

Public consultation

Review of the Registration standard: Endorsement for scheduled medicines and Guidelines for use of scheduled medicines

October 2025

Executive summary

The Optometry Board of Australia (the Board) is conducting a wide-ranging public consultation as part of its review of the Registration standard: Endorsement for scheduled medicines (the standard) and Guidelines for use of scheduled medicines (the guidelines).

The Board is seeking your feedback on a proposal to update its existing endorsement for scheduled medicines that would allow endorsed optometrists to prescribe oral medicines in addition to topical medicines for eye conditions.

The Board proposes to publish the lists of medicines that optometrists are qualified to prescribe on its website and no longer embed them in the guidelines. This would make it easier for consumers, practitioners, and other stakeholders to see what medicines optometrists are qualified to prescribe. The Board also proposes that the endorsement itself would not include a reference to the list. Instead for enforceability, the standard and guidelines would refer to there being approved lists. These changes together mean the lists can be updated in a timely way, while keeping the necessary safety checks in place.

The Board is also proposing to align the standard and guidelines to support cross-profession consistency where possible, and to remove outdated clinical guidance from the regulatory guidelines to future proof the guidance. The proposal would better use the skills and training of endorsed optometrists as an existing health workforce and give easier and greater patient access to primary eye care in a timely way, by reducing the need to see multiple health practitioners.

The proposal supports the National Medicines Policy and the National Strategy for Quality Use of Medicines to make the best possible use of medicines to improve health outcomes for all Australians. The proposal also supports the Health Professionals Prescribing Pathway and the need to improve consistency between professions on education and recognition of prescribing competence.

For the public, the proposed updates would give greater choice about which health practitioner a consumer chooses to see, for the same primary presenting eye condition. For example, where clinically appropriate, an endorsed optometrist would be able to treat a bacterial eye infection with a topical and/or oral prescription medicine at their primary visit, which means fewer appointments for patients. As a result of having better access to eye-care medicines, we expect consumers would save time and money while maintaining patient safety.

This public consultation opens in October 2025 for 8 weeks until close of business (AEDT) 24 December 2025.

Providing feedback during public consultation

The Board invites feedback, comments and evidence of the impact of the proposal on the draft revised standard and guidelines.

Please provide your feedback by email, marked 'Public consultation on the review of Endorsement for scheduled medicines' as a Word document (not PDF) using the template provided, to optomconsultation@ahpra.gov.au.

Alternatively, you're invited to answer this short two to five minute survey.

The Board acknowledges that Aboriginal and Torres Strait Islander Peoples bear the burden of gross social and health inequity. The Board aims to better support improved health outcomes and seeks to understand the impacts of the proposal on Aboriginal and Torres Strait Islander Peoples.

Publication of submissions

We publish submissions at our discretion. We generally publish submissions to our website to encourage discussion and inform the community and stakeholders about consultation responses. Please let us know if you do not want your submission published.

We will not place on our website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the subject to the consultation. Before publication, we may remove personally identifying information from submissions, including contact details.

We can 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. A 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 us know if you do not want us to publish your submission or if you want us to treat all or part of it as confidential.

Published submissions will include the names of the individuals and/or organisations that made the submission unless confidentiality is expressly requested.

Next steps

The Board will review and consider your feedback. More information about your submission may be requested if clarification is needed, however in general, individual stakeholder feedback will not be provided.

Your feedback will inform the final version of the revised standard and guidelines. The revised standard must be approved by the Health Ministers before it takes effect.

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Acknowledgement of Country

The Board and the Australian Health Practitioner Regulation Agency (Ahpra) through implementation of the National Registration and Accreditation Scheme (the National Scheme), would like to acknowledge the Traditional Custodians of the lands in which we regulate registered optometrists in Australia.

We acknowledge Aboriginal and Torres Strait Islander culture as the oldest continuing culture in the world. Aboriginal and Torres Strait Islander Peoples never ceded sovereignty and we recognise the impact colonisation continues to have on the health of Aboriginal and Torres Strait Islander Peoples to date.

We acknowledge Aboriginal and Torres Strait Islander Peoples for their continuing connection to culture, language and country; along with Elders past and present and the ancestors who walk with Aboriginal and Torres Strait Islander Peoples every day.

Purpose of the public consultation

The purpose of this public consultation is to:

- test with stakeholders the proposal to expand endorsed optometrists' prescribing rights to include contemporary topical and oral medicines for eye conditions
- propose revisions to the standard and guidelines, to improve their effectiveness, enforceability, efficiency and relevance
- increase transparency, seek input and feedback on the draft revised standard, guidelines and lists, and
- identify any unintended consequences and implementation issues before they arise.

The Board's current standard was published on 10 September 2018 and is due for review. Optometry Australia, the peak professional association for optometrists previously submitted a proposal to change the Board's endorsement to recognise that endorsed optometrists in Australia are qualified to prescribe oral medicines. Using Optometry Australia's Oral Therapeutic Prescribing by Australian Optometrists report and The Value of expanding Optometrists' prescribing rights in Australia 2025 report, and through the Board's own research, targeted consultations and preliminary consultation, the Board has strong evidence to progress and test the proposal at public consultation.¹

The guidelines were last published on 10 December 2021. They are being reviewed to align with the proposed updates to the existing endorsement and the draft revised standard.

Context

Under the National Law, the Board is the regulator of optometrists in Australia and protects the public by ensuring that only suitably qualified and competent optometrists are registered.² The Board is responsible for developing registration standards, codes and guidelines for optometrists and managing notifications (complaints and concerns) about optometrists and optometry students.

Current endorsement

The Board currently has an approved endorsement in relation to scheduled medicines approved by the Ministerial Council under section 14 of the National Law.³ Optometrists whose registration has been endorsed by the Board are 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, included in the list approved and published by the Board. The approval letter for the current endorsement is on the Board's website.

The *authorisation* to prescribe is provided under state or territory medicines and poisons legislation. An optometrist must both be recognised as qualified and authorised before they can prescribe Schedule 2, 3 or 4 medicines.

The current standard and guidelines are found on the Board's <u>website</u>. The Board's current approved lists of medicines are published in Appendix A and B of the current guidelines, which includes topical eye drops and eye ointments.

More information can be found in the background paper in Appendix K.

¹ Optometry Australia, Oral therapeutic prescribing by Australia Optometrists, 2022 and the <u>Value of expanding Optometrists'</u> <u>prescribing rights in Australia</u>, 2025

² The Health Practitioner Regulation National Law (the National Law), as in force in each state and territory.

³ The Ministerial Council for the National Scheme comprises the Health Ministers from each state and territory and the Commonwealth

What the proposal would change

Proposal summary

This proposal would expand an endorsed optometrist's prescribing scope to include contemporary oral medicines for the purposes of the practice of optometry and would update the current medicine lists.

Endorsed optometrists would be able to prescribe oral Schedule 4 medicines as required, such as:

- antibiotics for bacterial eye lid infections and meibomian gland dysfunction (posterior blepharitis)
- anti-virals for herpes zoster opthalmicus or prophylaxis for recurrent herpes simplex keratitis
- anti-allergics for allergic conjunctivitis
- anti-inflammatories for inflammation of the eye, including episcleritis
- · simple analgesics for short-term eye pain, and
- acetazolamide (single dose only) as an anti-glaucoma for emergency treatment of acute angle closure.

The detailed lists of Board approved medicines optometrists are qualified to prescribe would be published on the Board website as supporting guidance, so they are easy to locate. The proposed lists can be found at Appendix F and G.

Proposed updates to the existing endorsement

The key proposed updates to the existing endorsement are to:

- remove the specific reference to 'topical' administration, and
- remove the reference to 'the list approved and published by the Board'.

By removing 'topical' the proposal would expand endorsed optometrists' prescribing scope to include contemporary topical and oral medicines for the purposes of the practice of optometry. This would mean consumers would receive more complete eye care in one visit, without always needing to see another health professional. Currently, optometrists must refer to a medical practitioner if oral medicines are required.

The Board proposes that the endorsement itself not include the approved list of scheduled medicines. The Board proposes to publish the lists that optometrists are qualified to prescribe on its website, instead of being embedded in the appendices of the current guidelines. For enforceability, the standard and guidelines would still refer to there being approved lists of scheduled medicines. These proposed changes mean consumers, optometrists, pharmacists, medical practitioners and other stakeholders would be clear on what optometrists are qualified to prescribe. These changes together mean that the lists would be updated in a more timely manner, while still keeping the necessary safety checks in place. This would allow the Board to balance the rigour of keeping the lists up to date, with timeliness, agility, safety and enforceability.

A detailed background paper that addresses the evidence and requirements needed to amend an existing endorsement is in Appendix K.

Proposed updates to the standard and guidelines

The proposed updates to the standard and guidelines are to:

- reflect the proposed updates to the existing endorsement, as stated above
- link to the Boards' shared Code of conduct, and existing registration standards
- reflect the recency of qualification for endorsement with the proposed definition of a recent graduate in the current cross-profession review of the Recency of practice registration standard, for cross-profession consistency
- remove clinical guidance from the regulatory guidelines to future proof it, as it currently references rescinded clinical guidelines
- keep the guidelines contemporary, informed by best available evidence, and using Quality Use of Medicines principles
- align and support cross-profession consistency, where relevant
- · refine, simplify, clarify and contemporise wording, and
- remove duplication and reorganise the content to make the sequence more logical.

An outline of what the Board took into consideration to inform the proposed updates is in Appendix A.

Comparison tables that highlight the updates between the current and proposed standard and guidelines are in Appendix H.

Proposed updates to the medicine lists

The proposed updates to the detailed medicine lists are to:

- remove them from Appendix A and B of the current guidelines, and
- publish the updated medicine lists to the Board's website as supporting guidance.

The proposed draft medicine list for general optometrists for diagnostic use is in Appendix F and the proposed draft medicine list for endorsed optometrists is in Appendix G. The proposed changes/additions from the current lists are highlighted in yellow. High-risk Schedule 8 or Schedule 4 Restricted medicines (medicines that are considered to have a higher risk of patient abuse or dependence) are not included in the lists.

The lists would continue to be reviewed annually and as required. Relevant stakeholders would still be consulted.

More information about the lists is in Appendix K.

Safety of the proposal

The Board is required to adhere to policy directions handed down by the Ministerial Council from time to time. In 2019, the Ministerial Council passed down two policy directions. These were:

- paramountcy of public protection when administering the National Scheme, and
- the requirement to consult with patient safety bodies and healthcare consumer bodies on every new and revised registration standard, code and guideline.

In considering patient safety, examples from overseas countries with comparable health regulatory systems were reviewed. New Zealand provides clear evidence of safe optometrist prescribing of oral medicines, where no adverse events have been reported since optometrists first began prescribing oral medicines in 2014.⁴

Currently Australian optometry graduates that register in New Zealand can prescribe oral medicines in New Zealand, but with the current regulation in Australia, they can only prescribe topical medicines such as eye drops. The Optometrists and Dispensing Opticians Board of New Zealand (ODOB) currently recognises the qualifications of Australian trained endorsed optometrists to prescribe medicines, including oral medicines.

The Board has considered a number of potential risks related to prescribing errors, poly pharmacy, fragmentation of care, adverse events, and optometrists prescribing out of scope. The Board's proposed standard and guidelines and other safeguards in the system mitigate against these risks.

Comprehensive details about potential risks, risk mitigations, patient safety considerations and data from the New Zealand experience is in Appendix K.

Current service

Optometrists work in the community in a wide range of primary care settings, from private practice, low vision clinics and residential aged care facilities, through to the Visiting Optometrist Scheme in rural and remote areas and in Aboriginal Community Controlled Health Services. They are often the first health professional in the system to identify eye problems in the community. They also work in collaborative practice with ophthalmologists, general practitioners (GPs), nurses and Aboriginal and Torres Strait Islander Health Practitioners and workers to care for patients as part of a healthcare team in hospital and community settings.

As of 31 March 2025, there were 7079 optometrists with general registration in Australia. Of these, 79.2 per cent (5605) were also registered with an endorsement for scheduled medicines.⁵ Since 2014, all graduates of Board-approved programs of study automatically qualify for general registration and an endorsement for scheduled medicines. The number and percentage of endorsed optometrists continues to increase each year.

Optometrists have had a number of subsidised items on the Medicare Benefits Schedule (MBS) since 1975 and the Pharmaceutical Benefits Scheme (PBS) since 2008. Optometrists that are PBS prescribers can register eligible Aboriginal and/or Torres Strait Islander patients for the Closing the Gap PBS Co-payment Program for PBS medicines. Some optometrists charge gap fees in addition to the Medicare rebate for consultations in the same way that some GPs do, however, most optometrists (94.2 per cent) bulkbill their patients. Where a medicine is not on the PBS, an endorsed optometrist may issue a prescription that does not attract PBS funding (a private prescription) as authorised by each state and territory. Optometrists ensure informed financial patient consent in line with the shared Code of conduct and they are also trained to request and interpret diagnostic pathology.

⁴ Turnbull, P and Craig, J 2021, 'Oral medication prescribing by optometrists in New Zealand', Clinical and Experimental Optometry, Vol 104, No 3, pp 425-427

⁵ Optometry Board of Australia, <u>Statistics</u>, optometryboard.gov.au, 2025, accessed 30 July 2025

⁶ Department of Health, Medicare quarterly statistics, www.health.gov.au, Australian Government, accessed 30 July 2025

Demonstrated service need

If a patient requires a topical medicine such as eye drops, an endorsed optometrist can write a prescription based on the local medicines and poisons legislation and the medicine lists. However, a patient is currently sent to a GP for a prescription when the optometrist identifies that an oral medicine is required.

Supports the National Medicines Policy, National Strategy for Quality Use of Medicines and Health Professionals Prescribing Pathway

The <u>National Medicines Policy</u> aims to ensure equitable, timely, safe and affordable access to high-quality and reliable medicines-related services for all Australians. It ensures medicines are used safely, optimally and judiciously, with a focus on informed choice and well-coordinated person-centred care through Quality Use of Medicines. The aim of the <u>National Strategy for Quality Use of Medicines</u> is to make the best possible use of medicines that improve health outcomes for all Australians.⁷

The proposal also supports the Health Professionals Prescribing Pathway and the need to improve consistency between professions on education and recognition of prescribing competence.

If optometrists were able to work to their full scope of practice in line with international regulatory best practice and as recommended in the <u>Scope of Practice Review</u>, they could improve equitable, timely, safe and affordable access pathways for patients. Patients could be seen by the most appropriate health professional, at the right time, in the most suitable place for common primary eye conditions.⁸

Importantly, the proposal has the potential to reduce eye health inequities experienced by Aboriginal and Torres Strait Islander Peoples, people living in rural and remote areas, older people and people from lower socioeconomic backgrounds.

More information about international optometry prescribing, Health Professionals Prescribing Pathway and Quality Use of Medicines is found in the background paper in Appendix K.

More access to culturally safe eye care services is required in Aboriginal and Torres Strait Islander communities

Aboriginal and Torres Strait Islander Peoples are disproportionally impacted by eye conditions, experiencing blindness and vision loss at three times the rate of other Australians. Eye diseases and vision problems are the most common long-term health conditions reported by Aboriginal and Torres Strait Islander Peoples and yet they have lower rates of eye examinations than other Australians. Barriers to Aboriginal and Torres Strait Islander eye health include accessibility and availability of culturally safe eye health services, availability of transport and outreach services, their cost and location. The complexity of the eye health system and continuity of care between optometrists, GPs, ophthalmologists, nurses, Aboriginal and Torres Strait Islander Health Practitioners and other care providers can also be a barrier to eye health.¹⁰

^{7 &}lt;u>Department of Health, National Medicines Policy resources collection</u>, www.health.gov.au, Australian Government, accessed 30 January 2023

⁸ Department of Health, Disability and Ageing, <u>Unleashing the Potential of our Health Workforce – Scope of Practice Review Final Report</u>, www.health.gov.au, Australian Government, accessed 30 July 2025

⁹ Vision 20/20 Australia, Avoidable blindness and vision loss, www.vision2020australi.org.au, accessed 24 January 2023

¹⁰ Australian Institute of Health and Welfare, <u>Eye health measures for Aboriginal and Torres Strait Islander people 2024</u>, 2024, www.aihw. gov.au, Australian Government, accessed 4 August 2025

More access to eye care services is required in rural and remote Australia

Geographic maldistribution of the health workforce and inequality in healthcare access is a known problem throughout regional and remote Australia. The GP Supply and Demand Study results indicate that there will not be enough GPs required to keep up with demand for GP services in the community. Statistical modelling suggests that Australia will also face an undersupply of ophthalmologists.

The map (Figure 1) and graph (Figure 2) below illustrate that optometrists are geographically more accessible compared to ophthalmologists, especially in rural and remote areas.

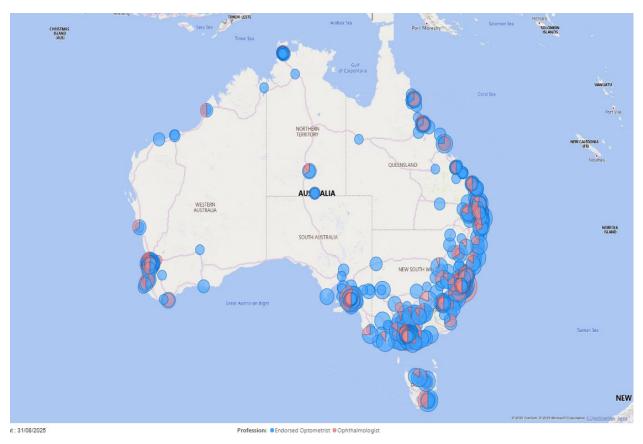


Figure 1. Map of Endorsed optometrists compared to ophthalmologists by principal place of practice – 30 September 2023 (Source: Ahpra data)

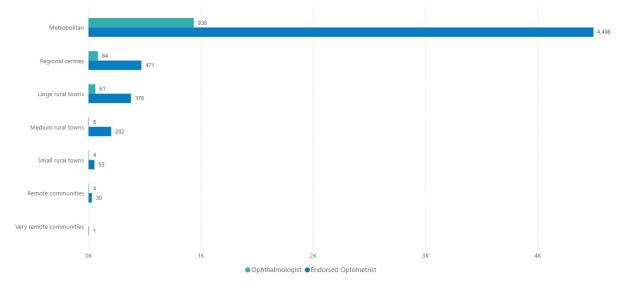


Figure 2. Distribution of endorsed optometrists compared to ophthalmologists by remoteness using the Modified Monash Model – 30 September 2023 (Source: Ahpra Data)

¹¹ Department of Health and Aged Care, Supply and Demand Study General Practitioners in Australia 2024, August 2024, www.health.gov.au, Australian Government, accessed 30 July 2025

¹² Department of Health, National Medical Workforce Strategy 2021–2031, 15 March 2022, <u>www.health.gov.au</u>, Australian Government, accessed 30 July 2025

There is an ongoing shortage of GPs and ophthalmologists in rural and remote areas, which contribute to the inequalities in timely patient access to eye care. Optometrists working to full scope in shared care arrangements with GPs would improve patient access in areas without ophthalmological coverage.

