

## EXPLANATORY STATEMENT

*National Health Act 1953*

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

**PB 49 of 2018**

#### **Authority**

Subsection 100(1) of the *National Health Act 1953* (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 purpose of this Special Arrangement is to allow three electronic medication management software vendors to trial their electronic medication order chart systems for the purposes of the Pharmaceutical Benefits Scheme (PBS) in twelve approved residential care services in New South Wales and South Australia. These systems provide a fully electronic version of the paper based residential medication chart currently available in all Australian approved residential care services.

This trial will allow approved prescribers (usually general practitioners) within approved trial facilities to prescribe pharmaceutical benefits directly from the electronic medication order chart system without developing a second paper-based prescription (often referred to as a medication order). Once rendered and electronically authenticated, these medication orders are sent directly to the approved supplier's dispensing software (or made available by electronic means) for dispensing. Once dispensed, the pharmaceutical item is sent to the approved residential care service for administration to the patient, and a claim for payment is sent electronically to the Chief Executive Medicare by the approved supplier.

Each electronic medication order will contain all information currently required for a paper based residential medication chart to be considered an approved form of medication chart under subsection 41(5) of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations), while allowing the use of electronic authentication for the prescribing and supply of pharmaceutical benefits.

All stages of this process (including all administration events) are captured within the electronic medication order chart system, which authenticates and records the identity of each user during each transaction. The medication management system incorporates an advanced IT security framework, which provides user and patient confidence and facilitates robust auditability functions for the purposes of the PBS.

The Department of Health (the Department) expects that the results of this trial will contribute to the development of national standards for electronic medication management systems in the residential aged care setting, and will also provide valuable information and a potential testing environment for future eHealth policy developments such as electronic prescribing.

**Consultation**

The Department has consulted with the New South Wales and South Australian state governments, Department of Human Services, Australian Digital Health Agency, participating software vendors, participating residential care services and their approved suppliers. As a result of these consultations, all parties are satisfied with the arrangements for the trial established by this Special Arrangement.

**Incorporation by reference**

In accordance with section 14 of the *Legislation Act 2003* (the Legislation Act), this Special Arrangement incorporates provisions of Commonwealth legislation, as in force from time to time.

Also in accordance with section 14 of the Legislation Act, this Special Arrangement incorporates the *Medication Chart Form – For PBS/RPBS Medication Chart prescriptions for persons receiving treatment in or at a residential care service at which the person is receiving residential care* as in force immediately before the commencement of this Special Arrangement. This document is available free of charge from

<http://www.health.gov.au/internet/main/publishing.nsf/Content/nrmc>

A provision by provision description of this Special Arrangement is contained in the Attachment.

**Commencement**

This Special Arrangement commences on 6 July 2018.

This Special Arrangement is a legislative instrument for the purposes of the Legislation Act.

**PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (ELECTRONIC NATIONAL RESIDENTIAL MEDICATION CHART TRIAL) SPECIAL ARRANGEMENT 2018 (PB 49 of 2018)***

**Section 1 Name of Special Arrangement**

This section provides that the Special Arrangement is the *National Health (National Residential Medication Chart Trial) Special Arrangement 2018* and that it may also be cited as PB 49 of 2018.

**Section 2 Commencement**

This section provides that the Special Arrangement commences on 6 July 2018.

**Section 3 Authority**

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

**Section 4 Definitions**

This section defines a number of expressions that are used in the Special Arrangement, including ‘NRMC approved supplier’, ‘approved residential care service’, ‘electronic medication order chart’ and ‘electronic medication order chart system’.

NRMC approved suppliers and approved residential care services are specified in the Schedule to the Special Arrangement.

An ‘electronic medication order chart system’ is defined as a software system, owned and operated by a software vendor specified in the Special Arrangement, used for prescribing and recording the administration of medicines to persons receiving residential care in a residential care service. Three software vendors are specified in the Special Arrangement and participating in the trial.

