

EXPLANATORY STATEMENT

National Health Act 1953

National Health Legislation (Repeal and Consequential Amendments) Instrument 2024

PB 36 of 2024

Purpose and operation

The *National Health Legislation (Repeal and Consequential Amendments) Instrument 2024* (Repeal and Consequential Instrument) revokes, on 1 April 2024, three instruments made under the *National Health Act 1953* (Act) that sunset on that date:

- *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (2012 Listing Instrument);
- *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (2011 EFC Special Arrangement); and
- *National Health (Prescriber bag supplies) Determination 2012* (2012 Prescriber Bag Determination).

The Repeal and Consequential Instrument also makes consequential amendments to various legislative instruments made under the Act. These consequential amendments are the result of the 1 April 2024 replacement of the 2012 Listing Instrument with the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (2024 Listing Instrument) and the 2011 EFC Special Arrangement with the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* (2024 EFC Special Arrangement).

These consequential amendments do not give effect to any change of policy. The primary aim of the Repeal and Consequential Instrument is to ensure legislative instruments made under the Act correctly reference the new 2024 Listing Instrument and 2024 EFC Special Arrangement. The opportunity has also been taken to update and improve the drafting of affected instruments to better clarify their intended operation.

Background

The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for the supply of drugs and medicinal preparations as pharmaceutical benefits. Part VII of the Act establishes the Pharmaceutical Benefits Scheme (PBS), which provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines.

The 2012 Listing Instrument, 2011 EFC Special Arrangement and 2012 Prescriber Bag Determination are a critical part of the legal framework that underpins the PBS.

These instruments sunset under the *Legislation Act 2003* on 1 April 2024 and will be remade with effect from that date.

The repeal of the 2012 Listing Instrument and 2011 EFC Special Arrangement and their replacement with the 2024 Listing Instrument and 2024 EFC Special Arrangement has necessitated the making of consequential amendments to the following legislative instruments made under the Act that form part of the legal framework for the PBS:

- *National Health (Chemotherapy Prescribing) Special Arrangement 2020;*
- *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018;*
- *National Health (Growth Hormone Program) Special Arrangement 2015;*
- *National Health (Highly Specialised Drugs Program) Special Arrangement 2021;*
- *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017;*
- *National Health (Price and Special Patient Contribution) Determination 2022;*
- *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023.*

Authority

The Repeal and Consequential Instrument is made under sections 84AF, 84AK, 85, 85A, 85B, 88, 92A, 93, 93AB, 100 and 101 of the Act.

Repeals

2012 Listing Instrument

The repeal of the 2012 Listing Instrument is made under sections 84AF, 84AK, 85, 85A and 88 of the Act, along with subsection 33(3) of the *Acts Interpretation Act 1901* (AIA). Subsection 33(3) provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Also, subsection 101(4AAA) of the Act empowers the Minister, by legislative instrument, to revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation. Where a revocation or variation of a subsection 85(2) declaration would have the result that a drug or medicinal preparation would cease to be a listed drug, the Minister must, under subsection 101(4AAB) of the Act, obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee (PBAC) before making the revocation or variation. Parliamentary tabling requirements apply in relation to the revocation or variation declaration and the advice from PBAC (see subsection 101(4AAC)).

Subsections 101(4AACB) and 101(4AAE) empower the Minister, by legislative instrument, to revoke or vary declarations under subsections 85(2AA) and 85(2A) respectively. These declarations relate to drugs or medicinal preparations (drugs) that should be supplied only under the prescriber bag provisions in the Act or a special arrangement under section 100 of the Act.

2011 EFC Special Arrangement

The repeal of the 2011 EFC Special Arrangement is made under section 100(2) of the Act which provides that the Minister may, by legislative instrument, vary or revoke a special arrangement made under subsection 100(1) of the Act.

2012 Prescriber Bag Determination

The repeal of the 2012 Prescriber Bag Determination is made under sections 93 and 93AB of the Act, along with subsection 33(3) of the AIA.

