From: [redacted]
To: State Development, Natural Resources and Agricultural Industry Development Committee
Cc: [redacted]
Subject: Submission from Orthoptics Australia to Medicines and Poisons Bill 2019
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Attachments: Medicines and Poisons Bill QLD 2019 V3.pdf
ATT00001.htm
FINAL DTP Orthoptist CH008007 - Att 1 FINAL.pdf
ATT00002.htm
ATT00003.htm

Dear Committee

Please find attached the submission and an Appendix 1 from Orthoptics Australia to the committee. We are very concerned about the proposed changes in the Bill and would seek changes to the proposal for orthoptists to continue to perform their duties in the Queensland health system. We have the support of our full Council and all our Queensland based orthoptists for our proposed changes.

We will be seeking endorsement for this position from the Australian Orthoptic Board and Royal Australian and New Zealand College of Ophthalmologists.

We would be happy to appear before the committee or provide any further information

orthoptics australia

Committee Secretary
State Development, Natural Resources and Agricultural Industry Development Committee
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Submission from Orthoptics Australia to Medicines and Poisons Bill 2019

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[redacted]

5 June 2019

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Summary

Orthoptics Australia proposes that the Queensland Medicines and Poisons Bill 2019 better reflect the current practice of Orthoptics and eye care in Australia and allow Registered Orthoptists to have the same rights for administering a topical S2, S3 or S4 medicine as Optometry which is a parallel Allied Health eye care discipline in Australia.

Background

The university-based education for orthoptists and the coverage of pharmacology in the course is taught to a similar standard as Optometry and Podiatry who, as Allied Health Practitioners, both administer drugs. Optometrists are able to administer these classes of medicines in the course of their everyday practice. Podiatrists can have endorsed status for both administration and prescription of drugs following a prescribed program following guidelines established by NPS Medicinewise and mentorship endorsed by the Podiatry Board of Australia. The basic pharmacology is similar for all 3 professions and in fact is shared at La trobe university with Podiatry students.

Orthoptists are extensively employed in public hospitals across Australia and Queensland. Orthoptists in Australia including Queensland have been administering topical ophthalmic preparations under approved protocols of medical practitioners for over 70 years.[1]

Orthoptists are employed in the majority of ophthalmic practices in Australia.[2]

Orthoptists are involved closely with ophthalmologists in the investigation treatment and management of all forms of eye disease across Australia. In many jurisdictions orthoptists already have approval protocols in place to administer the range of ophthalmic medicines including Queensland under existing protocols.

Current Proposal

The current bill proposes
Part 4 Orthoptists
8 Administering generally
(1)An orthoptist may administer a topical ophthalmic preparation on a prescription from an ophthalmologist.
(2)Unchanged

Recommendation

OA recommends that Clause (1) be changed to read:

An orthoptist may administer a topical S2 S3 or S4 medicine to a patient if the medicine is stated in an appendix on Australian Orthoptic Board Guidelines for the use of scheduled medicines.
Clause (2) remain unchanged
This statement, if adopted in the Bill , would bring Orthoptic practice into line with Optometry practice in Queensland.

This would bring the use of medicine by non-medical prescribers into general alignment with Optometry for non-medical prescribers.

Current Protocols for Registered Orthoptists

The current protocols in Queensland for registered orthoptists states clearly in the Health Act 1930 Amendment No 1 2011.
'170A Orthoptists
59

1. '(1) To the extent necessary to practise orthoptics, an orthoptist who has the relevant qualifications is authorised to—
    1. (a) obtain a restricted drug; and
    2. (b) possess a restricted drug; and

    (c) administer a restricted drug under a drug therapy protocol.
2. '(2) In this section—

relevant qualifications means the qualifications required under a drug therapy protocol to administer.

The Regulations pertain to a specified list of topical ocular preparations for use as specified under a Health Management Protocol. Written authorisation from a medical practitioner is not required on an individual patient basis for administration of a drug specified in the Drug Therapy Protocol by an orthoptist.

The proposed requirement under the new proposed bill to have a script in the patient's name would not allow orthoptists to perform their clinical duties in a timely manner. It would slow down clinical management of patients. It is impractical.

It is impossible for hospital pharmacies to fill scripts for each patient in their own name in a busy clinic and against standard practice regime of using topical drops for numerous patients under agree protocols.

