

## Public consultation paper

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1 February 2017

You are invited to provide feedback on this public consultation

*Revised Endorsement for scheduled medicines registration standard and Guidelines for use of scheduled medicines*

### Background

The Optometry Board of Australia (the Board) is releasing the attached consultation paper on the review of the *Endorsement for scheduled medicines registration standard and Guidelines for use of scheduled medicines*.

To provide feedback to this public consultation, please provide your comments in a word document by email to [optomconsultation@ahpra.gov.au](mailto:optomconsultation@ahpra.gov.au) by **close of business on 31 March 2017**. A response sheet has been provided with this consultation paper.

### How your submission will be treated

Submissions will generally be published unless you request otherwise. The Board publishes submissions on its website to encourage discussion and inform stakeholders and the community. However, the Board retains the right not to publish submissions at its discretion, and will not place on its website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the consultation.

Before publication, the Board will remove information that personally identifies individuals making submissions, including their contact details. Views expressed in submissions are those of the individuals or organisations who submit them and publication does not imply any acceptance of, or agreement with, those views by the Board.

The Board also accept submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the Freedom of Information Act 1982 (Cth), which has provisions designed to protect personal information and information given in confidence.

Please let the Board know if you do not want your submission published, or want all or part of it treated as confidential.

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1 February 2017

## General overview of consultation

### **Review of approved *Endorsement for scheduled medicines registration standard and Guidelines for use of scheduled medicines***

Under sections 38 and 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), the Optometry Board of Australia (the Board) may develop registration standards and guidelines to provide guidance to the health practitioners it registers.

The Board has approval in accordance with section 14 of the National Law from the Australian Health Workforce Ministerial Council (Ministerial Council) to endorse the registration of an optometrist as being **qualified** to administer, obtain, possess, prescribe or supply schedule 2, 3, or 4 medicines used in the topical treatment of conditions of the eye included in the list approved and published by the Board.

The Board developed an *Endorsement for scheduled medicines registration standard* (the current registration standard) which sets out the requirements for an optometrist to have their registration endorsed for scheduled medicines. The current registration standard was approved by the Ministerial Council and took effect on 1 July 2010.

The Board also developed and approved *Guidelines for endorsement for use of scheduled medicines* (the guidelines) that outline the Board's expectations about the use of scheduled medicines by optometrists. The guidelines have been revised and the current version took effect in December 2014.

The Board is reviewing the registration standard in keeping with good regulatory practice under section 40 of the National Law. It is also proposing some associated changes to the scheduled medicines guidelines and its approval in accordance with section 14 of the National Law to align with the proposed changes in the revised registration standard. The Board is inviting comments on the proposed draft revised registration standard and guidelines.

**Please provide feedback in a word document by email to [optomconsultation@ahpra.gov.au](mailto:optomconsultation@ahpra.gov.au) by close of business on 31 March 2017. A response sheet has been provided with this consultation paper.**

## Overview: Review of Endorsement for scheduled medicines registration standard and Guidelines for use of scheduled medicines

### Issues

The current *Endorsement for scheduled medicines registration standard* (the current standard) has been in place for over five years and is due for review. The Board is now consulting on proposed changes to it.

#### Improving the effectiveness and efficiency of the standard

The current standard attaches a list of schedule four (S4) medicines that optometrists holding a scheduled medicines endorsement are qualified to obtain, possess, administer, prescribe or supply for topical use in the treatment of conditions of the eye.

As the list is attached to the registration standard, any changes to the list require Ministerial Council approval. The process of seeking Ministerial Council approval involves considerable time and resources. This process is necessary to both remove scheduled medicines that are no longer available as well as to add newly available medicines, and the timeframes involved may inadvertently delay the public's ability to access up to date medications from an endorsed optometrist.

In order to achieve greater effectiveness and efficiency and to facilitate the delivery of eye health services, the Board has identified an opportunity to solve this issue through a simple change of wording.

The revised draft proposes that the registration standard removes the list of medicines from the standard and instead refers to classes of topical medications used in the practice of optometry. The classes proposed are schedule two (S2), schedule three (S3) and schedule four (S4) topical eye medications, being classes of topical medications that endorsed optometrists are currently qualified to use for the treatment of conditions of the eye. This proposed change does not alter the scope of the current endorsement.

This approach would establish a simpler, more responsive and more efficient way to ensure that patients of endorsed optometrists can access current topical eye medications from S2, S3 or S4 classes.

For additional clarity, the Board proposes to publish a list of the medications currently in the approved classes in the *Guidelines for use of scheduled medicines*.

The Board's Scheduled Medicines Advisory Committee (SMAC) will monitor the content of the list in each class approved by the Ministerial Council and advise the Board when the list needs to be updated. The SMAC is an expert, multidisciplinary committee of medical practitioners, pharmacists and optometrists.

The Board's current registration standard approved by the Ministerial Council ensures that endorsed optometrists are **qualified** in respect of use of scheduled medicines. However, the **authorisation**, in respect of the use of scheduled medicines remains the subject to state and territory legislation.

The classification of a medicine as a S2, S3 or S4 medication is regulated by a committee of the [Therapeutic Goods Administration \(TGA\)](#) which is the regulatory body for therapeutic goods including medicines.

The TGA is a division of the Department of Health established under the Therapeutic Goods Act 1989 (Cth). The TGA produces the Standard for the Uniform Scheduling of Medicines and Poisons which is a legislative instrument used by state and territory health departments in their state and territory based regulation of drugs and poisons.

#### Wording in the scope of application and public register about endorsed optometrists

A further issue involves the wording in the current standard in the sections headed *Scope of application* and *Wording to appear on the register*. Both sections include the wording 'treatment of conditions of the eye'. This wording does not align with that used in the majority of relevant state and territory legislation, for example section 17B of the New South Wales [Poisons and Therapeutic Goods Act 1966](#). The Board proposes amending the wording in the registration standard from 'treatment of conditions of the eye' to 'the purposes of the practice of optometry'.