Schedule 2 - Amendments

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 certain persons:

- living in isolated areas or who are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment; or
- where the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Amendments to the following special arrangements are made under subsection 100(2) of the Act:

- *National Health (Chemotherapy Prescribing) Special Arrangement 2020;*
- *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018;*
- *National Health (Growth Hormone Program) Special Arrangement 2015;*
- *National Health (Highly Specialised Drugs Program) Special Arrangement 2021;*
- *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023.*

Amendments to the *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017* are made under section 92A of the Act, along with subsection 33(3) of the AIA. Subsection 92A of the Act provides for the approval of a pharmacist or medical practitioner to supply pharmaceutical benefits to be subject to a range of specified conditions determined by the Minister in a legislative instrument.

Amendments to the *National Health (Price and Special Patient Contribution) Determination 2022* are made under subsection 85B(4) of the Act, along with subsection 33(3) of the AIA. Subsection 85B(4) of the Act provides that the Minister may determine the circumstances in which the Commonwealth is to pay the special patient contribution for a brand of a pharmaceutical item.

Commencement

The Repeal and Consequential Instrument commences 1 April 2024.

Consultation

No consultation was undertaken on the making of the Repeal and Consequential Instrument. It repeals instruments already due to sunset on 1 April 2024. The consequential amendments made by the Repeal and Consequential Instrument are a result of the replacement of the 2012 Listing Instrument with the 2024 Listing Instrument and the 2011 EFC Special Arrangement with the 2024 EFC Special Arrangement.

The Department has consulted extensively regarding these amendments. Consultation with both internal and external stakeholders such as Services Australia, the Department of Veterans' Affairs and Peak Organisations was undertaken in relation to the 2024 Listing Instrument, *National Health (Prescriber Bag Supplies) Determination 2024* and the 2024 EFC Special Arrangement. Stakeholders raised some concerns with the EFC Special Arrangement which were minor and required no amendments. No concerns were raised with the 2024 Listing Instrument and *National Health (Prescriber Bag Supplies) Determination 2024* proposed amendments.

General

The Repeal and Consequential Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Repeal and Consequential Instrument are set out in **Attachment A**.

The Repeal and Consequential Instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Details of the *National Health Legislation (Repeal and Consequential Amendments) Instrument 2024*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health Legislation (Repeal and Consequential Amendments) Instrument 2024* (Repeal and Consequential Instrument) and may also be cited as PB 36 of 2024.

Section 2 – Commencement

Section 2 provides that the Repeal and Consequential Instrument commences on 1 April 2024.

Section 3 – Authority

Section 3 provides that the Repeal and Consequential Instrument is made under sections 84AF, 84AK, 85, 85A, 85B, 88, 92A, 93, 93AB, 100 and 101 of the *National Health Act 1953* (Act).

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Repeal and Consequential Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule has effect according to its terms.

Schedule 1 – Repeals

Schedule 1 repeals the following legislative instruments:

- *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (2011 EFC Special Arrangement);
- *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (2012 Listing Instrument);
- *National Health (Prescriber bag supplies) Determination 2012* (2012 Prescriber Bag Determination).

Each of these legislative instruments has a sunset date of 1 April 2024 in accordance with Part 4 of Chapter 3 of the *Legislation Act 2003*.

Schedule 2 – Amendments

National Health (Chemotherapy Prescribing) Special Arrangement 2020

Item 1

This item omits the words “an infusion or related chemotherapy benefit under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*” in section 4 of the *National Health (Chemotherapy Prescribing) Special Arrangement 2020* (“Chemotherapy Prescribing Special Arrangement”).

It replaces those words with “a dose of a chemotherapy drug or related pharmaceutical benefit under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024*”.

This amendment therefore removes reference in section 4 to the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (2011 EFC Special Arrangement), and substitutes a reference to the new *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* (2024 EFC Special Arrangement).

In addition, the amendment made by this item reflects the terminology used in the 2024 EFC Special Arrangement, which refers to a ‘dose of a chemotherapy drug’ being prescribed and supplied, rather than an ‘infusion’ (which was the term used in the 2011 EFC Special Arrangement).

Item 2

This item omits “(1)” from subsection 5(1) of the Chemotherapy Prescribing Special Arrangement.

Noting that item 11 repeals subsection 5(2) of the Chemotherapy Prescribing Special Arrangement, the effect of item 2 is that subsection 5(1) of the Chemotherapy Prescribing Special Arrangement simply becomes section 5, with no subsections within the section.

Item 3

This item omits the words “section 9 or 9A of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*” from the definitions at subsection 5(1) of the Chemotherapy Prescribing Special Arrangement, and replaces those words with “section 12 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*”.

