

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024

The Amending Regulations amend the *National Health (Pharmaceutical Benefits) Regulations 2017* to clarify the requirements for supplying pharmaceutical benefits from electronic medication charts. The Amending Regulations align the existing Regulations with the policy framework, provide clearer definitions, and support pharmacists by ensuring they access relevant information to support clinical decision making and are not subject to unnecessary administrative burden.

The Pharmaceutical Benefits Scheme (PBS) was established under Part VII of the *National Health Act 1953* (the Act) and 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 supply of drugs and medicinal preparations as pharmaceutical benefits.

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 105 of the Act provides that the regulations may specify terms and conditions relating to the supply of pharmaceutical benefits and make provision for or in relation to the writing of prescriptions.

The *National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024* (the Amending Regulations) amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations) to clarify the requirements for supplying pharmaceutical benefits from an electronic medication chart and align the Regulations with the policy framework for this supply. The amendments are intended to:

- Improve quality use and safety of medicines in aged care by ensuring clinician access to accurate and timely information.
- Improve patient choice of pharmacy by ensuring any pharmacy selected by a patient has access to their real-time or near real-time medication chart.
- Support pharmacists by clarifying the requirements for the supply and claiming (including associated record keeping provisions) of pharmaceutical benefits from an electronic medication chart.

The Amending Regulations amend the Regulations to provide clearer definitions, ensure pharmacists access relevant information to support clinical decision making, and remove unnecessary administrative burden that should only be applicable to paper medication charts. These changes apply to the use of electronic medication chart products which are approved under the electronic prescribing conformance framework, and which are scheduled for testing from October 2024. It is anticipated that approved products will be available to market from November 2024.

In 2019, amendments were made to the Regulations to enable electronic medication charts, which included the use of electronic medication charts within hospitals and residential aged care services. Currently, the Regulations enable the approval of the form or information requirements for electronic medication chart prescriptions. As part of the electronic National Residential Medication Chart (eNRMC) Rollout consultation, several workflow and process issues were identified, primarily due to the evolution of paper-based workflows and processes to an electronic environment. Amendments to the Regulations are necessary address these process issues, to improve patient safety and choice of pharmacy.

The Amending Regulations will impact the supply of pharmaceutical benefits from electronic medication charts. The Department of Health and Aged Care (the Department) co-designed these changes with industry over a 12-month period through a range of industry forums, webinars and working groups. Industry as a whole supports the proposed amendments as they meet industry expectation, and their feedback and concerns have been discussed and addressed in the development of the Amending Regulations. Stakeholders consulted include:

- State and territory governments
- Commonwealth government agencies, including the Australian Digital Health Agency (ADHA), Australian Commission on Safety and Quality in Health Care (ACSQHC), Services Australia and Aged Care Quality and Safety Commission
- Peak industry bodies
- Medication Charting Software Vendors
- Pharmacists and General Practitioners

The Department will continue to work with the Medical Software Industry Association and medication charting software vendors to ensure system alignment with these changes as part of the electronic prescribing conformance testing process.

The Department will also be undertaking broader industry communication with doctors, pharmacists and aged care services to ensure understanding of these changes and impacts on the claiming and dispensing of medicines from electronic medication charts.

The Act specifies no conditions that need to be satisfied before the power to make the amendments to the Regulations may be exercised.

The Amending Regulations commence on the day after registration on the Federal Register of Legislation.

Details of the Amending Regulations 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 140 of the
National Health Act 1953

Details of the *National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024*

Section 1 – Name

This section provides that the title of the Amending Regulations is the *National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024*.

Section 2 – Commencement

This section provides that the Amending Regulations commence on the day after registration.

Section 3 – Authority

This section provides that the Amending Regulations are made under the *National Health Act 1953* (the Act).

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amending Regulations is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Amending Regulations has effect according to its terms. The Schedule amends the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations).

Schedule 1 – Amendments

Item [1] – Subsection 5(1)

Item 1 amends subsection 5(1) of the Regulations to insert a new definition for an ‘electronic medication chart system’. An electronic medication chart system is a software system used for the prescribing, supply and administration of pharmaceutical benefits to residents in aged care and patients receiving treatment within an approved hospital.

