Health Legislation Amendment Regulation (No. 2) 2014

Explanatory notes for SL 2014 No. 81

made under the

Health Act 1937
Radiation Safety Act 1999

General Outline

Short title

Health Legislation Amendment Regulation (No. 2) 2014.

Authorising law

Section 180 of the *Health Act 1937*.
Section 215 of the *Radiation Safety Act 1999.*

Policy objectives and the reasons for them

The objectives of the regulation are to:

- amend the rights of podiatrists to prescribe scheduled medicines under the *Health (Drugs and Poisons) Regulation 1996* (HDP Regulation), and to request plain film diagnostic images under the *Radiation Safety Regulation 2010* (RS Regulation);
- amend the RS Regulation to authorise physiotherapists to request plain film diagnostic images; and
- make other operational amendments to the HDP Regulation.

Podiatrists

Podiatry is the profession that deals with conditions affecting the human lower limb and foot. Podiatrists are educated to diagnose and treat a wide range of conditions, from the treatment of ingrown toenails using local anaesthetic, to the treatment of complex structural and functional abnormalities. Podiatrists work in a variety of locations including community health centres, private practice, hospitals, sports medicine clinics and nursing homes. To be able to practise in the podiatry profession in Queensland, podiatrists must be registered with the Podiatry Board of Australia under the Health Practitioner Regulation National Law (the National Law), which is scheduled to the *Health Practitioner Regulation National Law Act 2009* (Qld). To be eligible for registration, an applicant must hold a qualification in podiatry recognised by the Podiatry Board of Australia (the Board).

The scope of practice of podiatry, as determined by the Board, includes administering, possessing, prescribing, supplying or using various medicines listed on the *List of Scheduled Medicines Approved by the Podiatry Board of Australia* (the National Podiatry Scheduled Medicines List). To be able to administer, obtain, possess, prescribe, sell, supply or use scheduled medicines, a podiatrist must be granted an endorsement for scheduled medicines by the Board. Before granting an endorsement, the Board must be satisfied that the applicant has completed the necessary education pathways and is appropriately qualified to prescribe or supply certain medicines to patients for the treatment of podiatric conditions.

A podiatrist's scope of practice also includes requesting x-rays of the lower limb for patients in order to appropriately diagnose and treat various podiatric conditions. Podiatrists are considered to have the requisite knowledge and skills to assess the risk of radiation exposure inherent with x-rays against clinical need, since the use of radiography is explicitly dealt with in course work leading to a qualification for registration as a podiatrist.

Despite this scope of practice, podiatrists are still only able to prescribe medication, or request x-rays, in accordance with the legislation in the jurisdiction in which they practice. In Queensland, this is the HDP Regulation and the RS Regulation.

Under the HDP Regulation, podiatrists in Queensland are only authorised to obtain, possess and administer four medicines relating to the practice of podiatry. They are not able to prescribe or supply these medicines. Conversely, the National Podiatry Scheduled Medicines List authorises podiatrists to administer, obtain, possess, prescribe, or supply a much broader range of medicines. Similarly, podiatrists are considered appropriately qualified to request diagnostic imaging of the lower limb to complement podiatric care, however, the RS Regulation only authorises them to request images of the foot and ankle. Podiatrists in Queensland are consequently unable to work to their full scope of practice.

Amendments are required to the HDP Regulation to authorise podiatrists who hold a scheduled medicines endorsement issued by the Board to prescribe medicines from the National Podiatry Scheduled Medicines List. Amendments are also required to the RS Regulation to extend the authorisation for a podiatrist to request plain film diagnostic images of the lower leg, knee, thigh and hip. These amendments will enable podiatrists to work to their full scope of practice to better meet community needs in the provision of podiatric services.

Physiotherapists

Physiotherapy is a healthcare profession that assesses, diagnoses, treats and works to prevent disease and disability through physical means. Physiotherapists are experts in movement and function who work in partnership with their patients, assisting them to overcome movement disorders which may have been present from birth, acquired through accident or injury, or are the result of ageing or life-changing events. The scope of practice of physiotherapists ranges from minor problems, including treatment of acute sprains and strains, to the treatment of complex structural and functional abnormalities.