This item reflects that section 12 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (2024 Listing Instrument) corresponds to, and subsumes, both sections 9 and 9A of the 2012 Listing Instrument.

In addition, this item amends subsection 5(1) of the Chemotherapy Prescribing Special Arrangement, to remove reference to the 2012 Listing Instrument, and substitute a reference to the 2024 Listing Instrument.

Item 4

This item repeals the definitions of “chemotherapy medication chart”, “chemotherapy medication chart prescription”, “chemotherapy pharmaceutical benefit” and “electronic chemotherapy medication chart prescription” in subsection 5(1) of the Chemotherapy Prescribing Special Arrangement.

The reason for this is to align with the terminology used in the 2024 EFC Special Arrangement. Whilst the terms “chemotherapy medication chart”, “chemotherapy medication chart prescription” and “electronic chemotherapy medication chart prescription” were referred to in the 2011 EFC Special Arrangement, these terms are not used in the 2024 EFC Special Arrangement. Rather, what was previously referred to as a chemotherapy medication chart is now simply a “medication chart”, a chemotherapy medication chart prescription is now a “medication chart prescription” and an electronic chemotherapy medication chart prescription is now an “electronic medication chart prescription”.

In addition, the term “chemotherapy pharmaceutical benefit” is not used anywhere in the Chemotherapy Prescribing Special Arrangement. The definition of this term is therefore not needed.

Item 5

This item inserts the definition of an “electronic medication chart prescription” into subsection 5(1) of the Chemotherapy Prescribing Special Arrangement.

The 2011 EFC Special Arrangement referred to “electronic chemotherapy medication chart prescriptions”. However, this term is not used in the 2024 EFC Special Arrangement. Rather, the relevant term used in the 2024 EFC Special Arrangement is “electronic medication chart prescription.”

As such, by using the terminology used in the 2024 EFC Special Arrangement, this item achieves consistency between the Chemotherapy Prescribing Special Arrangement and the 2024 EFC Special Arrangement in this regard.

Item 6

This item repeals the definition of “electronic medication chart system” in subsection 5(1) of the Chemotherapy Prescribing Special Arrangement.

In the 2024 EFC Special Arrangement, the concept of an “electronic medication chart system” has been subsumed into the definition of an “electronic medication chart prescription.” As such, the 2024 EFC Special Arrangement does not separately define an “electronic medication chart system”. This item therefore achieves consistency between the Chemotherapy Prescribing Special Arrangement and the 2024 EFC Special Arrangement in this regard.

Item 7

This item repeals the definitions of “eligible private hospital patient” and “eligible public hospital patient” in subsection 5(1) of the Chemotherapy Prescribing Special Arrangement, and substitutes new definitions of those terms.

The new definition of an “eligible private hospital patient” is a person who is, or is to be treated as, an eligible person (as that term is defined in the *Health Insurance Act 1973*), and who is receiving treatment at or from a private hospital.

The new definition of an “eligible public hospital patient” is a person who is, or is to be treated as, an eligible person (as that term is defined in the *Health Insurance Act 1973*), and who is receiving treatment at or from a public hospital as a non-admitted patient, day admitted patient or patient on discharge.

The reason for repealing these definitions and substituting them with new definitions is because the Chemotherapy Prescribing Special Arrangement currently provides that the terms “eligible private hospital patient” and “eligible public hospital patient” have the meaning given by the 2011 EFC Special Arrangement. However, these terms are not used in the 2024 EFC Special Arrangement. The 2024 EFC Special Arrangement uses the term “eligible patient” instead, which is not suitable for the purposes of the Chemotherapy Prescribing Special Arrangement, as that term includes patients who are not receiving treatment at or from a hospital.

Item 8

This item repeals the definition of “infusion” in subsection 5(1) of the Chemotherapy Prescribing Special Arrangement.

The reason for this is because the 2024 EFC Special Arrangement does not make provision for the prescribing and supplying of “infusions”, which was the term used in the 2011 EFC Special Arrangement. The 2024 EFC Special Arrangement instead makes provision for the prescribing and supplying of a “dose of a chemotherapy drug”, rather than an infusion.

