority of the Commonwealth, and the medical practitioner is authorised by an authority of the State or Territory in which the hospital is located.

Medical practitioners—medication for the treatment of hepatitis C, lanreotide and octreotide

Subsection 7(4) provides that a medical practitioner is an authorised prescriber for the following HSD pharmaceutical benefits:

- a medication for the treatment of hepatitis C;
- lanreotide, if the description of its form does not include “Powder for suspension for injection” and it is for continuing treatment;
- octreotide, if the description of its form includes “Injection (modified release)” and it is for continuing treatment.

Accredited prescribers—for HSD pharmaceutical benefits for the treatment of hepatitis B, hepatitis C, HIV or AIDS, and schizophrenia

Subsection 7(5) provides that an accredited prescriber of medication for the treatment of a specified condition is an authorised prescriber for an HSD pharmaceutical benefit, if the medication is for the treatment of that specified condition. These persons and HSD pharmaceutical benefits are outlined in accordance with the table entitled ‘Authorised prescribers for certain HSD pharmaceutical benefits’ also in subsection 7(5).

Section 8 Definition of *eligible patient*

This section consolidates and clarifies the definition of eligible patient which was previously provided by section 9A of the Special Arrangement 2010. It incorporates the definition of ‘eligible patient’, used in the Special Arrangement 2010.

A person is an eligible patient for an HSD pharmaceutical benefit if the person is, or is to be treated as, an eligible person and if:

- the person is receiving treatment by a medical practitioner at or from a public hospital other than as an admitted patient (subsection 8(1)).
- for medication for the treatment of hepatitis C, the person is receiving treatment by an authorised nurse practitioner at or from a public hospital other than as an admitted patient (subsection 8(2)) or, the person is receiving treatment by an authorised nurse practitioner in, at or from a private hospital (subsection 8(5)).
- for an HSD pharmaceutical benefit that contains eculizumab, the person is receiving treatment by a medical practitioner in a public hospital as an admitted patient (other than a day admitted patient) (subsection 8(3)).
- the person is receiving treatment by a medical practitioner in, at or from a private hospital (subsection 8(4)).
- the person is receiving HSD pharmaceutical benefits that are community access medications (subsection 8(6)).

Division 2 *Supplies of HSD pharmaceutical benefits from hospitals*

Section 9 Supplies of HSD pharmaceutical benefits by approved hospital authorities to patients receiving treatment from hospitals

Subsection 9(1) provides for a reference to an approved hospital authority supplying pharmaceutical benefits to patients receiving treatment in or at the hospital of which it is a governing body or proprietor also includes a reference to the hospital authority supplying HSD pharmaceutical benefits to patients receiving treatment from the hospital.

The distinction is made between situations where a person is receiving treatment ‘in, at or from’ a hospital as provided in the sections prior to section 9. This section acknowledges that Part VII of the Act and regulations or other instruments made for the purposes of that Part usually refer to patients receiving treatment ‘in or at’ a hospital while HSD pharmaceuticals may also be supplied to patients receiving treatment ‘from’ a hospital.

Subsection 9(2) provides that subsection (1) applies in addition to section 94 of the Act.

Division 3 HSD hospital authorities

Division 3 sets out the requirements for hospital authorities to obtain approval to supply HSD pharmaceutical benefits as HSD hospital authorities under this instrument. The approval of hospital authorities to supply HSD pharmaceutical benefits is a decision of the Minister under section 94 of the Act and is capable of being reviewed by the Administrative Appeals Tribunal under subsection 105AB(7B) of the Act.

Section 10 HSD hospital authorities

This section replaces section 52 of the Special Arrangement 2010. It provides for hospital authorities to obtain approval to supply HSD pharmaceutical benefits, even if the condition of subsection 94(5) is not able to be met (for example, in rural locations where the hospital may not have an onsite dispensary). The supply of HSD pharmaceutical benefits would occur at a location other than at the hospital, however would still occur by or under the direct supervision of a medical practitioner or pharmacist.

Section 11 References to approved suppliers and approved hospital authorities

This section replaces paragraph 51(a) of the Special Arrangement 2010. It provides that reference to an ‘approved supplier’ or an ‘approved hospital authority’ in this instrument and in Part VII of the Act and regulations or other instruments made for the purposes of that Part, also includes a reference to an HSD hospital authority as provided by section 10.

Section 12 Numbers allotted to HSD hospital authorities

This section replaces paragraph 51(b) and subsection 52(4) of the Special Arrangement 2010. It provides that a number allotted to an HSD hospital authority under subsection 52(3) of the Special Arrangement 2010, or under subsection 52(3) of the previous special arrangement concerning the Highly Specialised Drugs program for public hospitals, is taken to have been allotted under subsection 16(4) of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations).

