### **EXPLANATORY STATEMENT**

### National Health Act 1953

### National Health (Electronic National Residential Medication Chart Trial) Amendment (Approved Residential Care Services) Special Arrangement 1 of 2021

### Authority

This instrument is made under section 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 (Electronic National Residential Medication Chart Trial) Special Arrangement 2018 (the Principal Instrument) allows three electronic medication management software vendors to trial their electronic medication order chart systems for the purposes of the Pharmaceutical Benefits Scheme (PBS) within a number of approved residential care services (as identified in the Schedule to the Principal Instrument). These systems provide a fully electronic version of the paper based residential medication chart currently available in all Australian approved residential care services.

The trial allows 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.

The purpose of the National Health (Electronic National Residential Medication Chart Trial) Amendment (Approved Residential Care Services) Special Arrangement 1 of 2021 (the Amending Instrument) is to amend the Schedule to this Special Arrangement to allow three additional electronic medication management software vendors (DigiMed, Sigma/MPS and Compact) and an additional 155 residential aged care facilities to participate in the trial.

These additional software vendors and residential aged care services will provide a greater capacity for Residential Aged Care Facilities (RACFs) to utilise electronic prescribing during COVID-19. The extension of the trial to the new software vendors will increase the competition within the industry and provide additional time for all software vendors, to test and troubleshoot their products prior to the broader roll out, ensuring a safe transition to electronic prescribing for RACFs. The vendors are aware that this trial is an interim arrangement, and that they will need to work towards electronic prescribing conformance by 30 June 2021.

The Department and the Australian Digital Health Agency have assessed each software vendor's proposal and viewed a software demonstration of each product to ensure they adequately support patient safety, privacy and security, as well as the requirements for the NRMC. The three software products have all met or exceeded these requirements, and both agencies are supportive of the extension of the eNRMC Trial to these vendors.

A provision by provision description of the Amending Instrument is contained in Attachment 1.

### Consultation

The Department has consulted with the participating software vendors, relevant state and territory governments, Services Australia, the Australian Digital Health Agency and the Australian Commission on Safety and Quality in Health Care regarding this amendment. Identified RACFs (and residential aged care providers as appropriate) and pharmacies, are also aware of the amendments to the legislation which enable their participation in the trial, and thoroughly understand the conditions surrounding their participation. Prior to commencing the trial, the Department also enters into a Deed of Agreement with each software vendor, RACF and pharmacy involved. These documents are detailed agreements between the parties, which clearly stipulate the obligations and expectations of all participants (including the Department) to support the trial.

### Commencement

The Amending Instrument commences the day after registration.

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

#### Provision by provision description of the National Health (Electronic National Residential Medication Chart Trial) Amendment (approved Residential Care Services) Special Arrangement 1 of 2021

#### Section 1 Name

This section provides for the Amending Instrument to be referred to as the National Health (Electronic National Residential Medication Chart Trial) Amendment (approved Residential Care Services) Special Arrangement 1 of 2021.

#### Section 2 Commencement

This section specifies that the legislation will come into effect from the day after the instrument is registered.

#### Section 3 Authority

This section provides that the Special Arrangement is made under section 100(2) of the *National Health Act* 1953.

#### Section 4 Schedules

This section provides for the amendments being made to the Schedule to the original instrument, adding additional sites to the Special Arrangement, enabling them to participate in the National Health Electronic National Residential Medication Chart trial.

#### 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) Amendment (Approved Residential Care Services) Special Arrangement 1 of 2021

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) to allow a number of additional residential aged care facilities to participate in the Electronic National Residential Medication Chart Trial.

The Principal Instrument allows approved electronic medication management software vendors to trial their electronic medication order chart systems for the purposes of the Pharmaceutical Benefits Scheme (PBS) within a number of approved residential care services (as identified in the Schedule to the Principal Instrument) located in the Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia and Victoria.

# 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 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. It is aimed to reduce the regulatory burden associated with the supply of pharmaceutical benefits and support residential aged care services to limit exposure of residents to COVID-19.

Accordingly, this instrument supports the right to health.

# Conclusion

This instrument is compatible with human rights as it enables advances in the protection of human rights, in particular the right to health.

# Simon Cleverley

A/g Assistant Secretary Digital Health and Services Australia Branch Benefits Integrity and Digital Health Division