Health Legislation Amendment Regulation (No. 2) 2019

Explanatory notes for SL 2019 No. 117

made under the

Health Act 1937
Public Health Act 2005
Radiation Safety Act 1999

General Outline

Short title

Health Legislation Amendment Regulation (No. 2) 2019

Authorising law

Section 180 of the *Health Act 1937*
Section 461 of the *Public Health Act 2005*
Section 215 of the *Radiation Safety Act 1999*

Policy objectives and the reasons for them

The Health Legislation Amendment Regulation (No. 2) 2019 (the Amendment Regulation) amends three regulations to support changes made to the *Health Act 1937*, *Public Health Act 2005* and *Radiation Safety Act 1999* by the *Health and Other Legislation Amendment Act 2019* (the Amendment Act). The Amendment Act amends various Health and other portfolio Acts to implement policy initiatives and improve the operation of legislation.

The Amendment Regulation:

- prescribes requirements for the prescription, dispensing and storage of medicinal cannabis;
- supports the establishment of a framework for notification of particular occupational dust lung diseases;
- prescribes the standard for people manufacturing, selling, supplying or using paint; and
- prescribes new categories of licence holders, called *prescribed licensees*, who are deemed to have a licence under the Radiation Safety Act and can use a specified radiation source or transport a radioactive substance in certain circumstances.

Health (Drugs and Poisons) Regulation 1996

The Amendment Act repeals the *Public Health (Medicinal Cannabis) Act 2016* (Medicinal Cannabis Act) so that medicinal cannabis is treated in the same way as other scheduled medicines. It also amends the definitions of *article*, *drug*, and *poison* in the Health Act to bring medicinal cannabis within the remit of the Health Act and the *Health (Drugs and Poisons) Regulation 1996*.

Public Health Regulation 2018

In May 2017, the Coal Workers' Pneumoconiosis Select Committee of the Queensland Parliament recommended that cases of coal workers' pneumoconiosis and other coal mine dust lung diseases identified or diagnosed by medical professionals should be compulsorily reported to the Chief Health Officer as a notifiable disease under the Public Health Act.

The Amendment Regulation amends the *Public Health Regulation 2018* to prescribe:

- the diseases required to be notified for the purposes of the definition of *notifiable dust lung disease* in the Amendment Act;
- the medical practitioners required to notify dust lung diseases for the purposes of the definition of *prescribed medical practitioner* in the Amendment Act; and
- the timeframe for a prescribed medical practitioner, upon diagnosing a notifiable dust lung disease, to provide notification to the chief executive.

The Amendment Act also amends the Public Health Act to provide that a person manufacturing, selling, supplying or using paint must comply with a standard prescribed in regulation. The Amendment Regulation prescribes this standard in the Public Health Regulation.

Radiation Safety Regulation 2010

The Radiation Safety Act prohibits a person from using a radiation source or transporting a radioactive substance unless they hold a use licence or a transport licence, respectively.

In some circumstances, persons required to hold these licences have already been assessed under another requirement as being suitable to use the radiation source or transport the radioactive substance. For example, through a professional registration process or an equivalent licence granted in another jurisdiction.

The Amendment Act amends the Radiation Safety Act to create a new category of licensee, being persons or classes of person who are prescribed in regulation as a *prescribed licensee*. A prescribed licensee is deemed to have a use or transport licence, and is therefore subject to the same requirements, standard conditions and penalties for contravention of the Act as other licensees.

The categories of persons who are prescribed licensees are identified in the *Radiation Safety Regulation 2010* by their qualification, registration status or training.

The Amendment Regulation amends the Radiation Safety Regulation to ensure that a prescribed licensee is not required to advise the chief executive of a change of name. This will be unnecessary as the chief executive will not issue a licence to the person.

Section 207 of the Radiation Safety Act provides that the chief executive must keep a register about licensees and that the register must contain the information prescribed under a regulation. The information required by regulation includes the licensee's name, the licence number and other general details about the licence.