The definition requires that the system must be accessible by approved suppliers such as approved pharmacists for the purpose of viewing and recording information about the supply of pharmaceutical benefits in electronic prescriptions generated by electronic medication charts in the system. The definition also requires that the software system must meet any functionality requirements specified by the Secretary of the Department of Health and Aged Care (the Secretary) under new section 12A of the Regulations (see item 3).

Item [2] – Subsection 5(1) (subparagraphs (b)(i) and (ii) of the definition of *electronic prescription*)

Item 2 substitutes subparagraphs (b)(i) and (ii) of the definition of ‘electronic prescription’ in subsection 5(1) of the Regulations. The new subparagraphs provide that for a prescription to be an electronic prescription for the purposes of the Regulations:

- for prescriptions other than medication chart prescriptions, the prescription must be in the form approved by the Secretary under subparagraph 40(2)(c)(ii) of the Regulations; and
- for medication chart prescriptions, the prescription must either be in the form approved by the Secretary under paragraph 41(5)(a) for the purpose of writing electronic prescriptions or meet the information requirements approved by the Secretary under paragraph 41(5)(b) for the purpose of writing electronic prescriptions.

Item [3] – At the end of Division 2 of Part 1

Item 3 inserts section 12A into the Regulations. Section 12A enables the Secretary to approve, by written instrument, electronic medication chart system functionality requirements for the purposes of the definition of an electronic medication chart system. The functionality requirements are to facilitate the safe and effective prescribing and supplying of pharmaceutical benefits on the basis of electronic medication charts.

Item [4] – After paragraph 41(1)(b)

Item 4 inserts new paragraph 41(1)(c) into the Regulations. Subsection 41(1) specifies when a PBS prescriber writes a medication chart prescription for the purposes of the Regulations. The requirements currently include that:

- the person for whom the benefit is prescribed is receiving treatment in or at a residential aged care facility where they are receiving residential care; and
- the prescriber completes a section of a medication chart in accordance with subsection 41(2) and (where applicable) subsection 41(3).

New paragraph 41(1)(c) also requires that if the prescription is an electronic prescription, it is written within an electronic medication chart using an electronic medication chart system.

Item [5] - Paragraph 45(2)(a)

Paragraph 45(2)(a) of the Regulations provides that before supplying pharmaceutical benefits from a prescription written using a medication chart, the approved supplier must have seen the chart or a copy of certain parts of the chart. This previously applied in the case of prescriptions written using both paper and electronic medication charts.

Item 5 amends paragraph 45(2)(a) of the Regulations by limiting its application to supplies from a prescription in a medication chart that is not an electronic medication chart (i.e., a paper medication chart). This is consequential on the insertion of new paragraph 45(2)(aa) (see item 6).

Item [6] – After paragraph 45(2)(a)

Item 6 inserts paragraph 45(2)(aa) into the Regulations. Paragraph 45(2)(aa) specifies what an approved supplier must see before making a supply from an electronic prescription written in an electronic medication chart. The approved supplier must either:

- see the medication chart in the electronic medication chart system (subparagraph 45(2)(aa)(i)); or

- in urgent situations, see a copy of the electronic medication chart that complies with requirements specified in new subsection 45(2A) and make the supply in accordance with new subsection 45(2B) (subparagraph 45(2)(aa)(ii)).

Subparagraph 45(2)(aa)(i) also provides that where an approved supplier is required to see the electronic medication chart in the electronic medication chart system, this is subject to subsection 45(8), which specifies certain information that does not need to be seen by the approved supplier (see item 12).

Item [7] - Paragraph 45(2)(c)

Item 7 amends paragraph 45(2)(c) of the Regulations, which sets out requirements for an approved supplier to write certain information on the medication chart or copy of the chart when supplying a pharmaceutical benefit from the chart.

The amendment limits the application of paragraph 45(2)(c) to supplies made on medication chart prescriptions in medication charts that are not electronic medication charts (i.e. paper medication charts). New paragraph 45(2)(d) (see item 8) specifies requirements for prescriptions in electronic medication charts.

Item [8] – At the end of subsection 45(2)

Item 8 inserts paragraph 45(2)(d) into the Regulations. Where an approved supplier is supplying a pharmaceutical benefit on the basis of a prescription written in an electronic medication chart, paragraph 45(2)(d) requires the supplier to write the following information on the electronic prescription written in an electronic medication chart (rather than in the medication chart itself):

- the approved supplier’s name and PBS approval number;
- the identification number for the supply; and
- the date of supply.

