Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020

Human Rights Certificate

Prepared in accordance with Part 3 of the *Human Rights Act 2019*

In accordance with section 41 of the *Human Rights Act 2019*, I, the Honourable Steven Miles MP, Minister for Health and Minister for Ambulance Services provide this human rights certificate with respect to the Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020 made under the *Medicines and Poisons Act 2019*.

In my opinion, the Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020, as tabled in the Legislative Assembly, is compatible with the human rights protected by the *Human Rights Act 2019*. I base my opinion on the reasons outlined in this statement.

Overview of the Subordinate Legislation

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. Rather, if they wish 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 (COAG) 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 fully commences. Before being deployed, the ICT system needs to be tested by Queensland Health. Testing 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.

To facilitate testing the database, it is necessary to commence certain provisions of the Medicines and Poisons Act and to make the Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020 (Database Testing Regulation) to prescribe matters to support the Act provisions. A separate proclamation will commence relevant definitions and provisions of the Medicines and Poisons Act that are necessary for Queensland Health to lawfully collect, use and disclose information for the database.

Database Testing Regulation

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. This will be all controlled drugs under the Health (Drugs and Poisons) Regulation. During the testing phase, only controlled drugs, or Schedule 8 medicines, will be prescribed as monitored medicines. However, when the medicines and poisons scheme commences, a broader range of prescription medicines will be prescribed.

For section 225(1) of the Medicines and Poisons Act, the Database Testing Regulation prescribes the information that must be recorded by the chief executive in the monitored medicines database during the testing phase. This 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 prescribing or supplying 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.

Finally, the Database Testing Regulation prescribes the users of the database and purposes for disclosure of information from the database for section 227 of the Medicines and Poisons Act. The prescribed purpose is to test the database, but for employees of Queensland Health the prescribed purpose also includes establishing the database and training using the database.

Human Rights Issues

Human rights relevant to the subordinate legislation (Part 2, Division 2 and 3 *Human Rights Act 2019*)

Section 25 of the Human Rights Act provides for a right to privacy and reputation.

The Database Testing Regulation may be interpreted as interfering with this right, as it will allow the disclosure of information about a person's treatment with controlled drugs, including all opioid treatment medicines.

In particular, clause 6 provides the information that the chief executive must record in the database, and clause 7 will allow the disclosure of information held in the database to a prescriber, a dispenser, or a person employed by Queensland Health for the purposes of training, establishing and testing the monitored medicines database.

Consideration of reasonable limitations on human rights (section 13 *Human Rights Act 2019*)

(a) The nature of the right

The right to privacy protects the individual from all interferences and attacks upon their privacy, home, correspondence and reputation. It is broad in scope and includes privacy in the sense of personal information and data collection. Only lawful and non-arbitrary intrusions may occur upon privacy.

The scope of the right is limited by an internal limitation. The Human Rights Act provides that a person has the right to not have their privacy *unlawfully* or *arbitrarily* interfered with. Case authority suggests that 'arbitrary' in the human rights context refers to conduct that is unpredictable or unjust, and also refers to interferences which are unreasonable in sense of not being proportionate to a legitimate aim that is sought.

(b) The nature of the purpose of the limitation, including whether it is consistent with a free and democratic society based on human dignity, equality and freedom

The limitations on the right to privacy in the Database Testing Regulation are important measures to achieve an important purpose – namely to further the implementation of a real-time prescription monitoring solution in Queensland.

This is expected to bring significant benefits to the health system in Queensland, by providing life-saving benefits to patients, assistance for doctors when prescribing medicines prone to

high-risk use, assistance for pharmacists when dispensing medicines prone to high-risk use, minimising over-prescription and reducing instances of patients consulting multiple prescribers to obtain monitored medicines.

(c) The relationship between the limitation and its purpose, including whether the limitation helps to achieve the purpose

The limitation on the right to privacy helps to achieve the purpose of implementing real-time prescription monitoring in Queensland, as it allows for the testing of the ICT solution that is necessary for the implementation of real-time prescription monitoring under the Medicines and Poisons Act.

(d) Whether there are any less restrictive and reasonably available ways to achieve the purpose

There are no less restrictive ways to achieve the purpose. 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.

There is already a requirement, under section 84 of the Health (Drugs and Poisons) Regulation 1996, that dispensers are required to submit information to the chief executive regarding the dispensing, administration and supply of Schedule 8 medicines. However, this involves dispensing pharmacies manually sending or uploading data on a weekly basis. Establishing the monitored medicines database will facilitate the automated collection of this information in real-time, enabling the capture of up-to-date data and reducing regulatory burden.

(e) The balance between the importance of the purpose of the limitation and the importance of preserving the human right, taking into account the nature and extent of the limitation

The significant benefits to be gained by implementing real-time prescription monitoring in Queensland outweigh the relatively minor impacts upon the right to privacy.

The limitations are not arbitrary, and their reach is clearly defined in the Database Testing Regulation. The data to be recorded in the database is clearly set out in the Database Testing Regulation, and the parties that are able to access the information are limited to those who play a role in patient care or the administration of the system.

(f) Any other relevant factors

The Database Testing Regulation does not represent a significant expansion of the data that is obtained or disclosed by Queensland Health for the purposes of monitoring the use of controlled drugs. Information is already provided to Queensland Health and disclosed to prescribers and dispensers under the existing legislative framework under the Health (Drugs and Poisons) Regulation. 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. The Database Testing Regulation is intended to help facilitate the exchange of this information in real time.

Conclusion

I consider that the *Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020* is compatible with the *Human Rights Act 2019* because it does limit, restrict or interfere with a human right, but that limitation is reasonable and demonstrably justified in in a free and democratic society based on human dignity, equality and freedom.

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