The Radiation Safety Regulation is amended to provide that the register does not include information about a prescribed licensee. As a licence will not be issued to the person, the chief executive will not have this information. However, if a prescribed licensee's licence is suspended or cancelled, details of a prescribed licensee and the suspension or cancellation must be included in the register.

Achievement of policy objectives

Health (Drugs and Poisons) Regulation 1996

The Amendment Regulation amends the Health (Drugs and Poisons) Regulation to ensure that medicinal cannabis can be prescribed and dispensed under Queensland's existing regulatory framework for scheduled medicines. It provides for the storage of medicinal cannabis products. It also provides for the transition of manufacturing and wholesaling approval holders under the repealed Act to equivalent licences under the Health (Drugs and Poisons) Regulation.

Public Health Regulation 2018

The Amendment Regulation amends the Public Health Regulation to:

- define a *notifiable dust lung disease* as each of the following diseases caused by occupational exposure to inorganic dust: cancer, chronic obstructive pulmonary disease including chronic bronchitis and emphysema, and pneumoconiosis including asbestosis, coal worker's pneumoconiosis, mixed-dust pneumoconiosis and silicosis;
- prescribe that a medical practitioner must notify the diagnosis of a notifiable dust lung disease within 30 days from the diagnosis;
- define a *prescribed medical practitioner* as a medical practitioner registered under the Health Practitioner Regulation National Law (National Law) as a specialist health practitioner in the fields of occupational and environmental medicine or respiratory and sleep medicine; and
- provide that the standard for a person manufacturing, selling, supplying or using paint is the Poisons Standard made under the *Therapeutic Goods Act 1989* (Cwlth).

Radiation Safety Regulation 2010

The Amendment Regulation amends the Radiation Safety Regulation to:

- provide that a person is taken to hold a use licence if they are registered under the National Law to practice as a dentist and may use an intra-oral dental radiation apparatus for intra-oral dental plain radiography;

- provide that a person is taken to hold a transport licence if they hold an authority under a corresponding transport law to transport a radioactive substance and are transporting the radioactive substance in to Queensland;
- provide that a prescribed licensee does not need to notify the chief executive of a change in their name; and
- update the provisions regarding the register of licensees to specify that the register does not need to keep information about a prescribed licensee except if the licence has been cancelled or suspended.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the Health Act, Public Health Act and Radiation Safety Act.

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 amendments to the Health (Drugs and Poisons) Regulation simplify access to medicinal cannabis for patients and their treating doctors. As Queensland-based approvals are no longer required for the majority of prescriptions, these amendments reduce the administrative burden on medical practitioners in applying for an approval and on Queensland Health in processing applications.

The amendments to the Public Health Regulation impose a small reporting obligation on prescribed medical practitioners to notify diagnoses of notifiable dust lung diseases. The requirement is limited to a small group of specialist practitioners in the fields of occupational and environmental medicine or respiratory and sleep medicine and is supported by the practitioners' representative bodies. There is a small cost to Queensland Health associated with the creation and maintenance of the new register. This will be met within existing resources.

The primary intent of the reforms to the Radiation Safety Regulation is to remove the administrative burden for prescribed licensees of licence application and renewal. As well as reducing the regulatory and financial burden on stakeholders, the amendment also reduces costs to the department associated with administrative work in processing licence applications and renewals.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with the fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*, with the possible exception discussed below.

Section 60 of the Public Health Act requires a person manufacturing, selling, supplying or using paint to comply with the provision of the standard prescribed by regulation. Proposed new section 60 of the Public Health Regulation, inserted by clause 15 of the Amendment Regulation, provides that the standard is part 2 of the current Poisons Standard as defined by section 52A(1) of the *Therapeutic Goods Act 1989* (Cwlth).

Prescribing requirements by reference to an external standard may be seen to breach section 4(5)(e) of the Legislative Standards Act, that is, whether subordinate legislation allows the subdelegation of a power delegated by an Act only in appropriate cases.

The Poisons Standard is a Commonwealth legislative instrument that classifies medicines and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. As a legislative instrument, the Poisons Standard is published on the Federal Register of Legislation (https://www.legislation.gov.au/). Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison required to protect public health and safety. The Poisons Standard is regularly reviewed and updated approximately three times per year following extensive committee meetings and decision-making processes regarding classification.