Part 2 Special arrangement supplies of HSD pharmaceutical benefits

Division 1 Preliminary

Section 13 Definition of *special arrangement supply*

This section replaces subsections 18(1) and 18(2) of the Special Arrangement 2010. It defines a ‘special arrangement supply’. The definition provides for the supply of an HSD pharmaceutical benefit for prescriptions written for public hospital patients, private hospital patients and community access arrangements. A supply of an HSD pharmaceutical benefit to a person is a ‘special arrangement supply’ of the benefit if, the person is an eligible patient for the benefit; the benefit is supplied by an approved supplier (public and private hospitals, community pharmacies and certain medical practitioners); and the benefit is supplied on the basis of a prescription written in particular circumstances, including being written by an authorised prescriber.

Division 2 Prescribing of HSD pharmaceutical benefits

Division 2 sets out the requirements for prescribing HSD pharmaceutical benefits under this instrument.

Section 14 Prescribing of HSD pharmaceutical benefits—authorised prescribers (Act s 88(1) and (1E))

This section replaces section 8 of the Special Arrangement 2010 and provides for who is able to prescribe an HSD pharmaceutical benefit. The definition of authorised prescriber is in section 7 of this instrument.

Subsection 14(1) provides that for the purposes of subsection 88(1) of the Act, a medical practitioner is able to prescribe HSD pharmaceutical benefits (the determined benefit) only if they are an authorised prescriber under this instrument. Subsection 88(1) provides that a medical practitioner is authorised to write a prescription for the supply of any pharmaceutical benefit determined from time to time by the Minister, for the purposes of subsection 88(1), by legislative instrument. It is necessary to modify this provision as only a limited class of medical practitioners are able to write a prescription for the supply of an HSD pharmaceutical benefit under this instrument.

Subsection 14(2) provides that subsection 9(1A) of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Listing Instrument) does not apply under this instrument other than for medications for the treatment of hepatitis C. Subsection 9(1A) of the Listing Instrument authorises a medical practitioner to write a prescription for the supply of any pharmaceutical benefit listed under the relevant part of that instrument. It is necessary to override this provision as only a limited class of medical practitioners are able to write a prescription for the supply of an HSD pharmaceutical benefit under this instrument. Medications for the treatment of hepatitis C are an exception as these medicines are listed under this instrument and also under section 85 of the Act.

Subsection 14(3) provides that for the purposes of subsection 88(1E) of the Act that an authorised nurse practitioner is able to prescribe HSD pharmaceutical benefits (the determined benefit) only if they are an authorised prescriber under this instrument. Subsection 88(1E) of the Act authorises an authorised nurse practitioner to write a prescription for the supply of any pharmaceutical benefit determined from time to time by the Minister, by legislative instrument.

Subsection 14(4) provides that medical practitioners and authorised nurse practitioners who are authorised prescribers under this instrument are not able to prescribe HSD pharmaceutical benefits that are mentioned in Part 2 of Schedule 1 of the Listing Instrument. Part 2 of Schedule 1 of the Listing Instrument lists those pharmaceutical benefits which are available to be supplied, but are not able to be newly prescribed, for a period of time, after which the pharmaceutical benefits will be fully de-listed from the PBS.

Section 15 Prescription circumstances—general (Act s 85(7)(a) and (b))

This section replaces section 9 of the Special Arrangement 2010. It provides general prescription circumstances for HSD pharmaceutical benefits.

Subsection 15(1) provides that an HSD pharmaceutical benefit is a relevant pharmaceutical benefit for the purposes of section 88A of the Act. 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. Section 88A of the Act provides that where a pharmaceutical benefit is determined to be a relevant pharmaceutical benefit for the purposes section 88A, 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).

Subsection 15(2) provides that the circumstances mentioned in Schedule 3 to this instrument are the circumstances in which a prescription for a special arrangement supply of an HSD pharmaceutical

benefit may be written for the purposes of paragraph 85(7)(b). Paragraph 85(7)(b) of the Act determines that the Minister may, by legislative instrument, determine the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written.

Subsection 15(3) provides that this section applies in addition to section 10 of the Listing Instrument, which determines the circumstances, if any, in which a prescription for the supply of a pharmaceutical benefit may be written.

Subsection 15(4) provides that this section has effect subject to section 17 of this instrument, which temporarily modifies the circumstances mentioned in Schedule 3 for circumstances codes for HSD pharmaceutical benefits that are pharmaceutical items described in Schedule 4, during the COVID-19 pandemic.

Section 16 Prescription circumstances—authority required procedures

This section replaces section 10 of the Special Arrangement 2010 and provides prescription circumstances for authority required procedures. The section sets out matters relevant to prescriptions where authorisation from the Chief Executive Medicare is required as outlined in the Listings Instrument. The requirements and procedures for authority required procedures are set out in the Listing Instrument.

Subsection 16(1) provides that this section applies where a circumstance determined for an HSD pharmaceutical benefit includes Compliance with Authority Required procedures or Compliance with Written Authority Required procedures.

