Queensland Health Departmental Standard

Requirements for an electronic prescription management system – version 1

27 September 2021

Queensland Government

Queensland Health Departmental Standard

Requirements for an electronic prescription management system

Version 1

Published by the State of Queensland (Queensland Health), September 2021

For more information contact:

Chief Medical Officer and Healthcare Regulation Branch, Prevention Division, Queensland Health, GPO Box 48, Brisbane QLD 4001, email HLIU@health.qld.gov.au.

Version control

Version	Replaces version	Date approved	Commencement date
1	NA	12 August 2021	27 September 2021

The Medicines and Poisons Act 2019 (the Act) establishes a contemporary framework for the regulation of medicines, poisons and prohibited substances, pesticides and fumigants in Queensland.

This framework includes three subordinate regulations (the Regulations):

- Medicines and Poisons (Medicines) Regulation 2021 (Medicines Regulation)
- Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021
- Medicines and Poisons (Pest Management Activities) Regulation 2021.

Chapter 7, Part 4, section 233 of the Act authorises the chief executive of Queensland Health to make departmental standards in relation to matters regulated under the Act.

A departmental standard outlines the mandatory expectations and specific requirements to ensure regulatory compliance with the Act and Regulations.

The Medicines Regulation states the requirements for an electronic prescription management system (Chapter 8, Part 1) to make or transmit prescriptions for dispensing medicines or retrieve prescriptions for dispensing medicines, including recording information relating to the dispensing of medicines. An electronic prescription management system must comply with the requirements stated in Chapter 8, Part 1 of the Medicines Regulation and this Standard.

This Standard (*Requirements for an electronic prescription management system*) has been made by the Director-General, Queensland Health in accordance with section 233 of the Act.

Scope

An electronic prescription management system (EPM system), comprises end-to-end conformant prescribing, prescription delivery and dispensing components. To enable safe and secure interconnected electronic prescription transactions, the 'prescribing component' and 'dispensing component' of the EPM system must be connected to a conformant prescription delivery service[1] (PDS) to store, exchange and record prescription information and dispensing activities.

Prescription information created, transferred, retrieved, dispensed and recorded by electronic means through an EPM system is referred to as an 'electronic prescription' or colloquially as a 'paperless' prescription.

Purpose

This Standard specifies the system component requirements that must be met to electronically prepare, transfer, retrieve and record prescription information for a medicine to be dispensed for a person, and to record dispensing and associated activities[2] in Queensland.

This Standard applies to the following requirements in the Medicines Regulation:

- The system manager must ensure the prescribing and/or dispensing components of the EPM system used at the entity complies with Chapter 8, Part 1 of the Medicines Regulation and the requirements specified in this standard.
- A prescriber may make an electronic prescription if it is prepared and transferred in a conformant EPM system (Medicines Regulation, section 83).
- An approved person who is authorised to dispense, may dispense medicines in accordance with an electronic prescription for a person only if the prescription is retrieved and dispensing activities are recorded using a conformant EPM system (Medicines Regulation, sections 114 and 120).

[1] A listed PDS software product on the *Electronic Prescribing – External Conformance Register* published by the Australian Health Digital Agency with a current valid Conformance identifier.

[2] Such as amending an electronic prescription (section 117); dispensing records for dispensed medicines (section 124); reporting and preventing use of unlawful electronic prescriptions (section 228(2)(g)) of the Medicines Regulation.

This Standard **does not** apply to paper prescriptions that are sent as a digital image, such as by fax or email, to a dispenser.

Conformant electronic prescription management system requirements

To meet the regulatory obligations under the Medicines Regulation, a conformant EPM system **must**:

1. Meet the requirements specified in Chapter 8, Part 1 of the Medicines Regulation;

AND

2a. Be a listed software product on the *Electronic Prescribing – External Conformance Register* (National conformance register) published by the Australian Health Digital Agency with a current valid conformance identifier (ID), for:

a. Prescribing System (PS) software to create and transfer prescription information for medicines to the 'prescription delivery service' (PDS) listed on the National conformance register, and/or

b. Dispensing System (DS) software to retrieve prescription information from the 'prescription delivery service' (PDS) listed on the National conformance register to dispense medicines for a patient, as well as record dispensing and associated activities;

OR

2b. Be an electronic medication order chart system using software owned and operated by an approved software vendor for the purposes of the Electronic National Residential Medication Chart Trial (the Trial) under the *National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018* (Cth) (the Arrangement) at approved participant entities as listed in the Schedule to the Arrangement.

Glossary

Term	Meaning
Australian Digital Health Agency	means the Australian Digital Health Agency established by the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (Cth) under the *Public Governance, Performance and Accountability Act 2013* (Cth).
conformance identifier (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.
electronic prescription	means a prescription in electronic form that has been prepared and transferred in a conformant EPM system to a person authorised to retrieve the prescription to dispense medicines for a person. An electronic prescription does not include a digital copy of a paper prescription.
Prescription Delivery Service (PDS)	means PDS software product listed on *the Electronic Prescribing – External Conformance Register* published by the Australian Health Digital Agency with a current valid Conformance identifier. The PDS within the EPM system is the component through which an electronic prescription is communicated, stored, exchanged and recorded from a person who is authorised to prescribe to be retrieved by a dispenser.
system manager	means an appropriately qualified person, appointed by the entity, who is responsible for establishing and controlling, including the appointment of system administrator/s to maintain, the EPM system used by authorised users at the entity.

A term used in this Standard that is defined in the Act or the Medicines Regulation, and is not referred to in this glossary, has the meaning stated in the Act or Medicines Regulation.