#### EXPLANATORY STATEMENT

National Health Act 1953

### National Health (Transitional Electronic National Residential Medication Chart) Special Arrangement 2025

#### **Authority**

This instrument is made under subsections 100(1) and 100(2) 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 (Transitional Electronic National Residential Medication Chart) Special Arrangement 2025 (the Instrument) repeals and replaces the National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018. It maintains the transitional framework to support continued use of Transitional electronic National Residential Medication Chart (eNRMC) systems (referred to throughout as transitional conformant electronic medication chart systems) in residential aged care homes (RACHs) for Pharmaceutical Benefit Scheme (PBS) prescribing, without requiring duplicate paper prescriptions. The Instrument supports the Department of Health, Disability and Ageing (Department) and the Australian Digital Health Agency's (Agency) policy objective of transitioning the aged care sector to conformant electronic prescribing systems, with a conformance deadline of 1 October 2025.

The Instrument provides for the continued use of Transitional eNRMC systems for PBS prescribing and supply. Transitional systems must be listed on the Transitional eNRMC Conformance Register, which is maintained by the Agency. The Transitional eNRMC Conformance Register is freely available online from the Agency's website.

To operate under this Special Arrangement eNRMC systems must meet the technical requirements of the Electronic Prescribing Conformance Profile version 3.0 and be approved by the Agency. From 1 October 2025, vendors must have an electronic prescribing (EP) conformant version of their product approved and available in order to maintain their transitional listing. This ensures that the Transitional Arrangement only applies to vendors who are actively progressing towards full electronic prescribing conformance.

The instrument clarifies that transitional prescriptions created before 1 October 2025 using systems listed on the Transitional eNRMC Conformance Register at that time remain valid for supply, even if the system is later removed from the Register. This provides legal certainty and continuity of PBS access during the transition period.

Prescribers using approved transitional systems are not required to produce a supporting paper prescription or National Residential Medication Chart. However, these systems are not permitted to transmit prescriptions via the National Prescription Delivery Service under this arrangement. Approved suppliers may access electronic medication orders for dispensing and must manually transcribe prescription information into their dispensing software. Once dispensed, the item is sent to the residential aged care home for administration, and the supplier may submit a manual claim for payment to the Chief Executive Medicare.

The Instrument removes the previous Schedule which listed RACHs that participated in the eNRMC Trial. The trial has now ceased and the Schedule is no longer relevant.

The Transitional eNRMC Conformance Register reference is incorporated by reference as in force on the day the Instrument commences (1 October 2025), 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.

## **Commencement and Repeal**

This instrument commences on 1 October 2025.

On commencement, this instrument repeals the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018*. The repeal reflects the conclusion of the trial phase and the transition to a broader, conformance-based framework for electronic prescribing in residential aged care.

#### Consultation

The Department of Health, Disability and Ageing has undertaken extensive consultation to support the changes to the eNRMC Transitional Arrangement. Consultation was conducted with:

- Australian Digital Health Agency (ADHA)
- Australian Commission into Safety and Quality in Health Care
- Services Australia
- Transitional eNRMC software vendors
- prescribing, pharmacy, and aged care peak bodies
- State and Territory governments via the Electronic Prescribing Working Group.

Stakeholders were engaged through workshops, meetings, and targeted communications to inform them of the updated requirements for participation in the Transitional Arrangement. All parties recognise the importance of transitioning to electronic

prescribing functionality to improve medication management in residential aged care and the changes to the Transitional Arrangement that support this. The transition to conformant eNRMC systems is expected to enhance the Quality Use of Medicines (QUM) and improve medication safety by reducing transcription errors, improving access to real-time prescribing information, and supporting safer, more efficient workflows across aged care, pharmacy, and prescriber settings.

To support implementation, the Department developed and distributed a suite of communication materials tailored to different user groups. These included webinars and factsheets, which were shared with peak bodies for dissemination to their members, ensuring broad awareness of the changes and associated timeframes. Stakeholders have also been made aware of the materials through working groups, governance forums and other presentations.

## <u>Details of the National Health (Transitional Electronic National Residential Medication Chart) Special Arrangement 2025</u>

## Part 1—Preliminary

#### Section 1 – Name

Section 1 provides that the name of the instrument is *National Health (Transitional Electronic National Residential Medication Chart) Special Arrangement 2025* and may also be referred to as PB 119 of 2025.

#### **Section 2 – Commencement**

Section 2 provides that the Instrument commences on 1 October 2025.

#### **Section 3 – Authority**

Section 3 provides that the Instrument is made under subsections 100(1) and 100(2) of the *National Health Act 1953* (Act).

#### Section 4 – Definitions

Section 4 provides definitions for terms used throughout the instrument, including references to other legislation such as the *National Health Act 1953*, the *National Health (Pharmaceutical Benefits) Regulations 2017*, and the *Aged Care Act 1997*.

#### Section 5 – Schedules

Section 5 outlines how amendments and repeals in the Schedule take effect.

# Part 2—Special arrangements for prescribing, supply and claiming of pharmaceutical benefits

#### Section 6 – Pharmaceutical Benefits Covered by this Special Arrangement

Section 6 outlines the scope of pharmaceutical benefits covered under this Special Arrangement. It confirms that the arrangement applies to PBS-listed medicines generally available under Part VII of the Act, with specific exclusions.

- Applies to all pharmaceutical benefits generally available for supply under Part VII of the Act.
- Excludes pharmaceutical benefits that may only be supplied under other Special Arrangements made under section 100 of the Act.