Subsection 16(2) provides that sections 11 to 14 of the Listing Instrument apply to the prescription of a relevant HSD pharmaceutical benefit that meets subsection 16(1) as if a reference in those provisions in the Listings Instrument were a reference to Schedule 3 of this instrument and that a reference to an authorised prescriber in those provisions in the Listing Instrument were a reference to an authorised prescriber within the meaning of this instrument.

Section 17 Prescription circumstances—modifications during COVID-19 pandemic (Act s 85(7)(a) and (b))

This section replaces section 9AA of the Special Arrangement 2010 and provides modifications to prescription circumstances during the COVID-19 pandemic.

Subsection 17(1) temporarily modifies the circumstances in which a prescription may be written by an authorised prescriber for the supply of an HSD pharmaceutical benefit that is a listed brand of a pharmaceutical item described in Schedule 4 to a person, if the authorised prescriber is satisfied the patient has, already been supplied with the benefit on the basis of a prescription. For prescriptions written, on or after 1 April 2021, the circumstances are set out in Schedule 3 of the instrument (see paragraph 17(1)(a)). For prescriptions written, before 1 April 2021, the circumstances are set out in Schedule 3 of the Special Arrangement 2010 (see paragraph 17(1)(b)).

Subsection 17(2) provides that for pharmaceutical benefits set out in Schedule 4, the circumstances set out in Schedule 3 of this instrument have effect as if each circumstance code for the HSD pharmaceutical benefit did not mention any circumstance that, having regard to the patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish those circumstances.

This subsection also states that where the above criteria are met, the prescriber is required to keep a written record of the reason it is not practicable to establish the circumstance.

Subsection 17(3) provides that this section, subsection 15(4) and Schedule 4 are repealed at the start of 1 January 2022.

Section 18 When medication chart prescriptions not to be written

This section replaces section 23 of the Special Arrangement 2010 and retains the original intent regarding medication chart prescriptions, brought together under one clause. It provides for when medication chart prescriptions are not to be written for HSD pharmaceutical benefits.

Subparagraphs 39(a)(ii) and 41(1)(a)(i) of the Regulations deal with writing prescriptions on medication charts and do not apply for a special arrangement supply of an HSD pharmaceutical benefit that has a CAR drug (subsection 18(1)) or for persons receiving treatment in residential care services (subsection 18(2)).

Section 19 Prescriptions not to direct repeated supplies for visitors to Australia

This section replaces section 20 of the Special Arrangement 2010. The section includes minor amendments which do not change the intent of this section. This section provides that an authorised prescriber must not write a prescription directing repeated supply for an HSD pharmaceutical benefit for a person who is a visitor to Australia even if the person is, in accordance with section 7 of the *Health Insurance Act 1973*, to be treated as an eligible person within the meaning of the Act. This section applies despite section 85A of the Act.

Section 20 Maximum quantity or number of units (Act s 85A(2)(a))

This section replaces sections 14 and 24 of the Special Arrangement 2010. It provides instructions for determining the maximum quantity or number of units for HSD pharmaceutical benefits. This section does not change the intent of the original sections but combines the maximum quantity restrictions for all HSD pharmaceutical benefits. A new Schedule 2 to this instrument replaces what was available as quantity exceptions and limitations in the previous section 24.

Subsection 20(1) sets out the maximum quantity or number of units of an HSD pharmaceutical benefit that may be directed by an authorised prescriber, to be supplied on any one occasion in one prescription, for a special arrangement supply of the benefit.

Subsection 20(2) provides that where a purposes code is mentioned in Schedule 1 to this instrument for the HSD pharmaceutical benefit and the supply of the benefit is for the purposes mentioned in Schedule 3 to this instrument, the maximum quantity or number of units is the amount mentioned in the column headed “Maximum quantity” in Schedule 1 to this instrument for the benefit and the purposes code.

Subsection 20(3) provides that if a purposes code is not mentioned in Schedule 1 to this instrument, (that is, only a circumstance code is mentioned), the maximum quantity or number of units is the amount mentioned in the column headed “Maximum quantity” in Schedule 1 to this instrument for the benefit, if available.

Subsection 20(4) provides that if a purposes code is not mentioned in Schedule 1 to this instrument, (that is, only a circumstance code is mentioned), and the words “See Schedule 2” appear in the column headed “Maximum quantity” in Schedule 1 to this instrument for the benefit and the

prescription is written in accordance with the circumstances mentioned in Schedule 3 for that benefit, the maximum quantity or number of units is the amount applicable under Schedule 2 of this instrument for the benefit and the circumstance code.

Subsection 20(5) states that where this section provides for a matter that is not provided for by the Listing Instrument, this section applies in addition to the Listing Instrument. The Listing Instrument determines the maximum quantities that the authorised prescribers may, in one prescription, direct to be supplied on the one occasion and the conditions, if any, which must be satisfied when writing a prescription for the supply of a pharmaceutical benefit.

Subsection 20(6) states that where this section makes a different provision for a matter provided for in the Listing Instrument, that is, modifies a provision that exists in the Listing Instrument, this section applies despite the Listing Instrument.