The Board also proposes to add the word 'use' to the registration standard and the guideline as it appears that it was unintentionally omitted in the original request in 2010. An example of clarification of terms 'administer' and 'use' is found on the Department of Health and Human Services [website](#), where 'use' is described as meaning to personally introduce a medicine to a person's body (or personally observe its introduction).

More information is found in the Drugs, Poisons and Controlled Substances Act 1981 and the Drugs, Poisons and Controlled Substances Regulations 2006.

As such, the Board will request to amend the approval under section 14 of the National Law from the Ministerial Council to endorse the registration of an optometrist as being qualified to administer, obtain, possess, prescribe, supply or **use** topical schedule 2, 3, or 4 medicines **for the purposes of the practice of optometry**.

The proposed approach would provide greater clarity and reduce inconsistent terminology about prescribing of scheduled medicines by optometrists.

**Note:** There are no changes to the current scope of the endorsement. The purpose of the proposed changes are to improve the efficacy of the standard with respect to patient access to topical eye medicines and to better reflect the wording in the current drugs and poisons legislation.

### Guidelines for use of scheduled medicines

Under section 39 of the National Law, a National Board may develop and approve codes and guidelines to provide guidance to the health practitioners it registers; and about other matters relevant to the exercise of its functions.

The Board's *Guidelines for use of scheduled medicines* (guidelines) were developed under Section 39 of the National Law to outline the Board's expectations about the use of scheduled medicines by optometrists.

The current version of the guidelines came into effect in December 2014. The proposed revisions include changes only as a consequence of the proposed changes to the registration standard.

### Options statement

#### Option 1 – Status quo (continue with current standard and guidelines)

Under this option, the current registration standard and guidelines would remain in effect. This approach maintains ministerial oversight of the list of S4 medicines attached to the registration standard. However, the Board has identified that there are unnecessary administrative costs and time involved to keep the list of S4 medicines up to date because Ministerial Council approval of any changes to the standard are required.

The status quo means that when a scheduled medicine has been removed from the market, for example due to patient safety reasons, the Board is unable to amend the list promptly.

Maintaining the status quo will continue the significant delay in optometrists being able to prescribe new topical S4 medicines for eye conditions. Until approval to add the new medicine is granted, optometrists will continue to refer patients requiring that medicine to a medical practitioner although optometrists are qualified to prescribe it.

## Option 2 – Revise the registration standard and guidelines

Under this option the registration standard would continue to define the requirements for endorsement for scheduled medicines, with the following changes:

- The proposed revised registration standard and guidelines would be edited to make them clearer and easier to understand.
- The Board-approved list of scheduled medicines currently attached to the standard will:
  - be attached to the guidelines, and
  - be replaced with a description of classes of schedule medicines to which the endorsement applies in the standard.
- The Board will endorse the registration of optometrists as being qualified to administer, obtain, possess, prescribe, supply or **use** medicines, in accordance with relevant state and territory legislation, in the following classes: topical schedule 2, 3 or 4 medicines for **the purposes of the practice of optometry** where:
  - ‘the purposes of the practice of optometry’ replaces the current term ‘treatment of conditions of the eye’ for additional clarity and consistency with state and territory drugs and poisons legislation, and
  - ‘use’ has been added for additional clarity and consistency with state and territory drugs and poisons legislation.

Under Option 2, the Board will continue to review its guidelines at least every three years and any amendment to the proposed guidelines after the review will require wide-ranging consultation. In addition, any minor changes to the list of scheduled medicines in [Appendix B](#) (before a scheduled review of the guidelines) will need consultation with relevant key professional bodies.

### Preferred option

The Board prefers option 2.

### Approval process

The proposed revised registration standard would be recommended by the Board for approval by the Ministerial Council and, subject to Ministerial approval of the registration standard, the Board would then approve the associated guideline.

### Issues for discussion

#### Potential benefits of the proposed option 2

The potential benefits of option 2 are that the draft revised registration standard and guidelines:

- continue to protect the public by ensuring that only suitably qualified and competent practitioners can have their registration endorsed for scheduled medicines
- provide that the list of S4 medications that endorsed optometrists are qualified to prescribe in the guidelines will, following consultation, enable the Board to keep this list up to date. The Board’s [Scheduled Medicines Advisory Committee](#) would continue to monitor and advise the Board of any changes to the medications in the classes in the registration standard
- improve patient access to medications that endorsed optometrists are qualified to prescribe, and
- provide greater clarity and consistency by aligning the language in the standard with that of relevant state and territory drugs and poisons legislation.

#### Potential costs of the proposal for option 2

The preferred option is expected to incur minimal additional costs. Identified costs are those that practitioners, other stakeholders and AHPRA will incur in becoming familiar with the new standard and guidelines. Practitioners and stakeholders will find the list of S4 medicines in the guidelines rather than the standard.

## **Estimated effect of the draft revised registration standard and guidelines**

The changes proposed in the revised registration standard will have a positive effect on the public.

Endorsed optometrists will be able to prescribe new medications in the classes in the standard without the additional administration and associated time and costs of gaining Ministerial Council approval. This will allow for a transparent and efficient mechanism to keep the list of medications up to date, while ensuring sufficient consultation with relevant key professional bodies.

The consequential changes proposed in the draft revised guidelines reflect the changes in the proposed revised registration standard. The Board does not expect there to be additional effects on practitioners, businesses and other stakeholders. There are no changes to the current scope of the endorsement as the purpose of the proposed changes is to improve the efficacy of the standard with respect to patient access to topical eye medicines and to better reflect the wording in the current drugs and poisons legislation. Stakeholders will now find the list of medicines in the guidelines rather than the standard.

Consultation will ensure that any unintended consequences are identified and addressed.

## **Relevant sections of the National Law**

Relevant sections include sections 14, 38, 39, 40 and 94.