More timely and affordable access to eye care required

Patients are experiencing longer wait times to see their GPs.¹³ The Australian Institute of Health and Welfare (AIHW) found that one in five (19 per cent) adults felt waiting times to see a GP were longer than acceptable.¹⁴ Patients are also experiencing longer wait times in public ophthalmology, where initial specialist appointment wait times can be more than 300 days for non-urgent cases.¹⁵ Along with longer waiting times, patients are also facing rising out-of-pocket costs for GP and specialist consultations, which impacts most on Aboriginal and Torres Strait Islander Peoples, people living in rural and remote areas, people of low socioeconomic status and older members of the community with urgent eye health needs.¹⁶ The proposal supports the work undertaken by National Cabinet and state and territory governments around health workforce and facilitates better access to primary healthcare.

More person-centred collaborative practice models required

The Board's proposal gives more opportunities for teams of health practitioners to work together to provide person-centred collaborative practice models to improve eye health outcomes for all Australians. These teams could comprise a range of health practitioners such as optometrists, ophthalmologists, GPs, nurses, and Aboriginal and Torres Strait Islander Health Practitioners and workers in community, residential aged care and hospital settings.

According to Australia's Future Health Workforce report, patients benefit from collaborative practice models between ophthalmology and optometry through accessible, high-quality eye care, reduced wait times and timely follow-up.¹⁷

More up to date medicine lists

The current process of updating the medicine lists in the Board's guidelines takes considerable time and resources. This is because the lists are attached to the appendices of the guidelines and the guidelines undergo reviews in line with the <u>Consultation process of National Boards</u>.

The Board is aware that the current timeframes involved may inadvertently delay the public's ability to access up to date and effective medicines from an endorsed optometrist.

The proposal to publish the medicine lists on the Board's website would mean that the Board is able to update the lists in a timely and more efficient manner. The Board would continue to consult key stakeholders on proposed changes to the lists. The proposal balances the rigour of maintaining the lists, with timeliness, safety and enforceability.

Potential benefits

Potential benefits and what the proposed update may mean for patients

The proposed updates would mean an endorsed optometrist would be able to prescribe contemporary topical and oral medicines for a patient with a primary care eye condition in a single visit. These medicines could include:

- antibiotics for bacterial eye infections
- antiviral medicines for viral eye infections
- anti-allergics for eye conditions caused by allergy
- · anti-inflammatories for inflammation of the eye
- simple analgesics for short-term eye pain, and
- emergency treatment for acute angle closure, a blockage in the drainage pathway of the eye that can cause blindness if not treated within a few hours.

For patients, the proposal means greater choice about which health practitioner they choose to see, to safely have their eye condition treated. The proposal gives patients the opportunity to decide how and when they receive primary eye care.

¹³ Australian Bureau of Statistics, More people waiting longer to see GPs for urgent medical care, 19 November 2022, www.abs.gov.au, accessed 24 January 2023

¹⁴ Deloitte, General Practitioner Workforce report 2022, May 2022, www.deloitte.com.au, accessed 16 June 2022

¹⁵ Optometry Australia, Working together for better eye care, 2021, www.optometry.org.au accessed 25 May 2022

¹⁶ A Scott, The concern of rising out of pocket health costs, 29 April 2022, www.racgp.org.au, accessed 30 January 2023

¹⁷ Department of Health, Ophthalmology – Australia's Future Health Workforce report, July 2018, www.health.gov.au, Australian Government, accessed 13 April 2022.

For patients who choose to see an endorsed optometrist, the proposal could mean:

- easier and greater access to the right level of eye care in a timely way
- improved patient journey
- reduced visits to multiple healthcare professionals
- potential savings in travel, waiting times and out-of-pocket medical consultation costs
- possible small increases in the cost of medicines not covered by government benefits, and
- prevention of vision loss.

Prevention of vision loss has many positive flow-on effects to patients and their carers, including improving a person's quality of life, independence, mobility, mental health, cognition, social function, employment, and educational achievement.

Potential benefits and what the proposed update may mean for Aboriginal and/or Torres Strait Islander patients

For Aboriginal and Torres Strait Islander patients, the proposal may also mean that the Visiting Optometrist Service or an Aboriginal Community Controlled Health Service could provide:

- improved access to timely, comprehensive, culturally safe primary eye care services
- reduced complexity and fragmentation of multi-referral or treatment pathways, and
- reduced wait times, travel, and costs for appointments for primary eye care.18

Potential benefits and what the proposed update may mean for endorsed optometrists

The proposed updates would mean optometrists would be able to practise to their full scope of practice. This would increase access pathways for patients to be seen by the most appropriate health professional, at the most appropriate time, in the most appropriate place for primary eye conditions.

For endorsed optometrists who prescribe medicines, the proposal would:

- allow for the prescription of a wider range of appropriate topical and oral medicines that may be more effective in treating eye conditions within the primary care environment
- allow for the use of qualifications and training, to work to full scope of practice
- allow optometrists to practise contemporary optometry in line with New Zealand, the United Kingdom, most of the United States and some parts of Canada
- mean optometrists would need to plan and identify how they can further develop competency in prescribing topical and oral medicines as part of a life-long process of continuing professional development (CPD), in line with the Board's current CPD registration standard, and
- provide clarity on what they are qualified to prescribe.

Potential benefits and what the proposed update may mean for other health practitioners

Optometrists are highly skilled in primary eye care and have the competencies to safely treat primary eye conditions with the appropriate eye equipment, e.g. slit lamps. Optometrists, medical practitioners, Aboriginal and Torres Strait Islander Health Practitioners and workers, pharmacists and nurses bring different perspectives and skills to benefit patients. The proposal may impact health practitioners in different ways.

For GPs and ophthalmologists, the proposal may mean:

- potentially more time to care for patients with more urgent and complex conditions and to address the backlog of appointments due to workforce shortages
- reduced patient waiting times
- clarity on what an optometrist is qualified to prescribe
- increased opportunities for GPs, optometrists, nurses, Aboriginal and Torres Strait Islander Health Practitioners and workers and ophthalmologists to work together in collaborative practice models
- they have reassurances that optometrists would continue to provide the patient with a referral to an ophthalmologist or ophthalmology service within four months of starting treatment for chronic glaucoma using patient-centred approaches, informed by the best available evidence and Quality Use of Medicines principles.

For Aboriginal and Torres Strait Islander Health Practitioners and workers, the proposal may mean:

- improved access to timely, comprehensive eye care services and treatment for their patients
- increased ability to coordinate care and facilitate access resulting in reduced workload

¹⁸ This has been provided by an Indigenous consultant who gathered feedback from Indigenous eye health experts.

- increased opportunities for Aboriginal and Torres Strait Islander Health Practitioners and workers, optometrists, GPs, nurses and ophthalmologists to work together in collaborative practice models, and
- enhanced skill set, job satisfaction and career prospects.

For pharmacists, the proposal may mean:

- they would dispense prescriptions from endorsed optometrists, where the medicine may be taken orally
- clarity on what an optometrist is qualified to prescribe by referring to the medicine lists on the Board's website²⁰
- that they could receive a private prescription from an endorsed optometrist to dispense Schedule 4 topical and oral medicines, and
- increased opportunities for pharmacists and optometrists to work together in collaborative practice models.

For nurses, the proposal may mean:

- more time to care for patients with the biggest impact expected for nurse case managers who are coordinating multi-disciplinary care and appointments for patients
- reduced patient waiting times, and
- increased opportunities for nurses, optometrists, GPs, Aboriginal and Torres Strait Islander Health Practitioners and workers and ophthalmologists to work together in collaborative practice models.

Potential benefits and what the proposed update may mean for governments

After a wide-ranging public consultation, the Board may make a recommendation to the Ministerial Council to approve the proposed variation to the existing scheduled medicines endorsement, for Ministerial Council assessment and decision.

For governments the proposal may mean:

- that an expansion of optometry prescribing could enable full scope of practice and facilitate better access to primary care, possibly reducing GP and ophthalmologist waiting times and reducing hospital admissions
- an improvement in consumer access to person-centred care, reduced duplication and the delivery of better eye health outcomes
- reduced wait times and improved availability of treatment options for Aboriginal and Torres Strait Islander Peoples through improved access to comprehensive eye-care services, particularly in rural and remote areas
- the prevention of blindness and vision impairment would reduce the burden on the health system, on National Disability Insurance Scheme, My Aged Care and time loss from work due to treatable eye conditions
- further support for the National Medicines Policy to ensure equitable, timely, safe and affordable access to high-quality and reliable services for all Australians
- further support for the National Strategy for Quality Use of Medicines to make the best possible use of medicines to improve health outcomes for all Australians
- more support for work carried out by National Cabinet and state and territory governments around health workforce and facilitating better access to primary healthcare, and
- some changes would be required to the current medicines and poisons legislation in Queensland, Tasmania and Western Australia and the Victorian Gazette in Victoria.

The background paper in Appendix K provides detailed information, evidence and data that the Board has considered to address the requirements in the Australian Health Ministers' Advisory Council Guidance for National Boards: Applications to the Ministerial Council for approval of endorsements in relation to scheduled medicines under section 14 of the National Law (AHMAC guidance) and further detail about what an update may mean for governments.

¹⁹ Provided by an Indigenous consultant, Delivering eye care services to Aboriginal and Torres Strait Islander People report, October 2022

²⁰ Pharmacists will still need to comply with the requirements of the medicines and poisons legislation in the relevant state or territory and the Optometrical PBS list for subsidised medicines.

Scenarios where the proposal may benefit the community

To help understand the application in practice of the revised standard and guidelines, the Board has developed the following scenarios. The scenarios have been adapted from real examples provided by endorsed optometrists.

These are not **clinical case studies**, rather they are intended to demonstrate how the proposed regulatory changes might benefit patients of endorsed optometrists.

Scenario one

Kirra, a 60-year-old woman had a painful, red, light-sensitive, right eye. Kirra went to the local Aboriginal Medical Service (AMS) and was able to see a visiting endorsed optometrist.

The optometrist found an ulcer on Kirra's right cornea at the front of her eye and a rash around her eye and on the tip of her nose. After discussing her medical history, the optometrist diagnosed that the ulcer was a complication of shingles, called herpes zoster keratitis, which can cause blindness. Evidence based treatment for this condition is oral antiviral therapy.

The optometrist prescribed oral antiviral therapy for seven days after considering contraindications and allergies. The optometrist advised Kirra's Aboriginal and Torres Strait Islander Health Practitioner and the GP of the diagnosis and treatment plan. At a telehealth review two days later, the optometrist confirmed that Kirra's eye had responded well to the oral antivirals. At the follow-up review seven days later, the symptoms had cleared and she was feeling and seeing much better. No follow up therapies were required.

With the current standard and guidelines, the optometrist would need to refer the patient to the GP or ophthalmologist to prescribe antiviral tablets. Kirra would have needed to wait until a GP or ophthalmologist was available or attended a hospital emergency room to obtain optimal treatment for her painful red eye, which means she would be in pain longer and the final outcome on her vision may be worse.

With the proposed standard and guidelines, endorsed optometrists could prescribe medicines, including oral medicines, for the purposes of the practice of optometry. The proposed guidelines would continue to provide guidance on appropriate use of medicines, Quality Use of Medicines, working with other practitioners and referrals. Optometrists would work collaboratively with GPs, nurses, Aboriginal and Torres Strait Islander Health Practitioners and workers.

For the endorsed optometrist, this scenario shows how they could prescribe oral antivirals, as an effective treatment for herpes zoster keratitis, in line with Quality Use of Medicine principles. The treatment of herpes zoster keratitis is most effective when started within 72 hours of a rash.

For the patient, this scenario shows how they could receive the right level of eye care directly from an optometrist, where existing GP waiting times could delay treatment. In this scenario, the earlier the treatment the more effective it is.

For the GP, this scenario shows how an optometrist can help relieve their workload, easing pressure on existing waiting times and freeing up time to care for patients with more complex conditions.

This scenario has been adapted from a real example provided by an Indigenous endorsed optometrist working in an Aboriginal Medical Service.

Scenario two

Hamzah, a nine-year-old boy, had a red swollen right eyelid that started the day before and seemed to be getting worse. His parents took him to their regular endorsed optometrist who saw him on that same day. The optometrist diagnosed Hamzah with a mild pre-septal cellulitis, a bacterial infection of his eyelid. After obtaining consent from Hamzah's parents, the optometrist prescribed a course of oral antibiotics in line with best available evidence, after considering other important factors, such as Quality Use of Medicines, paediatric dosage, contraindications, drug interactions, allergies and antimicrobial stewardship.

The optometrist advised Hamzah's parents to monitor him closely, and that if Hamzah's symptoms do not improve, or worsen, including any nausea, vomiting, headache, or fever, they should urgently present to Hamzah's GP or emergency department. The optometrist also wrote to Hamzah's GP updating them on Hamzah's condition, diagnosis and treatment.

At a follow-up appointment the next morning, Hamzah and his parents reported that the swelling and redness in his eyelid had improved, which was confirmed on clinical examination. The optometrist reinforced the importance of completing the course of antibiotics and to return if the symptoms worsen or came back again. The optometrist updated Hamzah's GP on the treatment plan.

With the current standard and guidelines, the optometrist needs to refer Hamzah to the GP to write a prescription for the required oral antibiotic. Currently there are increased waiting times for appointments with GPs and if out of business hours, some patients may choose to see a doctor in a hospital emergency department.

With the proposed standard and guidelines, endorsed optometrists could prescribe medicines, including oral medicines, for the purposes of the practice of optometry. The proposed guidelines would continue to provide guidance on appropriate use of medicines, Quality Use of Medicines, antimicrobial resistance and working with other practitioners.

For the endorsed optometrist, this scenario shows how they could prescribe oral antibiotics, as an effective treatment for mild pre-septal cellulitis, in line with Quality Use of Medicine and antimicrobial stewardship principles.

For the patient, this scenario shows how he could receive the right level of eye care directly from an optometrist. He wouldn't need to wait in pain until he could get to a GP appointment or attend a hospital emergency room, if no other options were available. The patient journey would be improved by easier access to primary eye care, without GP waiting times or out-of-pocket costs.

For the GP, this scenario shows how an optometrist can help ease pressure on existing waiting times and free up appointment times for patients with urgent and complex conditions.

Scenario three

Jeff developed a painful, red, and watery right eye with symptoms progressing to blurry vision and acute pain. Over the counter medicines were not helping the condition, so Jeff made an urgent appointment with his endorsed optometrist.

The optometrist examined Jeff's eye, and checked on Jeff's current medicines, allergies and family history, which included glaucoma. The endorsed optometrist diagnosed Jeff with acute angle closure. Acute angle closure causes a very rapid increase in the pressure in the eye with associated extreme pain due to the fluid drainage pathway of the eye suddenly becoming blocked. Left untreated, it could lead to irreversible vision loss from resulting glaucoma, or even blindness within hours.

Jeff's condition was a medical emergency. Use of eye drops in the consulting room did not lower the pressure in his eye. The optometrist called the closest hospital emergency department with access to an ophthalmology service but couldn't get through and left a message. The optometrist checked the best available evidence to help preserve the vision in Jeff's right eye.

After considering dosage, contraindications and allergies, the optometrist prescribed a single tablet of anti-glaucoma medicine. The optometrist gave Jeff the medicine from the clinic's emergency supply. This medicine decreased the pressure in Jeff's eye, allowing Jeff time to make the trip to the hospital emergency department to obtain appropriate additional treatment by an ophthalmologist, without risking his sight further.

The optometrist helped organise transport to the hospital, and when the ophthalmologist called back, the optometrist provided an update and a referral. The optometrist also wrote to Jeff's GP to advise on the diagnosis and ongoing treatment plan.

Once the surgical treatment was completed, the ophthalmologist gave Jeff written information about his ongoing treatment plan and advised a follow-up appointment with the optometrist. The ophthalmologist also scheduled ongoing consultations and wrote to the GP and optometrist to advise on the ongoing treatment plan.

The optometrist's early intervention was important in helping to ensure Jeff didn't lose his vision.

Although this scenario is a rare occurrence, urgent treatment by an optometrist with the anti-glaucoma oral medicine, a single tablet of oral acetazolamide, could save a patient's vision. With the current standard and guidelines, the optometrist would be unable to prescribe acetazolamide. The optometrist would need to liaise with a medical practitioner, for them to arrange supply of acetazolamide.

With the proposed standard and guidelines, endorsed optometrists could prescribe medicines, including oral medicines, for the purposes of the practice of optometry. The proposed guidelines would continue to provide guidance on appropriate use of medicines, Quality Use of Medicines, working with other practitioners and referrals.

For the endorsed optometrist, this scenario shows how they could prescribe oral acetazolamide for acute angle closure for immediate medical treatment. They would continue to refer to an ophthalmologist for transfer of care.

For the ophthalmologist, this urgent scenario shows how an optometrist could help initiate therapeutic

treatment in a medical emergency in the best interest of the patient. It also shows how ongoing collaborative practice arrangements can free up hospital resources.

For the patient, this scenario shows how they can receive better emergency care from a healthcare team that works collaboratively in their best interest.

While this example is adapted from the experience of a patient living in a metropolitan area, patients living in rural or remote communities are likely to see the most benefit from the proposed changes.

Scenario four

Carmel experienced dry, gritty, itchy, red, sore and blurry eyes along with itchy, red eyelids and persistent facial redness and flaky skin on their forehead for a few months. They had tried over-the-counter lubricating eye drops from the pharmacy with no relief, so then visited their endorsed optometrist.

After taking a thorough history, including medicines and allergies, the optometrist examined Carmel's eyes and vision. The optometrist diagnosed Carmel with posterior blepharitis associated with ocular rosacea. Blepharitis is a condition where the oil-secreting glands in the eyelid become inflamed and blocked, leading to chronic dry and irritable eyes and sore, itchy eyelids with crusting on the eyelashes. Ocular rosacea is caused by a disease involving the skin and eyes, where the skin becomes red, thick, flaky and irritated.

According to best available evidence, the optometrist prescribed an oral antibiotic with anti-inflammatory properties, a lubricating eye drop, gentle eyelid scrubs, warm compresses and eyelid massage. The optometrist wrote to Carmel's GP to update them on the treatment plan.

Carmel's eyes responded well to the course of oral antibiotics. By the three-month review, their eyes and eyelids were no longer red and itchy, and they were feeling and seeing much better. The oral antibiotics were stopped while the maintenance therapies, such as lubricating eye drops, gentle eyelid scrubs, warm compresses and eyelid massage were continued to reduce the risk of recurrence.

