

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Electronic Prescribing) Regulations 2021

Authority

Section 140 of the *National Health Act 1953* (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.

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make an instrument of a legislative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to amend or vary any such instrument.

Purpose

The *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescribing) Regulations 2021* (the Regulations) make amendments to the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) relating to the prescribing of pharmaceutical benefits using medication charts, in particular electronic medication charts.

The Regulations amend the Principal Regulations by:

- Providing authority for the Secretary to approve information requirements for electronic medication charts. Currently, the Secretary can only approve a specific form for a chart, which unnecessarily dictates formatting requirements.
- Extending the period of validity for electronic medication charts for use in residential aged care to six months. Paper medication charts in residential aged care will still expire after four months.
- Disallows the use of paper medication charts in residential aged care for prescribing pharmaceutical benefits which require approval by telephone or in writing by the Minister or the Chief Executive Medicare. This will ensure legislation aligns with the practical limitations of paper medication charts, which cannot support existing authority approval processes. As prescribers do not currently prescribe these items from paper medication charts in residential aged care, this change will not impact industry. Medicines with a streamlined authority code may still be prescribed using paper medication charts in residential aged care. However, all authority prescription items, including those requiring approval by telephone or in writing by the Minister or the Chief Executive Medicare, may be prescribed using electronic medication charts in residential aged care.

- Preventing the ongoing supply of pharmaceutical benefits referred to in Schedule 8 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*) on the basis of an electronic medication chart prescription in residential aged care. This will align Pharmaceutical Benefits Scheme (PBS) medication chart prescribing requirements with the current PBS prescription and supply requirements for medicinal items referred to in Schedule 8 to the current Poisons Standard, as amended on 1 June 2020 and 1 October 2020. The supply of these benefits from an electronic medication chart will be limited to a single maximum PBS quantity only. These medicinal items may not be prescribed, supplied or claimed from a paper medication chart in residential aged care.

Background

The PBS, established under the Act, 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.

Subsection 89(a) of the Act relevantly provides that a person is not entitled to receive a pharmaceutical benefit supplied by an approved pharmacist unless it is on presentation of a prescription written by a PBS prescriber in accordance with the Act and the Principal Regulations. PBS prescribers include approved medical practitioners, dentists, optometrists, midwives and nurse practitioners.

In the 2018-19 Budget, it was announced that prescribers and their patients would be provided with the option to use an electronic prescription or electronic medication chart as an alternative to a paper-based prescription. Electronic prescribing does not fundamentally change how current prescribing and dispensing processes operate. Patient choice of pharmacy remains central.

The Principal Regulations prescribe matters and set out details in relation to the operation of the PBS. These amendments strengthen the Principal Regulations that already allow for electronic prescribing, so they better support electronic prescribing from medication charts. All existing prescription requirements provided in the Principal Regulations (sections 40 and 41) must be met when writing an electronic prescription or electronic medication chart prescription.

Consultation

The Department has engaged in broad consultation with industry concerning these changes, including state and territory governments, clinical software, pharmacist, prescriber and residential aged care representatives. Industry are welcoming of these changes, noting that they will support prescribers and staff within the residential aged care sector to facilitate the ongoing supply of PBS medicines and medication management for residents within residential aged care facilities.

The Department has also been working with Services Australia to make necessary changes to the PBS Online Claiming System to support these changes, as well as the clinical software industry to ensure that PBS prescribing and claiming is supported.

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

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after registration.

Details of the *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescribing) Regulations 2021*

Section 1 – Name

This section provides that the title of the Regulations is the *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescribing) Regulations 2021*.

Section 2 – Commencement

This section provides that the Regulations commence on the day after they are registered.

Section 3 – Authority

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

Section 4 – Schedule(s)

This section provides that each instrument that is specified in a Schedule to the 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 Regulations has effect according to its terms.

Schedule 1 – Amendments

National Health (Pharmaceutical Benefits) Regulations 2017

Item [1] subsection 5(1)

Item 1 amends the definition of ‘electronic prescription’ under subsection 5(1) of the Principal Regulations to include medication charts that are prepared and submitted in accordance with information requirements approved by the Secretary under paragraph 41(5)(b) (medication chart prescriptions).

Item [2] subsection 41(3)

Item 2 amends subsection 41(3) of the Principal Regulations to disallow PBS prescribers from using paper medication charts when prescribing ‘authority required’ pharmaceutical benefits for residential aged care recipients where the prescription must be authorised by the Minister or the Chief Executive Medicare by telephone or in writing.

New subsection 41(3) provides that a PBS prescriber only completes a section of a medication chart to write an authority prescription if the section of the medication chart:

- includes the authority approval number (unless the prescription is being posted or delivered to the Chief Executive Medicare or Minister), or the streamlined authority code, for the pharmaceutical benefit; and
- if the person for whom the benefit is being prescribed is receiving treatment in or at a residential aged care service and the pharmaceutical benefit does not have a streamlined authority code, the medication chart is an electronic medication chart.

Items [3], [4] and [5] subsections 41(4), (5) and (6)

Items 3, 4 and 5 repeal and replace subsections 41(4), (5) and (6) respectively to enable the Secretary to approve information requirements that must be met in relation to a medication chart.

New subsection 41(4) amends the definition of a ‘medication chart’ to include both a chart in a form (if any) approved by the Secretary under paragraph 41(5)(a) or a chart meeting information requirements (if any) approved under paragraph 41(5)(b) and that is used for prescribing, and recording the administration of, pharmaceutical benefits to persons receiving treatment in or at a residential aged care service or a hospital. Previously, the Secretary could only approve a form of a medication chart.

