Health (Drugs and Poisons) Amendment Regulation (No. 3) 2020

Explanatory notes for SL 2020 No. 161

made under the

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons) Amendment Regulation (No. 3) 2020

Authorising law

Section 180 of the *Health Act 1937*.

Policy objectives and the reasons for them

The purpose of the *Health (Drugs and Poisons) Amendment Regulation (No. 3) 2020* (Amendment Regulation) is to amend the *Health (Drugs and Poisons) Regulation 1996* (HDPR) to authorise pharmacists to send their controlled drug data to Queensland Health (specifically, to the Department of Health (the Department)) via an automated online process. This process will require no additional actions from the pharmacist beyond their usual dispensing process. The Amendment Regulation will also ensure prescribers, such as doctors, nurse practitioners, dentists and endorsed midwives, contacting the Department will be provided with the most current and accurate information available about a person's drug treatment history.

Each year, over 1,200 Queensland pharmacies send the Department more than 1.5 million dispensed controlled drug prescriptions, which are uploaded electronically to the Department's Monitoring of Drugs of Dependence System (MODDS) database. A further 90,000 written instructions for supplied controlled drugs are sent to the Department. Written instructions are sent as paper or scanned images for manual data entry.

Only authorised departmental staff have direct access to MODDS, which they use to undertake their regulatory functions under the HDPR. For example, they provide controlled drug prescription histories to prescribers via the 13 S8INFO (13 78 46) enquiry service, which takes over 2,000 calls a month.

Third parties do not have direct access to MODDS. Authorised departmental staff disclose information held in MODDS to third parties in verbal and/or written form where appropriate and lawful. For example, information may be disclosed when a doctor calls 13 S8INFO seeking a controlled drug prescription history for a patient, or when information from MODDS is provided in writing to another entity pursuant to a lawful request.

MODDS information is relied on by prescribers to inform their clinical decision-making and to support their compliance with the HDPR.

Achievement of policy objectives

Section 84(3) of the HDPR requires dispensers to provide a prescription or written instruction to the Department, either in paper form or in an approved electronic form by electronic means, if they:

- dispense a controlled drug on a paper prescription; or
- dispense a controlled drug on an acceptable electronic copy of a paper prescription and later receive the paper prescription; or
- administer or supply a controlled drug on a written instruction.

Section 84A(3) of the HDPR requires a dispenser to provide the Department the electronic prescription by electronic means, if they:

- dispense a controlled drug on an electronic prescription; or
- dispense a controlled drug on an acceptable electronic copy of a paper prescription and later receive an electronic prescription for the controlled drug.

The 'approved electronic form' requires dispensing pharmacies to submit controlled drug data to the Department weekly, via a web-based 'File Upload System' portal. The pharmacist must actively go to the file upload system and submit their data every week. This data is then validated by departmental staff and uploaded into, and maintained in, the Department's MODDS database.

The Amendment Regulation amends the definition of *approved electronic form* in appendix 9 (Dictionary) of the HDPR to provide that for a prescription, the approved electronic form can be an entry in an approved prescription exchange system or an electronic form approved by the chief executive.

Currently, dispensers are required to send the whole electronic prescription to the Department, however, there are no means by which the content of the prescription, including any dispenser annotations, can be incorporated into the MODDS database. A valid electronic prescription includes significantly more data fields than may be stored in a MODDS record, so it is necessary to specify what data elements are required.

The purpose of the amendment is to specify the means by which electronic prescriptions may be sent to the Department, ensuring the secure transmission of data and improved usability of prescription information. Without using a system such as a Prescription Exchange Service (PES), the Department is unable to receive electronic prescriptions and use the dispensed prescription information.

A definition for an *approved prescription exchange system* is inserted into appendix 9 (Dictionary) of the HDPR, as an electronic system for recording or transferring prescriptions, or information in prescriptions, that is approved by the chief executive and provided by another entity. An approved PES includes both the virtual repository, the software that gives effect to the service and the secure transmission to send, exchange or receive prescriptions and dispensing information.

The Amendment Regulation also includes definitions for *receive* and *send* for an approved PES, which means either the prescription, or information in the prescription, entered into the system and available for downloading and retrieval. This amendment will facilitate the electronic transfer of information via the PES to QScript and clarifies that the entering of information into the system fulfils the dispenser's obligations in relation to sending the information in the timeframes specified. QScript is the Department's read-only system, which provides access to real-time prescription data and is technically able to incorporate the relevant data fields from an electronic prescription. Once fully implemented, the system will provide clinical alerts and notifications to help prescribers and dispensers identify when a patient may be at risk of harm or require further support.

A PES is the mechanism through which an electronic prescription or electronic prescription information is communicated from a prescriber to a dispenser. There are currently two PESs used in Australia: eRx Script Exchange and MediSecure. Information uploaded to and transmitted via either PES will flow through to a system known as 'Medication Knowledge', which is a joint venture of the two PES operators and facilitates interoperability of the two PESs. For example, if a prescriber prints a prescription with an eRx barcode but the dispensing pharmacist uses MediSecure, the pharmacist can still scan the barcode and download the prescription information from the PES.