In this scenario, with the current standard and guidelines, the optometrist would still need to refer the patient to the GP to write a prescription for the oral antibiotic.

With the proposed standard and guidelines, endorsed optometrists could prescribe medicines including oral medicines, for the purposes of the practice of optometry. The proposed guidelines would continue to provide guidance on appropriate use of medicines, Quality Use of Medicines, antimicrobial resistance and working with other practitioners.

For the endorsed optometrist, this scenario shows how they could prescribe oral antibiotics, as an effective treatment for blepharitis and ocular rosacea, in line with quality use of medicine and antimicrobial stewardship principles.

For the patient, this scenario shows how they could receive the right level of eye care directly from an optometrist, without additional trips to the GP. The patient journey would be improved by having easier access to primary eye care, without GP waiting times or out-of-pocket costs.

For the GP, this non-urgent scenario shows how an optometrist can help ease pressure on existing waiting times and free-up time for patients with more urgent and complex conditions.

Potential costs

All optometrists would need to become familiar with the new proposed standard and guidelines

Should Ministerial Council approve the proposal, all endorsed optometrists and new graduates from approved programs of study would be recognised as qualified and competent to prescribe according to the endorsement from the date of effect. Endorsed optometrists who prescribe medicines have an obligation to complete education and professional development in line with the Board's Continuing Professional Development (CPD) registration standard before prescribing any medicines new to their practise, or medicines that they do not have recent experience with.

The Board would work with CPD providers and approved programs of study to ensure that endorsed optometrists and new graduates understand the new standards and guidelines.

Other stakeholders would need to become familiar with the new proposed standard and guidelines

Other stakeholders would need to become familiar with the new proposed standards and guidelines. Stakeholders may be unsure of what medicines an endorsed optometrist would be able to prescribe with the relocation of the list.

If unsure, stakeholders could:

- refer to the standard, guidelines, support document and frequently asked questions (FAQs) published by the Board and available on the Board's website
- obtain advice from local contacts for state or territory medicines and poisons regulation units about what an optometrist is authorised to prescribe, and/or
- obtain support advice from Optometry Australia, the peak professional association, as it develops the entry-level competency standards for the profession.²¹

For information on the potential risks and risk mitigations that the Board has considered, refer to the background information in Appendix K.

Prescriptions and pathology testing would be at private prices

The financial cost of any oral and new topical medicines would be at private prices and would vary across pharmacies, until there are changes in the PBS. The difference in cost between a private prescription and PBS funded prescription for many of the proposed oral medicines for eye conditions is minimal or has no cost difference for non-concession holders. For concession holders, the medicine cost may be more, but it would save them wait times and out of pocket costs associated with further medical consultation and related travel.

Any related pathology tests would also be at private prices and would vary across pathology testing sites, until there are changes in the MBS. Optometrists would continue to ensure informed financial patient consent in line with the shared Code of conduct.

It is Optometry Australia, the peak professional association's role to advocate for medicines to be added to the PBS and pathology testing to be added to the MBS on behalf of the profession, and it would be able to do so if this proposal is approved. The Board has consulted with Optometry Australia on this, as it is the Board's intention not to disadvantage patients. If approved, Optometry Australia would use the transition period to advocate to add medicines to the PBS and pathology testing to the MBS, with the intention for this to be in place by the date of the commencement of the proposed standard. However, this cannot be guaranteed as additions to the PBS and MBS remain a decision for the federal government and its delegates.

Optometrists are currently able to register eligible Aboriginal and Torres Strait Islander patients for the Closing the Gap PBS Co-payment Program. Should the proposal be approved and medicines be added to the PBS, eligible Aboriginal and Torres Strait Islander patients would then be able to get medicines free with a concession card (or at concession prices without a concession card).

Other eligible consumers would be able to get these medicines at concession prices with a concession card. This would improve access to affordable medicines to those most in need.

²¹ Optometry Australia, Oral therapeutic prescribing by Australian Optometrists, 2022

Options

Option 1 - Status quo (keep things the same)

Under this option, the current endorsement, registration standard and guidelines would stay the same. This means endorsed optometrists would still not be able to prescribe contemporary oral and topical medicines for common eye conditions, even though they are trained and qualified to do so. Keeping things the same risks non-contemporary restrictions on the scope of practice of optometrists.

As a result, consumers would have fewer choices and may face delays in getting the eye care that they need in a timely manner. Optometrists would continue to refer patients to GPs or ophthalmologists for prescriptions that optometrists are qualified to write. Consumers would continue to experience long wait times, extra appointments, out of pocket costs for travel and medical consultations.

There are also concerns about keeping outdated guidance in the current guidelines. For example, Section 7: Guidelines for care of patients with, or at high risk of developing, chronic glaucoma is no longer contemporary or based on best available evidence as it references rescinded clinical guidelines. This can create confusion, pose a risk to the public and contradict the shared Code of Conduct. Including clinical advice in regulatory guidelines makes it challenging to keep them current.

Should the status quo continue, the opportunity for improvement would be missed and result in the standard and guidelines becoming progressively less contemporary, effective and relevant.

Option 2 - Revise the endorsement, standard and guidelines

This option proposes a full review and update of the endorsement, standard, and guidelines. The last major review was in 2018, with the guidelines undergoing minor revisions to its Appendix B in 2019 and 2021. There has subsequently been a proposal from the professional association to amend the existing endorsement with an opportunity to improve the standard and guidelines.

The Board would submit a proposal to update the existing endorsement and the revised standard to the Ministerial Council for approval. The proposed updates are informed by research, reflect international best practice, support cross-profession consistency (where appropriate), and promote regulation that is effective, proportionate to risk, and fit for purpose.

This option addresses the limitations of option 1, by enabling optometrists to work to their full scope, prescribing contemporary oral and topical medicines for common eye conditions. This option strengthens the Board's contribution to accessible and sustainable healthcare, by optimising health workforce efficiencies in the system.

It supports the National Medicines Policy and the National Strategy for Quality Use of Medicines, helping ensure medicines are used effectively and safely across the health system. ²²

It would give consumers greater choice and timely access to eye care at their primary visit, eliminating unnecessary appointments, reducing patient travel and out of pocket costs and improving eye health outcomes. It would give patients the right level of care at the right time.

The proposed standard and guidelines mitigate risks of prescribing errors, poly pharmacy, fragmentation of care and prescribing out of scope.

Contemporary standards and guidelines would clearly show what is expected of endorsed optometrists, helping the public, employers, regulators and professional groups understand these expectations.

Preferred option

The Board's preferred option is option 2.

²² Department of Health, <u>National Strategy for Quality Use of Medicines</u>, June 2002, www.health.gov.au, Australian Government, accessed 30 January 2023

Estimated impacts of option 2

The impact on practitioners, businesses, the public and other stakeholders arising from the updates proposed are expected to be small and positive for the general public. The positive impacts are more likely to affect:

- Aboriginal and Torres Strait Islander communities
- people in rural and remote areas
- · people from lower socioeconomic backgrounds, and
- older people, including people living in residential aged care facilities.

Although small in numbers, the benefits of these priority groups having increased choice and timely access to safe primary eye care outweighs the low risk of optometrists prescribing out of scope.

The Board anticipates the uptake of endorsed optometrists wanting to expand their scope of practice to prescribe oral medicines to be slow, conservative and safe, similar to the New Zealand experience.

The evidence and data outlined in the background paper in Appendix K indicate that the level of risk to the public is low and is outweighed by the benefits to the public. This includes increased access to care, and fewer health practitioner visits than would be required under option 1.

Consultation questions

The Board is inviting general comments on the proposed draft *Endorsement for scheduled medicines* registration standard and *Guidelines for the use of scheduled medicines*, as well as feedback on any or all of the following questions.

Consultation questions for consideration

- 1. Do you prefer option 1 (status quo) or option 2 (Board's proposal) and why?
- 2. Do the proposed updates have specific impact on Aboriginal and Torres Strait Islander Peoples? If yes, please describe.
- 3. Can you think of any unintended consequences from the proposal that haven't been addressed by the Board? If so, please describe them and provide evidence if possible.
- 4. Do you have any other comments?

The Board is also interested in your views on the following topics.

- 5. Is there anything that needs to be changed, added or removed in the proposed draft standard and guidelines? Please provide details.
- 6. Would the proposed updates result in any adverse cost implications for practitioners, consumers or other stakeholders? If yes, please describe.
- 7. Would the proposed updates result in any potential positive or negative unintended effects for members of the community at risk of experiencing poorer health outcomes? If so, please describe them
- 8. Do you have any feedback about the proposed draft medicine lists?
- 9. Can you identify any other potential regulatory impacts that the Board needs to consider?

If you prefer not to answer all the questions above, you may wish to only answer questions 1 to 4 in the <u>survey</u>.

When the proposal would come into effect

The stages for developing and finalising a proposal are below. The current stage is public consultation with stakeholders.



- Public stakeholder feedback will inform the revised standard and guidelines.
- As part of finalising the standard and guidelines:
 - the Board will finalise proposed revisions to the standard, and agree to submit the revised standard to the Ministerial Council for consideration
 - the final revised draft of the guidelines will be submitted to the Board for final approval
 - if the Board decides to approve changes to the guidelines, and the Ministerial Council decides to approve the revised standard, both will come into effect together
 - the Board will provide the start date to all stakeholders and advance notice of a 12 month implementation period, and
 - the Board will work with CPD providers and approved programs of study to ensure that endorsed optometrists and new graduates understand the new standards and guidelines should they be approved.^{23, 24}

Supporting consultation materials

Background paper

The background paper in Appendix K provides detailed information that the Board has considered to address the requirements of the AHMAC Guidance for National Boards: Applications to the Ministerial Council for approval of endorsements in relation to scheduled medicines under section 14 of the National Law (the AHMAC guidance) and Ahpra Guide for National Boards developing submissions under the AHMAC Guidance for National Boards: Applications to the Ministerial Council for approval of endorsements in relation to scheduled medicines under section 14 of the National Law (the Ahpra guide).

The background paper provides additional information, evidence and data that ensures the regulatory and quality control measures proposed are sufficient to support safe and effective use of scheduled medicines.

Consumer consultation guide

The Board has developed a snapshot and consumer consultation guide in Appendix B and C respectively. While they are not part of the draft standard or guideline, they may provide helpful context for consumers to participate in the consultation.

Frequently asked questions (FAQs)

The Board plans to publish a FAQs document. The FAQs will be informed by the feedback from stakeholders at the public consultation.

²³ Section 39 of the National Law, it is the Board's responsibility to develop and approve guidelines to provide guidance to optometrists.

²⁴ Section 38 of the National Law, it is the Board's responsibility to develop and recommend registration standards to the Ministerial Council.

Appendices

Appendix A: What informed the proposal

Appendix B: Snapshot of the public consultation

Appendix C: Consumer consultation guide

Appendix D: DRAFT Registration standard: Endorsement for scheduled medicines

Appendix E: DRAFT Guidelines for use of scheduled medicines

Appendix F: DRAFT Medicine list for general optometrists

Appendix G: DRAFT Medicine list for endorsed optometrists

Appendix H: Proposed draft standard and proposed draft guidelines comparison tables

Appendix I: Patient and consumer health and safety impact statement

Appendix J: Statement of assessment against Ahpra's Procedures for the development of registration

standards, codes and guidelines

Appendix K: Background paper

Appendix A: What informed the proposal

The Optometry Board of Australia (the Board) considered the following information when reviewing the standard and guidelines for the public consultation:

- Regulatory principles for the National Scheme
- Consultation process of National Boards
- <u>Procedures for the development of registration standards, codes and guidelines</u>, which outlines the requirements for the development and review of registration standards and guidelines in line with the National Law
- <u>COAG Health Council Policy Direction 2019–02</u> which directs National Boards and the Australian Health Practitioner Regulation Agency (Ahpra) to consult with patient safety bodies and healthcare consumer bodies on revised registration standards and guidelines
- National Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025
- AHMAC Guidance for National Boards: Applications to the Ministerial Council for approval of
 endorsements in relation to scheduled medicines under section 14 of the National Law (the <u>AHMAC</u>
 guidance), which outlines the requirements for a National Board to amend an existing scheduled
 medicines endorsement
- Ahpra Guide for National Boards developing submissions under the AHMAC Guidance for National Boards: Applications to the Ministerial Council for approval of endorsements in relation to scheduled medicines under section 14 of the National Law (the <u>Ahpra guide</u>), which expands on the AHMAC guidance and outlines the process of amending an existing scheduled medicine endorsement
- National Medicines Policy
- Quality Use of Medicines
- NPS MedicineWise Prescribing Competency Framework (now known as the National Prescribing Competencies Framework)
- The Health Professionals Prescribing Pathway
- · Medication management in the community.

The proposed changes to the standard and guidelines were informed by:

- the Board's and Ahpra's experiences with the standard and guidelines
- · Ahpra data of registered optometrist notifications related to prescribing
- Ahpra data of registered endorsed optometrists and ophthalmologists' principal place of practice
- Ahpra data and Optometrist and Dispensing Opticians Board of New Zealand data on registered practitioners under the *Trans-Tasman Mutual Recognition Act 1997*
- a desktop review of:
 - the health professions registered under the National Scheme with an endorsement for scheduled medicines, and
 - other jurisdiction's regulatory model of optometrists prescribing oral medicines in New Zealand, the United Kingdom, Canada and the United States
- Optometry Council of Australia and New Zealand / Queensland University of Technology report on Prescribing oral medicines by optometrists: a mapping of current education programs and professional practice standards to demonstrate the preparation of optometrists to prescribe medicines for oral administration – dated December 2020
- Optometry Australia report on Oral therapeutic prescribing by Australian Optometrists dated February 2022
- Optometrists and Dispensing Opticians Board of New Zealand 2021 data on safe oral prescribing of New Zealand optometrists
- workshops at the Optometry Regulatory Reference Group 2021 and 2022 meetings
- the cross-profession template in the Ahpra guide
- advice from the Board's Scheduled Medicine Advisory Committee
- advice from Ahpra's Scheduled Medicines Expert Committee
- advice from the **Consumer Advisory Committee**
- · advice from an Indigenous consultant and feedback from Indigenous eye health experts
- advice from the Wordsmithing Working Group of the <u>Aboriginal and Torres Strait Islander Health Strategy</u> Group.

The proposed changes to Section 7 of the current guidelines were informed by:

• the outcomes of a targeted consultation with relevant key professional ophthalmology and optometry

Appendix B: Snapshot

Who is the Optometry Board of Australia?

The Optometry Board of Australia (the Board) protects the public by regulating optometrists. The Board sets requirements for optometrists through their endorsement, code, registration standards and guidelines.

What is happening?

The Board is starting its public consultation on the review of the <u>Registration standard: Endorsement for scheduled medicines</u> (the standard) and <u>Guidelines for use of scheduled medicines</u> (the guidelines) and would like your views.

What is the Board proposing?

Right now, endorsed optometrists can prescribe topical eye drops and ointments for common eye conditions. The Board is proposing to:

- expand what endorsed optometrists are qualified to prescribe, so that optometrists can prescribe topical and oral medicines (taken by mouth) for common eye conditions
- change the endorsement, standard and guidelines to keep them up to date, to support consistency
 across registered health professions and so that everyone knows what optometrists are qualified and
 expected to do
- remove clinical guidance from the regulatory guidelines to future proof them, and
- move the medicine lists from the appendices of the Board's guideline to its website, so that everyone will easily see what optometrists are qualified to prescribe. This will make updates to the lists timelier, while continuing to keep safety checks in place.

Endorsed optometrists would treat common eye problems like infections, allergies and short term pain using both topical and oral medicines within the limits of their skill and training, without needing to send you to a medical practitioner, unless it's really required.

What does this mean for consumers?

- More choice: you decide who, how, when and where you receive primary eye healthcare.
- More timely access: it's easier, faster and more convenient to see your optometrist than your general practitioner or ophthalmologist, for common eye conditions. There's also less wait times.
- More affordable eye care: Receiving safe treatment for common eye conditions from your optometrist at your first visit, means less travel time and out of pocket consultation costs to see a medical practitioner (GP).
- Good eye health outcomes: early access to eye care can protect and save your vision.

If the proposal goes ahead, endorsed optometrists will be able to prescribe additional medicines. These will initially not be funded under the Pharmaceutical Benefits Scheme (PBS) and will be sold at private (non-PBS funded) prices, which will vary across pharmacies. You might notice a small increase in cost, but for most people it will be minimal for the proposed medicines. The peak optometry professional association will try to get these medicines added to the PBS, to help make them cheaper and easier to access, but this isn't guaranteed.

Why is the Board proposing this change?

The Board's current standard is due for a full review. The professional association requested a change to the Board's endorsement to recognise that endorsed optometrists in Australia are qualified to prescribe oral medicines. The Board has strong evidence to progress and consult on the proposal.

Where do I get more information?

See the consultation paper for more details, including a consumer guide at Appendix C and consumer impact statement in Appendix I.

How to make a submission?

Provide your feedback by COB (AEDT) 24 December 2025 by completing the short, two to five minute <u>survey</u>, or send the response template to <u>optomconsultation@ahpra.gov.au</u>.

Appendix C: Consumer consultation guide

Review of the Registration standard: Endorsement for scheduled medicines and Guidelines for use of scheduled medicines

The Optometry Board of Australia (Board) protects the public by regulating optometrists. The Board's endorsement, standard and guidelines outline the Board's expectations of optometrists.

As a patient or consumer, you have the right to choose your health practitioner for safe eye care. The Board is putting forward a proposal that may affect you, by providing more choice about which health practitioner you choose to see for an eye condition.

This consultation guide will help you understand the main proposed changes in the public consultation documents.

We want to hear what you think about the proposed changes.

What are the proposed changes?

Currently, endorsed optometrists are recognised by the Board as qualified and trained to prescribe topical eye drops and eye ointments.

The main proposed changes are to:

- expand what endorsed optometrists are qualified to do, so that optometrists can prescribe topical and oral medicines (taken by mouth) for common eye conditions
- change the endorsement, standard and guidelines to keep them up to date, to support consistency
 across registered health professions and so that everyone knows what optometrists are qualified and
 expected to do
- remove clinical guidance from the regulatory guidelines to future proof them, and
- move the medicine lists from the appendices of the Board's guideline to its website, so that everyone will easily see what optometrists are qualified to prescribe. This will make updates to the lists timelier, while continuing to keep safety checks in place.

These proposed changes would give you the choice of visiting an optometrist or your general practitioner (GP), for the same eye condition. This may reduce waiting times and out of pocket GP consultation costs. The Board believes this will help patients access the right care at the right time.

With this proposal, an optometrist would be endorsed as qualified to prescribe oral medicines (taken by mouth) for eye conditions such as:

- antibiotics for people with bacterial eye infections
- antihistamines for people with eye conditions caused by allergy
- antiviral medicines for viruses effecting the eye, and
- emergency treatment for acute angle closure, a blockage in the eye that can cause blindness if not treated within a few hours.