Current Practice

Ophthalmology clinical units use topical drugs for multiple patients in each clinic. It would mean delays in clinical management and investigation of patients in ophthalmology departments and clinics and impossible to administer in clinics away from local pharmacies. The incremental cost of a single use topical medicine for every patient in a diagnostic session is an unsustainable waste of medication and markedly increases the cost of eye health delivery. It would hinder investigation and management

of ophthalmic disease in a cost efficient and safe manner. It is contrary to modern ophthalmic practice in most jurisdictions around the world.

For orthoptists to have the right to administer an S 2, 3 ,4 medicine under an extended practice authority as is currently allowed under the above Health Bill with an extended practice authority does allow orthoptists to continue to provide the medical investigation for timely management of patients.

The proposed amendment is regressive and contrary to the established practice of best practice ophthalmic care in all states in Australia. Orthoptists possessing and administering topical medicine has been in common practice for over 70 years in Australia.

The current proposal to allow orthoptists to administer a topical ophthalmic preparation on a prescription for the patient from an ophthalmologist fundamentally changes the current concept of use in Queensland making ophthalmology clinics unworkable. Nearly every patient attending hospital department or private ophthalmology clinic requires topical ophthalmic medicines for investigation and management. Without the right to obtain administer and possess a restricted drug there will be unacceptable delays to receiving best practice care in Queensland.

Best practice clinical management should allow ophthalmology departments and clinics to have protocols in place to allow orthoptists to instil topical medicines without the necessity of individual scripts.

Suggested Protocols

Orthoptics Australia proposes that the Australian Orthoptic Board (AOB) could adopt a similar format to "Guidelines for use of scheduled medicines" made by the Optometry Board on 10th September 2018. This would ensure consistency of the use of scheduled medicine in orthoptic and optometric practice.

We note the clauses under external Standards and Guidelines including Schedule 8 Clause 3 in the Bill and propose that exactly the same exacting standards of listing scheduled medicines could apply to the AOB ensuring Queenslanders continue to receive industry best practice in the delivery of eye and health care.

Orthoptics Australia strongly believe that registered orthoptists are appropriately qualified, trained and regulated to possess and administer all these Scheduled ophthalmic preparations as listed on the Optometry Board website.

Their tertiary university education ensures competent and effective use ophthalmic medications to ensure patient safety and wellbeing.

Summary of Orthoptists Ability to Possess and Administer S2, 3,4 Drugs

1. Orthoptists are appropriately trained to possess, prescribe and administer Schedule 2,3,4 drugs,

and have equivalent university training to other allied health professionals who have existing administering rights in Australia.

2. The orthoptic profession is regulated by the Australian Orthoptic Board, an independent board established to register and maintain professional standards for orthoptists and to establish on going continuing professional guideline standards.
3. This registration board is recognised by Medicare, Veteran's Affairs, the National Disability Insurance Scheme and Medibank Private.
4. There is a public health need for increased scope of practice for orthoptists in Queensland in relation to the use of Scheduled ophthalmic drugs.
5. Allowing orthoptists to administer a wide range of topical ophthalmic medicine gives better patient access to investigation and treatment and decreases hospital waiting lists for access to clinical outpatients and inpatients.

Orthoptic Training in Australia

Currently, there are two orthoptic training centres in Australia: La Trobe University in Victoria and The University of Technology Sydney in New South Wales.

La Trobe University offers the Bachelor of Applied Science with honours in Orthoptics. The duration of this course is equivalent to 4 years of full-time study. Details of each of these subjects can be found on the La Trobe University website.

The University of Technology Sydney offers the Master of Orthoptics which is a two-year, full-time graduate entry course. The core subjects and details of each of these subjects can be found on the University of Technology Sydney website.

Regulation and Registration of Orthoptists

The Australian Orthoptic Board

The Australian Orthoptic Board (AOB) is the registration body for orthoptists in Australia. It is a company constituted of the directors of the Australian Orthoptists Registration Body Pty Ltd. The function of the Australian Orthoptic Board is to regulate the profession of orthoptics in order to protect the public. It investigates the professional conduct and fitness to practice of registered orthoptists.

