EXPLANATORY STATEMENT

National Health Act 1953

National Health (Claims and under co-payment data) Amendment (Electronic Prescriptions) Rules 2019

By authority of delegate of the Secretary for Health

Authority

The *National Health (Claims and under co-payment data) Amendment (Electronic Prescriptions) Rules 2019* (the Rules) are made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act).

In addition to the power to make the Rules under subsections 98AC(4) and 99AAA(8) of the Act, subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of 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 repeal, rescind, revoke amend or vary any such instrument.

Background

The Pharmaceutical Benefits Scheme (PBS) is established under 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.

Subsections 98AC(4) and 99AAA(8) of the Act provides that the Minister must, by legislative instrument, make rules defining the procedures to be followed by approved suppliers and by the Secretary, and specifying the information to be given to the Secretary by approved suppliers, in relation to the claim for payment relating to supply of pharmaceutical benefits. These rules are the *National Health (Claims and under co-payment data) Rules 2012* (the Principal Rules).

Purpose

In the 2018-19 Budget, it was announced that the Department of Health (the Department) would lead work to enable the prescribing, dispensing and claiming of PBS and Repatriation PBS (RPBS) medicines in a seamless electronic manner. Electronic prescribing will allow prescribers and their patients to have the option to use an electronic prescription as an alternative to a paper prescription. The introduction of electronic prescribing will not fundamentally change how current prescribing, dispensing and claiming processes operate.

The Principal Rules define the procedures to be followed by an approved supplier in giving information to the Secretary in order to obtain payment for subsidy under the PBS and RPBS in relation to a claim for the supply of pharmaceutical benefits. Clause 1 of Schedule 1 of the Principal Rules details information to be given when using the Claims Transmission System to give information to the Secretary by electronic means in relation the supply of a pharmaceutical benefit. The Principal Rules are the appropriate instrument that provides administrative detail supporting the Department of Human Services (DHS) administering payments for claims relating to the supply of pharmaceutical benefits.

The Rules amend the Principal Rules to require extra information to be given when using the Claims Transmission System in relation to the supply of pharmaceutical benefits upon electronic prescriptions. The Rules outline additional data elements required by DHS when claiming upon an electronic prescription, and are the basis for operational changes DHS are making to the Claims Transmission System. Clause 2 of Schedule 1 of the Rules details extra information to be provided for electronic prescriptions, in addition to all existing information that must be provided in accordance with Clause 1 of Schedule 1 of the Principal Rules.

The Rules additionally include technical corrections, which amend references to sections of the Regulations to reflect the renumbering of sections when the Regulations were remade in 2017.

As part of the existing information to be given when using the Claims Transmission System, prescription format codes are currently required in the claim to differentiate between electronic and paper versions of hospital medication chart prescriptions. This will be amended to cover all prescription claims, with ***P*** to identify a claim from a paper-based prescription (including one that is a medication chart prescription) and ***E*** to identify a claim from an electronic prescription (including one that is a medication chart prescription).

The Rules modify the patient categories to identify and differentiate all PBS and RPBS claims for residential aged care facility patients. The National Residential Medication Chart (NRMC) is an approved medication chart for use in residential aged care facilities under section 41 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations), and changes to the Rules will require ***R*** to denote claims from a PBS NRMC prescription and ***N*** to denote claims from a prescription that is not a PBS NRMC prescription.

PBS prescriber number is also included as information to be provided in relation to supply of a pharmaceutical benefit. The PBS prescriber number is existing information required to be written by the PBS prescriber on a prescription in accordance with sections 40 or 41 of the Regulations. Inclusion of the PBS prescriber number within the Rules will align with the requirements in the Regulations.

The Rules include requirements for a claim upon an electronic prescription to contain conformance identifiers provided to the Australian Digital Health Agency (the Agency) for each prescribing, dispensing and intermediary system to handle the 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 requirement to include a valid HPI-O and a valid HPI-I (if any) for both PBS prescriber and approved supplier identifies the healthcare provider organisations where the PBS prescriber and the approved supplier prepared and supplied the electronic prescription respectively, and identifies the PBS prescriber and approved supplier who prepared and supplied the electronic prescription respectively. Both PBS prescribers and approved suppliers are classified as healthcare providers within the definition of the *Healthcare Identifiers Act 2010*, and are bound to privacy requirements in accordance with the provision of healthcare as defined within the meaning of subsection 6(1) of the *Privacy Act 1988*.

