Health (Drugs and Poisons—Dispensing of Controlled Drugs) Amendment Regulation 2017

Explanatory notes for SL 2017 No. 186

made under the

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons—Dispensing of Controlled Drugs) Amendment Regulation 2017

Authorising law

Section 180 of the *Health Act 1937*.

Policy objectives and the reasons for them

Schedule 8 drugs, known as controlled drugs under the *Health (Drugs and Poisons) Regulation 1996* (HDPR), include dangerous and addictive opioids, such as the painkillers fentanyl, oxycodone and morphine. Controlled drugs may be dispensed under a prescription or written instruction from a doctor.

Due to the significant risk of misuse and unlawful diversion of controlled drugs, pharmacists are required to periodically report the dispensing of these drugs to the Department of Health (the department). Reports may be made electronically or in paper form. That information is recorded by the department in the Monitoring of Drugs of Dependence System database, and then matched against existing patient records to identify problematic anomalies and trends. These include excessive or long-term use, doctor shopping and, increasingly, black market trafficking of opioids. To assist in making decisions about whether to prescribe controlled drugs, information from the database is also available to doctors via a seven-day-a-week telephone inquiry service.

However, this system does not result in timely dispensing information being available to the department and prescribing doctors. Pharmacists are required under the HDPR to report this information monthly, and must make each monthly report within two weeks of the end of the month to which the report relates. This lengthy reporting period, followed by a similarly lengthy interval before reports must be made, means information may not be reported for up to six weeks after a controlled drug has been dispensed. This reduces the department's ability to take timely action in response to anomalies and trends identified in the reported data. It also potentially makes the most recent information available to a doctor considering prescribing a controlled drug significantly out of date.

To address this issue, and to enable a more effective regulatory response to the growing problem of misuse and illegal diversion of prescription painkillers, the Minister for Health and Minister for Ambulance Services recently announced the Government had decided to reduce the controlled drug reporting timeframe from monthly to weekly. The Minister indicated this is an interim step, with the goal ultimately being to move to real-time reporting of dispensing information.

Achievement of policy objectives

The amendment regulation gives effect to the Minister's announcement. It does this by making the following changes:

- The reporting period for controlled drugs dispensed under a prescription is shortened from one month to one week. This will have the effect of requiring pharmacists to report relevant dispensing information to the department within a specified period after the end of the calendar week in which a controlled drug is dispensed, rather than within a specified period after the end of the calendar month.
- The specified period within which a report must be made is shortened from 14 days after the end of the reporting period to seven days. This will halve the interval between the end of a reporting period and receipt of the dispensing information by the department, maximising the currency of the information recorded in the database.

As a written instruction relates to a person's participation in the strictly controlled opioid treatment program, which involves close monitoring of the doses of a controlled drug supplied over a month, the amendment regulation leaves unchanged the reporting period for controlled drugs dispensed under an instruction. However, as with prescriptions, the time within which dispensing under an instruction must be reported changes to weekly.

These amendments only affect reports made electronically. Reports in paper form are rare, and are already subject to appropriately short timeframes.

Consistency with policy objectives of authorising law

The amendment regulation is consistent with the policy objectives of the *Health Act 1937*, which protects public health by regulating access to potentially harmful substances.

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

As the controlled drug reporting requirements are imposed by regulation, an amendment regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

As noted above, the amendment regulation will significantly enhance the currency of controlled drug dispensing information available to the department and prescribing doctors. This will enhance the department's capacity to address the increasing problem of misuse and

illegal diversion of opioids, and will support doctors to make properly informed prescribing decisions.

To give effect to the amendment regulation, the department will implement systems for processing and validating the same volume of reported information more frequently. An initial increase in follow-up calls is also anticipated to ensure affected pharmacists are aware of, and comply with, their changed reporting requirements. This additional activity will be delivered through the employment of additional staff over the nine-month transition period from October 2017 to June 2018, funded through a one-off allocation from the existing departmental budget allocation.

The amendment regulation is not expected to result in appreciable additional costs for affected pharmacists. While pharmacists will be required to report dispensing information more frequently, the form and quantity of that information will not change as a result of the amendment regulation. Further, as this information is generally held and sent electronically, it is expected the obligation to report more frequently will be met through the automatic generation of more frequent reports, and will not require significant additional handling.

Consistency with fundamental legislative principles

The amendment regulation is consistent with fundamental legislative principles, as set out in section 4 of the *Legislative Standards Act 1992*.

Consultation

Due to the urgent need to take appropriate action to address this significant and growing issue, and because it relates to announced Government policy, the proposed regulatory amendments have not been subject to previous stakeholder consultation. Consultation is being undertaken with peak pharmacy, medical and primary health stakeholders in the lead-up to implementation.

The amendment regulation was assessed by Queensland Health, in accordance with *The Queensland Government Guide to Better Regulation,* as being excluded from regulatory impact assessment on the basis it is machinery in nature. The amendment regulation makes no substantive change in policy, requiring pharmacists to report the same information as previously, and facilitates routine tasks of government by ensuring the MODDS database and associated telephone hotline are operating optimally. Consultation with the Office of Best Practice Regulation in the Queensland Productivity Commission was therefore not required.

Notes on provisions

Short Title

Clause 1 provides the short title of the regulation.

Commencement

Clause 2 provides for the commencement of the regulation.

Regulation amended

Clause 3 provides the regulation amends the HDPR.

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

Clause 4 amends section 84 of the HDPR, which requires pharmacists who either dispense controlled drugs on a paper prescription, or administer or supply controlled drugs on a written instruction, to report that activity to the department.

Subclauses (1) and (2) provide that a pharmacist who electronically reports the dispensing of a controlled drug on a paper prescription must do so within seven days after the end of the week in which the drug was dispensed.

Subclause (3) provides that a pharmacist who electronically reports the administration or supply of a controlled drug on a written instruction must do so within seven days after the end of the month in which the drug was administered or supplied.

The maximum penalty of 40 penalty units for failing to comply with these reporting obligations continues to apply.

Amendment of s 84A (Dealing with electronic prescriptions)

Clause 5 amends section 84A of the HDPR, which requires pharmacists who dispense controlled drugs on an electronic prescription to report that activity to the department.

Subclauses (1) and (2) provide that a pharmacist must report the dispensing of a controlled drug on an electronic prescription within seven days after the end of the week in which the drug was dispensed.

The maximum penalty of 40 penalty units for failing to comply with these reporting obligations continues to apply.