

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Paperless Prescribing, Dispensing and Claiming Trial) Special Arrangement 2025

Authority

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

Subsection 100(1) of the Act relevantly enables the Minister to make special arrangements for providing that an adequate supply of pharmaceutical benefits will be available to persons, including where pharmaceutical benefits can be more conveniently or efficiently supplied under the arrangements.

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 of the Act, have effect subject to a special arrangement made under subsection 100(1).

Purpose

The purpose of this instrument is to ensure the continuing facilitation of safe and effective prescribing, supply and administration of pharmaceutical benefits using electronic medication chart orders at St Stephen's Hospital Hervey Bay Queensland. The current instrument, the *National Health (Paperless Prescribing, Dispensing and Claiming Trial) Special Arrangement 2014*, is scheduled to sunset on 1 April 2025. However, continuation of the existing arrangement is required until a national electronic medication chart framework is in place.

The Department of Health and Aged Care (**Department**) is in the process of establishing a National Electronic Medication Chart Framework (**NEMCF**). Once in place, it is expected that St Stephen's Hospital will transition to an approved Pharmaceutical Benefits Scheme (**PBS**) electronic medication chart under the new framework and this Special Arrangement will cease.

The approved prescribers will prescribe pharmaceutical benefits within the electronic medication charting system by making "electronic medication chart orders". These medication orders are electronically sent to the approved supplier's dispensing software for dispensing. Once dispensed, the pharmaceutical is administered to the patient and a claim for payment electronically sent to the Chief Executive Medicare by the approved supplier without paper copies of the medication order.

All stages of this process are captured within the electronic medication charting system, which records the identity of each user during each transaction. The medication charting system incorporates an advanced IT security framework, which provides user and patient confidence and facilitates robust PBS auditability functions.

Background

Part VII of the Act establishes the PBS, which provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for the supply of drugs and medicinal preparations as pharmaceutical benefits.

In 2019, amendments were made to the Regulations to enable electronic prescribing, which included the use of electronic medication charts within hospitals and residential aged care services. The Regulations enable the approval of the form or information requirements for electronic medication chart prescriptions.

The NEMCF Project aims to roll out PBS electronic medication charts to new clinical settings efficiently and effectively, by ensuring PBS electronic medication charts are as standardised and consistent as possible across clinical settings, with unique requirements managed by exception only. The project aims to develop ‘standard PBS electronic medication chart’ requirements that are applicable to many or most healthcare settings. It is expected that the ‘standard chart’ requirements will be suitable for use in most hospital, palliative, disability, aged care, mental health and rehabilitation settings, and multi-purpose services. Ahead of standard requirements being formulated, a trial was implemented at St Stephen’s Hospital from October 2014 to allow the hospital to use a fully electronic medication charting system to prescribe, dispense and claim pharmaceutical benefits.

Consultation

The Department consulted with the Department of Social Services, the participating hospital during the development of this Trial. As a result of these consultations, all parties have been satisfied with the outcomes and terms and conditions of the Paperless Prescribing, Dispensing and Claiming Trial to date. Given that this instrument provides for the continuation of existing arrangements, no specific consultation was undertaken in relation to this instrument.

The Instrument commences on 1 April 2025.

Details of the Instrument are set out in [Attachment A](#).

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Authority: Section 100 of the
National Health Act 1953

Details of the proposed *National Health (Paperless Prescribing, Dispensing and Claiming Trial) Special Arrangement 2025*

Section 1 – Name

This section provides that the title of the Instrument is the *National Health (Paperless Prescribing, Dispensing and Claiming Trial) Special Arrangement 2025*.

Section 2 – Commencement

This section provides that the Instrument commences on 1 April 2025.

Section 3 – Authority

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

Section 4 – Definitions

This section provides definitions for a number of expressions that are used in the Instrument.

Notably, the term “hospital” is defined as the hospital specified in Column 1 of the Schedule to the instrument, being St Stephen’s Hospital Hervey Bay. A “patient of the hospital” means an in-patient who occupies a bed in the hospital, or an out-patient of the hospital. These definitions are relevant to the scope of the instrument, which only applies to pharmaceutical benefits that are for the purpose of treating a patient at the hospital.

Other key terms defined by this section are “electronic medication chart order” and “electronic medication charting system”. These terms are relevant because an electronic medication chart order is the mechanism by which a pharmaceutical benefit can be prescribed under the Special Arrangement.

The note to section 4 also clarifies that certain expressions used in the Instrument 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.

Subsection (2) provides that benefits which can only be supplied in accordance with another special arrangement made under section 100 of the Act, cannot be supplied under this Special Arrangement

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. Where the Special Arrangement does not set out different requirements, it is intended that the normal provisions under Part VII of the Act and subordinate legislation will apply.

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 chart order. It also modifies the requirements for a prescription under section 41 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the **Regulations**), to allow the use of electronic authorisations instead of requiring written signatures.

Subsection 7(2) states that a prescription for the supply of a pharmaceutical benefit under the Special Arrangement may only be made for the purpose of treating a patient of the hospital specified in the Schedule.

Subsection 7(3) specifies that paragraph 41(2)(c) of the Regulations does not apply, with the effect that the prescriber does not need to write their signature on the medication chart when prescribing a benefit.

Instead, subsection 7(4) requires a PBS prescriber to electronically approve the prescription in the electronic medication charting system.

