

REPLACEMENT EXPLANATORY STATEMENT

National Health Act 1953

National Health (Electronic National Residential Medication Chart Trial) Amendment (Transitional Conformant Software Systems) Special Arrangement 2022

Authority

This instrument is made under subsection 100(1) of the *National Health Act 1953* (the Act).

Subsection 100(1) of the Act enables the Minister to make special arrangements for the supply of pharmaceutical benefits. Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

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

Purpose

The *National Health (Electronic National Residential Medication Chart Trial) Amendment (Transitional Conformant Software Systems) Special Arrangement 2022* (PB51 of 2022) (the Amending Instrument) amends the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018* (the Principal Instrument) to enable the use of Transitional Electronic National Residential Medication Chart (eNRMC) Products in aged care services not previously operating under the conditions of the eNRMC Trial.

The Principal Instrument allows electronic medication management (EMM) software vendors to utilise their electronic medication order chart systems in residential aged care services (RACs) for Pharmaceutical Benefits Scheme (PBS) prescribing. Under this Special Arrangement, prescribers do not need to produce a duplicate paper prescription or National Residential Medication Chart (NRMC) when creating a prescription in an electronic medication order chart. Only software vendors, RACs, and dispensing pharmacies that have been approved and listed in the Schedule to the Principal Instrument can participate under the conditions of the Special Arrangement.

Approved suppliers are given access to the electronic medication chart orders system and manually transcribe the electronic medication chart prescription information into the dispensing software. Once dispensed, the pharmaceutical item is sent to the approved residential care service for administration to the patient, and the approved supplier can manually send a claim for payment to the Chief Executive Medicare.

The Amending Instrument allows prescribers to use approved Transitional eNRMC Products for PBS prescribing in RACs without the need for these RACs or their supplying pharmacies to be listed on Schedule 1. This allows broader adoption of eNRMC software while Prescription Delivery Service (PDS) and dispensing software vendors work towards their products meeting conformance with the government requirements for electronic medication chart prescribing.

To operate under the conditions of this amendment to the Special Arrangement, electronic medication order chart software must be approved by the Australian Digital Health Agency (ADHA) as meeting the technical requirements of the electronic prescribing Conformance Profile version (CPv)3.0 and listed on the Transitional eNRMC Conformance Register. Software will not

be permitted to send electronic medication order chart prescriptions through a PDS under the conditions of this legislation. Prescribers can use Transitional eNRMC Products for PBS prescribing. Prescribers are not required to write a supporting paper prescription when creating electronic medication chart prescriptions using a Transitional eNRMC Product.

The Transitional eNRMC Conformance Register reference is incorporated by reference as in force on the day the Amending Instrument commences (1 July 2022), pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The *Transitional eNRMC Conformance Register* is freely available online from the Australian Digital Health Agency's website: <https://www.digitalhealth.gov.au/about-us/policies-privacy-and-reporting/registers>.

Consultation

The Department of Health and Aged Care (the Department) has undertaken extensive consultation with industry peak bodies, government stakeholders, Electronic Medication Management software vendors and the ADHA, through workshops and meetings to inform them of the amendment to the Principal Instrument. State and Territory governments were consulted through the Electronic Prescribing Working Group. The Australian Commission on Safety and Quality in Health Care and Services Australia have also been consulted on this amendment. All stakeholders are supportive and recognise the important role that eNRMCs play in supporting technological innovation for medication management in residential aged care.

Communication has also been undertaken with participating software vendors, residential aged care services and pharmacies. This ensures all parties are aware of the amendments to the legislation enabling their participation in the trial, and they thoroughly understand the conditions surrounding their participation. Prior to commencing operation under the conditions of the amendment, the Department will enter into a Deed of Agreement with each participating software vendor. The Deed of Agreement clearly stipulates the obligations and expectations of all participants operating under this instrument (including the Department).

Commencement

The Amending Instrument commences on 1 July 2022.

The Amending Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Amending Instrument are set out in the Attachment.

Details of *National Health (Electronic National Residential Medication Chart Trial) Amendment (Transitional Conformant Software Systems) Special Arrangement 2022 (PB 51 of 2022)*

Section 1 Name

This section provides that the name of the instrument is the *National Health (Electronic National Residential Medication Chart Trial) Amendment (Transitional Conformant Software Systems) Special Arrangement 2022*, which may also be cited as PB 51 of 2022.

Section 2 Commencement

This section specifies that the instrument commences on 1 July 2022.

Section 3 Authority

This section provides that the instrument is made under subsection 100(1) of the *National Health Act 1953*.

Section 4 Schedules

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

Schedule 1—Amendments

Part 1—Main amendments

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

Item 1 - Section 4

A note has been added under the heading in section 4 to cover expressions used within this instrument that are defined within the Act, including

- Chief Executive Medicare;
- Secretary.

Item 2 - Section 4

The definition of *approved residential care service* has been repealed as it is no longer used in this instrument.

Item 3 - Section 4

The definition of *approved supplier* and *CTS claim* have the same meaning as in Part VII of the Act.

Item 4 - Section 4

Within the definition of *electronic medication order* the word *medicine* has been replaced with *pharmaceutical benefit, consistent* with section 100 of the Act and other provisions in the Principal Instrument.

Item 5 - Section 4

Within the definition of *electronic medication order chart* the line *as in force immediately before the commencement of this Special Arrangement* has been replaced with *as in force at the start of 1 July 2022*.

Item 6 - Section 4

The definition of *electronic medication order chart system* has been amended to include provisions that ensure that:

- a pharmacist can view and annotate medication charts when dispensing medication
- medication chart orders are not sent to a Prescription Delivery Service.