Item 9

This item repeals the definition of a “medication chart” in subsection 5(1) of the Chemotherapy Prescribing Special Arrangement and substitutes a new definition of that term, to provide that the term “has a meaning affected by subsection 8(2).”

Item 13 inserts new section 8 (“Method of prescribing pharmaceutical benefits”) into the Chemotherapy Prescribing Special Arrangement. New subsection 8(2) makes provision for rules that apply to medication charts and provides that a medication chart referred to in subsection 8(1) is taken to be a medication chart for the purposes of the Regulations.

New subsection 8(1) relevantly provides that an authorised prescriber for a pharmaceutical benefit may write a prescription for supply of the pharmaceutical benefit to an eligible private hospital patient or eligible public hospital patient by completing a section of a medication chart that also directs the special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit to the patient under the 2024 EFC Special Arrangement.

The reason for this amendment is because the term “chemotherapy medication chart” was previously referred to in the Chemotherapy Prescribing Special Arrangement and in the 2011 EFC Special Arrangement, to describe what is now simply a “medication chart” in the 2024 EFC Special Arrangement. This amendment therefore aligns the terminology used in the Chemotherapy Prescribing Special Arrangement with the terminology used in the 2024 EFC Special Arrangement.

Item 10

This item amends subsection 5(1), to omit and substitute the reference to “2011” with “2024” in the definitions of “participating hospital authority” and “related pharmaceutical benefit”.

This amendment ensures that these definitions in subsection 5(1) of the Chemotherapy Prescribing Special Arrangement reference the new 2024 EFC Special Arrangement, instead of the 2011 EFC Special Arrangement.

Item 11

This item repeals subsection 5(2).

Subsection 5(2) provides that a reference to the supply of an infusion or a related pharmaceutical benefit refers to supply under the 2011 EFC Special Arrangement.

This subsection is repealed, as the content of this subsection is moved to new section 8 (“Method of prescribing pharmaceutical benefits”).

Item 12

This item omits the word “or” and substitutes it with “and” in paragraphs 6(2)(a) and (b).

This is a minor drafting amendment, to clarify the circumstances in which a pharmaceutical benefit is generally available for supply under Part VII of the Act (noting that the Chemotherapy Prescribing Special Arrangement only applies to pharmaceutical benefits generally available for supply under Part VII of the Act).

Item 13

This item repeals sections 8 and 9 and replaces those sections with new section 8 (“Method of prescribing pharmaceutical benefits”) and section 9 (“Variation of application of determination of maximum number of repeats or maximum number or quantity of units”).

New section 8 replicates the substance of existing section 8, with minor amendments to improve the drafting and to reflect the updated terminology used in the 2024 EFC Special Arrangement.

Existing section 9 is repealed, as the modifications it makes to the authority required procedures set out in sections 11 to 15 of the 2012 Listing Instrument are no longer needed. That is because the 2024 Listing Instrument does not include the same level of detail about the channels used to submit prescriptions for authorisation by the Chief Executive Medicare and to receive authorisation.

New section 9 provides that section 30 of the Regulations (“Variation of application of determination of maximum number of repeats or maximum number or quantity of units”) applies in relation to a prescription written under the Chemotherapy Prescribing Special Arrangement, as if a reference to a person receiving treatment in or at an approved hospital included a reference to a person receiving treatment *from* an approved hospital. New section 9 therefore reflects the amendments made by the 2024 EFC Special Arrangement.

The effect of new section 9 is that the rules set out in section 30 of the Regulations (regarding variations to maximum quantities and numbers of repeats) apply to prescriptions written under the Chemotherapy Prescribing Special Arrangement for patients receiving treatment *from* an approved hospital (including non-admitted day patients, day admitted patients or patients on discharge).

Item 14

Item 14 repeals subsections 10(3) and 10(4). These subsections modify the application of the Regulations to a supply made under the Chemotherapy Prescribing Special Arrangement.

Item 14 substitutes new subsections 10(3) and 10(4).

New subsection 10(3) provides that subsections 45(2) to (7) of the Regulations apply to a supply made under the Chemotherapy Prescribing Special Arrangement as if a reference to a person receiving treatment in or at a hospital includes a reference to a person receiving treatment from a hospital. The consequence is that the requirements set out in subsections 45(2) to (7) of the Regulations apply to supplies made on the basis of a medication chart prescription under the Chemotherapy Prescribing Special Arrangement to persons receiving treatment in, at or *from* an approved hospital (including non-admitted day patients, day admitted patients or patients on discharge).