Once the data flows through Medication Knowledge, it will be sent to the National Data Exchange, the Commonwealth's real-time prescription monitoring system. Based on business rules, the relevant prescription data will be sent from the National Data Exchange directly into QScript where it can be viewed by authorised officers of the Department. This will all happen within seconds of the dispensing event.

Approximately 93 per cent of Queensland pharmacies are already using a PES. The introduction of electronic prescriptions, which use PESs, is expected to increase this uptake.

Sections 82 and 193 of the HDPR specify the circumstances when a dispenser must not dispense a prescription, such as when the dispenser considers the prescription to be false or tampered with. Sections 82(6)(b) and 193(6)(b) require a dispenser to cancel the prescription and send the cancelled prescription to the chief executive within 14 days after cancelling it, to enable the investigation of the prescription. For an electronic prescription, a pharmacist may meet this obligation by sending an image of the computer screen showing the prescription or by sending it in an approved electronic form.

In the second half of 2020, the Australian Digital Health Agency's electronic prescription conformance profile will specify the technical requirements to enable a pharmacist to remove an electronic prescription from circulation when it is electronically cancelled. The Amendment Regulation provides a way which an electronic prescription can be cancelled and sent to the Department and ensures that timely notification is given to the Department of any events that impact the integrity of the regulatory system, such as attempts to obtain prescription medicines

based on false information or fraudulent prescriptions. The Department or the police can then investigate and take appropriate action.

The Amendment Regulation does not:

- expand the scope of data currently collected under sections 84 or 84A;
- expand the purposes for the use of the data currently collected under section 84 or 84A;
- expand the scope of persons to whom this data can be disclosed to;
- compel pharmacists to submit via a PES, but allows them to do this in addition to, or instead of, their current method of data submission; and
- provide prescribers and dispensers with direct access to QScript. It continues to allow the Department to provide information to prescribers via its 13 S8INFO enquiry service.

The Amendment Regulation simply changes the mechanism by which data on prescribed and dispensed controlled drugs can be collected and the specific information and communication technology (ICT) database in which the data is stored and accessed by Departmental staff, to undertake their regulatory functions under the HDPR. The use of QScript is a precursor to the full establishment of a real time prescription monitoring system, as envisaged by the *Medicines and Poisons Act 2019*.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the *Health Act 193*7.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

The Amendment Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The Amendment Regulation will significantly reduce the burden on pharmacists who use a PES, allowing their time and resources to be devoted to other activities as it will:

- provide pharmacists with an alternative way to comply with sections 84 and 84A of the HDPR, by authorising pharmacists to send their controlled drug data to the Department via an automated process. This process will require no additional actions from the pharmacist beyond what they do as part of their dispensing process, instead of having to manually send data weekly or fortnightly; and
- reduce the time spent by pharmacists liaising with the Department and rectifying and resubmitting late, incomplete or incorrect data submissions.

The Amendment Regulation will improve the timeliness of controlled drug data received by the Department, as the information will be received in real-time, rather than weekly or fortnightly.

As a result of the Amendment Regulation:

- prescribers contacting 13 S8INFO will be given more current and accurate information about a person's drug treatment history;
- prescribers will be issued HDPR approvals, such as approvals to treat drug dependent persons, based on more accurate and complete information, decreasing the risk of harm or death to those patients;
- drug-dependent or drug-seeking patients will be easier to identify, decreasing the risk that they are able to obtain controlled drugs that could cause them harm from an overdose, or that are diverted to illicit drug markets;
- access to healthcare for some patients may be improved, as prescribers will be more confident in prescribing controlled drugs to particular patients due to more current and reliable prescription history information; and
- the Department's capacity to undertake timely and meaningful surveillance, compliance monitoring and enforcement activities will be enhanced.

The costs of implementing the Amendment Regulation will be met within existing departmental resources. There will be no additional costs for pharmacists, as approximately 93 per cent of Queensland pharmacies are already using a PES. The Amendment Regulation does not compel pharmacists to submit via a PES, but allows them to do this in addition to, or instead of, their current method of data submission.

Consistency with fundamental legislative principles

The Amendment Regulation is consistent with fundamental legislative principles, as defined in section 4 of the *Legislative Standards Act 1992*.

Consultation

Specific consultation has not been undertaken on the Amendment Regulation as it only seeks to change the mechanism by which controlled drugs data can be collected and the specific ICT database in which the data is stored and accessed by departmental staff, to undertake their regulatory functions under the HDPR.