## **Questions for consideration**

The Board is inviting feedback on the following questions:

1. Is the proposed revised registration standard clearer and easier to understand compared with the current standard?
2. Is the proposed revised guideline clear and easy to understand?
3. Is there any content that needs to be changed or deleted in the proposed revised registration standard?
4. Is there any content that needs to be changed or deleted in the proposed revised guidelines?
5. Is there anything missing that needs to be added to the proposed revised registration standard?
6. Is there anything missing that needs to be added to the proposed revised guidelines?
7. Do you have any other comments on the proposed revised registration standard or guidelines?

## **State and Territory Drugs and Poisons legislation**

[Poisons Act 1971 \(Tas\)](#)

[Poisons and Therapeutic Goods Act 1966 \(NSW\)](#)

[Health \(Drugs and Poisons\) Regulation 1996 Qld](#)

[Drugs, Poisons and Controlled Substances Act 1981 Vic](#)

[Drugs, Poisons and Controlled Substances Regulations 2006 \(Vic\)](#)

[Medicines, Poisons and Therapeutic Goods Act 2008 ACT](#)

[Medicines, Poisons and Therapeutic Goods Regulation 2008 ACT](#)

[Controlled Substances Act 1984 SA](#)

[Controlled Substances \(Poisons\) Regulations 2011 SA](#)

[Poisons Act 1964 \(WA\)](#)

[Poisons Regulations 1965 \(WA\)](#)

[Medicines, Poisons and Therapeutic Goods Act 2012 \(NT\)](#)

## Attachments

The proposed revised *Endorsement for scheduled medicines registration standard* option 2 is on page 9 of this consultation document with the associated guideline on page 11.

The format of the proposed revised standards and associated guidelines has been updated for additional clarity, and changes that do not affect the substance of the standard or guideline are not highlighted. However, proposed substantive changes to the registration standards and guidelines are **highlighted to allow** for easy identification.

The current *Endorsement for scheduled medicines registration standard* is published on the Board's website, see the Registration Standards section at [www.optometryboard.gov.au](http://www.optometryboard.gov.au).

The current *Guidelines for use of endorsement for scheduled medicines* are published on the Board's website, see Policies, Codes and Policies section at accessible from [www.optometryboard.gov.au](http://www.optometryboard.gov.au).



## Draft revised *Endorsement for scheduled medicines registration standard*

Effective from: <<date>>

### Introduction

This standard describes how an optometrist can qualify for endorsement for scheduled medicines, the scope of this endorsement and what the Optometry Board of Australia (the Board) expects of practitioners with this type of endorsement.

This standard sets out the requirements that must be met to be granted an endorsement as an optometrist to administer, obtain, possess, prescribe, supply or **use** scheduled medicines.

### Does this standard apply to me?

This registration standard applies to all optometrists:

- applying to have their registration endorsed for scheduled medicines under section 94 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law) or
- whose registration is endorsed for scheduled medicines.

### Scope of endorsement

An endorsed optometrist is qualified to administer, obtain, possess, prescribe, supply or **use** medicines, in accordance with relevant state and territory legislation, in the **following classes**:

- **topical schedule 2, 3 or 4 medicines for the purposes of the practice of optometry**

The endorsement relates to relevant schedule 2, 3 or 4 medicine in the meaning of the current poisons standard under section 52D of the [Therapeutic Goods Act 1989](#) (Cth).

**A list of the medicines in each of the approved classes of scheduled medicines is published in the Board's *Guidelines for use of scheduled medicines*.**

### How can I qualify for endorsement?

To be eligible to be granted an endorsement for scheduled medicines under section 94 of the National Law, an applicant for registration or a registered optometrist must have successfully completed:

- an approved program of study in ocular therapeutics, or
- a program of study determined by the Board to be substantially equivalent to an approved program of study, or
- an examination or assessment in ocular therapeutics approved by the Board.

An approved program of study is one that has been accredited by the Optometry Council of Australia and New Zealand (OCANZ) and approved by the Optometry Board of Australia for the purpose of qualifying an optometrist for a scheduled medicines endorsement. An approved examination or assessment is one that has been approved by the Board for the purposes of qualifying an optometrist for scheduled medicines endorsement under section 94 of the National Law.

A list of approved programs of study and approved examinations or assessments is available on the Board's website ([www.optometryboard.gov.au](http://www.optometryboard.gov.au)).

## What must I do when I am endorsed?

### Guidelines

Endorsed optometrists are expected to comply with guidelines for use of scheduled medicines issued from time to time by the Optometry Board of Australia and developed in accordance with section 39 of the National Law on the Board's website at [www.optometryboard.gov.au](http://www.optometryboard.gov.au).

### State or territory authority

The endorsement of your registration indicates that you are qualified to administer, obtain, possess, prescribe, supply or **use** topical schedule 2, 3 or 4 medicines for the purposes of the practice of optometry specified in the endorsement but does not authorise you to do so.

The authorisation for you to administer, obtain, possess, prescribe, supply or **use** topical schedule 2, 3 or 4 medicines for the purposes of the practice of optometry in a state or territory will be provided by or under legislation of the state or territory.

You must administer, obtain, possess, prescribe, supply or **use** topical schedule 2, 3 or 4 medicines for the purposes of the practice of optometry in the scope of this state or territory authority at all times.

### Wording to appear on the Register of optometrists

*Endorsed as qualified to administer, obtain, possess, prescribe, supply or **use** topical schedule 2, 3 or 4 medicines for the **purposes of the practice of optometry**.*

### Authority

The Ministerial Council has decided that the Board may endorse optometrists to the extent described in this registration standard.

This standard has been approved by the Ministerial Council under section 12 of the National Law on <<date>>.

Registration standards are developed under section 38 of the National Law and are subject to wide ranging consultation.

### Definitions

**Approved program of study** for a health profession or for endorsement of registration in a health profession, means an accredited program of study:

- a. approved under section 49(1) by the National Board established for the health profession, and
- b. included in the list published by the National Agency under section 49(5).

**Ministerial Council** means Australian Health Workforce Ministerial Council.

**National Law** means the Health Practitioner Regulation National Law as in force in each state and territory.

### Review

This standard for endorsement of registration will be reviewed from time to time as required. The Board will review this standard at least every five years.