New subsection 10(4) makes provision in relation to a supply made under the Chemotherapy Prescribing Special Arrangement, on the basis of an electronic medication chart prescription. It provides that paragraph 45(2)(c) of the Regulations does not apply; that the participating hospital authority, approved hospital authority for a private hospital or approved pharmacist

must verify the supply and the date of supply in the electronic system used to write the prescription; and that section 61 of the Regulations applies as if the reference to the details referred to in paragraph 45(2)(c) of the Regulations includes a reference to the verification referred to in this subsection.

Item 15

Item 15 repeals section 11, which makes provision in respect of electronic chemotherapy medication charts. This section can therefore be repealed, given that these charts are no longer a concept under the 2024 EFC Special Arrangement or the Chemotherapy Prescribing Special Arrangement.

Item 15 also repeals section 12, which makes provision in respect of the modified application of legislative instruments, insofar as they relate to chemotherapy medication chart prescriptions.

Item 15 insert new section 11 (“Modified application of rules”), to provide that for the purposes of item 32 of the table in clause 1 of Schedule 1 to the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022*, an electronic medication chart prescription is taken to be a paper-based prescription.

National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018

Item 16

This item repeals and substitutes a new definition of “Rules” in section 4 of the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018* (ENRMCT Special Arrangement). The new definition refers explicitly to the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022*. These are the rules made under subsection 99AAA(8) and subsection 98AC(4) of the Act. This definition has been updated to assist readers to navigate section 10 of the ENRMCT Special Arrangement (“Claims for supply of pharmaceutical benefit”).

Items 17 and 19

These items repeal the definitions of “telephone authority required pharmaceutical benefit” and “written authority required pharmaceutical benefit” from section 4 of the ENRMCT Special Arrangement. These definitions have been repealed as the terms are no longer used in the ENRMCT Special Arrangement following the repeal of section 8 and repeal and substitution of a new subsection 10(3) by items 20 and 22 (discussed below).

Item 18

This item amends the definition of “Transitional eNRMC Conformance Register” in section 4 of the ENRMCT Special Arrangement. This amendment updates the date on which the Transitional eNRMC Conformance Register is incorporated by reference into the ENRMCT Special Arrangement. Rather than being incorporated by reference as at 1 July 2022, when the definition of “Transitional eNRMC Conformance Register” was first inserted into section 4, the Register will be incorporated as it existed on 19 March 2024.

The Transitional eNRMC Conformance Register lists each software product that has been verified by the Australian Digital Health Agency (the Agency) as meeting the technical specifications required to operate as a Transitional eNRMC product. Additional software

products have been added to the Transitional eNRMC Conformance Register between 1 July 2022 and 19 March 2024. Updating the date of incorporation of this document to 19 March 2024 allows these products to operate as Transitional eNRMC Products under the conditions of the ENRMCT Special Arrangement.

The Transitional eNRMC Conformance Register is publicly available online from the Agency's website: <https://www.digitalhealth.gov.au/about-us/policies-privacy-and-reporting/registers>.

Pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*, the new definition of “Transitional eNRMC Conformance Register” incorporates by reference the Transitional eNRMC Conformance Register as it existed on 19 March 2024, a date before the commencement of this amendment (i.e. 1 April 2024).

This amendment is the result of an undertaking made to the Senate Standing Committee for the Scrutiny of Delegated Legislation to include a specific date of incorporation for the Transitional eNRMC Conformance Register in section 4 of the ENRMCT Special Arrangement. This amendment also follows consultation with relevant participating software vendors and the Agency on this minor administrative update to the date of incorporation of the Transitional eNRMC Conformance Register.

Item 20

This item repeals section 8 of the ENRMCT Special Arrangement. Section 8 modified procedures in sections 11 to 15 of the 2012 Listing Instrument for submitting and receiving authorisation of the writing of PBS prescriptions by the Chief Executive Medicare (CEM).

Section 19 of the 2024 Listing Instrument, which replaces sections 11 to 15 of the 2012 Listing Instrument from 1 April 2024, does not contain the same level of detail concerning the procedures for submitting and receiving authorisation of PBS prescriptions. It is therefore not necessary for section 8 of the ENRMCT Special Arrangement to modify the operation of section 19 of the 2024 Listing Instrument.