Section 21 Maximum number of repeats (Act s 85A(2)(b))

This section replaces sections 14 and 25 of the Special Arrangement 2010. It provides instructions for determining the maximum number of repeats for HSD pharmaceutical benefits. This section does not change the intent of the original sections but combines the maximum repeat restrictions for all HSD pharmaceutical benefits. A new Schedule 2 to this instrument replaces what was available as repeat exceptions and limitations in the previous section 25.

Subsection 21(1) sets out the maximum repeats of an HSD pharmaceutical benefit that may be directed by an authorised prescriber to be supplied on any one occasion in one prescription for a special arrangement supply of the benefit.

Subsection 21(2) provides that where a purposes code is mentioned in Schedule 1 to this instrument for the HSD pharmaceutical benefit and the supply of the benefit is for the purposes mentioned in Schedule 3 to this instrument, the maximum repeats is the amount mentioned in the column headed “Maximum repeats” in Schedule 1 to this instrument for the benefit.

Subsection 21(3) provides that if a purposes code is not mentioned in Schedule 1 to this instrument, (that is, only a circumstance code is mentioned), the maximum repeats is the amount mentioned in the column headed “Maximum repeats” in Schedule 1 to this instrument for the benefit, if available.

Subsection 21(4) provides that if a purpose code is not mentioned in Schedule 1 to this instrument, (that is, only a circumstance code is mentioned), and the words “See Schedule 2” appear in the column headed “Maximum repeats” in Schedule 1 to this instrument for the benefit and the prescription is written in accordance with the circumstances mentioned in Schedule 3 for that benefit, the maximum repeats is the amount applicable under Schedule 2 of this instrument for the benefit and the circumstance code.

Subsection 21(5) states that where this section provides for a matter that is not provided for by the Listing Instrument, this section applies in addition to the Listing Instrument. The Listing Instrument determines the maximum quantities that the authorised prescribers may, in one prescription, direct to be supplied on the one occasion and the conditions, if any, which must be satisfied when writing a prescription for the supply of a pharmaceutical benefit.

Subsection 21(6) states that where this section makes a different provision for a matter provided for in the Listing Instrument, that is, modifies a provision that exists in the Listing Instrument, this section applies despite the Listing Instrument.

Section 22 No variation of application of determination of maximum number of repeats or maximum number or quantity of units—HSD pharmaceutical benefits that have CAR drugs

This section replaces section 26 of the Special Arrangement 2010, but maintains the policy intent modified for clarity. It provides for no variation to the maximum number of repeats or quantity for HSD pharmaceutical benefits that are CAR drugs, by expressly stating that section 30 of the Regulations does not apply. This has the effect that a practitioner (within the meaning given by section 29 of the Regulations) cannot prescribe more than the maximum number of repeats or maximum number or quantity of units of an HSD pharmaceutical benefit that has a CAR drug.

Section 23 Records to be kept—prescriptions for HSD pharmaceutical benefits that contain eculizumab

This section replaces section 23A of the Special Arrangement 2010. It retains the same intent as the original section 23A, but simplifies the section by referring specifically to the relevant HSD pharmaceutical benefit (i.e. containing eculizumab).

This section requires authorised prescribers of HSD pharmaceutical benefits that contains eculizumab to keep a copy of any clinical records relating to that prescription, including any such records required to demonstrate the prescription was written in compliance with the circumstances and purposes determined in relation to the benefit under subsection 85(7) of the Act.

Subsection 23(1) intends that either the approved hospital authorities or authorised prescribers keep the records in compliance with this section. The obligation to keep a copy of each relevant record is on the authorised prescriber or hospital authority i.e. it is not required that both parties keep these records simultaneously.

Subsection 23(2) requires these records to be kept for a period of two years.

Division 3 Supplying HSD pharmaceutical benefits

Division 3 sets out the requirements for supply of HSD pharmaceutical benefits under this instrument.

Section 24 Special patient contribution for certain HSD pharmaceutical benefits

This section replaces sections 46(3), 47(3), 48 and Schedule 4 of the Special Arrangement 2010. It provides for special patient contribution for certain HSD pharmaceutical benefits (commonly known as the brand price premium). This section does not change the intent of the original sections and combines all previous sections and schedule 4 relating to special patient contributions for certain HSD pharmaceutical benefits into one section.

Subsection 24(1) provides which HSD pharmaceutical benefits a special patient contribution applies. The table provides the claimed price for the HSD pharmaceutical benefits which includes the special patient contribution.

Subsection 24(2) outlines how the special patient contribution is calculated. The special patient contribution amount is the difference between the approved dispensed price of the HSD pharmaceutical benefit and the price that is claimed by the responsible person. The approved dispensed price for the HSD pharmaceutical benefits is determined in the *National Health (Price and Special Patient Contribution) Determination 2010*.

Subsection 24(3) states that this section applies despite 85B(5) of the Act. Subsection 85B(5) of the Act outlines how the special patient contribution is calculated for medicines under the PBS. This instrument provides its own calculation for the dispensed price for HSD pharmaceutical benefits (see sections 29 and 32 of this instrument) and so subsection 85B(5) does not apply.