This standard replaces the previous registration standard dated 31 March 2010.

## Draft revised *Guidelines for use of scheduled medicines*

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**Effective from: <<date>>**

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## Authority

The Optometry Board of Australia (the Board) has developed these *Guidelines for use of scheduled medicines* under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

National Board guidelines describe the professional standards the Board expects of registered practitioners.

Guidelines approved by the Board may be used as evidence of what constitutes appropriate professional conduct or practice for optometry in proceedings against a health practitioner under the National Law, or a law of a co-regulatory jurisdiction.

## Introduction

These guidelines outline the Optometry Board of Australia's (The Board) expectations about the use of scheduled medicines by endorsed and non-endorsed optometrists.

These guidelines provide information about how to meet the Board's requirements when you are applying for endorsement for scheduled medicines and when endorsed. You are expected to understand and apply these guidelines together with the *Endorsement for scheduled medicines registration standard*.

The public have a right to access safe and effective use of scheduled medicines from endorsed optometrists who are educated and competent to administer, obtain, possess, prescribe, supply or **use** topical schedule 2, 3 or 4 medicines for the purposes of the practice of optometry.

## Do these guidelines apply to me?

The guidelines apply to:

- optometrists with general registration who use scheduled medicines for diagnostic purposes, and
- optometrists whose registration is endorsed for scheduled medicines, who use scheduled medicines therapeutically to manage eye conditions independently and collaboratively with other healthcare practitioners.

Under the Board's *Code of conduct for optometrists*, optometrists have a responsibility to recognise and work within the limits of their competence and scope of practice. This includes ensuring they have the equipment, expertise and skills necessary to practise safely and effectively.

## What must I do?

You must meet the requirements of the *Endorsement for scheduled medicines registration standard*.

## Scope of endorsement

### 1. Endorsement for scheduled medicines

Under section 94 of the National Law, the Board may endorse the registration of suitably qualified optometrists to prescribe scheduled medicines<sup>1</sup>.

The Board's *Endorsement for scheduled medicines registration standard* describes the classes of medicines that optometrists with this endorsement are qualified to administer, obtain, possess, prescribe or supply or use for topical use. (Refer to [Appendix B](#) of these guidelines.)

The Board considers optometrists whose registration is endorsed for scheduled medicines to be qualified and competent to:

- obtain, possess, administer, prescribe, supply or **use** specified scheduled medicines, and

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<sup>1</sup> The term 'scheduled medicine' is a substance included in a schedule to the current Poisons Standard in the meaning of the Therapeutic Goods Act 1989 (Cth).

- use those medicines appropriately for the purposes of the practice of optometry.

Optometrists who hold this endorsement may only administer, obtain, possess, prescribe, supply or use scheduled medicines to the extent authorised under the legislation that applies in the state or territory in which they practise. Information is published on the Board's website about the authorities that apply in each state and territory of Australia.

### 1.1 Eligibility for endorsement

To be eligible for an endorsement for scheduled medicines, an applicant must, in accordance with the *Endorsement for scheduled medicines registration standard*, have successfully completed:

- an approved program of study in ocular therapeutics, or
- a program of study determined by the Board to be substantially equivalent to an approved program of study, or
- a Board-approved examination or assessment in ocular therapeutics.

### 1.2 Approved programs of study and assessments

Information about currently approved programs of study and assessments is published on the Board's website.<sup>2</sup>

## 2. Use of scheduled medicines by optometrists

In all Australian states and territories, optometrists with general registration are allowed to obtain, have in their possession and use scheduled medicines in the course of their practice for diagnostic purposes (for example anaesthetic and mydriatic eye drops).

[Appendix A](#) of these guidelines lists the scheduled medicines approved by the Board for administration for diagnostic purposes by optometrists holding general registration. An endorsement is not needed for an optometrist to use diagnostic medicines in the course of their practice.

### 2.1 Quality use of medicines

Optometrists who prescribe scheduled medicines should observe the Quality Use of Medicines (QUM)<sup>3</sup> principles as they apply to the scope of the endorsement.

Quality use of medicine means:

- a. selecting management options wisely by:
  - considering the place of medicines in treating illness and maintaining health, and
  - recognising there may be better ways than medicine to manage many disorders.
- b. choosing suitable medicines (if a medicine is considered necessary) so that the best available option is selected by taking into account:
  - the individual
  - the clinical condition
  - risks and benefits
  - dosage and length of treatment
  - any coexisting conditions
  - other therapies
  - monitoring considerations, and
  - costs for the individual, the community and the health system as a whole.
- c. using medicines safely and effectively to get the best possible results by:

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<sup>2</sup> See [www.optometryboard.gov.au](http://www.optometryboard.gov.au).

<sup>3</sup> The complete strategy can be found at [www.health.gov.au](http://www.health.gov.au).

- monitoring outcomes
- minimising misuse, over-use and under-use
- improving people's ability to solve problems related to medication, such as negative effects, and
- managing multiple medications.

## 2.2 Maintaining competence

All optometrists are expected to maintain their competence through continuing professional development and recency of practice, and need to meet the requirements set out in the Board's *Continuing professional development registration standard* and *Recency of practice Registration Standard*<sup>4</sup>.

This standard also outlines the specific requirements to be met by optometrists whose registration is endorsed for scheduled medicines.

## 2.3 Prescriptions

A prescription is a legal document. It is a precise written instruction from a prescriber to a pharmacist for preparing and dispensing a drug for a patient.

Optometrists whose registration is endorsed for scheduled medicines must ensure that, when authorising the supply of a schedule 4 medicine to a patient, the prescription is handwritten or computer generated.

When prescribing a schedule 2 or 3 medicine, the Board encourages endorsed optometrists to issue a prescription, to help ensure effective communication with the pharmacist.

The endorsed optometrist has a duty of care to provide a prescription that is legible; this reduces the potential for errors in treatment. Computer generated prescriptions are generally more legible than those that are handwritten.