Item 21

This item corrects a drafting error in subsection 10(2) of the ENRMCT Special Arrangement to ensure it refers to the correct item (item 25) of the table in clause 1 of Schedule 1 to the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022*.

Item 22

This item repeals and substitutes a new subsection 10(3) of the ENRMCT Special Arrangement. Subsection 10(3) identifies the kinds of supplies of pharmaceutical benefits to which the special claims requirements in section 10 of the ENRMCT Special Arrangement apply. The new subsection 10(3) replaces former paragraphs 10(3)(a) and (b) (which referred to the supply of “written authority” and “telephone authority” pharmaceutical benefits) with a new paragraph 10(3)(a). The new paragraph aligns the drafting of subsection 10(3) with the 2024 Listing Instrument by referring to a supply of a pharmaceutical benefit where the writing of a prescription for the supply required authorisation by the CEM under section 19 of the 2024 Listing Instrument. Section 19 of the 2024 Listing Instrument will, from 1 April 2024, outline the authority required procedures by which the CEM authorises the writing of prescriptions for the supply of certain pharmaceutical benefits.

Item 22 also ensures the drafting of paragraph 10(3)(b) of the ENRMCT Special Arrangement uses the correct terminology to describe the supply of pharmaceutical benefits having a drug referred to in Schedule 8 of the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*).

The new subsection 10(3) does not alter the effect of paragraphs 10(3)(a) and (3)(b) or section 10 more generally.

National Health (Growth Hormone Program) Special Arrangement 2015

Items 23 and 24

Item 24 repeals section 9A of the *National Health (Growth Hormone Program) Special Arrangement 2015* (Growth Hormone Program Special Arrangement). Section 9A modified procedures in sections 11 to 15 of the 2012 Listing Instrument for submitting and receiving authorisation of the writing of PBS prescriptions by the CEM.

Section 19 of the 2024 Listing Instrument, which replaces sections 11 to 15 of the 2012 Listing Instrument from 1 April 2024, does not contain the same level of detail concerning the procedures for submitting and receiving authorisation of PBS prescriptions. It is therefore not necessary for section 9A of the Growth Hormone Program Special Arrangement to modify the operation of section 19 of the 2024 Listing Instrument.

Item 23 repeals the definition of “main listing instrument” in section 4 of the Growth Hormone Program Special Arrangement. This is a consequential amendment resulting from the repeal of section 9A by item 24.

National Health (Highly Specialised Drugs Program) Special Arrangement 2021

Items 25 and 27

Item 25 inserts a definition of “General statement for drugs for the treatment of hepatitis C” in section 6 of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (HSD Special Arrangement).

The term is defined to have the same meaning as in the 2024 Listing Instrument (i.e. the statement in Schedule 6 of the 2024 Listing Instrument). The term is used in Schedule 3 to the HSD Special Arrangement as part of the circumstances and purposes in which a prescription for certain PBS medicines for the treatment of hepatitis C may be prescribed under the HSD Special Arrangement but was not defined. The amendment fixes a drafting oversight that the term was not defined in the HSD Special Arrangement.

Item 27 replaces the definition of “medication for the treatment of hepatitis C” with a new definition that reflects that there is now a definition for the General statement for drugs for the treatment of hepatitis C in the HSD Special Arrangement.

These amendments do not affect the content of the General statement for drugs for the treatment of hepatitis C itself, or which patients meet the criteria in the general statement.

Items 26 and 29

Item 26 makes a consequential amendment to the definition of “Listing Instrument” in section 6 of the HSD Special Arrangement to remove reference to the 2012 Listing Instrument and substitute reference to the 2024 Listing Instrument.

Item 29 amends paragraph 8(7)(a) of the HSD Special Arrangement to remove a reference to the 2011 EFC Special Arrangement and substitute a reference to the 2024 EFC Special Arrangement.

Items 28 and 30

Item 28 adds a new subsection (7) at the end of section 7 of the HSD Special Arrangement. Section 7 of the HSD Special Arrangement sets out the types of authorised prescriber for different types of PBS medicines that may be prescribed for the purposes of supply under the HSD Special Arrangement. New subsection 7(7) clarifies that a person is not an authorised prescriber, within the meaning of the HSD Special Arrangement, for an HSD pharmaceutical benefit only because the person is authorised in accordance with section 12 of the 2024 Listing Instrument to write a prescription for the supply of the pharmaceutical benefit.