Consultation was undertaken with a wide range of stakeholders in the development of the Medicines and Poisons Act. Key stakeholders that provided feedback included the Australian Medical Association Queensland, Pharmacy Guild of Australia and Pharmaceutical Society of Australia. As stated in the explanatory notes for the Medicines and Poisons Act, the pharmacy sector and the Australian Medical Association Queensland support the introduction of a real-time prescription monitoring system. The Amendment Regulation is a step towards the full implementation of a real-time prescription monitoring system.

The Amendment Regulation was assessed by the Office of Best Practice Regulation in accordance with *The Queensland Government Guide to Better Regulation* as being excluded from further regulatory impact analysis under category (k) – regulatory proposals designed to reduce the burden of regulation, or that clearly do not add to the burden, and it is reasonably clear there are no significant adverse impacts.

Notes on provisions

Short Title

Clause 1 states the short title is the *Health (Drugs and Poisons) Amendment Regulation (No. 3) 2020*.

Regulation amended

Clause 2 states the regulation amends the *Health (Drugs and Poisons) Regulation 1996*.

Amendment of s 82 (Conditions of dispensing)

Clause 3 amends section 82(1)(b) by replacing 'by electronic means' with 'electronically in the way'. This amendment has the effect that a dispenser must not dispense a controlled drug unless, if the prescription is an electronic prescription, the prescription is sent by the prescriber and received by the dispenser electronically in the way approved by the chief executive.

On 10 July 2020, the chief executive approved the requirements for electronic prescriptions, which enables the prescribing, sending and receiving, and dispensing of the prescription. The form approved by the chief executive incorporates the data the Department requires to satisfy the Australian Digital Health Agency's Electronic Prescribing Register of Conformance.

Clause 3(2) replaces section 82(6)(b) and inserts new sections 82(6)(b) and (c) to provide that the dispenser must:

- for a paper prescription, keep the prescription and send an acceptable electronic copy of the prescription to the chief executive within 14 days after cancelling the prescription; and
- for an electronic prescription, notify the chief executive of the cancellation, in an *approved electronic form*, within 14 days after cancelling the prescription.

This amendment provides that when a pharmacist cancels a prescription and notifies the Department, in the way approved by the chief executive, that it meets the requirements of the Australian Digital Health Agency electronic prescription conformance profile for a pharmacist cancelling an electronic prescription. The term *approved electronic form* is defined in appendix 9 (Dictionary), as inserted by clause 8.

Amendment of s 84 (Dealing with paper prescriptions and particular written instructions)

Clause 4 amends section 84(3)(b) by replacing 'means' with 'communication'. This amendment clarifies that the dispenser must send the chief executive the prescription or written instruction in paper form or in an approved electronic form by electronic communication. This is because the provision now refers to the defined term *electronic communication* instead of *electronic means*. Clause 8 of the Amendment Regulation omits the definition of *electronic means*.

Amendment of s 84A (Dealing with electronic prescriptions)

Clause 5 amends section 84A(3) by replacing 'by electronic means' with 'electronically in the way approved by the chief executive'. This amendment has the effect that the dispenser must send the chief executive the electronic prescription electronically in the way approved by the chief executive.

Amendment of s 93 (Dealing with purchase orders)

Clause 6 amends section 93(1)(c)(ii) and 93(2)(d)(ii) by replacing 'means' with 'communication'. This has the effect that the provision refers to the defined term *electronic communication* instead of *electronic means*. Clause 8 of the Amendment Regulation omits the definition of *electronic means*. The amendments have the effect that if:

- a pharmacist, or a person who is authorised to dispense a controlled drug under a pharmacist's personal supervision, sells a controlled drug on a purchase order, the pharmacist or person must send the order to the chief executive in an approved electronic form by electronic communication, within 14 days after the end of the month in which the drug is sold; or
- a person, other than a pharmacist or an authorised person sells a controlled drug on a purchase order, the person must within 14 days after the end of the month in which the drug is sold, send an approved electronic form of the order by electronic communication.

Amendment of s 193 (General conditions of dispensing)

Clause 7 amends section 193(1)(b) by replacing 'by electronic means' with 'electronically in the way'. This amendment has the effect that a dispenser must not dispense a restricted drug, unless if the prescription is an electronic prescription, the prescription is sent by the prescriber and received by the dispenser electronically in the way approved by the chief executive.

Clause 7(2) replaces section 193(6)(b) and inserts new sections 193(6)(b) and (c) to provide that the dispenser must:

- for a paper prescription, keep the prescription and send an acceptable electronic copy of the prescription to the chief executive within 14 days after cancelling the prescription; and
- for an electronic prescription, notify the chief executive of the cancellation, in an approved electronic form, within 14 days after cancelling the prescription.

This amendment ensures the cancelled prescription complies with the Australian Digital Health Agency electronic prescription conformance profile, similar to clause 3 above.

Amendment of appendix 9 (Dictionary)

Clause 8 replaces the definitions of *approved electronic form* and *electronic prescription*, inserts new definitions for *approved prescription exchange system*, *receive* and *send*, omits the definition of *electronic means* and amends the definition of *electronic communication*.