The essential information needed for a legal prescription may vary between states and territories. Optometrists need to be aware of these variances if practising in different jurisdictions.

Prescriptions must be handwritten or computer generated and include the:

- date of issue
- details of the prescriber, patient,
- medicine (including name of medicine by active ingredient, strength, quantity and where relevant, brand name)
- precise directions (except when directions are too complex and are provided separately, or when administration is to be carried out by a nurse or other person instructed in and authorised to administer), and
- the prescriber's signature.

### Self prescribing

The Board advises against endorsed optometrists self-diagnosing and then self-prescribing schedule 4 medicines.

## 2.4 Practice procedures

Optometrists should ensure that:

- scheduled medicines are stored securely and in accordance with the manufacturer's recommendations and as required under the legislation of the relevant jurisdiction
- details of in-practice administration of scheduled medicines are recorded on the patient's clinical record, and

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<sup>4</sup> Refer to the Registration Standards tab on the Board's website at [www.optometryboard.gov.au](http://www.optometryboard.gov.au).

- if required under the legislation of the jurisdiction, relevant authorities are notified of the loss or theft of a scheduled medicine.

## 2.5 Adverse event reporting

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods including medicines, medical devices, blood and blood products.

The TGA also collects reports of adverse events associated with medicines and medical devices. Monitoring of adverse events allows the TGA to investigate and take action on medicines safety issues.

Optometrists can help the TGA in safeguarding public health by reporting all suspected adverse events associated with medicines, particularly those associated with new products. This information forms an important part of the TGA's monitoring activities and plays a key role in helping identify potential relationships between a therapeutic good and a series of adverse events. When a link can be established, the TGA takes action to ensure that medicines available in Australia continue to meet appropriate standards of safety, efficacy and quality.

Further information can be found on the TGA website [www.tga.gov.au](http://www.tga.gov.au).

## 3. Supply of scheduled medicines

The Board supports the view that the division of responsibility between an optometrist with scheduled medicines endorsement who prescribes (authorises the supply of a scheduled medicine), and a pharmacist who dispenses the scheduled medicine to the patient, provides an important check designed to safeguard patients.

The expertise of the pharmacist in counselling patients is important in the follow-up care of the patient. This includes checking adherence to the prescriber's instructions, confirming administration times and techniques, screening for adverse reactions, and referring back to the prescriber for further investigations or advice when needed.

Circumstances when it is permissible for an optometrist to prescribe and supply a scheduled medicine to a patient include an emergency or when access to a pharmacy is impractical.

Optometrists who choose to supply a scheduled medicine directly to a patient must meet the labelling and recordkeeping requirements of the jurisdiction in which they are practising, provide counselling about the use of the medicine, its side effects and potential interactions and, if available, provide a Consumer Medicines information leaflet<sup>5</sup>.

## 4. Guidelines for the use of topical antimicrobials

All optometrists treating anterior eye infections with scheduled medicines must have a clear understanding of:

- microbiological and pathological processes relevant to anterior eye infection and their natural histories
- typical presentations of ocular surface infections and the differential diagnoses of these from other anterior eye conditions
- ocular infections that constitute true ocular emergencies and need immediate treatment
- identification of risk factors for ocular surface infections
- indications and mechanisms of referral for microbiological investigation, and
- interpretation of the results of microbiological investigation and appropriate management stratagems arising from these results.

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<sup>5</sup> Consumer Medicines information sheets are available at [www.medicines.org.au](http://www.medicines.org.au).



#### 4.1 Antimicrobial resistance

Optometrists using antimicrobial preparations should understand all issues relating to the emergence of resistance by pathogenic organisms and mechanisms for limiting this. Selection of an antimicrobial should always involve consideration of the risk that microbial resistance could develop. In particular, treatment regimens should be avoided that could result in:

- inappropriate drug selection
- insufficient therapeutics (i.e. drug regimen inadequate to control infection, either in duration or therapeutic effect)
- overuse, or
- inappropriate dosage.

At present, fluoroquinolones have broad-spectrum activity with relatively little microbial resistance. To maintain maximal efficacy of these preparations, fluoroquinolones should not be used when alternative, equally effective agents could be used instead.

Optometrists should consider a specialist opinion for patients who may need long-term antimicrobial use.

[NPS Medicinewise](#) provide a range of information for prescribers to help them understand the risks of antimicrobial resistance and what they can do to help contain this.

#### 5. Guidelines for the use of topical steroidal preparations

Optometrists seeking to treat ocular inflammation with scheduled medicines must have a clear understanding of the:

- immunological processes relevant to inflammatory conditions of the eye and their natural histories
- typical presentations of inflammatory conditions of the eye and the differential diagnoses of these from other anterior eye conditions
- inflammatory conditions of the eye that constitute true ocular emergencies and need immediate treatment
- identification of risk factors for developing ocular inflammation
- potential side effects of topical steroid preparations, including a propensity for raising intraocular pressure in susceptible individuals and the potential development of cataract, and
- management strategies for steroid-related intraocular pressure rises.

Optometrists should consider referral for a specialist opinion for those patients who may need long-term steroid use.

#### 6. Working with other practitioners

For the purpose of these guidelines, 'collaborative care' is when the care of a patient is provided by two or more health practitioners, each practising in their sphere of expertise in consultation with the patient.

Various collaborative care relationships between health care practitioners exist, ranging from ad hoc to formal documented shared-care agreements. For eye conditions, shared care is likely to vary according to the location of the patient and the skill-base of the local health care practitioners.

The Board's *Code of conduct for optometrists* provides further guidance on communication with patients and other health practitioners.

##### 6.1 Role, responsibilities and communication in collaborative care of patients

In any collaborative care arrangement, it is essential that the roles and responsibilities of the optometrist and the other health practitioner(s) are defined clearly and continue to be redefined as needed over time.

Communication is the linchpin of effective collaborative care. Participating practitioners and their patients must understand which practitioner is responsible for providing the various aspects of care.