Section 25 Modified application of conditions of approval of approved pharmacists

This section replaces section 17A of the Special Arrangement 2010 and retains the original intent. The definition of ‘Shelf life’, previously located in this section, has been moved to section 6 - Definitions.

Section 25 provides that section 8 of the conditions of approval made under paragraph 92A(1)(f) of the Act (in this instance, the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017*) (the Approved Pharmacists Determination), does not apply to the supply of an infusion, once prepared as a final product, when the infusion has a physical, chemical or biological stability restricting its clinically effective shelf life to 8 hours or less. This means that an approved pharmacist is not required to ensure that the conditions set out in sections 5 and 6 of the Approved Pharmacists Determination (relating to standards of practice) are satisfied when certain types of HSD pharmaceutical benefits are supplied as the short shelf life of the benefit may make it unlikely the conditions could be met before the benefit expires.

Section 26 Supplies by HSD hospital authorities need not be directly to persons

This section replaces subsections 18(3), (4) and (5) of the Special Arrangement 2010.

Subsection 26(1) provides that supplies by approved hospital authorities need not be made directly to the person and may be supplied through an agent. It retains the same intent as the original subsections 18(3), (4) and (5). For example, a hospital authority may arrange for an approved pharmacist to act as its agent to supply a HSD pharmaceutical benefit to a patient. In that case, the hospital authority is still the supplier for the purposes of claiming payment and other obligations on the supplier of a pharmaceutical benefit.

Subsection 26(2) states that this section applies in addition to section 94 of the Act, which provides that the Minister may approve a hospital authority for the purpose of it supplying pharmaceutical benefits to patients.

Section 27 Repeated supplies of pharmaceutical benefits

This section replaces section 19 of the Special Arrangement 2010. The intent and wording has not changed. In summary, section 51 of the Regulations does not apply in the public hospital, private hospital or community settings for the special arrangement supply of HSD pharmaceutical benefits. Section 51 of the Regulations deals with repeated supplies of pharmaceutical benefits.

Part 3 Payment for special arrangement supplies of HSD pharmaceutical benefits

Part 3 sets out the requirements for payment of special arrangement supplies of HSD pharmaceutical benefits under this instrument.

Division 1 Supplies by approved hospital authorities for public hospitals

Division 1 sets out the manner in which the payment for the special arrangement supply of an HSD pharmaceutical benefit by a public hospital is calculated under this instrument. The dispensed price is

the basis for working out the amount that a hospital authority may claim for supplying an HSD pharmaceutical benefit under this instrument.

Section 28 Rates of payment for approved hospital authorities for public hospitals (Act s 99(4))

This section replaces sections 35 and 46 of the Special Arrangement 2010 and retains the policy intent.

Subsection 28(1) sets out the amount payable to an approved hospital authority for a public hospital for the special arrangement supply of an HSD pharmaceutical benefit. In essence, the amount able to be claimed by an approved hospital authority for a public hospital is the dispensed price (determined in section 29) for the supply of the HSD pharmaceutical benefit minus the patient charge (commonly known as the co-payment), if the dispensed exceeds the co-payment amount. Section 99(4) of the Act provides approved hospital authorities the entitlement for payment from the Commonwealth for the supply of pharmaceutical benefits as determined by the Minister (see subsection 28(2) below).

Subsection 28(2) states this section applies despite the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017* (the Public Hospital Determination) which determines the Commonwealth Price for pharmaceutical benefits supplied by public hospitals. The dispensed price for HSD pharmaceutical benefits is determined in this instrument, not by the Public Hospital Determination and so the Commonwealth Price does not apply to special arrangement supplies of an HSD pharmaceutical benefit under this instrument.

Section 29 Dispensed price for approved hospital authorities for public hospitals

This section replaces sections 37, 38 and 44 of the Special Arrangement 2010 and determines the dispensed price for the special arrangement supply of an HSD pharmaceutical benefit by an approved hospital authority for a public hospital. It retains the same intent as the original sections 37, 38 and 44, but consolidates the dispensed price, broken quantities and rounding into one section.

Subsection 29(1) provides how the dispensed price for a special arrangement supply of an HSD pharmaceutical benefit by an approved hospital authority for a public hospital is calculated. In essence, the amount is the sum of the approved ex-manufacturer price (AEMP) or the proportional ex-manufacturer price (PEMP) as applicable for each pack quantity. Where the pack is a broken quantity, the calculation is determined in section 29(2).

Subsection 29(2) provides how the amount is calculated for broken quantities, that is, as a percentage of the pack quantity and then applying the percentage to the AEMP/PEMP.

Subsection 29(3) provides the dispensed price is rounded to the nearest cent, with half a cent being counted as 1 cent.

