

EXPLANATORY STATEMENT

Select Legislative Instrument No. XX, 2019

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019

By authority of the Minister for Health

The Pharmaceutical Benefits Scheme (PBS) is established under 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 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.

Paragraph 89(a) of the Act relevantly provides that a person is not entitled to receive a pharmaceutical benefit supplied by an approved pharmacist unless the supply is made on presentation of a prescription written by a PBS prescriber in accordance with the Act and the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations). PBS prescribers include approved medical practitioners, dentists, optometrists, midwives and nurse practitioners.

Section 105 of the Act provides that the regulations may specify terms and conditions relating to the supply of pharmaceutical benefits and provides rules about writing prescriptions for the purposes of the PBS.

In the 2018-19 Budget, it was announced that prescribers and their patients would be provided the option to use an electronic prescription 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. The *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019* (the Regulations) strengthen the Principal Regulations that already allow for electronic prescribing. The Regulations make adjustments to support the regulation of electronic prescriptions and specifically provide assurance for privacy and security.

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. The Regulations require the following additional information for electronic versions:

- Conformance ID of prescribing software.
- Unique electronic PBS prescription number.
- Valid PBS prescriber Healthcare Provider Identifier – Individual (HPI-I), if available.
- Valid PBS prescriber Healthcare Provider Identifier – Organisation (HPI-O).

The Regulations include requirements for the electronic prescription message to contain conformance identification numbers (Conformance IDs) provided to the Australian Digital Health Agency (the Agency) by the vendor of the clinical software used for the creation of an electronic prescription. This is in accordance with the technical conformance framework developed by the Agency, which details clinical software requirements around elements such as authentication, secure messaging and encryption and ensures adherence to privacy and security principles.

The inclusion of a valid PBS prescriber HPI-O and a valid PBS prescriber HPI-I (if available), identifies the medical practice where the PBS prescriber prepared the electronic prescription and the approved PBS prescriber who prepared the electronic prescription.

To help improve patient safety and quality use of medicines the Regulations also include that a patient's date of birth and the reason for the prescription may be included in the electronic prescription. Security and privacy of this information will be ensured through encryption of the electronic prescription that is only made available to authorised healthcare professionals, in alignment with the conformance framework.

The implementation of electronic prescribing also enables the use of electronic prescribing from PBS medication charts in the hospital and residential aged care settings.

As part of the regulatory framework and in support of the Regulations, amendments have been made to the *National Health (Claims and under co-payment data) Rules 2012* (Claims Rules), as well a new instrument defining the form and required data elements of the electronic prescription (Form of Prescription) approved by the Secretary of the Department of Health (the Department).

The Department has engaged in broad consultation with peak clinical and industry bodies regarding the implementation of electronic prescribing, receiving widespread support. The Department has been working with the Agency and Services Australia to progress the legislative, technical and operational elements required to enable electronic prescribing. The Department and the Agency have been working together to ensure alignment of the technical and legislative frameworks, which reinforce adherence to privacy and security principles. The Agency has developed the electronic prescribing technical framework through a co-design approach with industry, including clinicians, consumer groups, clinical software vendors and the pharmaceutical industry. The Department has led ongoing engagement with state and territory governments through the Electronic Prescribing Working Group (EPWG) to align regulation of prescribing processes across Australia. The Department consulted directly with the EPWG, the Agency, Services Australia and the Department of Veterans' Affairs through the release of an exposure draft of the proposed Regulations, and the feedback received was positive with only minor changes suggested and subsequently incorporated into the Regulations.

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

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

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

The Regulations commence on 31 October 2019.

Authority: Section 140 of the *National Health Act 1953*

Details of the *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019*

Section 1 – Name

This section provides that the title of the instrument is the *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019*

Section 2 – Commencement

This section provides that the instrument commences on 31 October 2019.

Section 3 – Authority

This section provides that the instrument is made under the *National Health Act 1953*(the Act).

Section 4 – Schedule(s)

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

National Health (Pharmaceutical Benefits) Regulations 2017 (the Regulations).

Item [1], [2], [3] and [4] - Subsection 5(1)

Subsection 5(1), removes the definition of *approved electronic communication* and introduce the definition of *eligible electronic communication*. Throughout the Regulations wherever occurring (sections 5, 9, 10, 30, 33 and 57), the reference to giving information "by means of an approved electronic communication" is changed to "by means of an eligible electronic communication". The proposed Regulations introduce a concept of eligible electronic communication in order to ensure that there is a broad concept of electronic communication consistent with the *Electronic Transactions Act 1999* that does not limit the types of electronic communications that can be used but provides the Secretary the ability to specify particular types of electronic communications if required.

Subsection 5(1) also inserts the definitions *healthcare identifier* and *healthcare provider organisation*.

These definitions have been introduced as the *healthcare identifier* and the *healthcare provider organisation* are new data elements required in an electronic prescription and were not previously defined in the Regulations. See Item 15 – additional requirements for electronic prescribing.

Item [5] – Paragraph 9(1)(b)

Item 5 replaces the word “approved” in paragraph 9(1)(b) in the definition of approved electronic communication with the word “eligible” as described in Item [1], [2], [3] and [4] - Subsection 5(1).

Item [6] – Paragraph 10(b)

Item 6 replaces the words “approved electronic” in paragraph 10(b), in the definition of approved electronic communication with the words “eligible electronic” as described in Item [1], [2], [3] and [4] - Subsection 5(1).

Item [7] – Sections 30 and 33

Item 7 replaces the words “approved electronic” in sections 30 and 33 (wherever occurring) in the definition of approved electronic communication with the words “eligible electronic” as described in Item [1], [2], [3] and [4] - Subsection 5(1).