Item 7 - Section 4

The definition of a *non-conformant electronic medication order chart system* has been added to refer to an electronic medication order chart system listed on Schedule 1 of this instrument, and not listed on the Transitional eNRMC conformance Register.

Item 8 - Section 4

The definition of *NRMC approved supplier* has been repealed as it is no longer used in this instrument.

Item 9 - Section 4

The definition of *PBS prescriber* and *pharmaceutical benefit* have the same meaning as in Part VII of the Act.

Item 10 - Section 4

The definition for *software vendor* has been repealed as this is within the definition of *electronic medication order chart system* and will have its ordinary meaning.

Item 11 - Section 4

The definition of *transitional conformant electronic medication order chart system* has been added to refer to a medication order chart system listed on the Transitional eNRM C Conformance Register.

The definition of *Transitional eNRM C Conformance Register* has been added and refers to the Transitional eNRM C Conformance Register maintained by the Australian Digital Health Agency.

This document is incorporated by reference as in force on the day this instrument commences (1 July 2022), pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The *Transitional eNRM C Conformance Register* is freely available online from the Australian Digital Health Agency's website: <https://www.digitalhealth.gov.au/about-us/policies-privacy-and-reporting/registers>.

Item 12 - Section 4

The note under the definition *written authority required pharmaceutical benefit* has been repealed as it has been included under the heading of this instrument.

Item 13 - Subsection 7(2)

Subsection 7(2) has been updated to include a *transitional conformant electronic medication chart* for the supply of a pharmaceutical benefit and to amend the reference to an electronic medication order chart system listed on Schedule 1 to a *non-conformant electronic medication order chart system*.

Item 14 - Subsection 7(3)

The note in subsection 7(3) is updated to remove the reference to *NRMC* for reference to *approved suppliers*.

Item 15 - Subsection 7(6)

Subsection 7(6) has been updated to change *will be taken, for the purposes of the Regulations (other than section 61) and the Rules*, to say *is, for the purposes of the Regulations (other than section 61) and the Rules, taken*. This will change the subsection to read in present tense rather than past tense.

Item 16 - Section 7

Prescription in paper-based form is not required has been added to the end of section 7. Subsection 7(7) has been added to specify that a PBS prescriber does not need to also provide a paper prescription if they create an electronic medication chart prescription using a conformant electronic medication order chart system or are using software that was already listed on the Schedule to the instrument.

Item 17 - Section 9

Section 9 has been repealed in full and substituted to allow approved suppliers to supply pharmaceutical benefits under this instrument to a person within in a residential care service if the prescription for the pharmaceutical benefit was made available to the approved supplier through a transitional conformant electronic medication order chart system.

Subsection 9(2) allows the use of a non-conformant electronic medication order chart system providing the prescription for the pharmaceutical benefit:

- is specified in column 1 of an item in the table in Schedule 1; and
- was made available to the approved supplier through a non-conformant electronic medication order chart system only if the approved supplier is specified in column 2 of Schedule 1.

Subsection 9(3) allows sections 45, 47 and 51 of the regulations apply to the supply of a pharmaceutical benefit by an approved supplier with modifications to:

- references to medication chart prescriptions are to be references to an electronic medication order;
- section 45 applies if an approved supplier is required to verify the electronic medication order that the pharmaceutical benefit has been supplied and the date on which it was supplied: and
- paragraph 45(2)(c) did not apply
- a reference to *immediate supply necessary* in section 51 is taken to reference the words within an electronic medication order.

Item 18 – Subsection 10(1)

Subsection 10(1) has been updated to remove the reference to *NRMC* for reference to *approved supplier*, to reflect that it applies to all approved suppliers.

Item 19 – Subsection 10(4)

Subsection 10(4) has been updated to reference to the Department that is administered by the Minister who administers the *Human Services (Centrelink) Act 1997*.

Item 20 - Subsections 10(5), (6) and (7)

Subsections 10(5), (6) and (7) have been updated to remove reference to *NRMC* when referenced to allow for reference to an approved supplier.

Statement of Compatibility with Human Rights

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

National Health (Electronic National Residential Medication Chart Trial) Amendment (Transitional Conformant Software Systems) Special Arrangement 2022

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

Overview of Legislative Instrument

The purpose of this instrument is to amend the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018* (the Principal Instrument). The amendments will allow vendors of approved software to implement their software in Residential Aged Care Facilities (RACFs) under trial conditions without the need for these RACFs or their supplying pharmacies to be listed on the legislative instrument.

This amendment also allows for administrative changes to update the details of participating pharmacies and RACFs, where necessary, and for RACFs and pharmacies to be removed from Schedule 1 once the software they are using has been approved and listed in Schedule 2.

Human rights implications

This instrument engages article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the right to health.

Right to Health

The right to health – the right to the enjoyment of the highest attainable standard of physical and mental health – is contained in article 12(1) of the ICESCR. Whilst the UN Committee on Economic Social and Cultural Rights has stated that the right to health is not to be understood as a right to be healthy, it does entail a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

Analysis

This instrument will expand the Electronic National Residential Medication Chart Trial, which will allow more RACFs to implement Electronic National Residential Medication Charts (eNRMCs) while software vendors are working towards conformance with Conformance Profile v3.0. It is aimed at reducing regulatory burden associated with the supply of pharmaceutical benefits and support safe and effective administration of medication in residential aged care, as recommended by the Royal Commission into Aged Care Quality and Safety.

Conclusion

This instrument is compatible with human rights as it promotes the protection of the human right to health.

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