An ‘electronic medication order chart’ is a chart within an electronic medication order chart system that contains all the standard fields required by the *Medication Chart Form – For PBS/RPBS Medication Chart prescriptions for persons receiving treatment in or at a residential care service at which the person is receiving residential care*. A paper based medication chart is also required to contain these fields to enable PBS subsidy for pharmaceutical benefits prescribed using the chart. An ‘electronic medication order’ is an order made using such a chart.

Section 4 also clarifies that certain expressions used in the Special Arrangement are defined in the Act.

**Section 5 Pharmaceutical Benefits covered by this Special Arrangement**

Subsection (1) provides that the Special Arrangement applies to all pharmaceutical benefits available for general supply under Part VII of the Act.

Subsections (2) and (3) provide that the following kinds of pharmaceutical benefits cannot be supplied under the Special Arrangement:

- benefits which can only be supplied in accordance with another special arrangement made under section 100 of the Act; and

- benefits supplied in the circumstances in which the supply may only be made in accordance with another special arrangement under section 100.

## **Section 6 Application of Part VII of the Act**

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

Subsection 6(1) of the Special Arrangement provides that the pharmaceutical benefits supplied under this Special Arrangement are supplied under Part VII. This is the situation under the Act and this section confirms that this is not intended to be modified by the Special Arrangement.

Subsection 6(2) confirms that the provisions of Part VII, or regulations or other instruments made for Part VII apply, subject to the Special Arrangement.

## **Section 7 Prescribing of Pharmaceutical Benefits**

This section sets out the circumstances in which a PBS prescriber can write a prescription in accordance with the Special Arrangement, and the information that the PBS prescriber needs to include in an electronic medication order. It also modifies the requirements for a prescription under section 41 of the *National Health (Pharmaceutical Benefits) Regulations 2018* (the Regulations), to allow the use of electronic signatures.

Subsection 7(2) states that a prescription for the supply of a pharmaceutical benefit under the Special Arrangement may only be made:

- for a person receiving residential care in a residential care service specified in the Schedule; and
- using an electronic medication order chart system supplied or made available by a software vendor mentioned in the Schedule.

Subsection 7(3) specifies that paragraphs 41(2)(c) and 41(2)(g) of the Regulations do not apply, with the effect that:

- the prescriber does not need to write their signature on the electronic medication order chart when prescribing a benefit; and
- electronic medication orders can be made under the Special Arrangement for pharmaceutical benefits that are referred to in Schedule 8 of the current Poison Standards (also known as controlled drugs).

Subsection 7(4) requires a PBS prescriber to electronically approve the prescription in the electronic medication order chart system.

Subsection 7(5) provides that the electronic medication order must contain any authority approval number for the prescription.

Subsection 7(6) provides that a prescription for the supply of a pharmaceutical benefit made in accordance with section 7 will be taken to be a medication chart prescription written in accordance with section 41 of the Regulations (other than for section 61 of the Regulations, which relates to the keeping of records of medication chart prescriptions). Section 10 of this Special Arrangement contains separate record keeping requirements.

## **Section 8 Authority required procedures**

This section outlines the additional requirements for PBS prescribers and approved suppliers to prescribe, dispense and claim for authority and written authority required pharmaceutical benefits directly from an electronic medication order chart.

Authority required pharmaceutical benefits are generally not able to be prescribed from a paper based residential medication chart due to the reduced availability of prescription data for audit and tracking purposes. However, section 8 modifies the usual processes for complying with authority required procedures in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* for pharmaceutical benefits prescribed under the Special Arrangement. The security surrounding authentication of system users, improvements to patient identification and transmission and storage of all prescription events through an electronic medication order chart means that it is appropriate to supply these pharmaceutical benefits through this Special Arrangement.

Subsection 8(2) sets out the modified processes that must be followed when submitting an electronic medication order for a written authority required pharmaceutical benefit for authorisation by the Chief Executive Medicare.

Subsections 8(4) and 8(5) set out the procedures through which the Chief Executive Medicare authorises an electronic medication order for a written authority required pharmaceutical benefit.