The Board would publish the proposed medicine lists (Appendix F and G) on its website, so that everyone will easily see what optometrists are qualified to prescribe.

What the change might mean for you

This proposal would mean you have more choices about the health practitioner you choose to see to treat eye conditions. Your right to choose your preferred health practitioner for eye care is important.

The proposed changes would allow your optometrist to prescribe a wider range of medicines for eye conditions. This can help you get the right care at the right time, without having to travel or wait to see another health professional. Your optometrist would work within the limits of their skill and continue to collaborate with or refer to a GP or ophthalmologist outside of these limits.

The Board has found that optometrists are often more accessible compared to ophthalmologists, especially in rural and remote areas. See figure 1 of the public consultation paper for a detailed location comparison.

Depending on where you live, the proposed changes could reduce delays in receiving treatment, save travel and waiting time, provide faster eye care, and could even prevent you from losing your eyesight.

This proposal is aiming to increase consumer access and affordability to eye care. Most optometrists bulk bill via Medicare and your optometrist's billing is not likely to change. The proposed medicines will not be covered by the Pharmaceutical Benefits Scheme but may be covered in the future. While consumers may notice a small increase in cost, for most people it will be minimal. Optometrists will continue to check that they have your financial consent as part of their service.

Occasionally optometrists may need to order pathology tests as part of your treatment. The cost of pathology tests is paid by the you, the consumer, as optometry requests are not currently covered by the Medicare Benefits Scheme.

The proposed changes may help to relieve some of the pressure on GP and ophthalmologist waiting times. The changes also support the <u>National Medicines Policy</u> to optimise health outcomes for all Australians through timely access to medicines in line with <u>Quality Use of Medicines</u> principles.

To read what has changed from the current versions of the standard and guidelines, please see Appendix H of the public consultation paper.

What does the change mean in practice?

Optometrists work in the community in a wide range of primary care settings, from private practice, low vision clinics, and residential aged care facilities, through to the Visiting Optometrist Scheme in rural and remote areas and via Aboriginal Community Controlled Health Services. They are often the first health professional in the healthcare system to identify eye problems in the community.

The proposal's potential benefits may affect people differently, depending on where you live in Australia and your situation. The following scenarios are adapted from real life examples provided by endorsed optometrists.

Scenario one

Kirra, a 60-year-old woman, had a painful, red, light-sensitive right eye. Kirra went to the local Aboriginal Medical Service (AMS) and was able to see a visiting endorsed optometrist.

The optometrist found an ulcer on Kirra's right cornea at the front of her eye, and a rash around her eye and on the tip of her nose. After discussing her medical history, the optometrist diagnosed that the ulcer was a complication of shingles, called herpes zoster keratitis, which can cause blindness. Evidence-based treatment for this condition is oral antiviral therapy.

The optometrist prescribed oral antiviral therapy for seven days after considering contraindications and allergies. The optometrist advised Kirra's Aboriginal and Torres Strait Islander Health Practitioner and the GP of the diagnosis and treatment plan. At a telehealth review two days later, the optometrist confirmed that Kirra's eye had responded well to the oral antivirals. At the follow-up review seven days later, the symptoms had cleared, and she was feeling and seeing much better. No follow-up therapies were required.

Visiting Optometrist Services, Aboriginal Community Controlled Health Services or local optometrists may offer a timely, accessible, affordable and culturally safe way of receiving primary health eye care for Aboriginal and Torres Strait Islander people living in rural or remote Australia. Being able to get treatment for common eye conditions by an optometrist where it's difficult to access multiple health professionals can improve eye health outcomes. Optometrists work collaboratively with GPs, nurses, Aboriginal and Torres Strait Islander Health Practitioners and Aboriginal and Torres Strait Islander Health Workers.

Under the current endorsement, Kirra would have needed to wait until a GP or ophthalmologist were available or attended a hospital emergency room to obtain optimal treatment for her painful red eye, which means she would have been in pain longer and the final outcome on her vision may have been worse.

Scenario two

Hamzah, a nine-year-old boy, had a red, swollen right eyelid that started the day before and seemed to be getting worse. His parents took him to their usual endorsed optometrist who saw him the same day. The optometrist diagnosed Hamzah with a mild preseptal cellulitis, a bacterial infection of his eyelid. The optometrist prescribed a course of oral antibiotics in line with best available evidence and after considering other important factors, such as paediatric tolerance, dosage, contraindications, allergies and antimicrobial stewardship. The optometrist advised Hamzah's parents to monitor him closely, and if his symptoms do not improve, or worsen, including any nausea, vomiting, headache, or fever, that they should urgently present to Hamzah's GP or emergency department. The optometrist also wrote to Hamzah's GP updating them on Hamzah's condition, diagnosis and treatment.

At a follow-up the next morning, Hamzah and his parents reported that the swelling and redness in his eyelid had improved, which was confirmed by the optometrist. The optometrist reinforced the importance of completing the course of antibiotics and to return if the symptoms came back again. The optometrist updated Hamzah's GP on the treatment plan.

The proposed changes may also increase convenience and choice for people living in urban areas. This may be particularly helpful when it is difficult to access a GP within an acceptable waiting time.

Under the current endorsement, Hamzah would have been referred to his GP, and would have waited in pain until he could either get an appointment or attend a hospital emergency room. His family may also have had additional out-of-pocket costs if his GP clinic does not bulk bill.

For more scenarios about how the proposal could benefit patients, see the section titled 'Scenarios where the proposal may benefit the community' in the public consultation paper.

What has brought about this consultation and proposed change?

The Board's current standard is due for review. The profession, via the peak optometry professional association Optometry Australia, requested a change to the Board's endorsement to recognise that endorsed optometrists in Australia are qualified to prescribe oral medicines. The Board has strong evidence to progress and consult on the proposal.

Why is the Optometry Board of Australia progressing this proposal?

The Board's primary purpose is to ensure safe and professional optometrists in Australia, by ensuring registered optometrists are suitably qualified and trained. The Board also has a role in strengthening accessible and sustainable healthcare.

The Board has carefully considered Optometry Australia's submission and commissioned its own research. The research found strong evidence that optometrists are qualified and trained to prescribe scheduled medicines for the purposes of the practice of optometry, including topical and oral medicines.

The Board believes the proposed change would be low risk, and that there are sufficient existing safeguards in place to allow optometrists to safely prescribe oral medicines.

To read more about the reasons and evidence for the proposal read Appendix K of the public consultation paper. For more information on the regulatory role of Ahpra and the Board, see the Ahpra website.

Has patient safety been considered in the proposal?

The safety of the public is the highest priority for the Board and is the basis for its decision making on all regulatory standards and guidelines. To ensure safe and professional optometrists in Australia, it has considered a broad range of issues including:

- · educational and training requirements for optometrists
- the history of complaints against optometrists (known as notifications)
- the current minimum requirements optometrists must have to practise. This includes their skills, knowledge, abilities, and attributes needed to perform safe and competent work with their patients
- continuing professional development for optometrists, which keeps their clinical skills up-to-date
- what optometrists in similar countries are qualified to prescribe, and
- the risks and benefits of the proposal.

The Board requires optometrists to recognise and work within the limits of their skills and competence and refer a patient to another practitioner, when this is in the patient's best interests.

To better understand the Board's considerations around safeguarding the safety of the public, please see the background paper in Appendix K.

What medicines can optometrists overseas prescribe for their patients?

New Zealand has a similar health regulatory system to Australia, and optometrists there have been able to prescribe oral and topical medicines for eye conditions without a Board approved list since 2014.

Currently optometrists who graduate from an Australian university can automatically gain registration in New Zealand and prescribe oral medicines for eye conditions within their scope of practice. However, the same optometrists can't prescribe oral medicines in Australia.

Qualified optometrists in New Zealand, the United Kingdom, most of the United States of America and some of Canada can prescribe oral medicines to their patients.

For more information on international examples, please see Appendix K.

What happens if we don't make these changes?

If we don't make these changes, the existing regulatory barriers preventing patients from accessing optometry care at the right time will remain in place. Patients will have less choices and may miss out on the benefits outlined in the 'Potential benefits' section of the public paper.

Why should I make a submission?

As a patient or consumer, you are a critical stakeholder for this review, as this affects your eyes, your care and your health. The Board invites you to provide input into decisions that affect you.

The Board wants to hear from a broad range of consumers about their views and what the proposed changes would mean to you.

How do I make a submission?

You may provide your feedback in the short two to five minute <u>survey</u> or by emailing the template provided to <u>optomconsultation@ahpra.gov.au</u>

What will you do with my submission?

Once you send us your survey answers or submission, we will review it and ensure your feedback is considered as part of our consultation process.

We will be publishing submissions to our website. Please let us know if you do not want us to publish your submission or if you want us to treat all or part of it as confidential.

It is important to note that the Board is part of a broader health regulatory environment which consists of several organisations with different areas of responsibility. This means that we sometimes receive submissions with feedback that is beyond our role, and cannot be addressed as part of the consultation.

For more information on the roles of different organisations regulating prescribing in Australia, see the background paper in Appendix K.

If you have any questions or comments about your submission, please contact us optomconsultation@ahpra.gov.au.

Appendix D: Draft Registration standard: Endorsement for scheduled medicines

Endorsement for scheduled medicines

Effective from <<date>>

This registration 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.

Does this standard apply to me?

This registration standard applies to optometrists:

- · applying for endorsement for scheduled medicines, or
- whose registration is endorsed for scheduled medicines.1

Scope of endorsement

An endorsed optometrist is qualified to administer, obtain, possess, prescribe, supply and/or use scheduled medicines in the following class:

• Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry

How can I qualify for endorsement?

You can qualify for endorsement through one of the following pathways:

- holding an approved qualification that includes the required ocular therapeutic components
- holding another qualification that the Board assesses as substantially equivalent to, or based on similar competencies to, an approved qualification that includes the required therapeutic components, or
- successful completion of an examination or assessment in ocular therapeutics approved by the Board.

What must I do when I am endorsed?

Guidelines

The Guidelines for use of scheduled medicines provide more information about what the Board expects of you when you are endorsed.

You are expected to understand and apply these guidelines together with this registration standard.

Approved list of scheduled medicines

The approved list of Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry is published by the Board.

You are expected to be familiar with the list.

State or territory authority

The endorsement of your registration indicates that you are qualified to administer, obtain, possess, prescribe, supply and/or use 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 and/or use 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 and/or use Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry in the scope of the state or territory authority at all times.

¹ Applications for endorsement may be made by those optometrists who hold registration with the Board or are applying for registration at the same time as the endorsement. Registration must be granted before the endorsement application can be granted.

Wording to appear on the Register of optometrists

Endorsed as qualified to administer, obtain, possess, prescribe, supply and/or use Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry.

What does this mean for me?

When you apply for endorsement for scheduled medicines

When you apply to have your registration endorsed for scheduled medicines you must meet the requirements of this registration standard.

You must lodge a complete application for endorsement of registration within one year of successfully completing a qualification, examination or assessment approved by the Board.

At renewal of registration

When you apply to renew your registration, you are also applying to renew your endorsement for scheduled medicines.

You must have recent practice relating to your endorsement for scheduled medicines in accordance with the Board's Registration standard: Recency of practice and must have completed continuing professional development (CPD) relevant to your endorsement in accordance with the Board's Registration standard: Continuing professional development.

When you apply to renew your registration, you must declare whether you have met the Board's recency of practice, CPD and professional indemnity insurance arrangements registration standards.

During the registration period

You must:

- administer, obtain, possess, prescribe, supply and/or use Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry in accordance with your endorsement and only to the extent that you are authorised by the relevant legislation and regulations in the state or territory in which you are practising
- be aware of, understand and comply with relevant state or territory medicines and poisons legislation and regulations including provisions relating to the secure storage of medicines in your possession
- comply with the relevant state, territory or Commonwealth legislation and regulations relating to the reporting of adverse medicine events and the advertising of therapeutic goods, including scheduled medicines
- ensure 'good practice' is in line with the Board's Code of conduct and work collaboratively with other practitioners within the healthcare system
- have recent experience in this scope of practice that meets the Board's Registration standard: Recency of practice, and
- maintain and enhance your competence to prescribe scheduled medicines including completing the required amount of CPD relevant to your scheduled medicines endorsement as set out in the Board's Registration standard: Continuing professional development.

What happens if I don't meet this standard?

The National Law establishes possible consequences if you don't meet this standard, enabling the Board to:

- refuse your application for endorsement or renewal of registration, or impose conditions on your endorsement (sections 102, 103 and 112 of the National Law), or
- use registration standards, codes or guidelines in disciplinary proceedings involving optometrists as evidence of what constitutes appropriate practice or conduct for the optometry profession (section 41 of the National Law).

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

Ministerial Council means <u>Health Ministers' Meeting</u>, the former Council of Australian Governments (COAG) Health Council comprising ministers of the governments of the participating jurisdictions and the Commonwealth with portfolio responsibility for health.

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

Schedule 2 medicine means Pharmacy Medicine in the <u>Poisons Standard</u> within the meaning of the *Therapeutic Goods Act 1989* (Cth).

Schedule 3 medicine means Pharmacist Only Medicine in the Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* (Cth).

Schedule 4 medicine means Prescription Only Medicine in the Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* (Cth).

Scheduled medicines means substances included in a schedule to the current Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* (Cth).

Review

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

This standard replaces the previous registration standard dated 10 September 2018.

Appendix E: Draft Guidelines for use of scheduled medicines

Guidelines for use of scheduled medicines

Effective from: <<date>>

Introduction

These guidelines provide information about how to meet the Optometry Board of Australia's (the Board) 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 *Registration standard: Endorsement for scheduled medicines* (the standard).

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

These guidelines also outline the Board's expectation about the use of scheduled medicines for diagnostic purpose by optometrists with general registration.

Do these guidelines apply to me?

These guidelines apply to optometrists:

- applying for endorsement for scheduled medicines, and/or
- whose registration is endorsed for scheduled medicines, who use scheduled medicines for the purposes of the practice of optometry, and/or
- with general registration who use scheduled medicines for diagnostic purposes.1

What must I do?

Optometrists must meet the requirements of the standard to be endorsed.

All registered optometrists (general and endorsed) are expected to understand and apply these guidelines where relevant. The standard only applies to endorsed optometrists.

Summary

These guidelines help you to understand what you need to do to administer, obtain, possess, prescribe, supply and/or use scheduled medicines safely and effectively for the purposes of the practice of optometry.

For optometrists with endorsement

Scope of endorsement

The standard outlines three parts to the scope of endorsement, which are described below:

- the class of the health practitioner: any person registered as an optometrist whose registration has been endorsed for scheduled medicines by the Board under section 94 of the National Law
- the type of use: endorsed as qualified to administer, obtain, possess, prescribe, supply and/or use a class of scheduled medicines, and
- the class of scheduled medicines: Schedule 2, 3, or 4 medicines for the purposes of the practice of optometry.

State or territory authority

The standard outlines the authorisation for optometrists with an endorsement to administer, obtain, possess, prescribe, supply and/or use 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 or regulation of the state or territory.

Medicine list for endorsed optometrists

The national approved list of Schedule 2, 3 or 4 medicines that endorsed optometrists are qualified to administer, obtain, possess, prescribe, supply and/or use for the purposes of the practice of optometry, is published on the Board's website.

You are expected to be familiar with this list.

For optometrists with general registration

Optometrists with general registration are qualified to obtain, have in their possession and use scheduled medicines in the course of their practice for diagnostic purposes. An endorsement is not needed for an optometrist to use diagnostic medicines in the course of their practice.¹

State or territory authority

The authorisation for optometrists with general registration to administer, obtain, possess and use for diagnostic use is provided by or under legislation or regulation of the state or territory.

Medicine list for general optometrists for diagnostic use

The approved list of scheduled medicines that an optometrist with general registration is qualified to administer, obtain, possess and use for diagnostic use, is published on the Board's website.

You are expected to be familiar with this list.

Maintaining competence

All optometrists are expected to maintain their competence and need to meet the requirements set out in the Boards':

- Registration standard: Recency of practice
- Registration standard: Continuing professional development, and
- Registration standard: Professional indemnity insurance arrangements.

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

Appropriate use of scheduled medicines

Quality Use of Medicines

Optometrists who administer, prescribe, supply and/or use scheduled medicines should observe the <u>Quality</u> <u>Use of Medicines</u> principles as they apply to the scope of the endorsement.

Quality Use of Medicines 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 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.

¹ 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-medicines-poisons-units.

³ For the safe and effective use of a medicine, endorsed optometrists must also be familiar with Therapeutic Goods Administration approved indications found in the product information.

- c. Using medicines safely and effectively to get the best possible results by:
 - · monitoring outcomes
 - · minimising misuse, over-use and under-use
 - improving people's ability to solve problems related to medicine, such as negative effects, and
 - managing multiple medicines.⁴

The Boards' shared Code of conduct details its expectations of good practice. This includes the expectation that optometrists facilitate Quality Use of Medicines based on the best available evidence and the patient's need.

Adverse event reporting

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, Disability and Ageing, and is responsible for regulating therapeutic goods including medicines.

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

Optometrists can help the TGA safeguard public health by reporting all suspected adverse events associated with medicines, particularly those associated with new products. Endorsed optometrists must be familiar with any additional specific reporting on adverse outcomes by the TGA, for example the Black Triangle Scheme.⁵

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 acts 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.

Prescriptions

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

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.

Regardless of the format of the prescription, endorsed optometrists need to ensure the details of each prescription are correct.

The essential information needed for a legal prescription may vary between states and territories. Endorsed optometrists need to be aware of these variances if practising in different jurisdictions. The requirements generally include:

- prescriber's name, address, telephone number and qualifications (and prescriber number, where relevant)
- patient's full name, address and date of birth
- date the prescription is written
- medicine name in full
- · medicine strength
- medicine form
- quantity of medicine to be supplied
- medicine dose, route of administration, frequency, and duration of treatment (if necessary)
- clear instructions for the patient (in English) it is not appropriate to write 'take as directed'
- any further instructions necessary for the pharmacist, and
- the signature of the prescriber.

The Board encourages endorsed optometrists to issue a prescription even for a Schedule 2 or 3 medicine when in the best interest of the patient, to help ensure effective communication with the pharmacist.

Information regarding what an optometrist can prescribe can be found in the Medicine lists on the Board's website.

Self-prescribing

The Board advises against optometrists self-diagnosing and then self-prescribing Schedule 4 medicines. The Boards' shared Code of conduct details its expectations of good practice regarding self-prescribing.

Supply of scheduled medicines

The Board supports the view that the division of responsibility between an endorsed optometrist who prescribes 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 required.