• Recognises that the Minister may declare or determine certain drugs or supply circumstances that require use of other Special Arrangements.

#### Section 7 – Application of Part VII of the Act

Section 7 clarifies the legal framework under which pharmaceutical benefits are supplied under this instrument.

- All supplies made under this Special Arrangement are considered to be made under Part VII of the Act.
- Provisions of Part VII, including associated Regulations and instruments, apply subject to the modifications set out in this Special Arrangement.

#### Section 8 – Prescribing of Pharmaceutical Benefits

Section 8 sets out the requirements for prescribing pharmaceutical benefits under this Special Arrangement, specifically through transitional electronic National Residential Medication Chart (eNRMC) systems.

- Prescriptions must be created as electronic medication orders within an electronic medication chart, in line with section 41 of the Regulations (as modified).
- Prescribing is limited to patients receiving residential care and must use a transitional conformant eNRMC system.
- Certain regulatory provisions (e.g. paragraphs 41(2)(c) and 41(2)(g)) do not apply, allowing prescriptions for Schedule 8 medicines under this arrangement.
- Prescribers must electronically approve the prescription within the system.
- Authority approval numbers or streamlined authority codes must be included in the electronic medication order where applicable.
- Prescriptions made under this section are treated as medication chart prescriptions for the purposes of the Regulations and the Rules (excluding section 61).
- Paper-based prescriptions are not required.

#### Section 9 – Supply of Pharmaceutical Benefits

Section 9 details the conditions under which approved suppliers may supply pharmaceutical benefits to residents in residential care services using a transitional conformant electronic medication chart system. It clarifies that prescriptions created and made available to the supplier via such a system prior to supply remain valid, including

those issued before the update, provided they meet transitional system requirements at the time of prescribing.

The section also outlines modifications to the application of certain regulatory provisions:

- Approved suppliers (or their authorised representatives) must verify in the electronic medication order that the pharmaceutical benefit has been supplied, including the date of supply.
- The requirement to write "immediate supply necessary" on a prescription is fulfilled by including these words in the electronic medication order.

#### Section 10 – Claims for Supply of pharmaceutical benefit

Section 10 sets out the process for approved suppliers to claim payment for the supply of pharmaceutical benefits under this Special Arrangement. It specifies that claims must be made in accordance with the Rules, as modified by this section. Key points include:

- Patient Category Coding: For certain supplies made using Fred IT Group software—specifically, those requiring Chief Executive Medicare authorisation or involving Schedule 8 medicines—the Patient Category for "Residential aged care facility patient (medication chart prescription)" must be recorded as '0' in claims.
- Submission of Electronic Medication Orders: If requested in writing by the Chief Executive Medicare, approved suppliers must submit a copy of the electronic medication order to the relevant Department.
- Electronic Pharmacy Records: For each supply based on an electronic medication order, suppliers must:
  - Prepare and retain an electronic pharmacy record for at least two years after supply.
  - Ensure the record contains all information required for a CTS claim under Schedule 1 to the Rules.
  - Submit a copy of the record to the Department if notified in writing by the Chief Executive Medicare.
- Notifications: Requests for copies of electronic medication orders or pharmacy records may apply to one or multiple records as specified in the notification.

This section clarifies record-keeping obligations and the conditions under which electronic records must be submitted, ensuring compliance and traceability for claims made under the Special Arrangement.

## Part 3 Application and transitional arrangements

**Section 11 – Definitions** 

Section 11 defines key terms used in the transitional provisions of the instrument. Transitional prescriptions are prescriptions made before 1 October 2025 under the 2018 Special Arrangement, using approved electronic medication chart systems. The former Special Arrangement refers to the National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018, as in force immediately before 1 October 2025.

Transition time is defined as 1 October 2025.

#### Section 12 – Supplies made on transitional prescriptions

Section 12 confirms the ongoing validity of supplies made on transitional prescriptions. Supplies of pharmaceutical benefits based on transitional prescriptions remain valid, even after the repeal of the 2018 Special Arrangement. Section 9 of the 2018 instrument continues to apply to these supplies, regardless of whether the supply occurs before, on, or after 1 October 2025.

#### Section 13 – Claims for supplies made on transitional prescriptions

Section 13 confirms that claims for supplies made on transitional prescriptions—created before 1 October 2025 using a system listed on the Transitional eNRMC Conformance Register at the time of prescribing—remain valid. These claims continue to be governed by section 10 of the 2018 instrument, ensuring continuity beyond the transition date.

#### Schedule 1 – Repeal of Previous Instrument

Schedule 1 repeals the National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018 in its entirety.

## **Statement of Compatibility with Human Rights**

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

# National Health (Transitional Electronic National Residential Medication Chart) Special Arrangement 2025

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**

This instrument replaces and repeals the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018*. It enables Residential Aged Care Homes (RACHs) to continue to use eNRMC systems for PBS prescribing and supply under transitional conditions without the need for these eNRMC systems, RACHs or their supplying pharmacies to be listed on the legislative instrument.

#### **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 facilitates continued used of transitional Electronic National Residential Medication Chart (eNRMC) systems for PBS prescribing and supply while software vendors transition their users to versions of their products that are conformant with the technical and legislative requirements for electronic prescribing set out in Electronic Prescribing Conformance Profile version 3.0.2. It reduces regulatory burden associated with the supply of pharmaceutical benefits and supports safer, more effective medication management in aged care settings—consistent with recommendations from 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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