## **Section 9 Supply of Pharmaceutical Benefits**

Subsection 9(1) provides that only NRMC approved suppliers specified in the Schedule can supply pharmaceutical benefits under the Special Arrangement, and only to persons receiving residential care in the relevant approved residential care service specified in the Schedule.

Subsection 9(2) provides that a pharmaceutical benefit cannot be supplied before the prescription for that benefit becomes available to the NRMC approved supplier through an electronic medication chart system.

Subsection 9(3) provides that sections 45, 47 and 51 of the Regulations apply to a supply made under the Special Arrangement, with certain modifications. These sections relate to supply on the basis of a (paper) medication chart prescription, information about the concessional status of a person to whom a pharmaceutical benefit is supplied on the basis of a (paper) medication chart prescription, and repeat supplies of pharmaceutical benefits, including on the basis of a (paper) medication chart prescription. Modifications include that references to a medication chart prescription is to be taken as a reference to an electronic medication order.

Paragraph 9(3)(c) provides that paragraph 45(2)(c) of the Regulations, which would ordinarily require an approved supplier to write information into a (paper) medication chart prescription, does not apply to a supply made under the Special Arrangement.

## **Section 10 Claims for supply of pharmaceutical benefit**

This section regulates how approved suppliers are to claim for the supply of pharmaceutical benefits under this Special Arrangement.

Subsection 10(1) provides that this Special Arrangement allows approved suppliers to make a claim for payment for the supply of a pharmaceutical benefit in accordance with the *National Health (Claims and under co-payment data) Rules 2012* as modified by section 10.

Subsections 10(3) and 10(3) modify the application of those Rules for claims for written or telephone authority required pharmaceutical benefits, or Schedule 8 pharmaceutical benefits, where the supply is made using Fred IT Pty Ltd dispensing and claiming software.

Subsection 10(4) requires NRMC approved suppliers to submit a copy of the electronic medication order to the Department of Human Services, if notified to do so by the Chief Executive Medicare.

Subsections (5) to (8) outline the requirement for NRMC approved suppliers to maintain appropriate records of electronic medication orders and their responsibility to make copies of electronic medication orders available to the Department of Human Services upon request by the Chief Executive Medicare. The requirement to keep records mirrors those in Part 6 of the Regulations.

### **The Schedule**

The Schedule specifies the name, address and approval number of the residential care services participating in this Special Arrangement, the name, address and approval number of the approved supplier associated with each residential care service participating in this Special Arrangement, and the electronic medication management system software vendor associated with each residential care service.

## **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) Special Arrangement 2018*

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 allow three electronic medication management software vendors to trial their systems in twelve residential care services in New South Wales and South Australia with the Pharmaceutical Benefits Scheme (PBS). These systems provide a fully electronic version of the paper based National Residential Medication Chart (NRMC) currently available in all Australian residential care services and able to be used to prescribe PBS subsidised drugs.

### **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 PBS assists with advancement of these human rights by providing for subsidised access by residents to medicines. The NRMC became available for use in residential care services Australia-wide in 2012. This trial will assist with uptake of the NRMC, which is expected to reduce the regulatory burden on prescribers, pharmacists and residential care services, and improve medication safety for residents.

The instrument requires NRMC suppliers, on request of the Chief Executive Medicare, to provide copies of electronic medication orders to the Chief Executive Medicare. As electronic medication orders contain patients' personal information, this instrument engages the right to privacy in Article 17 of the International Covenant on Civil and Political Rights. It is necessary for the Department of Human Services, through the Chief Executive Medicare, to access to electronic medication chart to ensure PBS benefits have been prescribed and claimed appropriately. The engagement with the right to privacy is reasonable and proportionate because officers that will handle the electronic medication orders will be subject to the Privacy Act 1988 and the secrecy provisions in section 135A of the National Health Act 1953. Further, personal information obtained under the instrument will be subject to the same safeguards as personal information obtained under the Pharmaceutical Benefits Scheme.

### **Conclusion**

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

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