Health (Drugs and Poisons) Regulation 1996

Approved requirements for electronic prescriptions

I, Professor Keith McNeil, pursuant to the *Health (Drugs and Poisons) Regulation 1996* (HDPR), certify in this instrument:

- for the purposes of sections 82(1)(b) and 193(1)(b) of the HDPR, a system that conforms with the requirements specified in Part 1A or Part 1B is the approved way an electronic prescription must be electronically sent by a prescriber and received by a dispenser;
- for the purposes of the definition of 'approved electronic form' in Appendix 9 of the HDPR, a prescription in electronic form that conforms with the requirements specified in Part 2A or Part 2B is an approved electronic form for an electronic prescription;
- for the purposes of the definition of 'electronically sign' in Appendix 9 of the HDPR, an electronic signature that conforms with the requirements of Part 3 is an approved electronic form of signature that may be used to electronically sign an electronic prescription;
- for the purposes of sections 79(8)(b) and 190(6)(b) of the HDPR, an amendment to an electronic prescription that conforms with the requirements of Part 4 is an approved way for section 79(8)(b) or a certified way for section 190(6)(b) that a prescriber may make an amendment to an electronic prescription;
- for the purposes of sections 82(6)(c) and 193(6)(c) of the HDPR, that Part 5 specifies the approved electronic form to notify the chief executive of the cancellation of an electronic prescription.

To remove any doubt, an electronic prescription sent by a prescriber to a dispenser is only certified to the extent that it is:

a) in the approved electronic form that meets the requirements of Part 2A or Part 2B;
b) signed in a way that meets the requirements of Part 3;
c) generated, sent and received by an electronic system that meets the requirements of Part 1A or Part 1B, including the stated requirements for the operation of the system; and
d) if the prescription is amended, amended in a way that meets the requirements of Part 4.

Definitions

Terms used in this instrument have the same definition as in the HDPR. Additional terms used within this instrument that have a particular meaning are defined below.

- **The Agency** means the Commonwealth Government's Australian Digital Health Agency.
- **Conformance ID** means a unique identifier of the specific release and/or version of software used to generate electronic prescriptions; send and receive electronic prescriptions; or dispense electronic prescriptions. Registration of a Conformance ID on the Agency's Electronic Prescribing Register of Conformance means the software vendor declares conformance with a current *Electronic Prescribing Solution Architecture, Participating Software Conformance Profile* (the **Conformance Profile**) published by the Agency.
- **Electronic medication order chart** and **electronic medication order chart system** have the same meaning as in the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018* (Cth).
- **Prescription Delivery Service** has the same meaning as in the Agency's Conformance Profile and includes any *approved prescription exchange system* as defined in the HDPR.

- **Relevant specialist medical qualification** means the qualification that enables a medical practitioner to hold specialist registration with the Medical Board of Australia in the medical specialty relevant to the specific regulated controlled drug or regulated restricted drug.
- **Sending and receiving a prescription** includes distribution of the electronic prescription via a Prescription Delivery Service and retrieval of the prescription at the point of dispensing.

Part 1A Electronic prescription system requirements

1. The electronic system that enables the prescribing, sending and receiving, and dispensing of the prescription must be listed on the Electronic Prescribing Register of Conformance published by the Agency with a currently valid Conformance ID.
2. The software used to generate and send the prescription must:
   a) manage defined roles with access rights that will allow only an authorised person to generate, send or receive an electronic prescription for controlled drugs or restricted drugs; and
   b) utilise requirements in the Agency's Conformance Profile to protect against fraud including granting a unique user account and secure access to the software to each person authorised to generate an electronic prescription or dispense an electronic prescription, and removing user access when no longer required; and
   c) be operated and maintained to ensure the integrity of the software system security and ensure retention of electronic records or documents to comply with any legislative requirements; and
   d) allow a dispenser to make a record of dispensing of the prescription and any repeat prescription.[1]
3. For records that must be retained in the system, the software audit log requirements and any documents (including an electronic prescription or an electronic prescription cancelled under sections 82 and 193) or records required to be kept must be capable of being accessed from the place the document or record was made or accessed by another means allowed by an inspector, and must be capable of being produced in the timeframe required by an inspector.

Part 1B Electronic prescription system requirements for the Electronic National Residential Medication Chart Trial (the Trial)

1. An electronic medication order chart system used for prescribing medicines to persons receiving residential care in an approved residential care service (e.g. nursing home) and sending the prescription to a dispenser participating in the Trial must be software owned and operated by a software vendor listed in Column 4 of the Schedule of the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018* as amended from time to time.

Part 2A Electronic form of prescription

1. An electronic prescription must include the particulars detailed in sections 79(4) and 190(2) of the HDPR, together with the information required in the Conformance Profile. [2]
2. For specialist medical practitioners endorsed to prescribe a regulated controlled drug or a regulated restricted drug, the qualifications included on the electronic prescription must include the relevant specialist medical qualification/s.

[1] Note there are requirements under the National Health (Claims and under co-payment data) Rules 2012 (Cth) that apply under Commonwealth Legislation.

[2] Note there are requirements under the National Health (Pharmaceutical Benefits) Regulations 2017 (Cth) and the Electronic Prescriptions Information Technology Requirements Instrument 2019 (Instrument of Approval) that apply under Commonwealth Legislation.

Part 2B Electronic form of a prescription for the Electronic National Residential Medication Chart Trial

1. An electronic prescription that is part of an electronic medication order chart, must be generated by a prescriber on an electronic medication order chart system and sent, received and dispensed in accordance with the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018*.
2. The prescription must be:
   a) for the treatment of a person at a nursing home in Queensland listed in Column 2 of the Schedule of the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018*, and
   b) for dispensing by a pharmacist at a place in Queensland listed in Column 3 of the Schedule of the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018*.

Part 3 Electronic signature

A prescriber is taken to electronically sign a prescription with an approved electronic signature if:

1. the electronic prescription system used to generate the electronic prescription is accessed by the prescriber using their unique user account and secure access; or
2. the prescription is generated using an electronic medication order chart system accessed by the prescriber using their unique user account and secure access.

Part 4 Amending an electronic prescription by a prescriber

1. A prescriber may only amend an electronic prescription, including an electronic prescription that is part of an electronic medication order chart by:
   a) cancelling the prescription and generating a new prescription in conformant software; or
   b) correcting a prescription using an operation included in conformant software to meet the requirements of the Conformance Profile.

Part 5 Cancelling an electronic prescription not to be dispensed

1. Where a dispenser cancels an electronic prescription as required under sections 82 and 193 of the HDPR (for example, suspected false or fraudulent prescriptions), the approved electronic form to notify the chief executive of the cancellation is:
   a) an email sent to MC&HTUInvestigations@health.qld.gov.au describing the reason/s and circumstance/s leading to the cancellation of the prescription; and
   b) attaching to the email or embedding in the email, a digital image of the cancelled electronic prescription as shown on the computer screen within dispensing software (for example, a printscreen capture or a photograph).

Certification

Approved requirements for electronic prescriptions Version 2.0

Certified at Brisbane on this 4th day of November 2020

Professor Keith McNeil

Acting Deputy Director-General and Chief Medical Officer, Prevention Division and Chief Clinical Information Officer
Queensland Health