To help improve patient safety and quality use of medicines, the Regulations include that the patient date of birth and the reason for the prescription may be included in the electronic prescription. Optional inclusion of these items is reflected in the Rules, with this information only required to

be provided in the claim if it is 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. Further, once DHS receives the claims information, it will be protected by the secrecy provisions in the Act.

Optional inclusion of prescription information in AMT and SNOMED CT-AU will allow for improved quality and availability of data for analysis through a nationally recognised and consistent format. AMT is the national terminology with unique codes that unambiguously identify originator and generic brands of medicines commonly used in Australia, and was developed for the purpose of being implemented in clinical information systems to support electronic medication management. SNOMED CT is considered to be the most comprehensive multilingual health terminology in the world, and the Australian extension SNOMED CT-AU provides local variations and customisation of terms relevant to the Australian healthcare community. Use of AMT and SNOMED CT-AU is prevalent in the digital health sector, including within administration of the PBS, and is free of charge for users to access from the National Clinical Terminology Service operated by the Agency.

As part of the regulatory framework for electronic prescribing and in addition to the Rules, amendments have been made to the Regulations to allow the use of an electronic prescription. Two new administrative instruments that sit under the Regulations have additionally been developed defining the form of the electronic prescription and information technology requirements approved by the Secretary of the Department.

Consultation

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 DHS 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 additionally led ongoing engagement with state and territory governments through the Electronic Prescribing Working Group (EPWG) to align regulation of prescribing processes across Australia.

Details of the Rules are set out in the Attachment.

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

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

The Rules commence on 31 October 2019.

ATTACHMENT

Details of the *National Health (Claims and under co-payment data) Amendment (Electronic Prescriptions) Rules 2019*

Section 1 - Name

This section provides that the title of the instrument is the *National Health (Claims and under co-payment data) Amendment (Electronic Prescriptions) Rules 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 subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act).

Section 4 - Schedules

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

Part 1 - Main amendments

National Health (Claims and under co-payment data) Rules 2012 (the Rules)

Item [1] - Subrule 4(1)

Item 1 insert definitions of *approved supplier*, *healthcare identifier* and *healthcare provider organisation*. These definitions have been introduced to the Rules, in alignment with the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations), as both individual and organisational healthcare provider identifiers for PBS prescribers and approved suppliers are new information fields for information to be given for supply of a pharmaceutical benefit upon an electronic prescription. See Item [7] - Extra information required when using Claims Transmission System in relation to supply of pharmaceutical benefits upon electronic prescriptions.

Item [2] - Subrule 4(1)

Item 2 repeals paragraphs (c) and (d) of the definition of *prescription* and substitutes a new paragraph (c) "an electronic prescription".

The intent of this is to avoid duplication of prescriptions by preventing an electronic prescription from being changed to a paper prescription, or vice versa, and to clarify that a prescription may be either paper or electronic. The decision for either a paper or an electronic prescription will be made at the point of prescribing, and any subsequent change to a different format would require cancellation of the existing prescription and preparation of a new prescription. This will assist with traceability and management of prescriptions for patients and healthcare providers.

Item [3] - Clause 1 of Schedule 1

This item inserts a note to provide that Clause 2 requires the approved supplier to give extra information in relation to the supply of a pharmaceutical benefit upon an electronic prescription.

This extra information is to be provided in addition to the information in Clause 1 of Schedule 1 of the Rules - Information required when using Claims Transmission System. The intent is that for a claim in relation to supply of a pharmaceutical benefit upon a paper prescription, the information in Clause 1 of Schedule 1 is required to be provided by the approved supplier. For a claim in relation to supply of a pharmaceutical benefit upon an electronic prescription, the information in both
Clause 1 and Clause 2 of Schedule 1 is required to be provided by the approved supplier. See Item [7] - Extra information required when using Claims Transmission System in relation to supply of pharmaceutical benefits upon electronic prescriptions.

Item [4] - Clause 1 of Schedule 1

Item 4 repeals the details in column 2 of table item 23 in Clause 1 of Schedule 1 relating to patient category and substitutes a new list. In effect there are changes only to two of the patient categories.