To avoid repetition and confusion, each party must have a clear understanding of:

- the diagnoses, treatment(s) and ongoing recommendations to the patient of the other treating practitioners
- the information to provide to other parties involved in the care of the patient
- timeframes in which this information should be provided
- the preferred format for this information
- who is responsible for ongoing patient care and the follow up of patients who miss scheduled appointments, and
- the roles and responsibilities of each person participating in the shared care.

The Board recommends the use of protocols and forms to clarify responsibilities and facilitate the transfer of information and communication between practitioners. Such systems may involve standardised forms used by all parties participating in the arrangement or may be a less regimented agreement that each party should provide or forward a report to others after each consultation with the patient<sup>6</sup>.

Ongoing discussion between the optometrist and the other treating practitioner(s) should involve reviewing these protocols and making changes necessary over time to ensure optimal care of the patient.

## 6.2 Patient involvement

In any collaborative care arrangement, patients must consent to the arrangement and be clearly informed about who is responsible for their primary eye care and when they need to attend reviews with each practitioner.

Written information for patients about collaborative care may prove a useful addition to verbal discussions with treating practitioners.

## 7. Guidelines for care of patients with, or at high risk of developing, chronic glaucoma

The following guidelines for care of patients with, or at high risk of developing, chronic glaucoma should be read in conjunction with:

- section 6 of these guidelines 'Collaborative care guidelines'
- National Health and Medical Research Council of Australia's NHMRC Guidelines for the screening, prognosis, diagnosis, management and prevention of glaucoma 2010 (the NHMRC guidelines)<sup>7</sup>, and
- *A guide to glaucoma for primary health care providers – a companion document to NHMRC Guidelines for the screening, prognosis, diagnosis, management and prevention of glaucoma*<sup>8</sup>.

The NHMRC guidelines and the companion document outline a series of recommendations and supporting evidence for all practitioners involved in the screening, prognosis, diagnosis, management and prevention of glaucoma.

In terms of collaborative care of patients with glaucoma, the Board endorses the recommendation from the NHMRC guidelines 'that the professional roles, responsibilities and referral pathways are best determined in individual cases based on location, resources, skill-base of local health care practitioners and patient choice'.<sup>9</sup>

When an initial diagnosis of chronic glaucoma is made, or a patient is at high risk of developing the disease, optometrists whose registration is endorsed for scheduled medicines must:

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<sup>6</sup> Optometrists Association Australia has published a position statement on shared care. This may inform the development of such protocols and or forms.

<sup>7</sup> Published at [www.nhmrc.gov.au/guidelines/publications/cp113-cp113b](http://www.nhmrc.gov.au/guidelines/publications/cp113-cp113b).

<sup>8</sup> Ibid.

<sup>9</sup> National Health and Medical Research Council of Australia's (NHMRC) Guidelines for the screening, prognosis, diagnosis, management and prevention of glaucoma 2010, p 83, see [www.nhmrc.gov.au/guidelines/publications/cp113](http://www.nhmrc.gov.au/guidelines/publications/cp113).

- refer the patient for specialist assessment and advice about confirmation of diagnosis and ongoing management, or
- develop a management plan that includes initiation of treatment and monitoring of the patient's response.

Instillation of anti-glaucoma eye drops is the preferred primary intervention in chronic glaucoma management<sup>10</sup>. However, in certain cases patients will need assessment by an ophthalmologist for possible surgical intervention or laser treatment. Optometrists must be able to identify those cases and refer where appropriate.

Optometrists should refer to the NHMRC guidelines when setting target intra-ocular pressures and when making decisions about glaucoma management plans, including the frequency of review appointments. The patient's risk factors for progression, their disease state and capacity to self-manage will dictate the frequency of review<sup>11</sup>.

### 7.1 Referral

The optometrist must provide a referral for ophthalmological assessment and advice after making an initial diagnosis and initiating treatment for chronic glaucoma<sup>12</sup>:

- if the anti-glaucoma treatment does not stabilise the patient's condition
- if a patient needs assessment by an ophthalmologist or ophthalmology service for possible surgical intervention or laser treatment, or
- if a patient experiences side effects of initial treatment.

In any event, the optometrist must provide the patient with a referral to an ophthalmologist or ophthalmology service within four months of starting treatment for chronic glaucoma.

### 7.2 Communication

The Board expects that optometrists managing patients with glaucoma will maintain regular communication with the patient's general practitioner, ophthalmologist, physician or other health care practitioner. Clear communication between practitioners is crucial to ensure each practitioner understands who is responsible for providing each aspect of the patient's care.

### 7.3 Equipment

To comply with these guidelines, optometrists must have the equipment to measure and/or assess a patient's intraocular pressure, central corneal thickness, threshold visual fields, anterior chamber angle, optic nerve head and retinal nerve fibre layer. Optometrists should refer specifically to the sections on 'Diagnosis of glaucoma' and 'Monitoring: long-term care' in the NHMRC guidelines.

### 7.4 Emergency management of acute primary angle closure

Individuals suffering from an acute angle-closure event may present to an optometrist or, rarely, an angle-closure event may be induced through routine pupil dilation.

The standard management of such a patient is emergency referral to an ophthalmologist or hospital. However, both the nature of the condition and endorsement for scheduled medicines enable the optometrist to, in collaboration with a medical practitioner, provide first-aid for such patients to stabilise their ocular state (refer to [Appendix C](#) of this document for suggested first aid for an angle closure event).

As the definitive intervention in acute angle-closure is procedural intervention (laser therapy), the optometrist should seek ophthalmological input, if possible, before administering first aid to lower intraocular pressure and reduce pain. Exceptions to this include when an ophthalmologist cannot be

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<sup>10</sup> NHMRC guidelines, p. 108.

<sup>11</sup> NHMRC guidelines, p. 91.

<sup>12</sup> Note: Referral means providing a referral letter to the patient and sending a copy to the ophthalmologist or ophthalmology service.

contacted and the best interests of the patient are served by initiating treatment before emergency referral to the most convenient ophthalmologist or hospital.

### Review

The Board will monitor this guideline for effectiveness and review it at least every three years. This guideline replaces any previously published National Board guidelines on use of scheduled medicines.

