

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Electronic National Residential Medication Chart Trial) Amendment (Approved Residential Care Services) Special Arrangement 2 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 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 2 of 2021* (the Amending Instrument) is to amend this Special Arrangement to:

1. Make consequential amendments to subsection 7(5) of the Principal Instrument, following an amendment to the *National Health (Listing of Pharmaceutical Benefits) Listing Instrument 2012*. This change aligns the requirements under the principal instrument with the information requirements for prescribing PBS streamline authority items under the *National Health (Listing of Pharmaceutical Benefits) Listing Instrument 2012*;

2. Amended the Schedule to the Special Arrangement to reflect minor administrative changes to participating pharmacy and/or approved residential care services details. For example change of pharmacy approval numbers or ownership.
3. Amended the Schedule to the Special Arrangement to include one (1) additional site to the trial, due to the difficult circumstances the facility is facing as a regional care home. The RACF is located where there are no local doctors currently servicing this town. This amendment removes the requirement for the paper charts and enables electronic prescribing, which can be carried out remotely by prescribers in neighbouring regions; and
4. Remove 126 residential care services and their servicing pharmacies from the Electronic National Residential Medication Chart Trial instrument, as they are unable to operate under the trial at this time.

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

Consultation

The Department has undertaken extensive consultation with industry and government stakeholders to inform the Electronic National Residential Medication Chart Trial, including the Australian Digital Health Agency, relevant state and territory governments, the Australian Commission on Safety and Quality in Health Care and the Aged Care Quality and Safety Commission. All stakeholders are supportive, and recognise the important role that the Electronic National Residential Medication Chart Trial plays in supporting technological innovation for medication management in residential aged care.

Extensive consultation has also been undertaken with participating software vendors, residential care services and pharmacies to ensure all parties are 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, residential care service 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.

The Department has consulted with the residential care services and pharmacies being removed from the trial, and are aware of the need to use appropriate PBS prescriptions or paper national residential medication charts to support PBS prescribing, supply and claiming. Vendors are also aware of these changes and are working closely with the Department of Health to support their sites to understand applicable PBS prescribing, supply and claiming requirements outside of 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 2 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 2 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 in this Special Arrangement. The amendment will be allowing the removal of 126 residential care services and their servicing pharmacies no longer participating in the Electronic National Residential Medication Chart Trial from the Schedule to the Principal Instrument. The amendment instrument also allows for administrative changes to contemporise the details of participating pharmacies and Residential Aged Care Facilities (RACFs), where necessary and add one additional site due to exceptional circumstances.

Schedule 1 - Amendments

Item [1] Subsection 7 *Creating electronic medication orders - authority prescriptions*

This item makes a minor amendment to note the requirement for prescribers participating in the trial to provide the relevant PBS Streamline Authority Code when prescribing a PBS Streamline Authority item directly from the medication chart.

Item [2] 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.

This item provides for the amendments being made to the Schedule to the original instrument in this Special Arrangement. The amendment will be allowing the removal of 126 sites which will no longer be participating in the electronic National Residential Medication Chart Trial (the Trial). The amendment instrument also allows for administrative changes to contemporise the details of participating pharmacies and Residential Aged Care Facilities (RACFs), where necessary and adds one additional site due to exceptional circumstances.

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 2 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). The amendments will allow for administrative errors and inconsistencies to be amended, to include a consequential amendment, remove 126 residential aged care facilities withdrawn from the trial as well as including an additional site to 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.

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