Item [9] – After subsections 45(2)

Item 9 inserts new subsections 45(2A) and 45(2B) into the Regulations. The subsections deal with requirements that must be met in order for an approved supplier to supply pharmaceutical benefits based on a copy of an electronic medication chart, for supply in urgent situations under subparagraph 45(2)(aa)(ii) (see item 6).

Under the provisions :

- the copy of the electronic medication chart must meet the information requirements specified in writing by the Secretary under new subsection 45(9) (see item 12);
- the copy of the electronic medication chart must contain a time and date stamp to reflect the time and date of generation of the copy;
- the copy of the electronic medication chart can only be used by an approved supplier to make the supply within 72 hours from the date and time the copy is generated (as indicated by the stamp required); and
- only up to a single maximum PBS quantity for the pharmaceutical benefit can be supplied from the copy of the medication chart on the one occasion of emergency supply on the copy.

Items [10] and [11] - Subparagraphs 45(3)(a)(i) and (ii), Subsection 45(3) (example)

Item 10 repeals and substitutes subparagraphs 45(3)(a)(i) and (ii) in the Regulations. Paragraph 45(3)(a) deals with the period of validity for electronic medication charts for patients receiving residential aged care.

The period of validity previously started on the day in a calendar month (the first month) that the first prescription for a pharmaceutical benefit was written in the medication chart and ended on the last day of the fifth calendar month that started after the end of the first month.

New subparagraphs 45(3)(a)(i) and (ii) extend the period of validity for electronic medication charts to six full months after the day the first prescription was written in the chart.

Item 11 amends the example provided for the period of validity for medication charts, to reflect the extension of the period of validity for electronic medication charts. The example now provides (for electronic medication charts) that if the first prescription is written in the medication chart on 11 June, the period of validity of the chart starts on 11 June and ends on 11 December.

Item [12] – At the end of section 45

Item 12 inserts subsections 45(8) and 45(9) into the Regulations. The subsection is relevant where an approved supplier is seeking to supply pharmaceutical benefits on the basis of a copy of an electronic medication chart, in the case of urgency (see item 9).

New subsection 45(8) provides that the copy of the chart must include information about the dose, frequency of administration and route of administration required to be included in a prescription by subparagraph 41(2)(iii) of the Regulations. However, the copy seen by the approved supplier need not include other information about the administration of the pharmaceutical benefit to the person, for example information about the date or time that the medicine has been administered to the person, or who administered the medicine.

New subsection 45(9) provides that the Secretary may specify information, in writing, for the purposes of paragraph 45(2A)(a) (see item 9).

Items [13] and [14]– Before subsection 61(1), After paragraph 61(1)

Section 61 of the Regulations sets out requirements for approved suppliers to keep certain documents relating to the supply of pharmaceutical benefits on the basis of a medication chart prescription. The requirements were previously the same, whether the medication chart used to write the prescription was an electronic medication chart or a paper-based medication chart.

Amendments to section 61 made by items 14 and 15 will create different document-keeping requirements for paper and electronic medication chart prescriptions.

Item 13 inserts a subheading to subsection 61(1) to clarify that it now applies only where the medication chart in which the prescription is written is not an electronic medication chart.

Item 14 inserts paragraph 61(1)(aa) into the Regulations, which has the effect of limiting the operation of subsection 61(1) to supplies of pharmaceutical benefits on the basis of a medication chart prescription where the chart is not an electronic medication chart.

Items [15] and [16] – After subsection 61(1), Subsection 61(2)

Item 15 inserts subsection 61(1A) into the Regulations. This subsection creates an offence for approved suppliers who fail to retain certain documents where they supply a pharmaceutical benefit on the basis of a medication chart prescription where the chart is an electronic medication chart.

Approved suppliers are required to keep the electronic prescription written in the electronic medication chart, or a copy of the prescription, on which they wrote the details required by paragraph 45(2)(d) of the Regulations. These details are:

- the approved supplier's name and PBS approval number;
- the identification number for the supply; and
- the date of supply.