In other words, where the HSD Special Arrangement sets out additional requirements to be an authorised prescriber for the purposes of writing a prescription for supply under the HSD Special Arrangement, those additional requirements must be met by the prescriber. The additional requirements may relate to, for example, the practitioner being affiliated with a hospital or being approved by a State or Territory to prescribe that type of medication.

Item 28 also inserts a note to new subsection 7(7) which explains that a supply of an HSD pharmaceutical benefit is not a special arrangement supply of the benefit (defined in section 13 of the HSD Special Arrangement) unless the supply was prescribed by an authorised prescriber for the benefit.

Item 30 repeals section 14 of the HSD Special Arrangement. Subsections 9(1) and 9(1E) of the 2012 Listing Instrument determined for the purposes of section 88 of the Act the pharmaceutical benefits for which medical practitioners and authorised nurse practitioners, respectively, were authorised to write a prescription for PBS supply.

Section 14 of the HSD Special Arrangement previously determined medical practitioners and authorised nurse practitioners who met the requirements of an authorised prescriber for a HSD pharmaceutical benefit as authorised prescribers for the purposes of subsections 88(1) and 88(1E) of the Act, respectively. It also disappplied the operation of subsections 9(1A) and 9(4) of the 2012 Listing Instrument, with some limited exceptions for HSD pharmaceutical benefits with a drug for the treatment of hepatitis C or with the drug methadone. Section 14 had the effect that a medical practitioner or authorised nurse practitioner could not rely on meeting subsection 9(1) or 9(1E) of the 2012 Listing Instrument to prescribe relevant HSD pharmaceutical benefits under the HSD Special Arrangement, without meeting the additional requirements to be an authorised prescriber in section 7 of the HSD Special Arrangement.

Section 14 is no longer required as a result of the insertion of new subsection 7(7) by item 28.

The amendments made by items 28 and 30 do not affect the classes of authorised prescriber set out in section 7 of the HSD Special Arrangement for different HSD pharmaceutical benefits. In other words, patients and PBS prescribers will not see any practical impact from the amendments.

Items 31, 32 and 34

These items make consequential amendments to subsections 15(3), 16(2) and the note to section 50 of the HSD Special Arrangement to ensure these refer to the new 2024 Listing Instrument.

Item 33

This item amends paragraph 29(1)(c) of the HSD Special Arrangement. Subsection 29(1) sets out how the dispensed price for a supply by an approved hospital authority of a public hospital of an HSD pharmaceutical benefit under the HSD Special Arrangement is to be determined.

Paragraphs 29(1)(a), (b) and (c) provide for a different calculation depending on how the quantity of the HSD pharmaceutical benefit supplied relates to the ‘pack quantity’ of the benefit. This item omits reference in paragraph 29(1)(c) to the quantity of the benefit supplied being more than a multiple of a pack quantity of the benefit with reference to “neither paragraph (a) or (b) applies to the quantity of the benefit supplied”. This is to correct ambiguity as to whether there could be situations where paragraphs 29(1)(a) or (b) and paragraph 29(1)(c) could apply.

This amendment is a technical correction and will not affect quantum of the dispensed price for supplies of HSD benefits by an approved hospital authority of a public hospital.

National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017

Items 35 and 36

Item 35 makes a consequential amendment to the definition of “dispensing step” in section 5 of the Conditions for Approval Determination to ensure it references the 2024 EFC Instrument. This will ensure that pharmaceutical benefits supplied in accordance with the 2024 EFC Special Arrangement continue to be exempt from a requirement for approved pharmacists to include the brand of pharmaceutical benefit being dispensed on a label for the packaging of the pharmaceutical benefit as part of their conditions of approval under the Act.

Item 36 makes a consequential amendment to the definition of “extemporaneously-prepared pharmaceutical benefit” in section 5 of the Conditions for Approval Determination to provide it has the same meaning as in the new 2024 Listing Instrument.

National Health (Price and Special Patient Contribution) Determination 2022

Items 37 and 38

These items repeal and substitute a new paragraph 8(1)(c) and repeal and substitute a new subsection 8(2) of the *National Health (Price and Special Patient Contribution) Determination 2022* (Price and Special Patient Contribution Determination).