Division 2 Supplies by other approved suppliers

Division 2 sets out the manner in which payment for the special arrangement supply of an HSD pharmaceutical benefit by an approved pharmacist, approved medical practitioner or a private hospital is calculated under this instrument. The dispensed price is the basis for working out the amount that an approved pharmacist or approved medical practitioner may claim for supplying an HSD pharmaceutical benefit under this instrument.

Section 30 Entitlement to, and amount of, payment for approved pharmacists and approved medical practitioners

This section replaces sections 36(2) and 47 of the Special Arrangement 2010. It provides the entitlement to, and amount of, payment for approved pharmacists and medical practitioners. It retains the same intent as the original sections 36(2) and 47 but consolidates into one section.

Subsection 30(1) provides that this section applies to the special arrangement supply of an HSD pharmaceutical benefit supplied by an approved pharmacist or approved medical practitioner.

Subsection 30(2) provides that an approved pharmacist or approved medical practitioner is entitled to be paid an amount for the special arrangement supply of an HSD pharmaceutical benefit which is the dispensed price (determined in section 32) for the supply of the HSD pharmaceutical benefit minus the patient co-payment amount, if the dispensed exceeds the co-payment amount. This entitlement is subject to section 99AAA (claim for payment relating to supply of benefits) and conditions determined under section 98C (determinations by Minister) of the Act.

Subsection 30(3) modifies the application of subsections 99(2) and (2AA) of the Act. Subsections 99(2) and (2AA) of the Act set the amount for payment for approved pharmacists and approved medical practitioners rather than allowing for amounts to be determined (as in section 99(4) of the Act – see section 28 of this instrument). Subsections 99(2) and (2AA) of the Act have been modified in order to provide for the rate of payment for special arrangement supplies of HSD pharmaceutical benefits by approved pharmacists and approved medical practitioners (see section 31 below).

Section 31 Rates of payment for approved hospital authorities for private hospitals (Act s 99(4))

This section replaces sections 36(1) and 46 of the Special Arrangement 2010. It provides rates of payment for approved hospital authorities for private hospitals. It retains the same intent as the original sections 36(1) and 46 but consolidates into one section.

Subsection 31(1) sets out the amount payable to an approved hospital authority for a private hospital for the special arrangement supply of an HSD pharmaceutical benefit. In essence, the amount able to be claimed by an approved hospital authority for a public hospital is the dispensed price (determined in section 32) for the supply of the HSD pharmaceutical benefit minus the patient co-payment amount, if the dispensed exceeds the co-payment amount. Section 99(4) of the Act provides approved hospital authorities the entitlement for payment from the Commonwealth for the supply of pharmaceutical benefits as determined by the Minister (see subsection 32(2) below).

Subsection 31(2) states this section applies despite the *National Health (Commonwealth Price - Pharmaceutical benefits supplied by private hospitals) Determination 2020* (the Private Hospital Determination) which determines the Commonwealth Price for pharmaceutical benefits supplied by private hospitals. The dispensed price for HSD pharmaceutical benefits is determined in this instrument, not by the Private Hospital Determination and so the Commonwealth Price does not apply to special arrangement supplies of an HSD pharmaceutical benefit under this instrument.

Section 32 Dispensed price for approved suppliers other than approved hospital authorities for public hospitals

This section replaces sections 39, 41 and 44 of the Special Arrangement 2010. It provides the dispensed price for an approved supplier other than an approved hospital authority for a public hospital, that is, an approved pharmacist, approved medical practitioner or approved hospital authority

for a private hospital. It retains the same intent as the original sections 39, 41 and 44 but updates and consolidates the dispensed price, broken quantities and rounding into one section.

Subsection 32(1) provides how the dispensed price for a special arrangement supply of an HSD pharmaceutical benefit by an approved supplier (other than an approved hospital authority for a public hospital) is calculated. In essence, the amount is the sum of the AEMP/PEMP as applicable for each pack quantity, plus the mark-up (section 33) and the dispensing fee (section 34). Where the pack is a broken quantity, the amount to which the dispensing fee is added is calculated in section 32(2).

Subsection 32(2) provides how the amount is calculated for broken quantities, that is, as a percentage of the pack quantity and then applying the percentage to the sum of the AEMP/PEMP plus the mark-up.

Subsection 32(3) provides the dispensed price is rounded to the nearest cent, with half a cent being counted as 1 cent.

Section 33 Mark-up for ready-prepared pharmaceutical benefits

This section replaces section 40 of the Special Arrangement 2010 and retains the policy intent. It sets out the mark-up for ready-prepared pharmaceutical benefits for an HSD pharmaceutical benefit supply by an approved supplier other than an approved hospital authority for a public hospital. The amount of mark-up that is applicable depends on the AEMP/PEMP for the maximum quantity of the HSD pharmaceutical benefit and the corresponding mark-up for the item (tier) which is either a monetary amount or a percentage of the AEMP/PEMP.

Section 34 Dispensing fee

This section replaces sections 39 and 42 of the Special Arrangement 2010 and retains the same meaning.