The approved supplier must keep the prescription or copy of the prescription for at least 2 years from the date of supply of the pharmaceutical benefit. The penalty for failure to comply with subsection 61(1A) is 0.2 penalty units (currently a penalty unit is \$313). This is also the penalty for failing to keep documents required relating to supplies of pharmaceutical benefits made on prescriptions written in paper medication charts, and which previously applied for failing to keep documents required relating to supplies of pharmaceutical benefits made on prescriptions written in electronic medication charts under former subsection 61(1).

Item 16 amends subsection 61(2) of the Regulations to ensure that failure to comply with new subsection 61(1A) is an offence of strict liability, similarly to the offence in subsection 61(1).

Item [17] – In the appropriate position in Part 9

Item 17 inserts new section 105 into Part 9 of the Regulations. The section sets out the following application provisions:

- New paragraph 41(1)(c) of the Regulations, inserted by item 4, only applies to electronic prescriptions written on or after the commencement of the Amending Regulations. New paragraph 41(1)(c) requires that if a prescription is an electronic prescription, in order to be a medication chart prescription for the purposes of the Regulations it must be written within an electronic medication chart using an electronic medication chart system;
- The amendments made to section 45 of the Regulations by items 5 to 9 only apply to supplies of pharmaceutical benefits made on or after the commencement of the Amending Regulations. Those amendments relate to requirements before an approved supplier can supply a pharmaceutical benefit on the basis of a medication chart prescription;
- The amendments made to section 45 of the Regulations by items 10 and 11 only apply in relation to an electronic medication chart where the first prescription for a pharmaceutical benefit written in the chart is written on or after the commencement of

the Amending Regulations. The amendments to section 45 made by items 10 and 11 relate to the period of validity of an electronic medication chart;

- The amendments made to section 61 of the Regulations by items 13 to 15 only apply in relation to the supply of pharmaceutical benefit made on or after the commencement of the Amending Regulations. The amendments to section 61 made by items 13 to 15 affect requirements for approved suppliers to retain certain documents when supply a pharmaceutical benefit on the basis of a prescription written in a medication chart.

These application provisions together ensure that the Amending Regulations do not affect the validity of medication chart prescriptions written, or supplies made on the basis of medication charts, before the Amending Regulations take effect, or alter record keeping requirements in relation to supplies made on the basis of medication charts before the Amending Regulations take effect.

Details of consultation

The Amending Regulations would impact the supply of pharmaceutical benefits from electronic medication charts. The Department of Health and Aged Care (the Department) co-designed these changes with industry over a 12-month period through a range of industry forums, webinars and working groups. Industry supports the proposed amendments as they meet industry expectation, and their feedback and concerns have been addressed in the development of the proposed Amending Regulations. Stakeholders consulted include:

- State and territory governments
- Commonwealth government agencies
 - Australian Digital Health Agency
 - Australian Commission on Safety and Quality in Health Care
 - Services Australia
- Aged Care Quality and Safety Commission
- Peak industry bodies
 - Pharmacy Guild of Australia
 - Aged & Community Care Providers Association
 - Australian College of Rural and Remote Medicine
 - Royal Australian College of General Practitioners
 - Pharmaceutical Society of Australia
 - Society of Hospital Pharmacists of Australia
 - Australian Medical Association
- Medical Software Industry Association (MSIA)
- Medication Charting Software Vendors, and
- Pharmacists and General Practitioners

The Department will continue to work with the MSIA and medication charting software vendors to ensure system alignment with these changes as part of the electronic prescribing conformance testing process.

The Department will also undertake broader industry communication regarding the use of conformant electronic charts and the new arrangements that would be implemented by the

proposed Amended Regulations to ensure doctors, pharmacists, aged care services understand associated requirements and workflows. Communication activities would involve webinars, industry meetings and working groups, printed industry news articles and fact sheets.

Statement of Compatibility with Human Rights

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

NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) AMENDMENT (MEDICATION CHARTS) REGULATIONS 2024

The *National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024* (the Amending Regulations) are 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 Disallowable Legislative Instrument

This legislative instrument amends the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations) to clarify the requirements for supplying from an electronic medication chart and align the Regulations with the policy framework for this supply.

The measures are intended to:

- Improve quality use of medicines in aged care.
- Improve patient safety and choice of pharmacy.
- Support pharmacists to supply PBS medicines from an electronic medication chart.
- Streamline the process for supply of PBS medicines from an electronic medication chart.

The Amending Regulations amend the Regulations to provide clearer definitions, ensure pharmacists access relevant information to support clinical decision making, and removes unnecessary administrative burden that should only be applicable to paper medication charts.