Part 2 of the Poisons Standard sets out matters of technical detail for the control of medicines and poisons, such as requirements for labelling, storage and record keeping. As the Poisons Standard is updated regularly and contains matters of detail, it is appropriate to reference it in the Public Health Regulation rather than prescribing these matters.

This approach ensures the requirements in Queensland are consistent with the national requirements under the Poisons Standard.

Clauses 7 and 8 of the Amendment Regulation also prescribe requirements by reference to an external standard. In this case the external standard is the medicinal cannabis security standard, which is defined in clause 12 as the standard for security of medicinal cannabis stock, dated July 2019 and published on the department's website. The standard contains detailed requirements about the storage of medicinal cannabis, such as access controls, intruder resistance and detection and response.

Given the detailed nature of the standard, it is considered appropriate that this be incorporated by referencing an external standard rather than prescribing the detail in the Amendment Regulation. The standard is published on Queensland Health's website to ensure it is easily accessible to stakeholders and the public.

Consultation

Health (Drugs and Poisons) Regulation 1996

Targeted consultation was undertaken on repealing the Medicinal Cannabis Act and regulating medicinal cannabis under the Health (Drugs and Poisons) Regulation. A range of representative bodies for health practitioners and consumers, including the Royal Australian College of General Practitioners, Australian Medical Association Queensland, Health Consumers Queensland, Pharmacy Guild of Australia, and members of the Queensland Medicinal Cannabis Expert Advisory Panel were consulted.

The feedback received was supportive of the proposed repeal of the Act and regulating medicinal cannabis under the Health (Drugs and Poisons) Regulation.

Public Health Regulation 2018

The Thoracic Society of Australia and New Zealand, Royal Australian and New Zealand College of Radiologists and the Australasian and New Zealand Society of Occupational Medicine were consulted on the proposed notifiable dust lung disease register.

The proposed amendments relating to coal worker's pneumoconiosis and coal mine dust lung diseases were discussed with the Coal Mine Safety Health Advisory Committee, a tripartite committee with a membership comprising of industry, worker representative groups and the Resources Safety and Health regulator. The committee is chaired by the Commissioner of Mine Safety and Health and advises the Minister for Natural Resources, Mines and Energy on the safety and health of coal mine workers.

The CFMEU Mining and Energy (Queensland District) was also consulted.

The feedback received was supportive of the establishment of a notifiable dust lung disease register.

Radiation Safety Regulation 2010

The Radiation Advisory Council, Australian Dental Association (Queensland Branch) (ADAQ), and the Transport Workers Union were consulted on the amendments to the Radiation Safety Regulation. The Radiation Advisory Council and ADAQ responded supporting the amendments.

Office of Best Practice Regulation

All the amendments were assessed in accordance with *The Queensland Government Guide to Better Regulation* (the Guidelines).

The amendments to the Public Health Act about the establishment of a dust lung disease register were assessed by the Office of Best Practice Regulation as not requiring further analysis under the Guidelines as the impacts are unlikely to be significant.

The amendments to the Radiation Safety Act and the Health (Drugs and Poisons) Regulation (in the context of the repeal of the Medicinal Cannabis Act) were assessed by the Office of Best Practice Regulation as not requiring further analysis under the Guidelines as they are expected to reduce the regulatory burden on stakeholders.

Notes on provisions

Part 1 Preliminary

Short title

Clause 1 provides that the short title of the regulation is the *Health Legislation Amendment Regulation (No. 2) 2019.*

Commencement

Clause 2 provides that the regulation commences on 1 July 2019.

Part 2 Amendment of Health (Drugs and Poisons) Regulation 1996

Regulation amended

Clause 3 provides that part 2 amends the *Health (Drugs and Poisons) Regulation 1996*.

Amendment of s 78A (Approved drug–nabiximols)

Clause 4 replaces section 78A(1) and provides that, subject to section 74(3), a person must not dispense, prescribe, supply or use a controlled drug that is medicinal cannabis unless the person is a specialist medical practitioner or the action is done under an approval. This will ensure that medicinal cannabis is able to be prescribed under the Health (Drugs and Poisons) Regulation.