A register of currently registered orthoptists is held by the Board and this can be accessed from their website. As of May 2018, there were nearly 800 orthoptists registered with the Australian Orthoptic Board.

Requirements for Registration

Requirements for registration with the Australian Orthoptic Board include graduation from a specified Australian orthoptic program such as those detailed above.

Orthoptists who have trained in a country other than Australia are required to hold a qualification recognised by the International Orthoptic Association. In addition, internationally trained orthoptists must submit their curriculum of their training for scrutiny by the AOB and may be required to pass an exam to demonstrate that they meet Australian training standards before Board registration is granted.

Recognition of Orthoptists by other Regulatory and Government Bodies
Registered orthoptists may apply for a Medicare provider number using Medicare form HW073.

They are eligible to apply to be a registered provider for the National Disability Insurance Scheme Disability scheme. Under the Veterans' Entitlements Act of 1986, registered orthoptists can also apply to register as a Repatriation Commission provider.

Medibank Private recognises that orthoptists with a certificate of currency from the Australian Orthoptic Board meet the requirements of providers under the Federal Private Health Insurance Act of 2007. In addition, the Australasian Sonographers Accreditation Registry recognises registration with the Australian Orthoptic Board as appropriate for orthoptists to undertake sonography in relation to ocular structures.

For orthoptists to have the right to administer an S 2, 3, 4 medicine under the proposed protocol of individual scripts does not allow flexibility and takes the decision making on good clinical management away from the public hospital ophthalmology clinics, ophthalmologist and orthoptist. It is detrimental to good clinical management and patient experience.

Current Orthoptic Practice

Traditional orthoptic practice involves the diagnosis and management of eye movement disorders, strabismus and amblyopia. The current guidelines for investigation of these conditions require the use of cycloplegic agents, and management options for amblyopia include the use of atropine.[8, 9] Current evidence shows that atropine is effective in treating amblyopia and has a more favourable psychosocial impact than occlusion therapy in children.[10-12] Therefore, in order for orthoptists to successfully diagnose and manage strabismic conditions and amblyopia, they are required to possess and administer cycloplegic topical agents, including atropine.

It is also imperative that orthoptists have access to and the right to administer topical ophthalmic local anaesthetics, cycloplegics and mydriatics to perform their duties as an orthoptist while investigating other ophthalmic conditions. As seen in the Outpatient Diagnostic Eye Drop Procedure protocol of the Royal Victorian Eye and Ear Hospital routine administration of tropicamide 0.5% eye drops is required in every outpatient clinic. Proxymeacaine 0.5%, oxybuprocaine 0.4% and phenylephrine 2.5% eye drops are also required in the majority of clinics.

Current restrictions are also a barrier to developing innovative service delivery models to address increasing demand for eye care services. Ophthalmic clinics in public hospitals are already overburdened by the number of patients requiring care.[13, 14] Orthoptic lead integrated care programs have been implemented in several locations to provide effective care to patients in a timely manner

and reduce the financial burden associated with ophthalmic care.[13, 15-19] However, in order for these programs to generate maximum cost effectiveness and patient benefit, orthoptists must have access to scheduled medicines and be able to use their clinical reasoning skills to determine to whom ophthalmic preparations should be administered.

For orthoptists to have the right to administer an S 2, 3, 4 medicine under the proposed protocol of individual scripts does not allow flexibility and takes the decision making on good clinical management away from the public hospital ophthalmology clinics, ophthalmologist and orthoptist. It is detrimental to good clinical management and patient experience.

Further Information on Ophthalmic Medications

In the practice of their profession, medical practitioners authorise orthoptists to administer several Schedule 4 ophthalmic preparations including those listed in Table 1 across various jurisdictions in different Australian states.

The use of each of the preparations listed in Table 1 can be categorised into three main groups: those required for diagnostic purposes, those required prior to or following ophthalmic procedures, and those required for treatment. Diagnostic drugs include those required for assessment of ocular alignment, refraction, contact lens fitting, electrophysiological testing, ocular biometry, pachymetry, tonometry, triage, ocular imaging and assessment of the fundus. In-office laser procedures, minor surgical procedures, intravitreal injections and day surgical procedures all require the prior administration of Schedule 4 drugs.