The changes made by the Amending Regulations include a new requirement that for an electronic prescription written by a PBS prescriber to be a medication chart prescription for the purposes of the Regulations, the prescription must be written in an electronic medication chart using an ‘electronic medication chart system’.

An electronic medication chart system is defined by the Regulations to be a software system used for prescribing and recording the administration of pharmaceutical benefits to a person receiving treatment in or at a residential care service where they are receiving residential care, or in or at an approved hospital. The system must also be accessible by approved suppliers for viewing and recording supply information in electronic prescriptions written in electronic medication charts within the system. In addition, the system must meet any electronic medication chart system functionality requirements approved by the Secretary of the Department of Health and Aged Care. The purpose of the functionality requirements is to facilitate the safe and effective prescribing and supply of pharmaceutical benefits using electronic medication charts.

The changes to the Regulations made by the Amending Regulations will also require that where an approved supplier seeks to supply a pharmaceutical benefit on the basis of a prescription written in an electronic medication chart, the approved supplier must have seen

the medication chart in the electronic medication chart system (although the chart does not need to include information about the day to day administration of the benefit to the patient, such as the dates or times of administration). This requirement is to ensure that approved suppliers have access to all necessary clinical information (such as all medicines currently being administered to the resident, allergies, and clinical recording) to make safe and appropriate supply decisions. The changes will allow an approved supplier to supply pharmaceutical benefits from a copy of an electronic medication chart, in the case of urgency. However, for these urgent supplies:

- The copy of the medication chart seen by the approved supplier must comply with requirements approved by the Secretary about the information that must be in the copy;
- The approved supplier must supply the benefit within 72 hours of the date and time marked on the copy indicating when the copy was created;
- The approved supplier can only supply up to the PBS maximum quantity for the pharmaceutical benefit and can only supply on one occasion on that presentation of the copy.

The Amending Regulations will also alter the offence provisions relating to documents that must be kept by an approved supplier when making a supply on the basis of a prescription written in an electronic medication chart. Previously, the same documents (the medication chart or a copy of the medication chart) were required to be kept for supplies made on the basis of medication charts, whether the medication chart was paper based or electronic. Under new requirements, where the prescription was written in a medication chart that is an electronic medication chart, the approved supplier must keep the prescription or a copy of the prescription on which the approved supplier wrote certain information identifying the approved supplier and the particular supply.

These changes do not affect the time for which documents must be kept (at least 2 years) or the penalty (0.2 penalty units).

Application provisions are included in the Amending Regulations to ensure that they do not affect the validity of medication chart prescriptions written, or supplies made on the basis of medication charts, before the Amending Regulations take effect, or alter record keeping requirements in relation to supplies made on the basis of medication charts before the Amending Regulations take effect.

Human rights implications

The Amending Regulations promote 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 Amending Regulations address a number of clinical safety risks and improve patient access to timely supply of medicines. These risks were identified through stakeholder consultation across industry, including with the Commission on Safety and Quality in Health

Care, where suppliers were relying on outdated copies of electronic medication charts to supply medicines to residential aged care home residents.

These changes will improve patient access and help mitigate medicine safety risks, by:

1. Ensuring approved suppliers have the required access to the electronic medication chart system, to ensure they are accessing the most recent version of the medication chart and relevant prescriptions;
2. Ensuring approved suppliers access and review the medication chart in the electronic medication chart system prior to supplying medicines, and consider the available clinical information to inform supply;
3. Restricting the use of copies of electronic medication charts to emergency situations and the duration these copies can be used to enable supply with improved safeguards;
4. Updating existing provisions within the regulations, to ensure that legislative requirements account for administrative and record keeping functionality provided by electronic prescribing and dispensing systems.

Improvement of the clinical requirements and use of PBS electronic medication charts improves patient safety, quality use of medicines, and the health outcomes for consumers. These systems reduce administrative burden for residential aged care homes and hospital staff, prescribers and pharmacies. The use of these systems also streamlines processes to assist aged care facilities in meeting their reporting and audit obligations under the Aged Care Act 1997 and the Aged Care Quality Standards, to ensure consumers receive safe and quality healthcare.

Conclusion

The Amending Regulations are compatible with human rights as they promote the progressive realisation of the rights to health, do 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.