Where the responsible person for a pharmaceutical benefit and the Minister cannot reach agreement on the maximum PBS price for the pharmaceutical benefit, the Minister may nevertheless list the benefit on the PBS with a determined price. Where a pharmaceutical benefit has a determined price, it will also have an additional special patient contribution that is usually payable by the patient. However, the Commonwealth will pay the special patient contribution in circumstances determined for subsection 85B(4) of the Act.

Section 8 of the Price and Special Patient Contribution Determination determines circumstances for subsection 85B(4) of the Act.

The former paragraph 8(1)(c), together with the former subsection 8(2), relevantly provided that one of the circumstances under 85B(4) of the Act was that the writing of the prescription for the pharmaceutical benefit must have been authorised by the CEM in accordance with

‘authority required’ circumstances determined under subsection 85(7) of the Act or, if a requirement for authorisation was not determined for subsection 85(7) of the Act, the prescription for the pharmaceutical benefit was nevertheless submitted and authorised in the way provided for by such authority required procedures.

These authority required procedures were set out in sections 11 to 15 of the 2012 Listing Instrument which have been replaced, from 1 April 2024, by section 19 of the 2024 Listing Instrument.

Under the new paragraph 8(1)(c) of the Price and Special Patient Contribution Determination:

- the writing of the prescription must be authorised in accordance with section 19 of the 2024 Listing Instrument; or
- if the circumstances for writing a prescription do not require it to be authorised, the following requirements in the new subsection 8(2) must be satisfied:
 - the prescription or details of the prescription are submitted the CEM;
 - the prescription is authorised by the CEM for the purposes of the payment of the special patient contribution by the Commonwealth;
 - a number is allotted to the prescription by the CEM; and
 - the allotted number is written on the prescription.

These amendments are not intended to substantively alter arrangements for enabling Commonwealth payment of the special patient contribution. Rather, they are intended to improve the drafting of paragraphs 8(1)(c) and subsection 8(2) and clarify existing arrangements. The amendments take account of the replacement of sections 11 to 15 of the 2012 Listing Instrument with section 19 of the 2024 Listing Instrument.

National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023

Items 39 to 41

These items make consequential amendments to the definition of “Listing Instrument” in section 6, subsection 8(2) and note 2 to subsection 8(2) of the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023*. These amendments ensure the provisions reference the new 2024 Listing Instrument.

The amendment made by item 41 to note 2 to subsection 8(2) also reflects the repeal of section 14 of the HSD Special Arrangement by item 30.

Statement of Compatibility with Human Rights

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

National Health Legislation (Repeal and Consequential Amendments) Instrument 2024 **(PB 36 of 2024)**

This Disallowable Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Disallowable Legislative Instrument

The *National Health Legislation (Repeal and Consequential Amendments) Instrument 2024* (Repeal and Consequential Instrument) revokes, on 1 April 2024, three instruments made under the *National Health Act 1953* (Act) that sunset on that date:

- *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (2012 Listing Instrument);
- *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (2011 EFC Special Arrangement); and
- *National Health (Prescriber bag supplies) Determination 2012* (2012 Prescriber Bag Determination).

The Repeal and Consequential Instrument also makes consequential amendments to various legislative instruments made under the Act. These consequential amendments are the result of the 1 April 2024 replacement of the 2012 Listing Instrument with the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (2024 Listing Instrument) and the 2011 EFC Special Arrangement with the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* (2024 EFC Special Arrangement).

Human rights implications

This Disallowable Legislative Instrument does not engage any of the applicable rights or freedoms.

The consequential amendments in the Repeal and Consequential Instrument do not give effect to any change of policy. The primary aim of the Repeal and Consequential Instrument is to ensure legislative instruments made under the Act correctly reference the new 2024 Listing Instrument and 2024 EFC Special Arrangement. The opportunity has also been taken to update and improve the drafting of affected instruments to better clarify their intended operation. In accordance with best practice drafting standards, the Repeal and Consequential Instrument repeals the 2012 Listing Instrument, 2011 EFC Special Arrangement and 2012 Prescriber Bag Determination with effect from 1 April 2024. These three instruments were due to sunset on 1 April 2024 and will be replaced by new legislative instruments.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

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