Paragraph 34(1)(a) provides the dispensing fee is the amount determined in the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020* (the Pharmacists Determination) for either a ready-prepared or extemporaneously-prepared pharmaceutical benefit.

Paragraph 34(1)(b) provides that where the supply of the total quantity or number of units under repeated supply is directed to be supplied on one occasion, only one dispensing fee is included in the dispensed price. For example, where a medical practitioner has directed the supply be made under section 49 of the Regulations (circumstances in which quantity of repeated supply can be directed to be supplied on one occasion), the dispensing attracts one dispensing fee for the supply.

Subsection 34(2) provides the drugs and forms of HSD pharmaceutical benefits for which the extemporaneously-prepared dispensing fee applies in accordance with section 10(2) of the Pharmacists Determination.

Part 4 Claims for payment for special arrangement supplies of HSD pharmaceutical benefits

Section 35 Rules for providing information about supplies—definition of *under co-payment data*

This section replaces subsection 51(f) of the Special Arrangement 2010 and retains the same meaning.

This section provides that the *National Health (Claims and under co-payment data) Rules 2012* (the Rules) for a special arrangement supply of an HSD pharmaceutical benefit apply with a modified definition of ‘under co-payment data’ for the purposes of claims made under this instrument.

The Rules relate to the supply of pharmaceutical benefits and concern (i) transmission of claims data, and (ii) transmission of data for medicines priced at or below the patient co-payment threshold.

Part 5 *Miscellaneous*

Section 36 **Compliance and audit arrangements**

This section replaces section 49 of the Special Arrangement 2010 and retains the same meaning as the original section 49. It provides compliance and audit arrangements.

Subsection 36(1) provides that an authorised supplier that makes a special arrangement supply of an HSD pharmaceutical benefit under this arrangement must keep adequate, secure and auditable records of all supplied HSD pharmaceutical benefits for which a claim is made.

Subsection 36(2) provides that the records must be kept in systems that are able to be audited by the Chief Executive Medicare on reasonable notice being given to the approved supplier.

Section 37 *Value for safety net purposes for supplies*

This section replaces section 50 of the Special Arrangement 2010 and retains the same meaning. It provides the value for safety net purposes. It simplifies and clarifies the calculation for the value for safety net purposes for supplies by approved hospital authorities and separately for supplies by approved pharmacists and approved medical practitioners modified under this instrument. This section applies to the amount paid by a person in accordance with provisions made under this instrument, for example rates of payment and dispensed price.

Subsection 37(1) provides the value for safety net purposes for supplies made by an approved hospital authority. In essence, the value for safety net purposes for a person is the amount paid by the person (e.g. the co-payment) for the supply of an HSD pharmaceutical benefit minus the special patient contribution (or brand price premium). Subsection 87(5) of the Act relates to limited charges for pharmaceutical benefits able to be charged by an approved hospital authority.

Subsection 37(2) provides the value for safety net purposes for supplies made by an approved pharmacist or an approved medical practitioner. In essence, the value for safety net purposes for a person is the amount paid by the person (e.g. the co-payment) for the supply of an HSD pharmaceutical benefit minus the special patient contribution (or brand price premium). Section 87 of the Act relates to limited charges for pharmaceutical benefits charged by an approved pharmacist or an approved medical practitioner including the co-payment (subsection 87(2)) and brand price premium (subsection 87(2A)).

Subsection 37(3) states that this section applies despite section 17A of the Regulations. Section 17A of the Regulations sets out the value for safety net purposes for the supply of a pharmaceutical benefit which has been modified in subsections 37(1) and (2) above.

Part 6 ***Application, saving and transitional provisions***

Division 1 ***Provisions relating to this instrument as made***

Section 38 **HSD hospital authorities**

This section replaces section 53 of the Special Arrangement 2010 updated in this instrument. It provides for an approval that was in force under subsection 52(2) or under section 53 of the Special Arrangement 2010 continues to be in force as if it were an approval under section 94 of the Act, as modified by section 10 of this instrument.

Schedule 1 HSD pharmaceutical benefits and related information

This Schedule sets out the HSD pharmaceutical benefits covered by this instrument and also specifies the circumstances, purposes, maximum quantities and maximum repeats for HSD pharmaceutical benefits. Further information relating to HSD pharmaceutical benefits in this Schedule can be found in Schedule 1 of the Listings Instrument (ready- prepared pharmaceutical benefits) including schedule equivalent, responsible person, authorised prescriber, pack quantity, determined quantity and section 100/prescriber bag only.

The Note to Schedule 1 explains that it relates to the definitions of ‘highly specialised drug’ and ‘HSD pharmaceutical benefit’ in section 6, and sections 13, 15, 20 and 21 of this instrument.

The Note to the table explains 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) of the Act respectively.

Schedule 2 Maximum quantities and repeats for certain HSD pharmaceutical benefits

This Schedule sets out the maximum quantity or number of units and the maximum number of repeats for prescribing certain HSD pharmaceutical benefits in certain circumstances. This is a new schedule which updates and clarifies the text previously provided in sections 24 and 25 of the Special Arrangement 2010.