The RS Regulation provides that a person must not prescribe a therapeutic procedure or request a diagnostic procedure involving the irradiation of another person unless the first person is authorised to do so under a regulation.

The RS Regulation sets out who is an authorised person to request a diagnostic procedure or prescribe a therapeutic procedure. Physiotherapists are currently not authorised to request any plain film diagnostic images (x-rays). If a physiotherapist requires an x-ray of their patient in order to accurately diagnose their condition and complement their physiotherapy care, they must send their patient to a medical practitioner to request the x-ray. This places an additional time and financial burden on the patient, with a consultation by another health professional required for diagnosis of a condition that has already been identified by a physiotherapist, resulting in delays to treatment.

An amendment to the RS Regulation is required to authorise physiotherapists to request plain x-rays. This will enable physiotherapists in Queensland to work to their full scope of practice, and better meet the needs of the community in the provision of physiotherapy services.

Miscellaneous amendments

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products. The TGA approves and regulates therapeutic goods based on an assessment of risks against benefits, taking into consideration factors such as side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the products is intended for use. The *Therapeutic Goods Act 1992* (Cwth), and Therapeutic Goods Regulations and Orders set out the requirements for the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods.

The Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) is a legislative instrument consisting of decisions regarding the classification of medicines and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. The Poisons Standard aims to promote uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia. However, jurisdictions may also impose additional restrictions on access to substances and/or the labelling and packaging of therapeutic goods.

In Queensland, drugs, poisons and therapeutic substances are regulated under the HDP Regulation. The main aim of the HDP Regulation is to protect the public from the health risks associated with the inappropriate use of drugs, poisons and therapeutic substances and to minimise the risk of those substances being diverted for unlawful purposes.

Amendments to the Poisons Standard and the Australian Register of Therapeutic Goods regarding certain drugs have resulted in inconsistencies between the TGA and HDP Regulation. These amendments relate to:

- the addition of *lisdexamfetamine* (to the Poisons Standard) as a controlled drug for the treatment of attention deficit and hyperactivity disorder, and the treatment of narcolepsy and brain damage in children;
- the removal of *phenmetrazine* from the Australian Register of Therapeutic Goods, due to issues associated with abuse of this drug, resulting in it no longer being available in Australia; and

- the rescheduling of *alprazolam* in the Poisons Standard from a restricted drug to a controlled drug.

Achievement of policy objectives

Podiatrists

To achieve the policy objectives, the regulation amends the HDP Regulation to specify that an endorsed podiatrist is authorised to obtain, administer, prescribe or possess a restricted drug, or obtain, administer, prescribe or supply a poison in accordance with the newly inserted Appendix 2C. An 'endorsed podiatrist' is a podiatrist whose registration is endorsed by the Board under section 94 of the National Law, and who holds a scheduled medicines endorsement issued by the Board.

Similarly, the regulation amends the RS Regulation to extend the authorisation for a podiatrist to request plain film diagnostic images of the lower leg, knee, thigh and hip.

Physiotherapists

The regulation also amends the RS Regulation to authorise physiotherapists to request plain film diagnostic images.

Miscellaneous amendments

To ensure consistency with the TGA, the Australian Register of Therapeutic Goods, and the Poisons Standard, the regulation amends the HDP Regulation to:

- add *lisdexamfetamine* to the list of specified condition drugs;
- remove *phenmetrazine* from the list of specified condition drugs; and
- remove *alprazolam* from the list of restricted drugs of dependency.

Consistency with policy objectives of authorising law

The regulation is consistent with the main objectives of the *Health Act 1937* and the *Radiation Safety Act 1999*.

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 is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The above mentioned amendments are not expected to impose significant financial or other costs.

Consistency with fundamental legislative principles

The amendments to the HDP Regulation regarding prescribing rights of podiatrists may be considered to be a sub-delegation of power under section 4(5)(e) of the *Legislative Standards Act 1992*. The amendments authorise an endorsed podiatrist to obtain, possess, administer, prescribe or supply drugs and poisons listed in the new Appendix 2C to the HDP Regulation.