The National Residential Medication Chart (NRMC) is an approved medication chart for use in residential aged care facilities. Changes to patient category fields relating to NRMC will allow identification and differentiation of all PBS and RPBS claims for residents in aged care facilities, for both paper and electronic prescriptions, and will be consistent with the existing patient categories relating to use of the PBS Hospital Medication Chart (HMC) in public and private hospitals. ***R*** is changed from "residential aged care facility patient (medication chart prescription)" to "residential aged care facility patient (PBS NRMC prescription)", and ***N*** is changed from "nursing home patient" to "residential aged care facility patient (prescription that is not a PBS NRMC prescription)".

Item [5] - Clause 1 of Schedule 1

This item inserts a new table item 25A to Clause 1 of Schedule 1, to provide that the number (if any) allotted to the approval of the PBS prescriber under section 16 of the Regulations must be provided for the claim in relation to supply of a pharmaceutical benefit. The PBS prescriber number is existing information required to be written by the PBS prescriber on a prescription in accordance with
section 40 (prescriptions other than medication chart prescriptions) or section 41 (medication chart prescriptions) of the Regulations. Inclusion of the PBS prescriber number in the claim will align with the requirements within the Regulations.

Item [6] - Clause 1 of Schedule 1

Item 6 repeals the cell at column 2 of table item 28A in Clause 1 of Schedule 1 relating to prescription format, and substitutes new details relating to prescription format. ***P*** will be for a claim from a paper-based prescription, including one that is a medication chart prescription, and ***E*** will be for a claim from an electronic prescription, including one that is a medication chart prescription. Previously this information was only required for a medication chart prescription in or at an approved private hospital or public hospital, but will now be required for all prescriptions.

Item [7] - At the end of Schedule 1

Item 7 adds a new table, Clause 2 at the end of Clause 1 of Schedule 1, to provide for extra information required when using Claims Transmission System in relation to supply of pharmaceutical benefits upon electronic prescriptions. This information is in addition to the information required under Clause 1 of Schedule 1. For the purposes of paragraph 7(e) of the Rules, an approved supplier must give, in relation to the supply of a pharmaceutical benefit upon an electronic prescription, the information referred to in an item in the table in accordance with that item. This item inserts a table which applies for the purposes of an approved supplier giving under co-payment data (see subsection 98AC(1) of the Act) or information required to be given because the approved supplier is making, or proposing to make, a claim (see subsection 99AAA(3) of the Act). The details of column 2 of an item in the table may have the effect that information is not required to be given under that item in relation to a particular supply.

Table item 1 relates to the approved supplier individual healthcare provider identifier (HPI-I). This is the healthcare identifier (if any) assigned to the supplier if the supplier is an individual, or to the individual who supplied the pharmaceutical benefit on behalf of the supplier. This table item requires that if there is a relevant identifier for the approved supplier then the identifier must be provided in the claim. Inclusion of the HPI-I is not mandatory which allows for scenarios where an approved supplier may not hold a valid HPI-I, such as in the case where the approved supplier is a hospital authority.

Table item 2 relates to the approved supplier organisation healthcare provider identifier (HPI-O). This is the healthcare identifier assigned to a healthcare provider organisation to which the supplier, or the individual who supplied the pharmaceutical benefit on behalf of the supplier, is linked (within the meaning of the *Healthcare Identifiers Act 2010*). This would be the identifier assigned to the organisation such as a pharmacy or hospital where the pharmaceutical benefit was supplied.

Table item 3 relates to the dispensing software conformance identifier, which is the valid conformance identifier provided to the Agency in relation to the software used to dispense the pharmaceutical benefit. Software used to facilitate dispensing an electronic prescription must adhere to the technical requirements in the Agency's technical conformance framework to gain a conformance identifier. The identifier should be valid at the time of dispensing.

Table item 4 relates to conformance identifiers for intermediary systems. Claims information must include a valid conformance identifier provided to the Agency in relation to any software used to store or transmit the prescription until the pharmaceutical benefit is dispensed. Intermediary systems sit between the prescribing software and dispensing software and hold the electronic prescription securely in an encrypted format. They enable patient choice of prescriber and dispenser by allowing a prescriber to upload the electronic prescription to an intermediary system where it can then be downloaded by an approved supplier chosen by the patient. These intermediary systems are not permitted to view prescription information without the consent of the patient, and must adhere to the Agency's technical conformance framework in order to gain a valid conformance identifier. There may be multiple intermediary systems in use and a requirement of the technical framework is that they must be interoperable. It is possible that a prescriber may upload the electronic prescription to one intermediary system which then passes it securely to another system so it can be retrieved by the supplier. In this case it is required for the claim to include the conformance identifiers of both intermediary systems. In the case that there is no intermediary system, such as in a hospital setting where a single system is used for prescribing and

dispensing a pharmaceutical benefit, no intermediary system conformance identifier would be required.