Tropicamide (0.5%), cyclopentalate (1%), atropine (0.1%, 0.5% and 1%), tetracaine (0.5%) and fluorescein sodium (1%) are among the ophthalmic topical solutions listed on the World Health Organisation Model List of Essential Medicines.[3] The list names the most efficacious, safe and cost-effective medicine needed for a basic health-care system.

Table 1: Schedule 4 drugs currently administered by orthoptists in the practice of their profession in various jurisdictions

Therapeutic class	Name (Concentration)	Purpose[a]
Anti-infective	Aciclovir (≤3%)	C
	Chloramphenicol (≤0.5%)	B, C
	Ciprofloxacin hydrochloride (≤0.3%)	B, C
	Ofloxacin (≤0.3%)	B, C
	Tobramycin (≤0.3%)	B, C
Cycloplegics, Mydriatics and Miotics	Atropine (≤1%)	A, B
	Cyclomydryl (Cyclopentolate hydrochloride 0.5% and phenylephrine hydrochloride 1%)	A, B A, B
	Cyclopentolate hydrochloride (≤1%)	A, B, C
	Homatropine hydrobromide (≤2%)	A, B
	Tropicamide (≤1%)	A, B

	Phenylephrine hydrochloride (≤10%) Pilocarpine hydrochloride (≤4%)	A, B
Non-steroidal anti-inflammatory	Diclofenac sodium (≤0.1%)	B, C
Ophthalmic local anaesthetics	Lignocaine hydrochloride (≤4%) Oxybuprocaine hydrochloride (benoxinate ≤0.4%) Proxymetacaine hydrochloride (≤0.5%) Tetracaine hydrochloride (≤0.5%)	B B A, B A, B
Ocular anti-hypertensive	Apraclonidine hydrochloride (≤0.5%) Betaxolol hydrochloride (≤0.5%) Bimatoprost (≤0.03%) Brimonidine (≤0.2%) Brinxolamide (≤1%) Dorzolamide hydrochloride (≤2%) Latanoprost (≤0.005%) Levobunolol hydrochloride (≤0.5%) Timolol maleate (≤0.5%) Travoprost (≤0.004%) Acetazolamide[b] (≤250 mg)	C C C C C C C C C C
Ocular Steroids	Dexamethasone (≤0.1%) Fluorometholone (≤0.1%) Predneferin forte (Prednisolone acetate 10% and phenylephrine hydrochloride 1.2%) Prednisolone acetate (≤0.1%)	C C C C C
Miscellaneous	Sodium fluorescein (≤2%) Fluorescein sodium solution[c] (≤10%)	A A

[a] Purpose of drops in orthoptic practice:
A: Diagnostic
B: Pre- or post- ophthalmic procedure
C: In office treatment
[b] To be administered orally
[c] To be administered intravenously

Risk of Complications from the use of Ophthalmic Preparations

Mydriatics, by design, decrease the field of focus and increase photosensitivity. These effects are temporary and expected. Unwanted side effects of tropicamide, an anticholinergic agent, include a transient rise in intraocular pressure. It can rarely lead to acute-angle-closure glaucoma in individuals with narrow anterior chambers. However, a systematic review published in 2000 found that the incidence of acute glaucoma following mydriasis with tropicamide alone was close to zero, and was 1 in 18,020 following dilation by any of atropine, homatropine, phenylephrine, tropicamide, cyclopentolate or hydroxyamphetamine.[4] The risk of angle closure can be minimised by assessing anterior chamber depth before instillation of mydriatic agents.

A meta-analysis completed in 2015 found no evidence of increased heart rate or blood pressure after the installation of 2.5% phenylephrine eye drops, and that any increase after the installation of 10% phenylephrine eye drops was short lived.[5] The authors concluded that 2.5% phenylephrine was safe to use as diagnostic aid clinical practice.

The systemic side effects of atropine include flushing of the face, tachycardia, dry mouth and irritability. Atropine is contraindicated in certain populations and therefore its use must be carefully considered.

The side effects of ophthalmic topical local anaesthetics are rare but the abuse of these agents can lead to corneal pathology in patients who are allowed unrestricted access.[6] In orthoptic practice, local anaesthetics are either given in a single application for diagnostic testing, or repeated application over a short period of time in preparation for ophthalmic procedures. In a double-blind randomised clinical trial, 1% tetracaine hydrochloride drops applied up to every 30 minutes for 24 hours did not result in any ocular complications.[7]

As can be seen from the included evidence the risk of harm is low and orthoptists are well qualified to understand the risks and management of complications.