If a minor change to the list of scheduled medicines in [Appendix B](#) is proposed before a scheduled review of these guidelines, the relevant key professional bodies will be consulted.

**Date of issue:** <<date>>

**Date of review:** <<date>

## Appendix A

### List of scheduled medicines for diagnostic use approved by the Optometry Board of Australia for administration by optometrists holding general registration

The Optometry Board of Australia has approved the following diagnostic drugs for optometrists to administer in the course of their practice:

- anaesthetics, local (synthetic cocaine substitutes) — when prepared and packed in the form of eye drops
- tropicamide — when prepared and packed in the form of eye drops containing one (1) per cent or less of tropicamide
- cyclopentolate hydrochloride — when prepared and packed in the form of eye drops containing one (1) per cent or less of cyclopentolate hydrochloride
- atropine — when prepared and packed in the form of eye drops containing one (1) per cent or less of atropine sulphate
- homatropine — when prepared and packed in the form of eye drops containing two (2) per cent or less of homatropine hydrobromide, and
- pilocarpine nitrate — when prepared and packed in the form of eye drops containing two (2) per cent or less of pilocarpine nitrate

~~physostigmine salicylate — when prepared and packed in the form of eye drops containing 0.5 per cent or less of physostigmine salicylate.~~

Registered optometrists should be familiar and comply with the current requirements of state and territory drugs and poisons legislation in the jurisdictions in which they practise. ~~The Board will publish on its website a list of authorities that apply in each state and territory.~~<sup>13</sup>

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<sup>13</sup> Advice on the legal requirements in a particular state or territory may be obtained from the relevant authority found at [www.tga.gov.au/contacts-stateterritory-drugs-poisons-units](http://www.tga.gov.au/contacts-stateterritory-drugs-poisons-units).

## Appendix B

Board-approved list of topical schedule 2, 3 and 4 medicines that optometrists with a scheduled medicines endorsement are qualified to administer, obtain, possess, prescribe, supply or use for the purposes of the practice of optometry<sup>14</sup>

### Schedule 2 Pharmacy Medicine

#### Anti-infectives

Dibromopropamide  
Propamide

#### Anti-inflammatories

Antazoline  
Azelastine  
Ketotifen  
Levocabastine

#### Decongestants/ anti-allergics

Lodoxamide  
Naphazoline  
Pheniramine  
Sodium Cromoglycate

#### Miotics, mydriatics and cycloplegics

Phenylephrine <1%

### Schedule 3 Pharmacist Only Medicine

#### Anti-infectives

Chloramphenicol

### Schedule 4 Prescription Only Medicine

#### Anti-infectives

Aciclovir  
Azithromycin  
Bacitracin  
Cephazolin  
Ciprofloxacin  
Framycetin  
Gentamicin  
Gramicidin  
Neomycin  
Ofloxacin  
Polymyxin  
Tetracycline  
Tobramycin  
Vidarabine

#### Anti-inflammatories

Cyclosporin  
Dexamethasone  
Diclofenac  
Fluorometholone  
Flurbiprofen  
Hydrocortisone  
Ketorolac  
Loteprednol  
Prednisolone

#### Decongestants/ anti-allergics

Olopatadine

#### Anti-glaucomas

Apraclonidine  
Betaxolol  
Bimatoprost  
Brimonidine  
Brinzolamide  
Carbachol  
Dipivefrin  
Dorzolamide  
Latanoprost  
Levobunolol  
Pilocarpine  
Tafluprost  
Timolol  
Travoprost

#### Miotics, mydriatics and cycloplegics

Atropine  
Cyclopentolate  
Homatropine  
Pilocarpine  
Phenylephrine  
Tropicamide

#### Local anaesthetics

Amethocaine  
Lignocaine  
Oxybuprocaine  
Proxymetacaine

<sup>14</sup> Registered optometrists with a scheduled medicines endorsement must be familiar and comply with the current requirements in the jurisdictions in which they practice. Advice on the legal requirements in a particular state or territory may be obtained from the relevant authority found at [www.tga.gov.au/contacts-stateterritory-drugs-poisons-units](http://www.tga.gov.au/contacts-stateterritory-drugs-poisons-units). For the safe and effective use of a medicine, endorsed optometrists must also be familiar with TGA approved indications found in the product information. The product information may be found at [www.ebs.tga.gov.au](http://www.ebs.tga.gov.au).

## Appendix C

### First aid for acute angle-closure event

The following immediate interventions are suggested, unless otherwise contraindicated in a given patient, for the emergency management of acute primary angle closure.

Optometrists whose registration is endorsed for scheduled medicines are not currently authorised under state and territory drugs and poisons legislation to prescribe, possess or supply acetazolamide (Diamox). In urgent cases, and when allowed by legislation in the relevant jurisdiction, a pharmacist can supply Diamox to the patient when requested to do so via a telephone order from a medical practitioner. Optometrists are advised to liaise with a medical practitioner to arrange the supply of Diamox for the patient.

- a. An oral dose of acetazolamide 500mg (Diamox) can be administered provided there are no contraindications. If Diamox cannot be tolerated orally, the patient is likely to need intramuscular or intravenous administration of Diamox and/or treatment with other therapeutic agents. In this situation, referral and transfer to an ophthalmologist or hospital emergency department should occur without delay.
- b. Instil the following topical medications (allowing about two minutes between each drop):
  - One (1) drop beta-blocking agent (e.g. timolol, 0.5 per cent).
  - One (1) drop alpha agonist (e.g. apraclonidine, 0.5 per cent).
  - One (1) drop carbonic anhydrase inhibitor (e.g. brinzolamide, 1.0 per cent).If the eye is red and inflamed, one (1) drop high-penetrance topical steroid — with the optometrist or patient to instil a further three (3) drops at regular intervals in the first hour, then hourly thereafter.
- It is preferable to withhold instillation of pilocarpine until the intra-ocular pressure (IOP) has been reduced (except in the rare instance of an angle-closure event being caused through routine pupil dilation, in which case instillation of pilocarpine should start immediately).
- c. Just before the patient is transferred, and after discussion with the ophthalmologist confirming that instillation of pilocarpine is indicated, instil:
  - One (1) drop pilocarpine, 2 per cent (with the optometrist or patient to instil a further drop in 15 minutes).