Optometrists who choose to supply a scheduled medicine directly to a patient need to meet the labelling and record-keeping 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.⁶

Antimicrobial resistance

Antimicrobial resistance (AMR) is the ability of a microorganism (like bacteria, viruses and parasites) to stop an antimicrobial (such as antibiotics, antivirals and antimalarials) from working. As a result, standard medical treatments become ineffective, and infections persist and may spread to others. Healthcare professionals are left with limited or in some instances, no available treatment options.

Endorsed 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 and route of administration should always involve consideration of the risk that microbial resistance could develop.

Information about the risks of AMR and what prescribers can do to help contain it is available on the <u>Australian Government Antimicrobial Resistance</u> and the <u>Australian Commission on Safety and Quality in Health Care Antimicrobial Stewardship</u> websites.

Working with other practitioners and referrals

The Board expects optometrists to practise safely, effectively and in partnership with patients, colleagues, and other health practitioners. Optometrists are expected to use patient-centred approaches, informed by the best available evidence, and aligned with Quality Use of Medicines principles to achieve optimal patient outcomes.

Optometrists have a responsibility to recognise and work within the limits of their skills and competence and refer a patient to another practitioner when necessary. This includes ensuring they have the equipment, expertise and skills necessary to practise safely and effectively. Specifically, regarding the care of patients with chronic glaucoma, optometrists must provide the patient with a referral to an ophthalmologist or ophthalmology service within four months of starting treatment for chronic glaucoma using patient-centred approaches, informed by the best available evidence and Quality Use of Medicines principles.

As outlined in the Boards' shared Code of conduct, optometrists must ensure good practice when working in a team or collaboratively with other practitioners within the healthcare system. Patient care is improved when there is mutual respect and clear, culturally-safe communication, as well as an understanding of the responsibilities, capacities, constraints and ethical codes of each other's health professions.

The professional roles, responsibilities and referral pathways for collaborative practice arrangements, such as in glaucoma co-management, are best determined in individual cases based on location, resources, skill-base of local health care practitioners and patient choice. In any collaborative practice arrangement, patients must consent to the arrangement and be clearly informed about who is responsible and when they need to attend reviews with each practitioner.

The Boards' shared Code of conduct includes guidance on working with other health practitioners, collaboration, effective communication, informed patient consent, referrals, and Aboriginal and Torres Strait Islander health and cultural safety.

Authority

The Optometry Board of Australia has developed these guidelines under section 39 of the National Law.

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

Definitions

Ministerial Council means the <u>Health Ministers' Meeting</u> (former Council of Australian Governments (COAG) Health Council) comprising ministers of the governments of the participating jurisdictions and the Commonwealth with portfolio responsibility for health.

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

Patient means a person who has entered into a therapeutic and/or professional relationship with a registered health practitioner. The term 'patient' includes 'clients' and 'consumers'. It can also extend to their families and carers, and to groups and/or communities as users of health services, depending on context.

Practice means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a practitioner in their regulated health profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct, non-clinical relationship with patients, working in management, administration, education, research, advisory, regulatory or policy development roles and any other roles that have an impact on safe, effective delivery of health services in the health profession.

Quality Use of Medicines means selecting management options wisely; choosing suitable medicines if a medicine is considered necessary; and using medicines safely and effectively. The full definition is in the <u>National Strategy for Quality Use of Medicine and the National Medicines Policy</u>.

Referral involves one practitioner sending a patient to obtain an opinion or treatment from another practitioner. Referral usually involves the transfer (in part) of responsibility for the care of the patient, usually for a defined time and a particular purpose, such as care that is outside the referring practitioner's expertise or scope of practice.

Schedule 2 medicine means Pharmacy Medicine in the <u>Poisons Standard</u> within the meaning of the *Therapeutic Goods Act 1989* (Cth).

Schedule 3 medicine means Pharmacist Only Medicine in the Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* (Cth).

Schedule 4 medicine means Prescription Only Medicine in the Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* (Cth).

Scheduled medicines means substances included in a schedule to the current Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* (Cth).

Review

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

Date of issue: <<insert date>>
Date of review: <<insert date>

[Note: The main changes from the current list (found in Appendix A of the current guidelines) are highlighted in yellow]

Appendix F: DRAFT Medicine list for general optometrists for diagnostic use

[Date]

The following is the Optometry Board of Australia's approved list of scheduled medicines that optometrists with a general registration are qualified to administer, obtain, possess and use for diagnostic use in the course of their practice.¹

- 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
- phenylephrine when prepared and packed in the form of eye drops containing two and a half (2.5) per cent or less of phenylephrine
- apraclonidine when prepared and packed in the form of an eye drop containing a half (0.5) per cent or less of apraclonidine

Review

This list will be reviewed annually and as required.² Relevant stakeholders will be consulted.

¹ Optometrists with general registration should be familiar and comply with the current requirements of state and territory drugs and poisons legislation in the jurisdictions in which they practise. 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.

² Medicine availability can vary. Medicines discontinued in Australia may be retained on the list to ensure they remain accessible should the medicines by reintroduced at a later stage.

[Note: The main changes from the current list (found in Appendix A of the current guidelines) are highlighted in yellow]

Appendix G: DRAFT Medicine list for endorsed optometrists

[Date in effect]

The following is the Optometry Board of Australia's approved list of Schedule 2, 3 and 4 medicines that optometrists with a scheduled medicines endorsement are qualified to administer, obtain, possess, prescribe, supply and/or use for the purposes of the practice of optometry.¹

Topical medicines

Schedule 2 Pharmacy	Medicine		
Anti-infectives	Anti-inflammatories	Decongestants/	Miotics, mydriatics and
Dibromopropamidine	Beclometasone ²	anti-allergics	cycloplegics
Propamidine	Budesonide ²	Antazoline_	Phenylephrine ≤2.5%
	Ciclesonide ²	Azelastine ³	
	Fluticasone ²	Ketotifen	
	Mometasone ²	Levocabastine ³	
		Lodoxamide	
		Naphazoline	
		Pheniramine	
		Sodium Cromoglycate	
Schedule 3 Pharmacist	Only Medicine		
Anti-infectives			
Chloramphenicol			
Schedule 4 Prescriptio	n Only Medicine		
Anti-glaucomas	Anti-infectives	Anti-inflammatories	Decongestants/
Apraclonidine	Aciclovir	Ciclosporin	anti-allergics
Betaxolol	Azithromycin	Dexamethasone	Olopatadine
Bimatoprost	Bacitracin	Diclofenac	
Brimonidine	Cephazolin	Fluorometholone	
Brinzolamide	Ciprofloxacin	Flurbiprofen	
Dorzolamide	Framycetin	Hydrocortisone	
Latanoprost	Ganciclovir	Ketorolac	
Pilocarpine	Gentamicin	Lifitegrast	
Tafluprost	Gramicidin	Loteprednol	
Timolol	Neomycin	Nepafenac	
Travoprost	Ofloxacin	Prednisolone	
	Polymyxin		
	Tetracycline		
	Tobramycin		
Miotics, mydriatics and	Local anaesthetics		
cycloplegics	Amethocaine		
Atropine	Lignocaine		
Cyclopentolate	Oxybuprocaine		
Homatropine	Proxymetacaine		
Pilocarpine			
Phenylephrine			
Tropicamide			

¹ Endorsed optometrists should be familiar and comply with the current requirements of state and territory medicines and poisons legislation in the jurisdictions in which they practise. 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.

² Nasal spray

³ Eye drop and nasal spray

Oral medicines

Schedule 2 Pharmac	cy Medicine		
Analgesic Paracetamol	Anti-inflammatories	Decongestants/ anti-allergics	Proton pump inhibitors Esomeprazole
T di doctamor	Ibuprofen	Cetirizine	Omeprazole
	Naproxen	Desloratadine	Pantoprazole
		Fexofenadine	
		Loratadine	
Schedule 3 Pharmac	ist Only Medicine		
Analgesic	Anti-inflammatories	Decongestants/	Proton pump inhibitors
Paracetamol	Diclofenac	anti-allergics	Esomeprazole
	Ibuprofen	Dexchlorpheniramine	Omeprazole
	Naproxen	· ·	Pantoprazole Pantoprazole
Schedule 4 Prescrip	tion Only Medicine		
Analgesic	Anti-glaucomas	Anti-infectives	Anti-inflammatories
Paracetamol	Acetazolamide ⁴	Aciclovir	Diclofenac
		<u>Amoxicillin</u>	Ibuprofen
		Amoxicillin and clavulanic	Indometacin
		acid	Naproxen
		Azithromycin	
		Cefalexin	
		Ciprofloxacin	
		Clindamycin	
		Dicloxacillin	
		Doxycycline	
		Erythromycin	
		Face at all as the	
		Famciclovir Flucloxacillin	

Review

This list will be reviewed annually and as required. 5 Relevant stakeholders will be consulted.

⁴ As part of initial first aid for angle-closure

⁵ Medicine availability can vary. Medicines discontinued in Australia may be retained on the list to ensure they remain accessible should the medicines by reintroduced at a later stage.

Appendix H: Proposed draft standard and proposed draft guidelines comparison tables

Comparison table 1 Registration standard: Endorsement for scheduled medicines

The current <u>Registration standard</u>: <u>Endorsement for scheduled medicines</u> (standard) has been revised to align with the cross-profession template registration standard, provided on page 17 in Appendix C of the *Ahpra Guide for National Boards developing submissions under the AHMAC Guidance for National Boards:* applications to the Ministerial Council for approval of endorsements in relation to scheduled medicines under section 14 of the National Law (the <u>Ahpra guide</u>). The table below provides a high level outline of the proposed changes to the current standard to bring into effect the proposal at option 2 of the public consultation paper.

Current standard heading	Proposed standard heading	Change to proposed standard			
Introduction		Heading removed to align with cross-profession template.			
Does this standard apply to me?	Does this standard apply to me?	Wording simplifed to align with cross-profession template.			
Scope of endorsement	Scope of endorsement	pdated to reflect the proposed amendment to the endorsement.			
How can I qualify for	How can I qualify for	Wording amended to improve clarity and align with cross-profession template.			
endorsement	endorsement	Removed definition of approved program of study and examination, to simplify and avoid duplication with content on the Board's <u>website</u> .			
What must I do when I am	What must I do when I am	Wording amended to improve clarity and align with cross-profession template.			
endorsed?	endorsed?	Addition of sub-section 'Approved list of scheduled medicines'.			
Wording to appear on the Register of optometrists	Wording to appear on the Register of optometrists	Updated to reflect the proposed amendment to the endorsement.			
Authority	Authority	Date to be updated.			
	What does this mean for me?	Addition to what the registrations standards means for the practitioner at application, registration and renewal stages, for clarity. This includes content that links to the Board's Code of conduct and a focus on working collaboratively with other practitioners within the healthcare system.			
		The section clarifies the Board's requirement that a complete application must be lodged for endosement of registration within one year of successfully completing an approved qualification, examination or assessment.			
	What happens if I don't meet this standard?	Addition of new section to improve clarity on the possible consequences under the National Law if the registration standard is not met.			
Definitions	Definitions	Removed 'Approved program of study' as it is no longer referenced within the standard.			
		Added the definitions of Schedules 2, 3 and 4 and Scheduled medicines to improve clarity.			
Review	Review	Minor wording changes to align with cross-profession template.			

Comparison table 2 Guidelines for the use of scheduled medicines

The current <u>Guidelines for use of scheduled medicines</u> (the guidelines) has been revised to align with the cross-profession template guideline provided on page 20 in Appendix D of the <u>Ahpra guide</u>. The table below provides a high level outline of the proposed changes to the current guidelines to bring into effect the proposal at option 2 of the public consultation paper.

Current guidelines heading	Proposed guidelines heading	Change to proposed guidelines			
Authority	Authority	Wording amended to align with cross-profession template and the section has been moved to later in the document.			
Introduction	Introduction	Wording amended to improve clarity and align with cross-profession template.			
		Optometrists without endorsement are now referred to as optometrists with general registration to reflect the category on the public register.			
Do these guidelines apply to me?	Do these guidelines apply to	Wording amended to improve clarity and align with cross-profession template.			
	me?	Last paragraph merged under 'Working with other practitioners and referrals'.			
What must I do?	What must I do?	'You' replaced by 'endorsed optometrists' to improve clarity on who the guidance applies to.			
	Summary	Addition of 'Summary' section to align with cross-profession template.			
Scope of endorsement		Merged into 'For optometrists with endorsement'.			
Endorsement for scheduled medicines	For optometrists with endorsement	Subheading '1. Endorsement for scheduled medicines' removed and new section added to improve clarity on who the guidance applies to.			
		Wording amended to align with cross-profession template and make sequencing more logical.			
		Additional information on the class of health practitioner, the type of use and the class of scheduled medicines has been added under 'Scope of endorsement' to clarify the three parts of the Board's standard.			
		References to 'topical' and 'Appendix B' removed.			
	Scope of endorsement	New subheading added to section.			
	State or territory authority	New subheading added to section.			
	Approved lists of scheduled medicines	New subheading added to section.			
1.1 Eligibility for endorsement		Removed as it is covered under 'How can I qualify for endorsement' in the standard.			
1.2 Approved programs of study and assessments		Removed to align with cross-profession template and as information on approved programs is published on the Board's website.			
	For optometrists with general registration	New section added to improve clarity on who the section applies to.			
	State or territory authority	New subheading added to section.			
	Approved lists of scheduled medicines	New subheading added to section.			

2. Use of scheduled medicines by	Appropriate use of scheduled	Subheading elevated to increase prominence and wording updated.				
optometrists	medicines	The first two paragraphs have been amended and merged under 'State or territory authority' to improve clarity and to make sequencing more logical.				
		Reference to 'Appendix A' has been removed.				
2.1 Quality use of medicines	Quality use of medicines	Minor rewording to align with cross-profession template.				
		Addition of reference to the Boards' shared Code of conduct, link to Quality Use of Medicines website and footnote link to the National Strategy for Quality Use of Medicines website.				
2.2 Maintaining competence	Maintaining competence	Section moved to earlier in the document to give increased prominence. Reworded to improve clarity, provide additional information and align with cross-profession template.				
		Addition of reference to Registration standard: Professional indemnity insurance arrangements, to improve clarity.				
2.3 Prescriptions	Prescriptions	Minor rewording to align with cross-profession template.				
		Additional information on what should be included on prescriptions.				
		References to handwritten or computer-generated prescriptions removed.				
Self-prescribing	Self-prescribing	Addition of information on expectations set by the Boards' shared Code of conduct regarding self-prescribing.				
2.4 Practice procedures		Removed section to align with cross-profession template. Legislative requirements are adequately covered in the proposed guidelines and record keeping is addressed in the Boards' shared Code of conduct and other resources on its website.				
2.5 Adverse event reporting	Adverse event reporting	Minor rewording and moved section to align with cross-profession template and to make sequencing more logical.				
		Additional information about specific reporting on adverse outcomes has been moved from the footnote of the current guidelines Appendix B to this section.				
3. Supply of scheduled medicines	Supply of scheduled medicines	Minor rewording to align with cross-profession template.				
4. Guidelines for the use of topical antimicrobials		Heading removed and information merged with 'Antimicrobial resistance'.				
4.1 Antimicrobial resistance	Antimicrobial resistance	Reworded to align with cross-profession template.				
		References of 'antimicrobial' already encompasses fluoroquinolones and removing fluoroquinolones keeps the guidelines contemporary and future proof.				
		References to NPS Medicinewise removed because custodianship and functions have transitioned to the Australian Commission on Safety and Quality in Health Care. Relevant links added to improve clarity				
5. Guidelines for use of topical steroidal preparations		Removed as the use of topical steroidal preparations is part of contemporary optometry practice. Clinical guidance is removed from the regulatory guidelines to future proof it. Optometrists are expected to use patient-centred approaches, informed by the best available evidence and Quality Use of Medicines principles.				

	Working with other practitioners and referrals	Heading now includes referrals.				
practitioners		Subheadings have been removed, and section has been reworded, simplified and refined links to the Boards' shared Code of conduct added. 'Collaborative care' is now referred to 'collaborative practice' to align with the Boards' shared Code of conduct and links have been added to improve clarity.				
		The proposed changes capture the Quality Use of Medicines principles and strengthen the guidance on collaborative practice, referrals and communication from a holistic perspective, so that the regulatory guidelines are contemporary and future proof.				
		Reference to Aboriginal and Torres Strait Islander health and cultural safety has been added.				
		'Specifically, regarding the care of patients with chronic glaucoma, optometrists must provide the patient with a referral to an ophthalmologist or ophthalmology service within four months of starting treatment for chronic glaucoma using patient-centred approaches, informed by the best available evidence and QUM principles' has been added to this section.				
		The outer four-month referral limit remains the same. Reference to 'Best available evidence' has been added, which will mean that the optometrist may need to provide the patient with a referral earlier than four months. 'Quality Use of Medicines principles' has been added for clarification and ensures the individual, including their treatment preference is taken into account.				
		This was informed by a targeted consultation with relevant ophthalmology and optometry bodies.				
6.1 Role responsibilities and communication in collaborative care of patients		Heading removed, content merged into 'Working with other practitioners and referrals' and now aligns and refers to the Boards' shared Code of conduct.				
6.2 Patient involvement		Heading removed and content merged into 'Working with other practitioners and referrals'. Content further emphasises that patients must be properly informed about and consent to any collaborative practice arrangement.				
7. Guidelines for care of		Heading removed and content merged into 'Working with other practitioners and referrals'.				
patients with, or at high risk of developing, chronic glaucoma		The Board consulted with the relevant key professional bodies in a targeted consultation on section 7 of the current guidelines prior to preliminary and public consultation and the outcomes of the targeted consultation have informed the proposed wording of this section.				
		The section was no longer contemporary or based on the best available evidence. The National Health and Medical Research Council of Australia (NHMRC) have rescinded the <i>Guidelines for the screening, prognosis, diagnosis, management and prevention of glaucoma 2010</i> (the NHMRC guidelines) and the related companion document. References to the NHMRC guidelines have been removed.				
		Guidance on the collaborative care of patients with glaucoma in this section has been retained for clarity.				
		Footnote 13 has been removed. The Boards' shared <i>Code of conduct</i> definition has been added to the definitions section of the proposed guidelines for cross-profession consistency.				
		Additional information on effective communication and culturally safe communication have been added.				