The definition retains the explanation that a medication chart can be used for another purpose and can include other information. An example of other information a medication chart might include is records of patient blood pressure or blood sugar levels.

New subsection 41(5) enables the Secretary to approve in writing not only one or more forms for a medication chart but also approve information requirements to be met in relation to a medication chart.

New subsection 41(6) substitutes a new definition of ‘electronic medication chart’ that includes reference to a chart used for writing an electronic prescription that meets the information requirements approved under subsection 41(5).

The type of information requirements that may be approved by the Secretary include information required to be provided for a PBS claim, or to support a resident or patient’s care. This includes information to support identification of a patient or resident, any known allergies or adverse drug reactions, information concerning clinical indications or treatment requirements, details of the facility in which they reside and information concerning their regular treating physicians.

The purpose of these amendments is to enable users of electronic medication charts which meet information requirements approved by the Secretary to prescribe, supply and claim PBS medicines from these charts without providing a duplicate paper prescription.

Item [6] subsection 45(3)

Item 6 amends subsection 45(3) of the Principal Regulations to provide for an extended period of validity for electronic medication charts used to prescribe a pharmaceutical benefit to a person receiving treatment in residential aged care. New subsection 45(3) provides that the period of validity for such charts is:

- (i) in the case of a paper medication chart – the period starting on the day in the calendar month when the first prescription is written using the chart and ending on the last day of the third full calendar month after that calendar month; and
- (ii) in the case of an electronic medication chart – the period starting on the day in the calendar month when the first prescription is written using the chart and ending on the last day of the fifth full calendar month after that calendar month.

The period of validity for a medication chart is relevant for the period during which PBS supplies can be made on the basis of the chart.

Item [7] paragraphs 45(5)(a) and (b)

Item 7 amends the ongoing supply provisions in paragraphs 45(5)(a) and (b) of the Principal Regulations, which set out when a PBS supplier can supply up to the maximum quantity of a pharmaceutical benefit more than once on the basis of a particular medication chart prescription.

The effect of the amendments is that the maximum quantity of a pharmaceutical benefit cannot be supplied more than once from a single medication chart prescription, for a person receiving treatment in residential aged care, if the benefit is referred to in Schedule 8 of the Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*).

Where the pharmaceutical benefit is not a Schedule 8 benefit, the existing arrangements are maintained. In other words, a PBS supplier can supply more than once from a particular medication chart prescription if the prescription indicates the ongoing supply is authorised for the period of validity for the chart, or there is a stop date indicated for the supply of the benefit and, based on the prescribed dose and frequency of administration of the benefit, more than one supply of the maximum quantity of the benefit is required before the stop date.

Item [8] subsection 45(7)

Item 8 amends a cross-reference in subsection 45(7) to reflect the revised drafting of subsection 45(5).

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 (Electronic Prescribing) Regulations 2021

The *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescribing) Regulations 2021* (the 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

The Regulations amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) to support electronic prescribing from medication charts in residential aged care services under the Pharmaceutical Benefits Scheme (PBS). The amendments:

- enable the Secretary to approve information requirements for electronic medication charts, as an alternative to approving a form of medication chart;
- extend the period of validity for electronic medication charts for use in residential aged care to six months. Paper medication charts in residential aged care will still expire after four months;
- prevent the ongoing supply of pharmaceutical benefits referred to in Schedule 8 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*) on the basis of an electronic medication chart prescription. The supply of these benefits from an electronic medication chart will be limited to a single maximum PBS quantity only;
- prevent the use of paper medication charts in residential aged care for prescribing authority required pharmaceutical benefits requiring approval by telephone or in writing by the Minister or the Chief Executive Medicare.

The PBS provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The PBS operates under Part VII of the *National Health Act 1953* which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. The Principal Regulations prescribe matters and set out details in relation to the operation of the PBS.

Human rights implications

Broadly, the PBS is a benefits scheme which assists with providing subsidised access to medicines for people in the community. It engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), as it is a positive step towards attaining the highest standard of health for all Australians, and it assists in 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 Principal Regulations are compatible with Articles 2 and 12 of the ICESCR as they contribute to the efficient operation and effective administration of the scheme.

The Regulations strengthen the Principal Regulations that already allow for electronic prescribing from medication charts, supporting the supply of PBS medicines for residents residing within residential aged care facilities in Australia which employ electronic medication charts. Electronic prescribing provides an option for prescribers and their patients to use an electronic medication chart as an alternative to a paper-based prescription or medication chart, supporting medication management and quality use of medicine.

The amendment of the Regulations to disallow the prescribing and supply of Authority medicines (other than Streamline Authority items) does not restrict a resident's ability to access these medicines in residential aged care. It merely supports existing prescribing practices and workflows due to the physical limitations of paper medication charts and the requirements of the telephone and written authority approval processes. Residents still have access to these medicines which can be prescribed using paper or electronic prescriptions, or electronic medication charts.

Under these amendments, medicinal items identified within Schedule 8 of the Poisons Standard can still be prescribed for residents in residential aged care using paper or electronic prescriptions, or electronic medication charts. This amendment does not restrict resident's access to these medicines, but ensures prescribers are carefully monitoring the prescribing and supply of these dangerous drugs which have a high risk of dependency for this vulnerable patient category. These amendments also align with the amended PBS prescription and supply requirements for medicinal items referred to in Schedule 8 to the current Poisons Standard, which came into effect on 1 June 2020 and 1 October 2020. These changes reduced pack sizes for these items and encourage prescribers to taper opioid medication in those who are receiving minimal benefit or experiencing harm.

Conclusion

The Regulations are compatible with human rights as they do not raise any human rights issues or impinge on any applicable rights or freedoms.

The Hon. Greg Hunt MP, Minister for Health and Aged Care