An endorsed podiatrist is a podiatrist whose registration is endorsed under section 94 of the National Law as being qualified to administer, obtain, possess, prescribe, sell, supply or use a restricted drug or poison stated in Appendix B of the podiatry guideline. The 'podiatry guideline' means the document called *Guidelines for endorsement for scheduled medicines*, published by the Board.

By allowing an external document, which is not subject to Parliamentary scrutiny, to stipulate substances with which an endorsed podiatrist may do particular things, the relevant amendments arguably do not have sufficient regard to the institution of Parliament.

However, the National Law specifies that the functions of a National Board (in this instance, the Podiatry Board of Australia) include developing or approving standards, codes and guidelines for their health profession, including the development and approval of codes and guidelines that provide guidance to health practitioners registered in the profession.

The National Law goes on to specify that a National Board must develop and recommend to the Australian Health Workforce Ministerial Council registration standards, including registration standards about the scope of practice of health practitioners registered in the profession. A National Board may develop and approve guidelines to provide guidance to the health practitioners it registers. The Podiatry Board Guideline supplements the requirements set out in the Board's *Endorsement for Scheduled Medicines Registration Standard* (the Standard). The Standard specifies that endorsed podiatrist must comply with Podiatry Board Guideline.

The National Law goes on to provide that if a National Board develops a guideline, it must ensure there is wide ranging consultation about its content. The Podiatry Board Guideline was released for public consultation on 5 November 2010. Consultation closed on 3 December 2010. Submissions were received from a range of stakeholders, including:

- Australian College of Podiatric Surgeons
- Australian Orthopaedic Association
- Australian Podiatry Association (Queensland) Inc
- Australian Podiatry Association (Western Australia)
- LaTrobe University
- Services for Australian Rural and Remote Allied Health
- Australian Medical Association
- Australian Podiatry Association (South Australia) Inc.

Targeted consultation was also undertaken with State health departments, health services, and the podiatry workforce.

In passing the National Law in Queensland, it was Parliament's intention that registration standards, and the guidelines that support these standards, was a function that sat most appropriately with the National Boards.

The rigour surrounding the development of the Podiatry Board Guideline is considered to balance any sub-delegation issue that may arise by referring to this document in the Regulation, and is consistent with the functions of the Board under the National Law.

Consultation

The Board was consulted in relation to the amendments regarding prescribing rights for podiatrists under the HDP Regulation, and to extend the authorisation of podiatrists under the RS Regulation. The Board is supportive of the amendments.

Notes on provisions

Part 1 Preliminary

Short title

Clause 1 provides the short title of the regulation.

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

Regulation amended

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

Amendment of s 78 (Specified condition drugs-amphetamine, dexamphetamine, methylamphetamine, methylphenidate, phenmetrazine)

Clause 3 amends section 78 of the HDP Regulation to include a reference to lisdexamfetamine in the heading of this section, and include lisdexamfetamine as a specified condition drug. The clause also removes the reference to phenmetrazine from both the heading and body of section 78.

Amendment of s 79 (Prescribing controlled drugs)

Clause 4 amends section 79(4)(k) of the HDP Regulation to include a reference to lisdexamfetamine, and remove the reference to phenmetrazine.

Amendment of s 82 (Conditions of dispensing)

Clause 5 amends section 82 of the HDP Regulation to include a reference to lisdexamfetamine, and remove the reference to phenmetrazine.

Insertion of new ss 172B and 172C

Clause 6 inserts a new section 172B and 172C into the HDP Regulation.

The new section 172B authorises an endorsed podiatrist to obtain, administer, prescribe or possess a restricted drug in accordance with the requirements set out in appendix 2C.

An endorsed podiatrist is defined (at clause 9) as a podiatrist whose registration is endorsed under the Health Practitioner Regulation National Law as being qualified to administer,

obtain, possess, prescribe, supply or use a restricted drug or poison stated in Appendix B of the *Guidelines for endorsement for scheduled medicines*, dated 15 March 2011, and published by the Podiatry Board of Australia..