7.1 Referral		Heading removed and content merged into 'Working with other practitioners and referrals'
		This section has been simplified and the inconsistent referral criteria removed. It now refers to 'best available evidence' and 'Quality Use of Medicines' principles. The outer four-month referral limit for care of patients with chronic glaucoma remains the same.
		Referral guidance was duplicated and inconsistent between guidelines 7 and 7.1.
		Section 7 required optometrists to refer a patient for specialist assessment and advice after diagnosis of chronic glaucoma, or when a patient is at high risk of developing chronic glaucoma. Section 7.1 had different criteria for referral for ophthalmological assessment.
		Furthermore, different jurisdictions have different state-wide referral criteria, making it challenging to provide consistent, enforceable national regulatory guidance.
		Guidelines 7 and 7.1 in the existing guidelines did not specifically take into account the individual patient, which risks non-compliance with Quality Use of Medicines. They require optometrists to refer patients to an ophthalmologist, regardless of the treatment preferences and circumstances of the patient. However, Quality Use of Medicines requires person-centred care. Specifically, selecting management options wisely, choosing suitable medicines (if necessary) by taking the individual into account and using medicines safely and effectively to get the best possible results.
		This was informed by a targeted consultation with relevant ophthalmology and optometry bodies.
7.2 Communication		Removed as this is covered in the section 'working with other practitioners and referrals' and the Boards' shared Code of conduct.
7.3 Equipment		Removed and a statement on having the equipment, expertise and skills necessary is included in 'Working with other practitioners and referrals'.
7.4 Emergency management of acute primary angle closure		Removed clinical guidance from the regulatory guidelines to future proof it. Optometrists are expected to use patient-centred approaches, informed by the best available evidence and Quality Use of Medicines principles.
		Clinical guidance within regulatory guidelines is challenging to maintain and can quickly become out of date, putting patient safety and the public at risk. Keeping clinical guidance also risks over-regulating optometrists, where glaucoma management (including referral) is integrated into contemporary optometry practice.
	Definitions	New section added to align with cross-profession template and improve clarity.
Review		Minor wording changes to align with cross-profession template and remove references to Appendix B.
Appendix A		Removed. The list will be published on website.
Appendix B		Removed. The list will be published on website.
Appendix C		Removed clinical guidance from the regulatory guidelines to future proof it. Optometrists are expected to use patient-centred approaches, informed by the best available evidence and Quality Use of Medicines principles.

Appendix I: Optometry Board of Australia's Patient and Consumer Health and Safety Impact Statement

Public consultation on the review of the Registration standard: Endorsement for scheduled medicines and Guidelines for use of scheduled medicines

Statement purpose

The National Boards Patient and Consumer Health and Safety Impact Statement (Statement)¹ explains the potential impacts of a proposed registration standard or guideline on the health and safety of the public, particularly those vulnerable to harm in the community which includes those subject to stigma or discrimination in health care, and/or experiencing health disadvantage and Aboriginal and Torres Strait Islander Peoples.

The four key components considered in the Statement are:

- 1. The potential impact of the proposed revisions to the registration standard or guideline on the health and safety of patients and consumers particularly those vulnerable to harm in the community including approaches to mitigate any potential negative or unintended effects.
- 2. The potential impact of the proposed revisions to the registration standard or guideline on the health and safety of Aboriginal and Torres Strait Islander Peoples including approaches to mitigate any potential negative or unintended effects.
- 3. Engagement with patients and consumers particularly those vulnerable to harm in the community about the proposal.
- 4. Engagement with Aboriginal and Torres Strait Islander Peoples about the proposal.

The National Boards Patient and Consumer Health and Safety Impact Statement aligns with the <u>National Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020–2025, National Scheme engagement strategy 2020–2025, the National Scheme Strategy 2020–25 and reflects key aspects of the Ahpra <u>Procedures for the development of registration standards, codes, guidelines and accreditation standards</u>.</u>

The Optometry Board of Australia (the Board) is committed to the National Scheme's Aboriginal and Torres Strait Islander Cultural Health and Safety Strategy 2020–2025, which focuses on achieving patient safety for Aboriginal and Torres Islander Peoples as the norm, and the inextricably linked elements of clinical and cultural safety (refer to *Definition of cultural safety for the National Scheme* below).

Below is the Board's initial assessment of the potential impact of a proposed of the Registration standard: Endorsement for scheduled medicines (the standard) and Guidelines for use of scheduled medicines (the guidelines) for optometrists on the health and safety of patients and consumers, particularly those vulnerable to harm in the community, and Aboriginal and Torres Strait Islander Peoples. This statement will be updated after consultation feedback.

1. How will this proposal impact on patients' and consumers' health and safety, particularly those vulnerable to harm in the community? Will the impact be different for people vulnerable to harm in the community compared to the general public?

The Board has carefully considered the impacts the proposed draft standard and guidelines could have on patient health and safety, particularly members of the community at risk of experiencing poorer health

¹ This statement has been developed by Ahpra and the National Boards in accordance with section 25(c) and 35(c) of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law). Section 25(c) requires Ahpra to establish procedures for ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice. Section 35(c) assigns the National Boards functions to develop or approve standards, codes and guidelines for the health profession including the development of registration standards for approval by the Ministerial Council and that provide guidance to health practitioners registered in the profession. Section 40 of the National Law requires National Boards to ensure that there is wide-ranging consultation during the development of a registration standard, code or guideline.

outcomes, in order to put forward what we think is the best option for consultation. Members of the community at risk of experiencing poorer health outcomes include Aboriginal and Torres Strait Islander Peoples, people living in rural and remote areas, people of low socioeconomic status and older people, including people living in residential aged care facilities.

In the development and early consultation process, the Board engaged with the Consumer Advisory Council and an Indigenous consultant to build its understanding of the proposal's impact on patient and consumer health and safety, in particular members of the community at risk of experiencing poorer health outcomes.

In the preliminary consultation, the Board engaged with a number of First Nations stakeholders and consumer stakeholders.

Our engagement through further wide-ranging public consultation will help us to better understand the impact of the proposed changes on the community and meet our responsibilities to protect patient safety and healthcare quality. It will help us to understand if the impact will be different for members of the community at risk of experiencing poorer health outcomes, when compared to the general public.

The Board believes these proposed changes will improve patient centered eye health care outcomes in the community by increasing patient choice and improving timely, affordable access to primary eye care, where vision impairment can be prevented or treated with early detection.

Patients will have the power to decide how and when they receive primary eye care. It will mean more choice about which health practitioner they decide to see, to safely have their eye health needs met at their primary visit and to have better access to eye-care medicines. It will mean greater convenience and easier access to the right level of eye care in a timely fashion. Reducing delays in receiving primary eye care treatment and removing travel, waiting times and out of pocket costs related to seeing an ophthalmologist or medical practitioner may also improve the patient journey and quality of life.

There are potentially small positive outcomes for the general public living in urban areas, older people and people from low-socioeconomic households where it would mean an added convenience, affordability and choice for patients when it is difficult to access a medical practitioner within an acceptable waiting time.

There are potentially greater positive outcomes for the general public living in rural and remote areas where there are currently long wait times to see a general practitioner and specialist eye care is limited.

There are potentially greater positive impacts for Aboriginal and Torres Strait Islander Peoples (refer to question 4 below).

2. How will National Boards engage with patients and consumers, particularly those vulnerable to harm in the community during consultation?

In the development and early consultation process, the Board engaged with the Consumer Advisory Council to build its understanding of how better to engage with the community, in particular members of the community at risk of experiencing poorer health outcomes. The Board also engaged an Indigenous consultant to collect and gather feedback from Aboriginal and Torres Strait Islander eye health experts to provide advice on who and how to better engage with Aboriginal and Torres Strait Islander stakeholders before the preliminary consultation stage.

The Board has undergone targeted and preliminary consultation to inform this public consultation. In these consultations the Board has engaged with Aboriginal and Torres Strait Islander organisation stakeholders and consumer organisation stakeholders.

In line with the <u>consultation processes</u> and the National Law, the Board will carry out a wide-ranging public consultation over a period of eight-weeks. We will engage with patients and consumers, peak bodies, community organisations, Aboriginal and Torres Strait Islander organisations and other relevant organisations to get input and views from members of the community, in particular those at risk of experiencing poorer health outcomes.

The Board will publish a one page snapshot, a consumer consultation guide and an option to answer a short survey with key questions to encourage and support consumer participation in the consultation.

3. What might be the unintended impacts for patients and consumers, particularly people vulnerable to harm in the community? How will these be addressed?

Consulting with relevant organisations and members of the community at risk of experiencing poorer health outcomes will help us to identify any unintended impacts of the Board's proposal. This will enable us to fully consider and act to address any potential negative impacts for patients that may be raised during consultation, particularly for members of the community at risk of experiencing poorer health outcomes.

Consumers would need to pay private prices for the oral and new topical medicines prescribed by optometrists and any related pathology tests, until any such time that there are changes in the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Schedule (MBS). The difference in cost

between a private prescription and PBS funded prescription for many of the proposed oral medicines for eye conditions is minimal or has no cost difference. Optometrists will continue to ensure informed financial patient consent in line with the shared Code of conduct.

It is the peak professional association's role to advocate for the profession to add medicines to the PBS and pathology testing to the MBS, and they would be able to do so if this proposal is approved. The Board has consulted with Optometry Australia on this, as it's the Board's intention not to disadvantage patients. If approved, Optometry Australia will use the transition period to advocate to add medicines to the PBS and pathology testing to the MBS, with the intention of having these added at the date of commencement of the proposed standard.

Should the proposal be approved and medicines be added to the PBS, eligible consumers would be able to get these medicines at concession rates. This would improve access to affordable medicines to those most in need.

4. How will this proposal impact on Aboriginal and Torres Strait Islander Peoples? How will the impact be different for Aboriginal and Torres Strait Islander Peoples compared to non-Aboriginal and Torres Strait Islander Peoples?

Potentially greater positive outcomes for Aboriginal and Torres Strait Islander Peoples have been identified, including more immediate treatment of common eye conditions without having to access multiple health professionals. Having the choice to see an optometrist through a Visiting Optometrist Service or through an Aboriginal Community Controlled Health Service (ACCHS) or local Community Health Centre could improve timeliness, access and affordability. This approach may mean the patient receives more culturally safe, quality, primary health eye care.

The Board acknowledges that Aboriginal and Torres Strait Islander Peoples bear the burden of gross social and health inequity and it is important to consider cultural safety in the context of Aboriginal and Torres Strait Islander health specifically. As part of the consultation, the Board will be asking Aboriginal and Torres Strait Islander consumer and health professional practitioner stakeholders how the proposal impacts them. The Board is committed to listening to these representatives, to better understand possible impacts and better address these impacts to protect patient safety and health care quality.

In the development process, the Board engaged an Indigenous consultant to better understand the possible impacts on Aboriginal and Torres Strait Islander Peoples. The following impacts were provided by the Indigenous consultant:

'Possible impacts for Aboriginal and Torres Strait Islander consumers include:

- improved access to timely comprehensive eye care services/treatment
- reduced complexity and fragmentation across the referral/treatment pathways, and
- reduced wait times, costs, and visits or appointments for eye care services/treatments.

Possible impacts for Aboriginal and Torres Strait Islander Health Practitioners:

- improved access to timely comprehensive eye care services and treatment for their clients
- increased ability to coordinate care and facilitate access resulting in reduced workload
- improved efficiency and effectiveness of the support to access eye care treatments, and
- enhanced skill set, job satisfaction and career prospects.

Delivering eye care in ACCHS or in environments where care is taken to help Aboriginal and Torres Strait Islander people feel culturally safe, has also proven to increase access and retention for clients accessing eye care services.' ²

A recurring concern raised in the feedback from Aboriginal and Torres Strait Islander stakeholders at preliminary consultation was the cost of the private medicines. As mentioned above, if approved, Optometry Australia will use the transition period to advocate to add medicines to the PBS, with the intention of having these added at the date of commencement of the proposed standard. Should the proposal be approved and medicines be added to the PBS, Aboriginal and Torres Strait Islander Peoples may be able to get medicines free with a concession card (or at concession prices, where eligible) under the Closing the Gap PBS Copayment Program. This would improve access to affordable medicines to Aboriginal and Torres Strait Islander communities. However, this cannot be guaranteed as the federal government and its delegates decides on the PBS, and the federal government and the Coalition of Aboriginal and Torres Strait Islander peak bodies decides on the Closing the Gap Agreement.

² Provided by an Indigenous consultant, Delivering eye care services to Aboriginal and Torres Strait Islander People report, October 2022

5. How will consultation about this proposal engage with Aboriginal and Torres Strait Islander Peoples?

Building understanding of Aboriginal and Torres Strait Islander practitioner and patient needs and embedding cultural safety in policies and processes is a key initiative in the Board's Regulatory Workplan. Culturally safe eye care has been a key initiative in the Board's Regulatory Workplan since 2021. This includes building networks with Aboriginal and Torres Strait Islander health and practitioner organisations.

In the development process, the Board engaged an Indigenous consultant to build its understanding of how to better engage with Aboriginal and Torres Strait Islander stakeholders before the preliminary consultation stage and gather feedback from Indigenous eye health experts to provide advice on who and how to better engage with Aboriginal and Torres Strait Islander stakeholders.

The Board is committed to engaging with Aboriginal and Torres Strait Islander Peoples during its wide-ranging public consultation, including meeting with First Nations stakeholders and receiving a variety of submissions.

6. What might be the unintended impacts for Aboriginal and Torres Strait Islander Peoples? How will these be addressed?

The Board has carefully considered what might be any unintended impacts of the proposal and believes that Aboriginal Torres Strait Islander health and community organisations are well placed to provide advice to the Board on potential impacts of the proposal and will listen to the advice of our Aboriginal and Torres Strait Islander stakeholders.

Continuing to engage with relevant organisations and Aboriginal and Torres Strait Islander Peoples will help us to identify any unintended impacts. We will consider and take actions to address any other potential negative impacts that may be raised during consultation.

7. How will the impact of this proposal be actively monitored and evaluated?

Compliance with the Board's registration standards is monitored, with optometrists required to make a declaration that they have met the registration standards for the profession every year at registration renewal. Part of the Board's work in keeping the public safe is ensuring that all standards and guidelines are regularly reviewed. The Board also conducts random audits to ensure registered optometrists keep their skills up to date. The Board's Registration Notifications Committee will continue to review notification matters about a practitioner's health, conduct or performance, including any notifications about prescribing and will advise the Board on any arising policy issues and emerging trends relating to notifications.

Other monitoring safeguards coexist in the Australian healthcare and regulatory system. The Optometry Council of New South Wales manages concerns about registered health practitioners in New South Wales and the Office of the Health Ombudsman manages concerns about registered health practitioners in Queensland. The Medicare compliance program monitors the MBS and PBS and any practitioner conduct or performance matters are referred to the Board. The Provider Benefits Integrity Hotline is available for suspected noncompliance of PBS prescribing.

Should the proposal be approved and additional antibiotics be added to the PBS, there will also be reporting and monitoring of antimicrobial prescriptions supplied under PBS by <u>Antimicrobial Use and Resistance in Australia</u> in the community for primary care.

The Therapeutic Goods Administration is responsible for monitoring the continuing safety, quality, and efficacy of medicines in Australia through <u>adverse event reporting</u> by consumers and health professionals.

Definition of cultural safety for the National Scheme

The strategy group, led by the Aboriginal and Torres Strait Islander members and in partnership with the National Health Leadership Forum, consulted on and finalised a baseline definition of cultural safety for use in the National Scheme. The consultation report is published on the <u>Past consultations</u> page.

Cultural safety definition

Principles

The following principles inform the definition of cultural safety:

- Prioritising the Ministerial Council's goal to deliver healthcare free of racism supported by the National Aboriginal and Torres Strait Islander Health Plan 2013–2023
- Improved health service provision supported by the Safety and Quality Health Service Standards User Guide for Aboriginal and Torres Strait Islander Health
- Provision of a rights-based approach to healthcare supported by the United Nations Declaration on the Rights of Indigenous Peoples
- Ongoing commitment to learning, education and training

Definition

Cultural safety is determined by Aboriginal and Torres Strait Islander individuals, families and communities.

Culturally safe practice is the ongoing critical reflection of health practitioner knowledge, skills, attitudes, practising behaviours and power differentials in delivering safe, accessible and responsive healthcare free of racism.

How to

To ensure culturally safe and respectful practice, health practitioners must:

- Acknowledge colonisation and systemic racism, social, cultural, behavioural and economic factors which impact individual and community health.
- Acknowledge and address individual racism, their own biases, assumptions, stereotypes and prejudices and provide care that is holistic, free of bias and racism.
- Recognise the importance of self-determined decision-making, partnership and collaboration in healthcare which is driven by the individual, family and community.
- Foster a safe working environment through leadership to support the rights and dignity of Aboriginal and Torres Strait Islander people and colleagues.

Appendix J: Statement of assessment against Ahpra's Procedures for the development of registration standards, codes and guidelines

Public consultation on the review of the Registration standard: Endorsement for scheduled medicines and Guidelines for use of scheduled medicines

Introduction

Section 25 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law) requires Australian Health Practitioner Regulation Agency (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.

The Ahpra Procedures for the development of registration standards, codes and guidelines (2023) is available at on the Ahpra Resources webpage.

Context - issue or problem statement

It is good regulatory practice to review registration standards and guidelines on a planned, regular basis to test their workability, clarity, and continued relevance. The current *Registration standard: Endorsement for scheduled medicines* (the standard) has been in effect since 2018 and is therefore due for review. The related *Guidelines for the use of scheduled medicines* (the guidelines) are being reviewed to reflect the proposed changes in the standard.

The Optometry Board of Australia (the Board) is also proposing to update its existing endorsement for scheduled medicines to allow the prescribing of oral medicines in addition to topical medicines for eye conditions as part of the scheduled reviewed of the standard and guidelines in response to a submission from the peak professional association.

The Board also proposes to publish the lists of medicines that optometrists are qualified to prescribe on its website, as supporting information, and no longer embed them in the guidelines. This will make it easier for consumers, practitioners, and other stakeholders to see what optometrists are qualified to prescribe. The Board also proposes that the endorsement itself, would not include the reference to the list. Instead for enforceability, the standard and guidelines would refer to there being approved lists. These changes together, mean the lists can be updated in a timely way, while keeping the necessary safety checks in place.

To future proof the guidance the Board is proposing to align the standard and guidelines to support cross-profession consistency where possible and to remove outdated clinical guidance from the regulatory guidelines.

The proposal would better use the skills and training of endorsed optometrists as an existing health workforce where they will be able to work to their full scope of practice, in line with international optometry regulatory best practice and as recommended in the Scope of Practice Review. This would provide easier and greater patient access to primary eye care in a timely way, by reducing the need to see multiple health practitioners.

The proposal supports the <u>National Medicines Policy</u> and the <u>National Strategy for Quality Use of Medicines</u> to make the best possible use of medicines to improve health outcomes for all Australians. The proposal also supports the Health Professionals Prescribing Pathway and the need to improve consistency between professions on education and recognition of prescribing competence.

Assessment

Below is the Board's assessment of its proposal for the draft standard and guidelines taking account of the Ahpra procedures.

1. Describe how the proposal

- 1.1 takes into account the paramount principle, objectives and guiding principles in the National Law³
- 1.2 draws on available evidence, including regulatory approaches by health practitioner regulators in countries with comparable health systems

The Board's proposal takes into account the National Scheme's paramount principle of protecting the public and maintaining public confidence in the safety of services provided by optometrists.