Clause 4 also amends the heading of section 78A and repeals section 78A(3), which contained definitions that are no longer relevant to the section as amended.

Amendment of s 79 (Prescribing controlled drugs)

Clause 5 replaces the reference to 'dronabinol' in section 79(4)(j) with 'medicinal cannabis'. Section 79(4) provides for the particulars that must appear on the front of a paper prescription or in an electronic prescription for a controlled drug, including requiring the word "Approved" if the controlled drug is dronabinol. Dronabinol is a synthetic form of medicinal cannabis and was regulated separately under the Health (Drugs and Poisons) Regulation rather than the Medicinal Cannabis Act, as it is registered on the Australian Register of Therapeutic Goods. As all medicinal cannabis products will now be regulated under the Health (Drugs and Poisons) Regulation, this provision needs to be updated to cover all medicinal cannabis products.

The effect of this change is that this will require the word 'Approved' to appear as a particular on a prescription for schedule 8 medicinal cannabis.

Amendment of s 82 (Conditions of dispensing)

Clause 6 replaces the reference to 'dronabinol or nabiximols' in section 82(2)(g) with 'medicinal cannabis'. Section 82(2) provides for the conditions under which a dispenser must not dispense a controlled drug on a prescription. This includes, in section 82(2)(g), if the prescription is for dronabinol or nabiximols and does not have "Approved" on it. Nabiximols

is a medicinal cannabis product that is registered on the Australian Register of Therapeutic Goods, along with dronabinol, and was therefore already regulated under the Health (Drugs and Poisons) Regulation. This change updates the regulation to ensure pharmacists do not dispense any schedule 8 medicinal cannabis unless the prescription has the particular 'Approved' on it.

Amendment of s 118 (Storage of controlled drugs at institutions)

Clause 7 amends section 118 to include additional requirements for the storage of medicinal cannabis at institutions. It requires that medicinal cannabis be stored in a way that complies with the medicinal cannabis security standard. It does not alter storage requirements for other controlled drugs.

Amendment of s 119 (Storage of controlled drugs generally)

Clause 8 amends section 119 to include additional requirements for the storage of medicinal cannabis generally. It requires that medicinal cannabis be stored in a way that complies with the medicinal cannabis security standard. It does not alter storage requirements for other controlled drugs.

Amendment of s 120 (Notice required if lengthy treatment with controlled drug)

Clause 9 removes the requirement in sections 120(1) and 120(2) that a relevant practitioner must immediately give the chief executive a written report about the circumstances of a patient's treatment with any controlled drug, if the treatment is or is intended to be for over two months.

In circumstances where a patient is being treated with any controlled drug for over two months, the section will continue to allow the chief executive to request additional information from the relevant practitioner about the treatment.

Clause 9 also amends the section heading to reflect this change.

Insertion of new ch 5, pt 2, div 5

Clause 10 inserts new chapter 5, part 2, division 5 of the Health (Drugs and Poisons) Regulation.

New section 316 inserts a definition of *repealed regulation* for the division. The *repealed regulation* is the repealed *Public Health (Medicinal Cannabis) Regulation 2017*.

New section 317 provides for the continuance of manufacturing approvals that existed under the repealed regulation. New section 317(2) provides that if the manufacturing approval authorised the manufacture of a controlled drug, the person is taken to hold a controlled drug manufacturer licence under the Health (Drugs and Poisons) Regulation. New section 317(3) provides the equivalent for a manufacturing approval for a restricted drug.

New section 318 provides for the continuance of wholesaling approvals that existed under the repealed regulation. New section 318(2) provides that if the wholesaling approval authorised the wholesale of a controlled drug, the person is taken to hold a controlled drug wholesaler licence under the Health (Drugs and Poisons) Regulation. New section 318(3) provides the equivalent for a wholesaling approval for a restricted drug.