The new section 172C authorises a podiatrist undergoing an approved program of study to administer a restricted drug listed in appendix 2C. However, the podiatrist may only administer the restricted drug on the conditions mentioned in appendix 2C, and only when acting under the personal supervision of a doctor or endorsed podiatrist.

Amendment of s 200 (Authorised persons to obtain restricted drugs on purchase order)

Clause 7 amends sections 200 to authorise an endorsed podiatrist to place a purchase order for a restricted drug.

Amendment of s 235 (Wholesale and retail sales by manufacturers and wholesalers)

Clause 8 amends section 235(2)(b)(i) to authorise poison manufacturers and wholesalers to sell an S2 or S3 poison to an endorsed podiatrist.

Insertion of new ss 260B and 260C

Clause 9 inserts a new section 260B and 260C into the HDP Regulation.

The new section 260B authorises an endorsed podiatrist to obtain, administer, prescribe or supply a poison in accordance with the requirements set out in appendix 2C.

The new section 260C authorises a podiatrist undergoing an approved program of study to administer a poison listed in appendix 2C. However, the podiatrist may only administer the poison on the conditions mentioned in appendix 2C, and only when acting under the personal supervision of a doctor or endorsed podiatrist.

Insertion of new appendix 2C

Clause 10 inserts a new appendix 2C into the HDP Regulation. Appendix 2C sets out the restricted drugs and poisons (and any conditions associated with their administration or prescription) which endorsed podiatrists and trainee endorsed podiatrists can obtain, administer, prescribe, possess or supply. The conditions for administering restricted drugs and poisons set out in column 3 of appendix 2C should be read in conjunction with the already established definition of ‘administer in appendix 9 of the HDP Regulation. That is, to give a person a single treatment dose of the drug or poison to be taken by the person immediately.

Amendment of appendix 8 (Restricted drugs of dependency)

Clause 11 amends appendix 8 or the HDP Regulation to remove the entry for alprazolam.

Amendment of appendix 9 (Dictionary)

Clause 12 amends appendix 9 of the HDP Regulation to include definitions for the terms 'approved program of study', 'endorsed podiatrist', 'podiatric procedure', 'podiatry guideline', and 'trainee endorsed podiatrist'.

An 'approved program of study', for a trainee endorsed podiatrist, means an approved program of study for endorsement of registration in podiatry under the Health Practitioner Regulation National Law.

An 'endorsed podiatrist' is a podiatrist whose registration is endorsed under section 94 of the Health Practitioner Regulation National Law as being qualified to administer, obtain, possess, prescribe, sell, supply or use a restricted drug or poison stated in Appendix B of the podiatry guideline.

A 'podiatric procedure' means a diagnostic or therapeutic procedure relating to the foot, ankle or lower leg.

'Podiatry guideline' means the *Guidelines for endorsement for scheduled medicines*, published by the Podiatry Board of Australia. The guidelines are available on the website of the Board at www.podiatryboard.gov.au.

A 'trainee endorsed podiatrist' is a podiatrist undergoing an approved program of study.

Part 3 Amendment of Radiation Safety Regulation 2010

Regulation amended

Clause 13 specifies that this part amends the *Radiation Safety Regulation 2010*.

Amendment of sch 6 (Authorised persons)

Clause 14 amends schedule 6, part 1, item 3, column 2 to include a physiotherapist as a person authorised to request plain film diagnostic radiography.

The clause also amends schedule 6, part 1, item 5, column 1 to extend the authorisation for a podiatrist to request plain film diagnostic images of the lower leg, knee, thigh and hip (in addition to the foot and ankle).

Amendment of sch 9 (Dictionary)

Clause 15 amends schedule 9 of the RS Regulation to include a definition for 'physiotherapist'. A physiotherapist is a person registered under the Health Practitioner Regulation National Law to practise in the physiotherapy profession, other than as a student.

ENDNOTES

1 Laid before the Legislative Assembly on . . .

2 The administering agency is Queensland Health.