The proposed variation to the existing endorsement, if approved, means the Board will meet objectives:

- 2(e) in facilitating access to services provided by health practitioners in accordance with the public interest
- 2(f) in enabling the continuous development of a flexible, responsive and sustainable Australian health workforce and innovation in the education of, and service delivery by endorsed optometrists, and
- 2(ca) in building the capacity of the Australian health workforce to provide culturally safe health services to Aboriginal and Torres Strait Islander Peoples.

The proposed standard and guidelines, if approved, will continue to meet objective 2(a) in providing protection of the public by ensuring that optometrists who are suitably trained and qualified to practise in a competent and ethical manner are registered with an endorsement.

The proposal has considered the National Scheme's paramount principle 3A(1)(a) of protecting the public and maintaining public confidence in the safety of services provided by endorsed optometrists. The proposal particularly improves the Board's efforts to align with principle 3A(2)(c), where restrictions on the practice of optometrists are imposed under the scheme only where necessary, to ensure health services are provided safely and are of an appropriate quality.

The proposal also supports the National Scheme to operate in a transparent, accountable, efficient, effective and fair way. A comprehensive list of what the proposal has considered, and what the Board has drawn from the best available evidence to inform the review is outlined in Appendix A. The list includes evidence from comparable regulatory models overseas, providing examples of optometrist oral medicines prescribing in New Zealand, the United Kingdom, Canada and the United States.

2. Outline steps that been taken to:

- achieve greater consistency within the National Scheme (for example, by adopting any available template, guidance or good practice approaches used by National Scheme bodies)
- · meet the wide-ranging consultation requirements of the National Law

The review of the draft standard and guidelines has been informed by the <u>AHMAC guidance</u> and the 2018 <u>Ahpra guide</u> to achieve greater consistency within the National Scheme.

The proposed revised standard and guidelines have adopted the cross-profession registration standard and guidelines template in Appendices C and D of the Ahpra guide, where possible. This template supports consistency in the structure and content of the regulatory instruments that enable endorsement for scheduled medicines.

The proposal meets the steps to safe and competent prescribing as per the principles outlined in the Health Professionals Prescribing Pathway (HPPP). The HPPP provides a model for consistency, where practicable, across professions with regard to setting qualifications, clinical practice standards and guidelines, education, curriculum and systems to support the quality use of medicines.

The National Law requires wide-ranging consultation on the proposed standard and guidelines. The National Law also requires National Boards to consult each other on matters of shared interest. The Board has undergone targeted and preliminary consultation to inform this public consultation.

The Board will now ensure that there is the opportunity for broader public comment via an eight week public consultation in line with <u>consultation processes</u>. This includes publishing a consultation paper on the Optometry Board and Ahpra websites and informing health practitioners, stakeholders and the community of the review and inviting feedback.

The Board will consider the feedback received when finalising the proposed draft standard and guidelines. Feedback will also inform the development of FAQs and other supporting materials.

³ See section 3 and section 3A of the National Law

3. Address the following principles:

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

The Board considers this proposal at option 2, to be the best option for achieving public safety, high quality professional practice, regulatory effectiveness and improved public access to primary eye care.

The Board believes the proposal achieves effective and fit-for-purpose regulation that is proportionate to the risk, while minimising administrative burden on the Board, businesses, community organisations and individuals.

b. whether the proposal results in an unnecessary restriction of competition among health practitioners

The proposal is unlikely to restrict competition and will remove current unnecessary restriction of competition among health practitioners. The proposal is expected to have a slow, small increase in competition between endorsed optometrists, general practitioners (who provide primary general healthcare) and ophthalmologists (who provide specialist secondary and tertiary eye care), if approved by the Ministerial Council.

The proposal would mean that endorsed optometrists who choose to expand their scope of practice, would be able to prescribe a wider range of appropriate topical and oral medicines, for the purpose of practising optometry. Currently, optometrists must refer to a medical practitioner if oral medicines are required.

c. whether the proposal results in an unnecessary restriction of consumer choice

The proposal is unlikely to restrict consumer choice and will instead increase consumer choice about which health practitioner they choose to see, to safely have their eye health needs met at their primary visit and to have better access to eye-care medicines. If approved, the proposal will give consumers the chance to decide how and when they receive primary eye care. It will provide consumers with greater access to endorsed optometrists across Australia, should they choose to see an endorsed optometrist instead of a medical practitioner.

It would improve the patient journey as endorsed optometrists would be able to provide safe, timely, accessible, affordable primary eye care services within a single visit. This is important for Aboriginal and Torres Strait Islander communities, people in rural and remote areas, people from lower socio-economic backgrounds, older people and people living in residential aged care facilities.

d. whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved

The Board has closely considered the potential costs associated with the proposal (as discussed below) during the development of this consultation paper and believes they are reasonable in relation to the benefits achieved. The Board expects the proposal will impact a small percentage of the registrant base, with a slow, safe, conservative uptake similar to that of the New Zealand experience.

If approved, members of the public would need to pay private prices for the oral and new topical medicines prescribed by optometrists and any related pathology tests, until any such time that there are changes in the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Schedule (MBS). The difference in cost between a private prescription and PBS funded prescription for many of the proposed oral medicines for eye conditions is minimal or has no cost difference. Optometrists will continue to ensure informed financial patient consent in line with the shared *Code of conduct*.

It is the peak professional association's role to advocate for the profession to add medicines to the PBS and pathology testing to the MBS, and they would be able to do so if this proposal is approved. The Board has consulted with Optometry Australia on this, as it's the Board's intention not to disadvantage patients. If approved, Optometry Australia will use the transition period to advocate to add medicines to the PBS and pathology testing to the MBS, with the intention of having these added at the date of commencement of the proposed standard. However, this cannot be guaranteed as additions to the PBS and MBS remain a decision for the federal government and its delegates.

Should the proposal be approved and medicines be added to the PBS, Aboriginal and Torres Strait Islander Peoples would be able to get medicines free with a concession card (or at concession prices, where eligible) under the Closing the Gap Pharmaceutical Benefits Scheme.

Other eligible consumers would be able to get these medicines at concession prices. This would improve access to affordable medicines to those most in need.

Stakeholders would need to become familiar with the proposed new standard and guidelines. Queensland, Tasmanian and Western Australian medicines and poisons regulation would need to change to harmonise with the proposal. Victoria would need to update its Victoria Government Gazette.

The Board considers there may be future health costs savings as some eye diseases, if not diagnosed and treated early in a primary care setting, can result in more expensive surgical intervention.

The Board also notes that other monitoring safeguards coexist in the Australian healthcare and regulatory system. The Optometry Council of New South Wales manages concerns about registered health practitioners in New South Wales and the Office of the Health Ombudsman manages concerns about registered health practitioners in Queensland. The Medicare compliance program monitors the Medicare Benefits Schedule and Pharmaceutical Benefits Scheme and any practitioner conduct or performance matters are referred to the Board.

Should the proposal be approved and medicines be added to the PBS, there will be reporting and monitoring of antimicrobial prescriptions supplied under PBS by Antimicrobial Use and Resistance in Australia in the community for primary care. There will also be existing safeguards in the system, such as the <u>Provider Benefits Integrity Hotline</u> for suspected non-compliance of PBS prescribing.

The Therapeutic Goods Administration is responsible for monitoring the continuing safety, quality, and efficacy of medicines in Australia through adverse event reporting by consumers and health professionals.

The Board has carefully considered the inherent risks of prescribing errors and adverse events and the risks of optometrists prescribing out of scope. The Board believes the risks are minimal as they are mitigated by the safeguards in the existing system. The Board believes the Australian experience will be similar to the New Zealand experience, where they have not been alerted to any out of scope prescribing and the uptake of optometrists wanting to expand their scope of practice to prescribe oral medicines has been slow, conservative and safe. The Board considers the proposal provides public benefit that supports the National Strategy for Quality Use of Medicines and outweighs the minimal costs.

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

The Board is committed to a plain English approach that will help practitioners and the public understand and apply the requirements of the revised standard and guidelines.

The Board will publish a one page snapshot and a consumer consultation guide for consumers to understand the requirements during public consultation. Supporting materials, including the Board's medicine lists and a FAQ sheet in plain English will be published on the Board's website at the transition phase and implementation phase of the consultation process. The Board has aligned its existing standard and guidelines to the cross-profession template and reviewed the wording to make them easier to understand and comply with. The format is consistent with the format currently used.

f. whether the Board has procedures in place to ensure that the proposed standard remains relevant and effective over time.

The Board has procedures in place to support a review of the proposed standard at least every five years, as it is good regulatory practice to do so. If approved, the Board will review the guidelines at least every three years.

The Board may choose to review the proposed standard or guidelines earlier, in response to any issues which arise, or new evidence which emerges to ensure its continued relevance and workability.

4. Closing statement

Feedback on any regulatory impacts identified during the public consultation process will be provided to the Board and Ministerial Council to inform decision-making.

The Board has completed a patient health and safety impact statement for consultation and will also provide a patient and safety impact assessment (if the proposal is approved).

Appendix K: Background paper

This background paper provides additional considerations, evidence and data that the Optometry Board of Australia (the Board) has taken into account to address the requirements in the <u>AHMAC Guidance</u> and what it may mean for the Ministerial Council. The Board considers the level of detail in this paper is commensurate with the scope of the proposed change.

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Purpose of the proposed submission to Ministerial Council

After wide-ranging public consultation, the Board may propose to ask Ministerial Council to approve a variation of the existing scheduled medicines endorsement for optometry, as highlighted in yellow below.

Current approved endorsement under section 14 of the National Law:

"Class of health practitioners – any person registered as an optometrist under the National Law whose registration has been endorsed by the Board in accordance with section 94 of the National Law

Type of use – endorsed as qualified to administer, obtain, possess, prescribe, supply or use a class of scheduled medicines (as per below)

Class of scheduled medicines – topical Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry, included in the list approved and published by the Board"

Proposed variation of endorsement (highlighted in yellow):

"Class of scheduled medicines – topical Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry", included in the list approved and published by the Board"

Ministerial Council will be requested to approve:

"Class of health practitioners – any person registered as an optometrist under the National Law whose registration has been endorsed by the Board in accordance with section 94 of the National Law

Type of use – endorsed as qualified to administer, obtain, possess, prescribe, supply and/or use a class of scheduled medicines (as per below)

Class of scheduled medicines - Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry"

Change in circumstances that has prompted the proposal

The Board's current standard was published on 10 September 2018 and is due for review.

The change proposal was initiated by <u>Optometry Australia</u>, the peak professional association to change the Board's endorsement to recognise that endorsed optometrists in Australia are qualified to prescribe oral medicines. They have also provided a report on *Oral therapeutic prescribing by Australian Optometrists* as part of their submission to the Board and since published *The Value of expanding Optometrists' prescribing rights in Australia* 2025 report.¹

The Board has considered Optometry Australia's submission and through further research and targeted consultation the Board has found there is strong evidence and service need to progress and test the proposal.

¹ Optometry Australia, Oral therapeutic prescribing by Australia Optometrists, 2022 and the <u>Value of expanding Optometrists'</u> <u>prescribing rights in Australia</u>, 2025

Legislative arrangements

An endorsement indicates an optometrist is *qualified* to administer, obtain, possess, prescribe, supply or use the scheduled medicine or class of medicines specified in the endorsement, but does not authorise the practitioner to do so.

The *authorisation* of an optometrist to administer, obtain, possess, prescribe, sell, supply or use scheduled medicines in a participating jurisdiction is provided by or under the Act of that jurisdiction. There are differences between jurisdictions in terms of what a general and endorsed optometrist is authorised to prescribe.

Table 1 is a summary of the relevant state and territory medicines and poisons legislation that authorises endorsed optometrists to use scheduled medicines and general optometrists to use scheduled medicines for diagnostic purposes.

Table 1

Jurisdiction	Relevant medicines and poisons legislation
Australian Capital Territory (ACT)	Legislation Act 2021 – Effective 27 November 2025 Part 1 Meaning of optometrist Medicines, Poisons and Therapeutic Goods Act 2008 – Effective 2 June 2025 Dictionary – reference to the definition of optometrist Medicines, Poisons and Therapeutic Goods Regulation 2008 – Effective 17 June 2025 41(1)(j), 123(d), 161(k), Schedule 1 Part 1.8, Part 9.6, 490(1)(2)
New South Wales (NSW)	Poisons and Therapeutic Goods Act 1966 – Effective 3 July 2025 17B Poisons and Therapeutic Goods Regulation 2008 – Effective 28 June 2024 3(1)(b), 33(5), 43(5), 59(1)(iii)
Northern Territory (NT)	Medicines, Poisons and Therapeutic Goods Act 2012 – Effective 10 December 2022 23(1), 23(2)(b), 27(1), 68(a)(b), 73(1)(2)(3), 81(1)(a)(i)(ii), 82(1)(a)(i)(ii), 86(1)(2)(3) Medicines, Poisons and Therapeutic Goods Regulations 2014 – Effective 10 December 2022 8
South Australia (SA)	Controlled Substances Act 1984 – Effective 26 May 2025 4 Definition of a registered health practitioner 18(1)(a)(ii), 18(1c)(b)(ii), 18(1d)(a)(ii) Controlled Substances (Poisons) Regulations 2011 – Effective 23 January 2025 3 – Interpretation – Meaning of optometrist 18(2)
Victoria (VIC)	Drugs, Poisons and Controlled Substances Act 1981 – Effective 1 July 2025 4 Definition of registered optometrist 13(1)(c), 13 (2A), 14(4) Drugs, Poisons and Controlled Substances Regulations 2017– – Effective 12 November 2024 5 Definition of authorised optometrist Regulation 7(1), 16(1), 22, 25(3)(4) 25A(3)(4), 26(3), 28, 29, 34, 41, 44(3), 73(1)(a), 77(1), 82, 86, 94, 107(a) (ix), 139, 144(1), 144(1A)(i), 145(1), 145(1A)(i), 152(1)(a)(iv), 160(1)(a)
Queensland (QLD)	Medicines and Poisons Act 2019 – Current from 1 July 2024 30, 54 Therapeutic Goods Act 2019 – Current from 14 October 2024 Medicines and Poisons (Medicines) Regulation 2021 – Current from 8 August 2025 1 Definition of Optometry Board and optometry guidelines, 2 Definition of optometrist, 3, 4 and 5
Tasmania (TAS)	Poisons Act 1971 – Current from 1 July 2025 3 interpretation, Meaning of authorised health professional and 25C Poisons Regulations 2018 – Current from 1 July 2025 3 interpretation of optometrist and Optometry Board of Australia, 7 and 8
Western Australia (WA)	Medicines and Poisons Act 2014 – Current from 30 August 2024 25 Medicines and Poisons Regulations 2016 – Current from 11 July 2025 37, 58, 59, 60

The Board reviewed the relevant state and territory medicines and poisons legislation as at 11 January 2023 and was updated on 19 August 2025. Table 2 summarises what may need to change if Ministerial Council approves the proposal to ensure endorsed optometrists will also have the authorisation to prescribe.

Inconsistencies between jurisdictions can create a regulatory barrier and removes the benefits of workforce flexibility and mobility that has been delivered with the National Registration and Accreditation Scheme (the National Scheme). The Board will seek input and work closely with jurisdictions to identify and address some aspects of the proposal.

Table 2

Jurisdiction	Legislation changes required for the proposal	For discussion with jurisdictions
ACT	No	
NSW	No	
NT	No	
SA	No	
VIC	No	Recommend:
		Updating the Victoria Government Gazette
QLD	Yes	Recommend:
	Currently an optometrist with general registration is authorised to give a purchase order or possess a S4 medicine, or administer a topical S2, S3 or S4 medicine mentioned in Appendix A of the optometry guidelines. Currently an endorsed optometrist is authorised to give a purchase order or possess a S4, or prescribe, give a treatment dose or administer an S2, S3 or S4 medicine mentioned in Appendix B or appendix C of the optometry guidelines. With the proposal to remove Appendix A, B and C, changes to the legislation will be required. Noting that the lists will be published on the Board's website.	 removing references to 'topical', 'appendix A of the optometry guidelines' and 'appendix B or C of the optometry guidelines' in the Medicines and Poisons (Medicines) Regulation 2021 changing Part 2 of the Medicines Regulation 2021 to authorise optometrists with general registration to administer scheduled medicines to the extent they are qualified under the Health Practitioner Regulation National Law 2009, for diagnostic purposes, and changing Part 3 of the Medicines Regulation 2021 to authorise endorsed optometrists to administer, obtain, possess, prescribe, supply and use scheduled medicines to the extent they are qualified under the Health Practitioner Regulation National Law 2009.
TAS	Yes	Recommend:
	Currently an optometrist with general registration may administer substances listed in the optometry guidelines as being a scheduled medicine approved by the Optometry Board of Australia. With the proposal to remove Appendix A, changes to the legislation will be required. Noting that the list will be published on the Board's website.	changing Regulation 8 of the <u>Poisons Regulations</u> 2018 to authorise optometrists with general registration to administer scheduled medicines to the extent they are qualified under the Health Practitioner Regulation National Law 2009, for diagnostic purposes.
WA	Yes	Recommend:
	Currently an endorsed optometrist is authorised to administer, possess, prescribe and supply S4 medicine listed in the Standard for Optometrists. The definition states "Standard for Optometrists means the Endorsement for Scheduled Medicines Registration Standard Table 1 approved by the Australian Health Workforce Ministerial Council". This reference is out of date as Table 1/list is in Appendix B of the current guidelines. With the proposal to remove the appendices/lists from the guidelines, changes to the legislation will be required. Noting that the lists will be published on the Board's website.	 removing the reference to Table 1 in the definition and under Regulation 60(1) of the Medicines and Poisons Regulations 2016. removing references of 'listed in the Standard for Optometrists' under Regulation 60(2), 60(3) and 60(4) of the Medicines and Poisons Regulations 2016, and changing the legislation to authorise endorsed optometrists to administer, obtain, possess, prescribe, supply and use scheduled medicines to the extent they are qualified under the Health Practitioner Regulation National Law 2009.

Other details of the proposal

Existing international precedents



United Kingdom (since 2008)



New Zealand (since 2014)



United States (most states)

Qualified optometrists in countries with comparable health regulatory systems such as New Zealand, the United Kingdom, the Netherlands, most of the United States of America and some provinces in Canada are able to prescribe oral medicines to their patients.²

The Board has focussed on New Zealand, as it is the most similar country to Australia from a health and regulatory perspective.

