Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020

Explanatory notes for SL 2020 No. 59

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020

Authorising law

Section 240 of the *Medicines and Poisons Act 2019*.

Policy objectives and the reasons for them

Section 224 of the *Medicines and Poisons Act 2019* requires Queensland Health to keep an electronic database to record information about the prescription and supply of certain prescription medicines prone to high risk use known as the monitored medicines database. The purpose of the *Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020* (Database Testing Regulation) is to provide for the establishment and testing of the database.

The Medicines and Poisons Act and its supporting regulations are expected to fully commence in 2021. The Database Testing Regulation will apply temporarily to allow the database to be tested before commencement of the medicines and poisons scheme. The Database Testing Regulation will be repealed when the medicines and poisons scheme fully commences.

Background

Medicines in Queensland are currently regulated by the *Health Act 1937* and *Health (Drugs and Poisons) Regulation 1996*. The Health (Drugs and Poisons) Regulation provides a wide range of controls over the possession, supply, administration and other activities involving medicines.

Section 84 of the Health (Drugs and Poisons) Regulation requires dispensers to provide information to Queensland Health if they dispense, administer or supply a controlled drug (also known as a schedule 8 or S8 medicines). Queensland Health stores this information in an internal database. Health practitioners do not have direct access to this database. If a health

practitioner wishes to obtain information about a patient's prescription history, they must contact Queensland Health.

The National Drug Strategy 2017-2026, released by the Commonwealth Department of Health in 2017, noted that implementation of real-time monitoring of prescription medicines such as pharmaceutical opioids could assist in reducing the supply of illicit and illicitly used drugs. In April 2018, the Council of Australian Governments Health Council supported the implementation of a national real-time reporting solution.

The Office of the Health Ombudsman's 2016 report, *Undoing the knots constraining medicine regulation in Queensland*, was also strongly supportive of real-time prescription monitoring. The report noted that such a tool would have significant benefits for the effective and efficient monitoring of prescribing and dispensing of S8 medicines in Queensland and help to manage risks to the health and safety of the public.

Monitored medicines database

The Medicines and Poisons Act requires Queensland Health to establish the monitored medicines database, which will be a real-time prescription monitoring system to manage the use of certain prescription medicines that are prone to high-risk use. The development and implementation of a real-time prescription monitoring system will aid clinical decision-making by requiring prescribers and dispensers to check real-time prescription and dispensing information before they prescribe or dispense certain substances. It will provide life-saving benefits to patients, assistance for doctors when prescribing prescription medicines, minimise over-prescription and reduce drug seeking for non-medical purposes.

When the monitored medicines database is fully deployed, whenever a prescription for a monitored medicine is dispensed, for example, in a Queensland pharmacy, the prescription information will be transmitted to the database in real time.

Queensland Health is currently developing the ICT system for the monitored medicines database. It is intended that the system be ready for full deployment when the new medicines and poisons framework commences. Before being deployed, the ICT system needs to be tested by Queensland Health, and this will require Queensland Health to be able to lawfully collect, use and disclose patient information as provided in chapter 7, part 3 of the Medicines and Poisons Act. The information included in the database during testing will include information received by Queensland Health in relation to the prescribing or supply of S8 medicines.

A Proclamation will commence relevant definitions and certain provisions of the Medicines and Poisons Act to enable the Database Testing Regulation to be made.

Achievement of policy objectives

To achieve the policy objectives, the Database Testing Regulation prescribes the matters necessary for the testing of the monitored medicines database ICT solution.

The Database Testing Regulation prescribes the medicines that are a 'monitored medicine' for schedule 1 of the Medicines and Poisons Act, which will capture all controlled drugs under the Health (Drugs and Poisons) Regulation. During the testing phase, only controlled drugs, or S8 medicines, will be prescribed as monitored medicines. However, when the database is fully deployed, a broader range of prescription medicines will be prescribed.

Section 225(1) of the Medicines and Poisons Act provides that a regulation may prescribe the information that must be recorded by the chief executive in the monitored medicines database. The Database Testing Regulation provides that information collected during the testing phase will be information related to a *monitored medicine treatment activity*, which is an activity that is performed by the holder of an authority or a relevant approval under the Health (Drugs and Poisons) Regulation that is the same as the prescription or supply of a monitored medicine under the Medicines and Poisons Act. The Health (Drugs and Poisons) Regulation uses different terminology to the Medicines and Poisons Act, so the Database Testing Regulation requires an activity that is the same as, or equivalent to, prescription or supply to be recorded.

The Database Testing Regulation provides for historical information held by Queensland Health about a patient treated under the opioid treatment program to be included in the database. The Queensland Opioid Treatment Program began in 1977 and provides treatment for opioid dependence, including prescription opioids. A patient's history of drug dependence is a strong predictor of a patient relapsing into drug seeking behaviour. Information about a patient's registration in the Queensland Opioid Treatment Program is currently disclosed to clinicians to aid their decision making. Including historical information about a patient treated under the program will help ensure that it can be considered in clinical decision-making for high-risk scenarios when the ICT solution is fully deployed.

The Database Testing Regulation does not require prescribers or dispensers to provide any additional historical information to Queensland Health. Rather, it ensures that patient information about treatment under the Queensland Opioid Treatment Program that Queensland Health has already collected under the *Health Act 1937* can be included in the monitored medicines database.