Subsection 7(5) provides that the electronic medication chart order must contain any authority approval number for the prescription, or the relevant streamlined authority code for the pharmaceutical benefit. This requirement relates to provisions under the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* which require authorisation from the Chief Executive Medicare when prescribing certain pharmaceutical benefits. The requirement to note the relevant number or code in the order is consistent with the normal requirements under section 40 to 41 of the Regulations, which require this information to be included in prescriptions.

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). That is, for the purposes of the Regulations and the *National Health (Supply of Pharmaceutical Benefits—Under Co payment Data and Claims for Payment) Rules 2022* (**Rules**), an electronic medication chart order made under the Special Arrangement will be treated as if it were a medication chart prescription.

However, there is an exception for section 61 of the Regulations, which sets out general record keeping requirements for medication chart prescriptions. Section 9 of this Special

Arrangement contains separate record keeping requirements that are intended to apply in the case of electronic medication chart orders.

Subsection 7(7) specifies that a PBS prescriber does not need to also provide a paper prescription to the approved supplier if they create an electronic medication chart order. This gives effect to the general intention of the Special Arrangement, which is to provide for a fully electronic medication charting system to prescribe, dispense and claim pharmaceutical benefits.

Section 8 – Supply of Pharmaceutical Benefits

Subsections 8(1) and (2) provide that only approved suppliers specified in the Schedule can supply pharmaceutical benefits under the Special Arrangement, and only for the purpose of treating a patient of the hospital specified in the Schedule.

Subsection 8(3) applies sections 45, 47 and 51 of the Regulations to supplies under the Special Arrangement, with modifications. These sections set out requirements for supplies of pharmaceutical benefits, continued dispensing supplies on the basis of a medication chart prescription, and repeated supplies. The modifications are directed at ensuring that the requirements can readily apply to electronic medication chart orders. For example, paragraph 8(3)(b) provides that the approved supplier is required to “verify” in the electronic medication chart order that the pharmaceutical benefit has been supplied, and the date of supply, instead of writing this information on the prescription or the medication chart. Similarly, paragraph 8(3)(c) provides for words to be included within the electronic medication charting system rather than written on the prescription.

Section 9 – Claims for supply of pharmaceutical benefit

Subsection 9(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 provisions relating to Claims Transmission System claims under the Rules and Act

Subsection 9(2) outlines the requirement for approved suppliers to maintain appropriate records of electronic medication chart orders and their responsibility to make copies of electronic medication chart orders available to the Department administered by the Minister who administers the *Human Services (Centrelink) Act 1997* upon request by the Chief Executive Medicare. The requirement to keep records mirrors those in Part 6 of the Regulations.

Subsection 9(3) outlines the requirement for the hospital to maintain appropriate records of electronic medication chart orders and their responsibility to make copies of electronic medication orders available to the Department administered by the Minister who administers the *Human Services (Centrelink) Act 1997* upon request by the Chief Executive Medicare.

Subsection 9(4)-(6) set out requirements for electronic pharmacy records. For each supply of a pharmaceutical benefit made by an approved supplier based on an electronic medication chart order, the approved supplier must prepare an electronic pharmacy record and retain that record for no less than two years after the day the pharmaceutical was supplied.

Subsection 9(5) provides that the electronic pharmacy record must contain all information required to be given to the Secretary by an approved supplier for a Claims Transmission System claim in relation to the supply of a pharmaceutical benefit under the Schedule to the Rules.

Statement of Compatibility with Human Rights

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

NATIONAL HEALTH (PAPERLESS PRESCRIBING, DISPENSING AND CLAIMING TRIAL) SPECIAL ARRANGEMENT 2025

The *National Health (Paperless Prescribing, Dispensing and Claiming Trial) Special Arrangement 2025* (the **Special Arrangement**) 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 the Legislative Instrument

The purpose of this Special Arrangement is to allow the private hospital, St Stephen's, located in Hervey Bay Queensland, to utilise an electronic medication charting system to prescribe, dispense and claim pharmaceutical benefits.

The approved prescribers will prescribe pharmaceutical benefits within the electronic medication charting system by making electronic medication chart orders. These electronic medication chart orders are electronically sent to the approved supplier's dispensing software for dispensing. Once dispensed, the pharmaceutical benefit is administered to the patient and a claim for payment is electronically sent to the Chief Executive Medicare by the approved supplier without the requirement for paper copies of the prescription.

Human rights implications

The Special Arrangement promotes Article 2 and Article 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 including through the safe and timely prescribing and supply of medicines.

The Pharmaceutical Benefits Scheme and the safety net scheme under the *National Health Act 1953* are benefit schemes which assist with the advancement of these human rights by providing patients with subsidised access to medicines.

The Special Arrangement helps to improve patient access to timely supply of medicines at St Stephen's Hospital Hervey Bay.

The Special Arrangement improves patient access and helps mitigate medicine safety risks. By ensuring all clinicians have the required information accessible in the electronic medication management system, it ensures they can make an informed clinical decision when prescribing, supplying and administering PBS medicines.

The use of electronic medication management improves patient safety, quality use of medicines, and the health outcomes for consumers. These systems reduce administrative burden for hospital staff, prescribers and pharmacies.

Conclusion

The Instrument of Approval is compatible with human rights as it promotes the progressive realisation of the rights to health, it does not raise any human rights issues or impinge on any applicable rights or freedoms. Human rights continue to be protected by ensuring access to affordable medicines for Australians.

Sam Peascod
Assistant Secretary
Digital and Service Design Branch
Medicare Benefits and Digital Health Division
Department of Health and Aged Care