Table item 5 introduces the date of birth of the person for whom the pharmaceutical benefit is prescribed as information to be provided in the claim, but only required if included in the electronic prescription. Patient date of birth may be included as additional information for a PBS prescriber to include when writing an electronic prescription, in accordance with section 41B of the Regulations. If this information is provided by the PBS prescriber it must be included in the claim, but it is not required if this information is not included in the prescription.

Table item 6 allows the inclusion of PBS dispensing notes, being notes of any clarification of the prescription at the time of the supply. This may assist suppliers record a reason in the instance of any minor discrepancy between what was prescribed and what was dispensed, provided it is within their legislative power to amend what was provided on the electronic prescription or is clarified with the appropriate PBS prescriber and in accordance with the Regulations.

Table item 7 relates to the PBS prescriber individual healthcare provider identifier (HPI-I). This is the healthcare identifier (if any) assigned to the PBS prescriber who wrote the electronic prescription. This information is only required if included in the electronic prescription.

Table item 8 relates to the PBS prescriber organisation healthcare provider identifier (HPI-O). This is the healthcare identifier assigned to a healthcare provider organisation to which the PBS prescriber is linked (within the meaning of the *Healthcare Identifiers Act 2010*). This would be the identifier assigned to the organisation such as a medical practice or hospital where the pharmaceutical benefit was prescribed.

Table item 9 relates to a new PBS/RPBS item receipt flag to be included in information to be given when using the Claims Transmission System in relation to supply of pharmaceutical benefits upon electronic prescriptions. This flag is an indication that the person to whom the pharmaceutical benefit was supplied, or an agent of that person, has acknowledged receiving the benefit. The purpose of the PBS/RPBS item receipt flag is to provide a mechanism that may replace the existing mechanism whereby a patient signs a paper prescription to acknowledge receipt of the benefit, and is in accordance with section 57 of the Regulations relating to receipt of pharmaceutical benefit.

Table item 10 relates to the code, in Australian Medicines Terminology, for the pharmaceutical benefit that is prescribed. This code is only required if it is included in the electronic prescription. This will assist with identification of the pharmaceutical benefit and will allow for improved quality and availability of data for supply and analysis through a nationally recognised and consistent format

Table item 11 relates to the prescribing software conformance identifier. In alignment with inclusion for conformance identifiers for other systems that handle the electronic prescription, it is required to include in the claim the valid conformance identifier provided to the Agency in relation to the software used to prepare the prescription. The conformance identifier must be valid at the time of prescribing. Prescribing software used to generate an electronic prescription must adhere to the technical conformance framework to gain a valid conformance identifier, which is required for inclusion in the electronic prescription in accordance with section 41A of the Regulations.

Table item 12 relates to the reason for prescription. This is the code, in SNOMED CT-AU clinical terminology, for the condition for which the pharmaceutical benefit is prescribed. This information is only required if included in the electronic prescription. The reason for the prescription is optional information a PBS prescriber may include on an electronic prescription under section 41B of the Regulations, and should be provided in SNOMED CT-AU clinical terminology.

Table item 13 similarly relates to the reason for supply. This is the code, in SNOMED CT-AU clinical terminology, for the condition for which the pharmaceutical benefit is supplied. This code would generally be the same as the code provided in table item 12, but may differ in instances where a generic brand or biosimilar medicine is supplied. This field is optional. This allows for systems that have not yet moved to SNOMED CT-AU to still participate in use of electronic prescriptions.

Table item 14 relates to the supplied pharmaceutical benefit. Similar to the prescribed pharmaceutical benefit at table item 10, this is the code, in Australian Medicines Terminology, for the pharmaceutical benefit that is supplied. This field is optional.

Table item 15 is the unique PBS electronic prescription number. This is a globally unique identifier for the prescription generated by the software used to prepare the prescription, in accordance with section 41A of the Regulations.