Item [8] – Paragraphs 39(a) and (b)

Item 8 amends paragraphs 39(a) and (b) so that a prescription for the supply of a pharmaceutical benefit is written in accordance with section 40 (prescriptions other than medication chart prescriptions) or section 41 (medication chart prescriptions), and if the prescription is an electronic prescription additionally in accordance with section 41A. As inserted below see item 15 – these are additional requirements for all electronic prescriptions.

Item [9] – Paragraph 40(1)(b)

Item 9 amends terminology in paragraph 40(1)(b), to replace "to be supplied" with "prescribed". This will ensure consistent terminology in the context of a PBS prescriber writing a prescription.

Item [10] – Subparagraph 41(1)(b)(ii)

Item 10 inserts the words “other than an authority prescription referred to in subsection (3A)” after “authority prescription”, see item 13 below for details of this new subsection 3A.

Item [11] – Paragraph 41(2)(g)

Item 11 amends paragraph 41(2)(g) to enable benefits referred to in Schedule 8 of the Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*) for an electronic medication chart, while still prohibiting the prescribing of these medicines when using a paper-based medication chart.

This is enabled by inserting “and the chart is not an electronic medication chart” after the word “service”.

Item [12] – Paragraphs 41(3)(a) and (b)

Item 12 amends paragraphs 41(3)(a) and (b) to align the wording of authority requirements for streamlined, telephone and written authorities prescribed using medication charts with the current wording for general PBS authority requirements. See section 40(1)(i).

Item [13] – After subsection 41(3)

Item 13 creates a new subsection 41(3A) to align authority prescription requirements for medication charts with the general PBS authority requirements. This section specifies the inclusion of authority approval numbers in some circumstances to be eligible for the payment of a special patient contribution by the Commonwealth. See section 40(5) (prescriptions other than medication chart prescriptions).

Item [14] – At the end of section 41

Item 14 adds the definition of electronic medication charts to ensure an electronic medication chart is in a form approved under subsection (5) for the purpose of writing an electronic prescription.

Item [15] – After section 41

Item 15 creates subsection 41A which details additional requirements for writing all electronic prescriptions. A PBS prescriber must include in the metadata of the prescription the conformance identifier of the prescribing software, and a unique electronic prescription identifier generated by that software. The electronic prescription must include the Healthcare Provider Identifier - Individual (HPI-I) assigned to the PBS prescriber (if available), and the Healthcare Provider Identifier - Organisation (HPI-O) assigned to the healthcare provider organisation to which the PBS prescriber is linked. The inclusion of a valid PBS prescriber HPI-I (if available) and PBS prescriber HPI-O, identifies the approved PBS prescriber who prepared the electronic prescription and the medical practice where the PBS prescriber prepared the electronic prescription.

Item 15 also creates subsection 41B that states patient date of birth and the reason for prescribing the pharmaceutical benefit may be included as additional information when writing an electronic prescription.

Item [16] – Paragraph 57(2)(a)

Item 16 amends paragraph 57(2)(a), to replace the words “approved electronic” in the definition of approved electronic communication with the words “eligible electronic” as described in Item [1], [2], [3] and [4] - Subsection 5(1).

Item [17] – Subsection 59(3)

Item 17 amends subsection 59(3) by inserting the word “of” after the word “purpose” to ensure this subsection reads correctly – “For the purposes of subsection (1), if the supply was on the basis of an electronic prescription, the approved supplier must keep:”

Item [18] – Paragraph 59(3)(a)

Item 18 amends paragraph 59(3)(a) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting “prescription, or copy of the electronic” after “electronic”. This change aligns with document keeping requirements for paper-based prescriptions.

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 Prescriptions) Regulations

The National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019 (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 Legislative Instrument

The Regulations amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) to support amendments to the *National Health Act 1953* (the Act) made by the *National Health Amendment (Pharmaceutical Benefits – Budget and Other Measures) Act 2018*.

The Pharmaceutical Benefits Scheme (PBS) provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The PBS operates under Part VII of the Act 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.

The primary purpose of the *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019* (the Regulations) is to strengthen the Principal Regulations that already allow for electronic prescribing. The Regulations make adjustments to support the regulation of electronic prescriptions and specifically provide assurance for privacy and security.

In addition to the existing prescription requirements set out in the Principal Regulations (sections 40 and 41), the Regulations require the following additional information for electronic versions:

- Conformance ID of prescribing software.
- Unique electronic PBS prescription number.
- Valid PBS prescriber Healthcare Provider Identifier – Individual (HPI-I), if available.
- Valid PBS prescriber Healthcare Provider Identifier – Organisation (HPI-O).

To help improve patient safety and quality use of medicines the Regulations also include that a patient's date of birth and the reason for the prescription may be included in the electronic prescription. Security and privacy of this information will be ensured through encryption of the electronic prescription that is only made available to authorised healthcare professionals.

The implementation of electronic prescribing enables the use of electronic prescribing from PBS medication charts in the hospital and residential aged care setting.

As part of the regulatory framework and in support of the Regulations, amendments have been made to the *National Health (Claims and under co-payment data) Rules 2012* (Claims Rules), as well a new instrument defining the form and required data elements of the electronic prescription (Form of Prescription) approved by the Secretary of the Department of Health (the Department).

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, strengthening the legislative assurance for privacy and security in relation to electronic prescriptions. Electronic prescribing provides an option for prescribers and their patients to use an electronic prescription as an alternative to a paper-based prescription. Electronic prescribing will not fundamentally change how existing prescribing and dispensing processes operate. Patient choice of pharmacy remains central.

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