The Note to Schedule 1 explains that it relates to sections 20 and 21 and Schedule 1, columns headed “Maximum quantity” and “Maximum repeats” of this instrument.

Schedule 3 Circumstances and purposes

This Schedule sets out circumstances and purposes for circumstance codes and purposes codes for HSD pharmaceutical benefits covered by this instrument. This information is also set out in Schedule 4 Part 1 of the Listings Instrument without specific reference to the pharmaceutical benefits as HSDs.

The Note to Schedule 1 explains that it relates to sections 13, 15, 16, 20 and 21 of this instrument.

Schedule 4 HSD pharmaceutical benefits with modified prescription circumstances during COVID-19 pandemic

This Schedule was previously Schedule 5 of the Special Arrangement 2010. It sets out HSD pharmaceutical benefits with modified prescription circumstances during the COVID-19 pandemic and relates to section 17 of this instrument.

Schedule 5 Repeals

This schedule repeals the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) instrument.

Statement of Compatibility with Human Rights

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

National Health (Highly Specialised Drugs Program) Special Arrangement 2021 PB 27 of 2021

This 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 Instrument

Pursuant to subsections 100(1) and 100(2) of the Act, *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (the instrument) revokes and remakes the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) (the Special Arrangement 2010). Along with section 100 of the Act, this instrument is also made under sections 85 (pharmaceutical benefits), 85A (Determinations of forms of pharmaceutical benefits or pharmaceutical items with respect to classes of persons), 88 (Prescribing of pharmaceutical benefits) and 99 (Payment for supply of benefits) of the Act.

The provisions in this instrument retain substantially similar content to that of the Special Arrangement 2010, 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. The changes also include updating obsolete references and providing definitions for terms used, but not defined in the Special Arrangement 2010. The provisions have been rewritten, reordered, and renumbered using modern drafting principles and language.

Background

The Highly Specialised Drugs (HSD) program provides access to specialised Pharmaceutical Benefits Scheme (PBS) medicines to eligible patients, for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied.

Under this arrangement, HSD pharmaceutical benefits may be supplied by hospital authorities for public and private hospitals to an eligible patient receiving treatment in, at or from a public or private hospital. If the eligible patient is receiving treatment in, at or from a private hospital, the HSD pharmaceutical benefits may also be supplied by an approved pharmacist. An approved pharmacist may also supply an HSD pharmaceutical benefit to an eligible patient receiving treatment at or from a public hospital if the HSD pharmaceutical benefit has a CAR drug. HSD pharmaceutical benefits that are community access medicines may be supplied by approved suppliers. A prescription for an HSD pharmaceutical benefit written by an authorised prescriber in a public hospital cannot be supplied by a private hospital and vice versa.

The prescribing of HSD pharmaceutical benefits is in most cases limited to practitioners who have undertaken particular training or are affiliated with a specialised hospital unit. To better align existing HSD program arrangements with current clinical practice and models of care, hospital affiliation is not required for prescribers of community access medicines. Authorised nurse practitioners are authorised prescribers for HSD pharmaceutical benefits used for the treatment of HIV, hepatitis B and hepatitis C.

This instrument provides for matters relating to the prescribing and supplying of HSD pharmaceutical benefits to eligible patients. The instrument also specifies how claims for payment for the supply of HSD pharmaceutical benefits may be made, the amount of reimbursement 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 of a HSD pharmaceutical benefit.

The key updates provided for in the instrument are:

- provides simplified wording throughout,
- provides only for where overarching PBS legislation has been modified. The instrument avoids repetition of provisions or positions made available in other legislation e.g. prescribing methods and claims rules,
- substitutes definitions of affiliated specialist medical practitioner (now ‘affiliated’) and eligible patient in line with current policy. The definitions provide clarity for prescribers in both the private and public hospital settings and further clarify the policy intent in view of previously raised enquiries from stakeholders,
- improves and clarifies reference to the community access arrangements that were introduced in 2015,
- clarifies intent through revising the provision for approval of hospital authorities without an onsite dispensary that are otherwise unable to seek approval under section 94 of the Act. In the instrument the provision for approval of hospital authorities without an onsite dispensary is provided as a modified section 94 approval for the purposes of supplying HSD pharmaceutical benefits only. In practice, the application process for a hospital authority remains the same,
- amends the current sections relating to quantity and repeat exceptions for Written Authority Required prescriptions to provide the information in a table format in Schedule 2 of the instrument which will provide clarity and increased useability, and
- simplifies the columns in the Schedules to minimise duplication and streamline their use.

Human rights implications

This instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with the advancement of this human right by providing for subsidised access by patients to 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. This instrument assists with the advancement of this right by ensuring continued access to PBS subsidised highly specialised drugs for the treatment of chronic conditions.

Conclusion

This instrument is compatible with human rights because it promotes the protection of human rights.

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