Best Practice Recommendations for Monitoring Eye Disease

An integrative care model can also be extended to monitoring ophthalmic diseases of aging such as glaucoma and diabetic retinopathy.[13, 19] The increasing prevalence of ophthalmic diseases in older Australian adults has had a considerable impact on the economy.[20 21-23] It is necessary to restructure the current models of care to ensure the future sustainability of ophthalmic care, and the ability of orthoptists to possess and administer scheduled drugs is essential for the success of these revised models. These motivating factors led to the exemptions to prescribing regulations for orthoptists in the United Kingdom in 2016. Where orthoptists can also prescribe S4 drugs with protocols similar to the current requirement for Optometrists in Australia. A summary of the perceived impact of these regulations can be reviewed online.

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Appendix A

Health (Drugs and Poisons) Regulation 1996. Drug Therapy Protocol - Orthoptist

Health (Drugs and Poisons) Regulation 1996

Drug Therapy Protocol - Orthoptist

Environmental Health Branch
15 Butterfield Street
PO Box 2368
Fortitude Valley BC 4006
Telephone (07) 3328 9310
Facsimile (07) 3328 9354

Health (Drugs and Poisons) Regulation 1996

Drug Therapy Protocol - Orthoptist

This drug therapy protocol, made under s170(A)(1) and s256AA(1) of the *Health (Drugs and Poisons) Regulation 1996* states the circumstances and conditions under which an orthoptist[1] is authorised to administer a Scheduled restricted drug or Scheduled poison listed in Appendix 1 to this document.

Conditions and circumstances of this Drug Therapy Protocol

1. An orthoptist may only administer those restricted drugs or poisons listed in Appendix 1 for which a Health Management Protocol has been developed and approved by their employer. The required minimum contents of the Health Management Protocol are contained in Appendix 2.

2. The actions of the orthoptist must at all times be in accordance with this Drug Therapy Protocol and the Health Management Protocol.

3. The orthoptist must have access to current versions of the following literature:
   3.1 A copy of this Drug Therapy Protocol; and
   3.2 The current Health Management Protocol relevant to this Drug Therapy Protocol; and
   3.3 A current MIMS Annual and Australian Medicines Handbook; and
   3.4 A current copy of the *Health (Drugs and Poisons) Regulation 1996.*

4. The orthoptist must be aware that practising within the Drug Therapy Protocol does not relieve that person of their legal responsibility or accountability for that person's actions and may not provide immunity in case of negligence.

5. Prior to the administration of a restricted drug or poison, the orthoptist must familiarise themselves with the contra-indication(s) and known side effects of the drug or poison, and advise the patient accordingly.

6. The orthoptist must hold a qualification that is acceptable to the Australian Orthoptists Registration Body Pty Ltd ACN 095 117 678 to enable the orthoptist's name to be recorded in the Register of Orthoptists.

Certification

Certified at Brisbane on this 9th day of January 2012.

Dr Jeannette Young
Chief Health Officer
Queensland Health

[1] An orthoptist means a person whose name is recorded in the Register of Orthoptists kept by the Australian Orthoptists Registration Body Pty Ltd CAN 095 117 678

Appendix 1

SCHEDULED SUBSTANCES	APPROVED ROUTE OF ADMINISTRATION	RESTRICTIONS CONDITIONS
CYCLOPLEGICS MYDRIATICS MIOTICS		
Cyclopentolate Hydrochloride 1% or less	Ocular	1 drop each eye. May be repeated once after 5 or 10 mins if required.
Homatropine Hydrobromide 2% or less	Ocular	1 or 2 drops each eye. May be repeated once after 5 or 10 mins if required.
Atropine 1% or less	Ocular	1 drop each eye.
Tropicamide 1% or less	Ocular	1 or 2 drops each eye. May be repeated after 5 mins then again after 20 mins if required
Phenylephrine Hydrochloride 2.5% or less	Ocular	1 drop each eye. May repeat once after 1 hour if required.
Phenylephrine Hydrochloride 10%	Ocular	Under instruction from an ophthalmologist.
Pilocarpine Hydrochloride/Nitrate 4% or less	Ocular	1 drop each eye on the completion of examination on the instruction from an ophthalmologist.