Note: Pilocarpine should only be used for mechanisms involving phakic pupillary block or angle crowding. Use of pilocarpine is contraindicated for retrolenticular causes of angle closure as well as those involving aphakic or pseudophakic closure events.

## Statement of assessment

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The Optometry Board of Australia's (the Board) statement of assessment against the Australian Health Practitioner Regulation Agency's (AHPRA) *Procedures for development of registration standards, codes and guidelines* and *Council of Australian Governments (COAG) principles for best practice regulation*

The Australian Health Practitioner Regulation Agency (AHPRA) has *Procedures for the development of registration standards, codes and guidelines* which are available at [www.ahpra.gov.au](http://www.ahpra.gov.au).

These procedures have been developed by AHPRA in accordance with section 25 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), which requires AHPRA to establish procedures for the purpose of ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice.

Below is the Board's assessment of its proposal for its revised registration standard and guidelines against the three elements outlined in the AHPRA procedures.

### **1. The proposal takes into account the National Scheme's objectives and guiding principles set out in section 3 of the National Law**

#### **Board assessment**

The Board considers that the proposed revised registration standard and guidelines meet the objectives and guiding principles of the National Law.

The proposed revised draft registration standard, if approved, will continue to provide for the protection of the public by ensuring that optometrists seeking to have their registration endorsed for scheduled medicines are suitably qualified and competent to practise safely in this area of practice.

The proposed registration standard proposes a more efficient, effective and streamlined way to keep the registration standard current.

The proposed revised registration standard and guidelines also support the National Scheme to operate in a transparent, accountable, efficient, effective and fair way.

### **2. The consultation requirements of the National Law are met**

#### **Board assessment**

The National Law requires wide-ranging consultation on proposed revised registration standard and guidelines. The National Law also requires the Board to consult other boards on matters of shared interest.

The Board will ensure that there is public exposure of its proposals and there is the opportunity for public comment by carrying out a six week public consultation process. This process includes the publication of the consultation paper (and attachments) on its website.

The Board has drawn this paper to the attention of key stakeholders and the preliminary, confidential consultation stage is an important opportunity to 'road test' the proposed content with targeted stakeholders ahead of a public consultation process. Through this we can identify the operational effect and any issues or concerns with the proposed content of the registration standard and guidelines. This stage also considers any transitional issues that must be addressed in implementing the registration standard and guidelines.



The Board will take into account the feedback it receives when finalising its proposals before approval.

### **3. The proposal takes into account the COAG Principles for best practice regulation**

#### **Board assessment**

In developing the proposed revised registration standard and guidelines for consultation, the Board has taken into account the COAG *Principles for best practice regulation*.

As an overall statement:

- the Board has taken care not to propose unnecessary regulatory burdens that would create unjustified costs for the profession or the community.

**The Board makes the following assessment specific to each of the COAG principles expressed in the AHPRA procedures.**

#### **COAG principles**

##### **a. Whether the proposal is the best option for achieving the proposal's stated purpose and protection of the public**

#### **Board assessment**

The Board considers that its proposals are the best options for ensuring protection of the public.

The existing registration standard has been in place for over five years and is due for review. Concerns have been raised about keeping the list of Board-approved scheduled medicines current and up to date as the medication list is embedded in the registration standard and requires Ministerial Council approve to amend.

The Board considers that the proposed revised guidelines would have a small effect on the profession and are intended to help endorsed optometrists to deliver timely, safe, and quality health services. Any effects are significantly outweighed by the benefits of protecting the public and providing clearer, simpler requirements in the public interest that guide practitioners to meet the registration requirements as an endorsed optometrist. While the Board can endorse an optometrist as being qualified to prescribe, the authorisation of optometrists to prescribe specific scheduled medicines remains subject to state/territory drug and poisons legislation.

##### **b. Whether the proposal results in an unnecessary restriction of competition among health practitioners**

#### **Board assessment**

The Board considered whether its draft revised registration standard and associated guidelines could result in an unnecessary restriction of competition among health practitioners. The proposed revised registration standard and guidelines apply equally to all optometrists with scheduled medicines endorsements. As the scope of the current standard is not changing, this does not change the current relationships with other professions. Accordingly, the proposals are not expected to effect on the current levels of competition among health practitioners, given the nature of the revisions.

##### **c. Whether the proposal results in an unnecessary restriction of consumer choice**

#### **Board assessment**

The Board considers that the proposed revised registration standard will support consumer choice, by enabling a more responsive and timely ability for endorsed optometrists to provide up to date medications in response to consumer clinical needs.

**d. Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable about the benefits to be achieved**

**Board assessment**

The Board considered the overall costs of the revised draft registration standard and associated guidelines to members of the public, registrants and governments and concluded that the likely minimal compliance costs are appropriate when offset against the benefits that the proposed revised standard and guidelines contribute to the National Scheme.

**e. Whether the requirements are clearly stated using 'plain language' to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants**

**Board assessment**

The Board considers the proposed revised registration standard and guidelines have been written in plain English that will help practitioners to understand the requirements of the registration standard and guidelines. The Board has changed the structure of the guidelines and reviewed the wording to make the guidelines easier to understand and comply with. The format will be consistent with the contemporary format currently used.

**f. Whether the Board has procedures in place to ensure that the proposed registration standard, code or guideline remains relevant and effective over time**

**Board assessment**

If approved, the Board will review the revised registration standard and guidelines at least every five years, including an assessment against the objectives and guiding principles in the proposed National Law and the COAG principles for best practice regulation.

However, the Board may choose to review the registration standard and guidelines earlier, in response to any issues which arise or new evidence which emerges to ensure the guidelines' continued relevance and that it reflects best practice.