For the purposes of testing, the Database Testing Regulation will allow a limited number of health practitioners testing the database to access/view this historical information for the purpose of testing. This information is currently disclosed to prescribers, to assist in their clinical decision-making, when they call 13 S8INFO.

Finally, the Database Testing Regulation prescribes for section 227 of the Medicines and Poisons Act the users of the database and the purposes for disclosure of information from the database. If a user is a prescriber or dispenser, the prescribed purpose is to test the database. If the user is employed by Queensland Health, the prescribed purpose is establishing or testing the database and training using the database.

Consistency with policy objectives of authorising law

The Database Testing Regulation is consistent with the policy objectives of the Medicines and Poisons Act. It will enable the development of a database to support the modernisation and streamlining of medicines regulation in Queensland. It will support Queensland Health in monitoring and responding to health risks associated with inappropriate access to and use of certain prescription medicines prone to high-risk use.

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 Database Testing Regulation is the only effective means of providing a legal framework for the testing of the ICT solution for the monitored medicines database.

Benefits and costs of implementation

The Database Testing Regulation will ensure the ICT solution for the database is ready for full deployment when the Medicines and Poisons Act and its supporting regulations commence. When fully deployed, the database will have significant benefits for the prescribing and dispensing of monitored medicines in Queensland.

The costs of developing the ICT solution for the monitored medicines database are being met within existing budget allocations. The Database Testing Regulation does not impose any costs on prescribers or dispensers. Rather, it ensures that they can lawfully provide information to, and access information from, the new monitored medicines database within the context of the testing of the ICT solution.

Consistency with fundamental legislative principles

The Database Testing Regulation is consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

The right to privacy, the disclosure of private or confidential information, doctor-patient confidentiality, and privacy and confidentiality issues have generally been identified by the former Scrutiny of Legislation Committee as relevant to consideration of whether legislation has sufficient regard to individuals' rights and liberties.

Section 6(3) of the Database Testing Regulation provides that the information relating to a patient treated under the opioid treatment program that must be included in the monitored medicines database includes information given to, or recorded by on behalf of Queensland Health, any time before the commencement.

The inclusion of this information in the Database Testing Regulation may be seen to infringe upon the privacy of individuals. These provisions are considered to be justified as the information included in the database is already collected by Queensland Health and disclosed to prescribers to inform their clinical decision-making.

Consultation

Detailed 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.

Consultation was not undertaken on the Database Testing Regulation as it only provides for testing of the monitored medicines database before commencement of the legislative scheme and full deployment of the database.

The Database Testing 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

Part 1 Preliminary

Short Title

Clause 1 provides the short title of the regulation.

Commencement

Clause 2 states that the regulation commences on 1 May 2020.

Purpose

Clause 3 provides that the purpose of the regulation is to facilitate the establishment and testing of the monitored medicines database using information given and recorded under the *Health Act 1937*.

Definitions

Clause 4 defines relevant terms for the purposes of the regulation.

Part 2 Monitored medicines database

Monitored medicines—Act, sch 1

The definition of *monitored medicine* in schedule 1 of the *Medicines and Poisons Act 2019* provides that a monitored medicine is a medicine prescribed by regulation to be a monitored medicine.

Clause 5 provides that for the definition of *monitored medicine* in schedule 1 of the Act, a controlled drug is a monitored medicine.

A *controlled drug* is defined in Appendix 9 of the *Health (Drugs and Poisons) Regulation 1996* as an S8 substance. Section 5 of the Health (Drugs and Poisons) Regulation defines an S8 drug "as the drug in the schedule to the current Poisons Standard with the number given in the expression". The Poisons Standard is a legislative instrument made under the *Therapeutic Goods Act 1989* (Cwlth). It provides for the uniform scheduling of substances classified from Schedule 2 (S2) to Schedule 10 (S10). All States and Territories refer to the Poisons Standard when regulating possession, access and use of scheduled substances.

Departmental information for database—Act, s 225

Clause 6 prescribes the information that must be recorded in the database for the purposes of section 225(1) of the Act. This is:

- relevant health information that is given to, or recorded by or on behalf of, the chief executive under the Health Act on or after the commencement of section 225(1) and the information is kept electronically by the chief executive;

- relevant registration information for a monitored medicine treatment activity performed under an opioid treatment program that was given to, or recorded by or on behalf of, the chief executive under the Health Act at any time before the commencement and is kept electronically by the chief executive.

Clause 6 also defines *relevant health information* and *relevant registration information* for this clause.

This clause will ensure that Queensland Health can include patient histories under the Queensland Opioid Treatment Program in the database. This will help ensure that this historical information can be included in clinical decision-making for high-risk scenarios.

Users of database—Act, s 227

Section 227 of the Act provides that the chief executive may disclose information in the monitored medicines database to a user, for a purpose prescribed by regulation. It also provides that a user is an entity prescribed by regulation.

Clause 7 provides that a *user* is a prescriber, a dispenser, or a person employed by the chief executive. *Prescriber* and *dispenser* are both defined in clause 4 by referring to the definitions in schedule 9 of the Health (Drugs and Poisons) Regulation.

Purposes for disclosure—Act, s 227

Clause 8 provides that for section 227(2) of the Act, the following purposes for disclosure are prescribed:

- for a user who is a prescriber or dispenser – testing the monitored medicines database;
- for a user who is a person employed by the chief executive – establishing or testing the monitored medicines database, including training about using the database.