TOPICAL LOCAL ANAESTHETICS		
Proxymetacaine Hydrochloride 0.5% or less	Ocular	1 or 2 drops as required.
Oxybuprocaine Hydrochloride 0.4% or less	Ocular	1 or 2 drops as required.
Amethocaine Hydrochloride 0.5% or less	Ocular	1 or 2 drops as required.
Lignocaine Hydrochloride 4% or less Fluorescein 0.25%	Ocular	1 or 2 drops as required.
OCULAR STEROIDS		
Fluorometholone 0.1%	Ocular	Under instruction from an ophthalmologist.
Dexamethasone 0.1%	Ocular	Under instruction from an ophthalmologist.
Prednisolone sodium phosphate 0.5%	Ocular	Under instruction from an ophthalmologist.
OCULAR ANTI-INFECTIVE		
Chloramphenicol 0.5%	Ocular	Under instruction from an ophthalmologist.

Ciprofloxacin hydrochloride 0.3%	Ocular	Under instruction from an ophthalmologist.
Ofloxacin 0.3%	Ocular	Under instruction from an ophthalmologist.
Tobramycin 0.3%	Ocular	Under instruction from an ophthalmologist.
Aciclovir ophthalmic ointment 3%	Ocular	Under instruction from an ophthalmologist.
GLAUCOMA PREPARATIONS		
Betaxolol hydrochloride 0.5%	Ocular	Under instruction from an ophthalmologist.
Timolol maleate 0.5% or less	Ocular	Under instruction from an ophthalmologist.
Levobunolol hydrochloride 0.5% or less.	Ocular	Under instruction from an ophthalmologist.
Apraclonidine hydrochloride 0.5% or less	Ocular	Under instruction from an ophthalmologist.
Brimonidine 0.2% or less tartrate	Ocular	Under instruction from an ophthalmologist.
Brinzolamide 1%	Ocular	Under instruction from an ophthalmologist.
Dorzolamide hydrochloride 2%	Ocular	Under instruction from an ophthalmologist.

Latanoprost 0.005%	Ocular	Under instruction from an ophthalmologist.
Bimatoprost 0.03%	Ocular	Under instruction from an ophthalmologist.
Travoprost 0.004%	Ocular	Under instruction from an ophthalmologist.
OCULAR ANTI-INFLAMMATORIES		
Diclofenac sodium 0.1%	Ocular	Under instruction from an ophthalmologist

Appendix 2

Health Management Protocol – Minimum Requirements

1. The employer must have a current Health Management Protocol that supports and details the clinical use, being the administration of restricted drugs or poisons listed in Appendix 1 of this Drug Therapy Protocol.
2. The Health Management Protocol must be developed or another organisation's Health Management Protocol may be adopted by an interdisciplinary health team appointed by the employer under whose jurisdiction the Health Management Protocol will be implemented.
3. As a minimum, the interdisciplinary team must consist of an ophthalmologist, orthoptist and pharmacist, and may include other identified professional personnel as considered appropriate by the employing organisation.
4. Following a period of two years or sooner if considered necessary, the Health Management Protocol must be reviewed by an interdisciplinary team.

Content of a Health Management Protocol

The Health Management Protocol must clearly identify:

1. The procedures for clinical assessment, management, and follow-up of patients.
2. a clinical indication or time when medical referral/consultation must occur for that condition (where applicable)
3. The name, form and strength of the drug and the condition/situation for which it is intended.
4. The recommended dose of the drug.
5. The route of administration of the drug.
6. The frequency (including rate where applicable) and duration of administration of the restricted drug or poison.
7. The type of equipment and management procedures required for management of an emergency associated with the use of the drug.

Endorsement of a Health Management Protocol by the Chief Executive Officer of a Health Service District or Chief Executive Officer of a non-Queensland Health employing organisation.

1. A new or reviewed Health Management Protocol must be endorsed and dated by the Chief Executive Officer of a Health Service District or the Chief Executive Officer of a non-Queensland Health employing organisation.
2. The Health Management Protocol shall be effective for a maximum of two (2) years from the date of endorsement by the employer.