New section 319 provides that persons who are taken to hold a licence under sections 317 and 318 are not required to pay a fee for the renewal of the licence. This is consistent with how these licensees are treated under the existing legislative framework.

Amendment of appendix 1 (Provisions not applying to morphine or opium in compounded preparations)

Clause 11 amends appendix 1 to account for the changes to section 120 about reporting on lengthy treatment with a controlled drug.

Amendment of appendix 9 (Dictionary)

Clause 12 inserts in appendix 9 new definitions of *cannabis product*, *chief health officer*, *medicinal cannabis* and *medicinal cannabis security standard*.

Part 3 Amendment of Public Health Regulation 2018

Regulation amended

Clause 13 provides that part 3 amends the *Public Health Regulation 2018*.

Insertion of new pt 8, div 5

Clause 14 inserts new division 5 (Notifiable dust lung disease register) into part 8 of the Public Health Regulation.

New section 49A inserts a definition for *notifiable dust lung disease* for section 279AA of the Public Health Act. A *notifiable dust lung disease* is, if caused by occupational exposure to inorganic dust, each of the following respiratory diseases:

- cancer;
- chronic obstructive pulmonary disease, including chronic bronchitis and emphysema; and
- pneumoconiosis including asbestosis, coal worker's pneumoconiosis, mixed-dust pneumoconiosis and silicosis.

New section 49B prescribes who a *prescribed medical practitioner* is for the purposes of section 279AA of the Act. This is a medical practitioner registered under the Health Practitioner Regulation National Law as a specialist health practitioner in the fields of occupational and environmental medicine or respiratory and sleep medicine.

New section 49C prescribes that a prescribed medical practitioner has 30 days from the time they diagnose a person as having a notifiable dust lung disease to provide notification of the notifiable dust lung disease under section 279AF(2) of the Public Health Act.

Replacement of s 60 (Paint—Act, s 60)

Clause 15 replaces section 60 by providing the prescribed standard for a person manufacturing, selling, supplying or using paint is the current Poisons Standard under section 52A(1) of the *Therapeutic Goods Act 1989* (Cwlth).

Part 4 Amendment of Radiation Safety Regulation 2010

Regulation amended

Clause 16 provides that part 4 amends the *Radiation Safety Regulation 2010*.

Insertion of new pt 3, div 1, hdg

Clause 17 inserts a new heading 'Division 1 General' before section 10 of the Radiation Safety Regulation.

Amendment of s 11 (Notification of change of circumstances—Act, s 92(2))

Clause 18 replaces section 11(a)(i) to ensure that a change of name for a prescribed licensee will not be considered a change of circumstances for the purposes of section 92(2) of the *Radiation Safety Act 1999*. As the chief executive will not issue prescribed licensees with licences, there is no longer a need to require prescribed licensees to provide the chief executive with written notice of a change of circumstances.

Insertion of new pt 3, div 2

Clause 19 inserts new division 2 (Prescribed licensees) after section 14 of the Radiation Safety Regulation.

New section 14A prescribes the circumstances when a person is taken to hold a use licence for the purposes of section 103K of the Radiation Safety Act. The person must be registered under the Health Practitioner Regulation National Law to practice as a dentist, other than as a student. The person must be using an intra-oral dental radiation apparatus for intra-oral dental plain radiography. It is a condition of the licence that the use comply with the national *Code of Practice for Radiation Protection in Dentistry (2005).*

New section 14B prescribes the circumstances when a person is taken to hold a transport licence. The person must hold an authority under a corresponding transport law to transport a radioactive substance and to transport the radioactive substance into Queensland. It is a condition of the licence that the person transports the radioactive substance in accordance with the national *Code of Practice for the Security of Radioactive Sources (2007)*.

New section 14B also includes definitions for *authority* and *corresponding transport law*.

Amendment of s 81 (Register of licensees—Act, s 207)

Clause 20 prescribes that the register that the chief executive must keep about licensees under section 81 does not include prescribed licensees, except if the prescribed licensee's licence has been cancelled or suspended. In this case the licensee's name, the date of the cancellation or suspension and the period of suspension are required to be recorded on the register.