Part 2 - Technical Corrections

National Health (Claims and under co-payment data) Rules 2012

Items [8] to [15] - Subrule 4

These items amend the definitions of *authority prescription*, *deferred supply authorisation*, *paper-based prescription*, *prescriber bag supply form*, *Regulations*, and *repeat authorisation* to correct references to parts of the Regulations that were affected when the Regulations were remade in 2017. "Subregulation 13(5)" is omitted and substituted by "subsection 30(4)", "regulation 26A" is omitted and substituted by "section 53", the note relating to subregulation 31(4) is repealed, "regulation 16" is omitted and substituted by "section 33", "subregulation 18A(3)" is omitted and substituted by "subsection 36(4)", "subregulation 18A(5A)" is omitted and substituted by "subsection 36(7)", "*1960* made under the Act" in the definition of *Regulations* is omitted and substituted by "*2017*", and "regulation 26" is omitted and substituted by "section 52".

Item [16] - Subrule 4

This item inserts "of the Act" after "99(2B)" in paragraph (a) of the definition of *under co-payment data* to clarify that this subsection relates to the Act not the Regulations.

Item [17] - Paragraph 7(a)

Item 17 omits "regulation 8A" and substitutes it with "section 16" in paragraph 7(a) of the Rules to correct a reference to the Regulations that was affected when the Regulations were remade in 2017.

Item [18]-[21] - Clause 1 of Schedule 1

These items additionally correct references to the Regulations that were affected when the Regulations were remade in 2017. In table item 17, "regulation 25" is omitted and substituted by "section 51 of the Regulations". In table item 20, "regulation 24" in omitted and substituted

by "section 49 of the Regulations". In table item 21, "regulation 8A" is omitted and substituted by "section 16 of the Regulations".

Item 21 omits "under regulation 24" to substitute it with "under section 49 of the Regulations" in table items 31 and 32. This substitution amends the details in column 2 of the table only, while retaining the title "Regulation 24" in column 1. This is in accordance with paragraph 40(j) of the Regulations, which refers to a PBS prescriber writing on the prescription *Reg 24*, *Regulation 24*, *one supply* or *1 supply* if directing the first supply and all repeats to be supplied on the one occasion within the meaning of section 49 of the Regulations.

Statement of Compatibility with Human Rights

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

National Health (Claims and under co-payment data) Amendment (Electronic Prescriptions) Rules 2019

The *National Health (Claims and under co-payment data) Amendment (Electronic Prescriptions) Rules 2019* (the Rules) 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 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 *National Health Act 1953* (the Act) which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

Subsections 98AC(4) and 99AAA(8) of the Act provides that the Minister must, by legislative instrument, make rules defining the procedures to be followed by approved suppliers and by the Secretary, and specifying the information to be given to the Secretary by approved suppliers, in relation to the claim for payment relating to supply of pharmaceutical benefits. These rules are the *National Health (Claims and under co-payment data) Rules 2012* (the Principal Rules).

The Principal Rules define the procedures to be followed by an approved supplier in giving information to the Secretary in order to obtain payment for subsidy under the PBS in relation to a claim for the supply of pharmaceutical benefits. Clause 1 of Schedule 1 of the Principal Rules details information to be given when using the Claims Transmission System to give information to the Secretary by electronic means in relation the supply of a pharmaceutical benefit.

The Rules amend the Principal Rules to introduce a new Clause 2 of Schedule 1, requiring extra information to be given when using the Claims Transmission System in relation to the supply of pharmaceutical benefits upon electronic prescriptions. The Rules outline additional data elements required by the Department of Human Services (DHS) when claiming upon an electronic prescription, and are the basis for operational changes DHS are making to the Claims Transmission System for electronic prescribing.

The Rules additionally include technical corrections, which amend references to sections of the *National Health (Pharmaceutical Benefits) Regulations 2017* to reflect the renumbering of sections when the Regulations were remade in 2017.

As part of the regulatory framework for electronic prescribing and in addition to the Rules, amendments have been made to the Regulations to allow the use of an electronic prescription. Two new administrative instruments have additionally been developed defining the form of the electronic prescription and information technology requirements approved by the Secretary of the Department of Health.

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 Article 12 of the International Covenant on Economic,

Social and Cultural Rights (ICESCR), as it supports the right to health and it assists in realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The Principal Rules contribute to the efficient operation and effective administration of the scheme.

As a necessary part of the regulatory framework that establishes electronic prescribing, the Rules strengthen the legislative assurance for privacy and security in relation to electronic prescriptions, consistent with requirements in the Regulations and subordinate instruments. Electronic prescribing will allow prescribers and their patients to have the option to use an electronic prescription as an alternative to a paper-based prescription. The introduction of electronic prescribing will not fundamentally change how current prescribing, dispensing and claiming processes operate.

Conclusion

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

Thea Daniel, delegate of the Secretary for Health