New Zealand

New Zealand optometrists have been able to prescribe oral and topical medicines for primary eye conditions since 2014. Such eye conditions include bacterial and viral infections, inflammatory conditions, ocular allergies and acute angle closure glaucoma. Currently under the Trans-Tasman Mutual Recognition Agreement, optometrists who graduate from an Australian university can register as an 'authorised prescriber' and prescribe topical and oral medicines within their scope of practice in New Zealand without additional training, yet they cannot in Australia. As authorised prescribers in New Zealand, these optometrists are not restricted by the route of administration.³

The New Zealand Optometrist and Dispensing Opticians Board (ODOB) directly regulates the scope of practice of optometry in New Zealand. Oral medicine prescribing is considered within scope because it is an approved component of the accredited optometry programs. The Optometry Council of Australia and New Zealand (OCANZ) develops education and training standards for approval by the Board and assesses education providers and education programs against education and training standards and the framework. OCANZ accredits courses in New Zealand, using the same accreditation standards as those approved in Australia.⁴

According to ODOB on 13 September 2022, there were 20 optometrists registered in New Zealand with an Australian qualification. These optometrists are existing authorised prescribers that can prescribe oral medicines in New Zealand.

According to Ahpra data, there have been 34 New Zealand registered practitioners that have been registered with endorsement in Australia between 2014 and 2021. These practitioners were able to prescribe oral medicines in New Zealand but could not prescribe oral medicines in Australia due to existing legislation.

As of 31 March 2024, there were 845 optometrists with therapeutic prescribing rights out of 967 (87%) in New Zealand.⁵ ODOB has been monitoring prescribing reports from the Ministry of Health every month to ensure optometrists prescribe safely within their scope and have confirmed with the Board 'that there has been no evidence to suggest that optometrists prescribing orals pose a risk of harm'.⁶

Since 2014, ODOB has not been alerted to any out-of-scope prescribing of oral medicines, over-prescribing or any adverse incidents reported to the Accident Compensation Corporation or Health and Disability Commission. This suggests that the optometry profession in New Zealand is practicing appropriately, referring and/or co-managing rather than independently managing cases requiring more complex therapeutic management.³

The Board believes that the Australian experience of endorsed optometrists prescribing oral medicines would be similar to that of the New Zealand experience, which has demonstrated that the number and uptake of optometrist prescribing oral medicines has been measured, conservative, and safe.

² Optometry Australia, Oral therapeutic prescribing by Australian Optometrists, 2022

³ Turnbull, P and Craig, J 2021, 'Oral medication prescribing by optometrists in New Zealand', Clinical and Experimental Optometry, Vol 104, No 3, pp 425-427

⁴ See <u>www.ocanz.org/accreditation/standards</u> for more information

⁵ Optometrists and Dispensing Opticians Board, Annual reports, 2024, www.odob.health.nz, accessed 5 August 2025

⁶ J Chouhan, Optometrists and Dispensing Opticians Board, [Presentation at the Optometry Regulatory Reference Group Meeting 2021], 2021

Proposed education and training arrangements

Health Professionals Prescribing Pathway

The Health Professionals Prescribing Pathway (HPPP) was developed by Health Workforce Australia and was approved by Health Ministers in 2013. It provides a nationally recognised and consistent approach to the prescribing of medicines by non-medical health professionals registered under the National Scheme. The HPPP provides a model for consistency, where practicable, across professions with regard to setting education, curriculum, qualifications, clinical practice standards and guidelines and systems to support the quality use of medicines. The HPPP supports health professionals to meet the healthcare needs of the Australian community by safe prescribing within their recognised scope of practice.⁷

The Board is supportive of the HPPP and the need to improve consistency between professions on education and recognition of prescribing competence.

The National Prescribing Competencies Framework

In order to meet the education and training requirements described within the HPPP, health professional accredited prescribing education and training programs must align to the <u>National Prescribing Competencies Framework</u> (the framework).

The framework, originally developed and hosted by <u>NPS MedicineWise</u> is the nationally recognised approach to prescribing for all health professionals with prescribing rights and describes the competencies prescribers require to contribute to safe, person-centred and quality medicines use and the knowledge, skills and behaviours that support the development of these competencies.

The OCANZ accreditation standards and Optometry Australia's Entry-Level Competency Standards for optometry align to the framework and support the quality use of medicines.

Education and training arrangements

The optometry profession has eight entry level programs that vary between three and five years, depending on whether the university follows a semester or trimester system. Since 2014, entry level programs ensure all graduates automatically qualify for general registration and an endorsement for scheduled medicines. The profession also has two post-entry level ocular therapeutics programs that vary between 12 and 18 months for general optometrists who wish to prescribe and qualify for an endorsement. The approved programs of study include clinical placements under supervision.

In the Board's considerations of the education and training requirements for endorsed optometrists to expand their scope to safely prescribe oral medicines, the Board commissioned the OCANZ/QUT report on Prescribing oral medicines by optometrists – A mapping of current education programs and professional practice standards to demonstrate the preparation of optometrists to prescribe medicines for oral administration. It is important to highlight that the framework itself does not include route of administration as a specific prescribing competency and instead focuses on prescribing medicines according to reliable evidence, including evidence to support the most appropriate route of administration. The focus of the report was on whether optometrists could make appropriate prescribing decisions based on the best available evidence. Best available evidence is relevant to the patient and their needs and appropriate prescribing may lead to prescribing topical medicines or oral medicines or even nothing at all.8

Review E of the report showed that the entry level and post entry level programs are required to demonstrate alignment with the framework in order to meet <u>accreditation standards</u>, and therefore met the education and training requirements described within the HPPP. It also showed that optometry education and training programs included learning outcomes and assessments that clearly reflected the framework. Table 5 of the report showed that the proportion of optometry learning outcomes associated with prescribing was comparable to other prescribing professions.

⁷ Health Workforce Australia, Health Professionals Prescribing Pathway (HPPP) Project - Final Report, 2013

⁸ Optometry Council of Australia and New Zealand and Queensland University of Technology, Prescribing oral medicines by optometrists A mapping of current education programs and professional practice standards to demonstrate the preparation of optometrists to prescribe medicines for oral administration, December 2020

Table 5 Proportion of learning outcomes identified as specifically relevant to the elements of the Prescribing Competencies Framework

Prescribing Competencies Framework Element	Dentistry (DDM)	Medicine (MBBS)	Nurse Practitioner (MNP)	Optometry (B Vis\$ci MOptom)	Pharmacy (BPharm Hons)
	Proportion of LO specific to element (%)	Proportion of LO specific to element (%)	Proportion of LO specific to element (%)	Proportion of LO specific to element (%)	Proportion of LO specific to element (%)
2.2 Identifies appropriate medicines options that can be incorporated into the person's treatment plan	9.8	7.4	12.8	12.1	23.3
H1.2 Practices according to professional standards, codes of conduct, and within the health professional's own scope of practice	3.5	7.0	18.0	3.0	9.8
H1.4 Practices quality use of medicines	5.1	2.2	7.7	4.2	22.6
H2.4 Communicates effectively with the person using appropriate communication skills to enable the safe use of medicines	2.1	5.0	2.6	9.7	6.0
H2.5 Collaborates with other health professionals to achieve optimal health outcomes for the person	0.5	2.2	12.8	7.2	2.3
Notes	LO = Learning outcome Findings are reported as the proportion all learning outcomes identified as relevant to prescribing within each program of study				

Figure 1 Table 5 of the OCANZ/QUT report

All programs demonstrated an integrated curriculum that provides a strong foundation in prescribing skills, including the principles of quality use of medicines, safe prescribing practices, adverse event reporting and collaborative and inter-professional prescribing practices.

The report demonstrated that graduates from approved entry level and post graduate level programs can make appropriate prescribing decisions based on the best available evidence, including decisions regarding the optimal route of administration. Overall, the findings of the report show that graduates of entry level optometry programs and post entry level ocular therapeutics programs have the knowledge, skills and other professional attributes and competencies that are necessary for the entry level practice of optometry in Australia or New Zealand.¹⁰

OCANZ performs the same accreditation functions for the optometry approved programs of study in both Australia and New Zealand and New Zealand optometrists have been able to safely prescribe oral and topical medicines for primary presenting eye conditions without a Board approved list since 2014. Australian graduates that register in New Zealand have also been able to safely prescribe oral medicines in New Zealand since 2014¹¹

At the time of the OCANZ review, there were seven entry level programs and two post entry level programs. There are now eight entry level programs and two post entry level programs. The framework itself was further revised on 26 April 2021 and has been reviewed in 2025, the OCANZ accreditation standards for entry level optometry programs was revised on 1 January 2023 and the Optometry Australia Entry-Level Competency Standards 2022 were revised and came into effect on 22 February 2023. The Board has been working closely as a stakeholder with OCANZ and Optometry Australia to ensure their standards continue to align with the evolving framework.

The Board does not believe any additional formal education or supervised practice is required to ensure endorsed optometrists are competent for the proposed expanded scope of practice.

The Board will continue to recognise an optometrist's competence to prescribe via its endorsement. General registrants without endorsement will still need to complete an approved program of study to obtain endorsement to be able to expand their scope of practice to include prescribing of scheduled medicines.

The Board will recognise both recently graduating endorsed optometrists and existing endorsed optometrists to be qualified and competent to prescribe according to the endorsement. Endorsed optometrists will need to meet the Board's <u>Registration standard</u>: <u>Continuing Profession Development</u> (CPD registration standard), to define scope of practice, develop a learning plan targeted at the individual's scope of practice, obtain required hours of CPD (including 10 hours extra per year for endorsed optometrists) and reflect on the learning to consider how the knowledge gained will change and contribute to their practice.

⁹ Ibid

¹⁰ Ibic

¹¹ Turnbull, P and Craig, J 2021, 'Oral medication prescribing by optometrists in New Zealand', Clinical and Experimental Optometry, Vol 104, No 3, pp 425-427

Standard setting and practice monitoring arrangements

Maintain and enhance competence to prescribe within scope

Under this proposal, should an endorsed optometrist choose to expand their scope of practice to include prescribing oral medicines, the onus for further education and professional development would be on the optometrist in line with the Board's existing CPD registration standard.

The CPD registration standard requires optometrists to maintain a portfolio that documents their individual learning goals, planned CPD activities and reflections on what they have learned. The optometrist's learning goals are based on their chosen scope, practice of setting, professional interests, and patient needs. All optometrists must complete at least 20 hours of CPD each year. All endorsed optometrists must complete an additional 10 hours of CPD in relation to the endorsement, which may include CPD about route of administration or new oral medicines. CPD requires endorsed optometrists to keep their skills up to date and develop new ones to practise safely and protect patients.

The <u>Registration standard: Recency of Practice</u> requires optometrist to maintain experience in their chosen scope.

Monitoring

As a mature and established profession, the optometry profession has existing safeguards in its systems and is integrated into the existing safeguards in the Australian healthcare and regulatory system.

Compliance with the Board's registration standards is monitored, where optometrists must make a declaration that they have met the registration standards for the profession every year at registration renewal. The review period for the proposed draft standard would be after five years and the guidelines after three years or as required. The Board's SMAC and Ahpra's SMEC will continue to review and provide the Board with advice. All optometrists will continue to be subject to <u>audits</u> to ensure ongoing competence and to protect the public.

The Board's Registration and Notifications Committee will continue to monitor notifications or concerns about a practitioners health, conduct or performance, including any notifications about prescribing as part of its regulatory function. The Board's registration standards, shared Code of conduct and guidelines may be used as evidence of what constitutes appropriate professional conduct or practice for optometrists in proceedings against a health practitioner under the National Law, or a law of a co-regulatory jurisdiction. The Optometry Council of New South Wales is responsible for managing concerns about registered health practitioners in New South Wales and the Office of the Health Ombudsman is responsible for managing concerns about registered health practitioners in Queensland.

The <u>Medicare compliance program</u> is responsible for monitoring the Medicare Benefits Schedule and Pharmaceutical Benefits Scheme and any practitioner conduct or performance issues are referred to the Board.

National Medicines Policy

The vision of the <u>National Medicines Policy</u> is to achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment.

The benefits of the Board's proposal aligns with and complements the National Medicines Policy's aim to ensure equitable, timely, safe and affordable access to a high-quality and reliable medicines-related services for all Australians and to ensure that medicines are used safely, optimally and judiciously, with a focus on informed choice and well-coordinated person-centred care. The proposal's benefits, reduces health inequities that are currently experienced by members of the community at risk of experiencing poorer health outcomes. These members of the community include Aboriginal and Torres Strait Islander Peoples, people from culturally and linguistically diverse backgrounds, older people, people living in rural and remote areas and people of low socioeconomic status.

Quality use of medicines

The stewardship for QUM transferred from the Medicine Wise to the Australian Commission on Safety and Quality in Health Care (ACSQHC) on 1 January 2023. Quality use of medicines (QUM) is one of the central objectives of the National Medicines Policy.

The Board's guidelines have aligned to and complemented the <u>National Strategy for Quality Use of Medicines</u> (QUM) since 2013. The previous, current and proposed guidelines adopt the definition of QUM of selecting management options wisely, choosing suitable medicines, if a medicine is considered necessary so that the best available option is selected and using medicines safely and effectively to get the best possible results. The guidelines also advise optometrists to observe the QUM principles as they apply to the scope of the endorsement.

The Board's guideline has been adopted in the cross profession guideline template in the Ahpra guide. This also supports consistency in the structure and content of the regulatory instruments that enable endorsement for schedule medicines within the National Scheme.

QUM is already a part of OCANZ's accreditation standards (and therefore optometry education) and Optometry Australia's Entry-Level Competency Standards, clinical practice guides and continuing education. The Board will continue to work closely with them as a stakeholder to ensure they continue to support and integrate QUM with emerging needs.¹² Table 8 of the OCANZ/QUT report demonstrates that the proportion of prescribing competencies specifically identified in professional standards were 100%, *including 'practices quality use of medicines'*. Practice standards for optometry referred to the Optometry Australia's Entry Level Competency Standards for Optometry, the Board's Guidelines for Use of Scheduled Medicines and the Boards' shared Code of Conduct.¹³

Table 8 Proportion of prescribing competencies specifically identified in professional practice standards (comparison of professions)

Prescribing Competencies Framework Element	Dentistry	Medicine	Nurse Practitioner	Optometry	Pharmacy
	Proportion (%) of this element identified in practice standards*	Proportion (%) of this element identified in practice standards*	Proportion (%) of this element identified in practice standards*	Proportion (%) of this element identified in practice standards*	Proportion (%) of this element identified in practice standards*
2.2 Identifies appropriate medicines options that can be incorporated into the person's treatment plan	66.7	88.9	55.6	100.0	100.0
H1.2 Practices according to professional standards, codes of conduct, and within the health professional's own scope of practice	100.0	100.0	100.0	100.0	100.0
H1.4 Practices quality use of medicines	75.0	100.0	100.0	100.0	100.0
H2.4 Communicates effectively with the person using appropriate communication skills to enable the safe use of medicines	100.0	50.0	50.0	100.0	100.0
H2.5 Collaborates with other health professionals to achieve optimal health outcomes for the person *The professional practice standards reviewed for each professional	50.0 on as part of the AS	50.0 SPRINH Project are j	25.0 provided in Append	100.0 dix 1 Table 3.	25.0

Figure 2 Table 8 from the OCANZ/QUT report

Within the profession, Optometry Australia develops the *Entry-Level Competency Standards* that determine the skills, knowledge, abilities, and attributes needed to perform safe and competent optometry practice, including safe optometry prescribing. The OCANZ/QUT report also showed that the *Entry-level Competency Standards* reflected the competencies in the framework, further supporting consistency between professions on continuing education as described in the HPPP.¹⁴ The Board will continue to work with Optometry Australia to ensure endorsed optometrists will have the ongoing support to meet emerging needs. Optometry Australia develops evidence based clinical practice guides to support optometrists and is also a CPD provider. Optometry Australia's report highlighted that they are well placed to provide optometrists with comprehensive guidance and practical support in relation to prescribing medicines.¹⁵

Proposed model of prescribing under the HPPP

Optometrists have had a safe autonomous prescribing model with a limited formulary for over 20 years. Starting in Victoria in 1996 and now nationally under the National Scheme.

Since 2014 all graduates of Board approved programs of study are eligible for general registration, with endorsement for scheduled medicines.

The proposed safe model of prescribing under the HPPP will remain as autonomous prescribing. The Board would publish the medicine lists on the Board's website.

¹² Optometry Regulatory Reference Group, 14 October 2022

¹³ Optometry Council of Australia and New Zealand and Queensland University of Technology, Prescribing oral medicines by optometrists A mapping of current education programs and professional practice standards to demonstrate the preparation of optometrists to prescribe medicines for oral administration, December 2020

¹⁴ Optometry Council of Australia and New Zealand and Queensland University of Technology, Prescribing oral medicines by optometrists A mapping of current education programs and professional practice standards to demonstrate the preparation of optometrists to prescribe medicines for oral administration, December 2020

¹⁵ Optometry Australia, Oral therapeutic prescribing by Australia Optometrists, 2022

Pathway to qualify for endorsement

The pathways to qualify for endorsement will remain the same and are outlined in the proposed draft Standard:

You can qualify for endorsement through one of the following pathways:

- holding an approved qualification that includes the required ocular therapeutic components
- another qualification that the Board assesses as substantially equivalent to, or based on similar competencies to, an approved qualification that includes the required therapeutic components, or
- an examination or assessment in ocular therapeutics approved by the Board.

The pathways to qualify for an endorsement for an <u>overseas practitioner</u> remain the same, those without prior ocular therapeutics training will need to complete a postgraduate approved program of study.

The Board does not require any changes to existing education pathways for the proposal.

Administrative considerations for endorsement and implementation

Transition period: The proposal would come into effect one year after Ministerial Council has approved the final draft of the standard. As part of the Board's communications plan, it would ensure appropriate communications go out to all registered optometrists and affected stakeholders before any changes come into effect.

The Board would communicate that it will recognise existing endorsed optometrists and new graduates from approved programs of study to be qualified and competent to prescribe according to the endorsement, from the date of effect.

Proposed variation of endorsement on the public register (highlighted in yellow):

The public register would display for endorsed optometrists:

Registration type - General

Endorsements – Endorsed as qualified to administer, obtain, possess, prescribe, supply and/or use topical Schedule 2, 3 or 4 medicines for the purposes of the practice of optometry.

The public register would display for general optometrists without an endorsement:

Registration type - General

Endorsements - none

Notations – The optometrist is not qualified for endorsement for scheduled medicines and is not able to prescribe Schedule 4 medicines for the purposes of the practice of optometry the treatment of conditions of the eye.

Fees for registration: would not be impacted by the implementation of the proposed change.

Form changes: The common form, previously the *Application for endorsement of registration for scheduled medicines* AESM-50 form would be updated to reflect the changes in the endorsement, if approved.

The Board believes the proposed regulatory and quality control measures have been considered sufficient to support safe and effective use of scheduled medicines.

Communications plan: As part of the Board's communications plan, the Board would ensure effective communications with all registered optometrists and affected stakeholders before any changes come into effect.

The Board will publish a consultation report, a Patient and Consumer Health and Safety Impact Assessment and an FAQ. Consultation feedback will inform the FAQs.

Risks associated with the proposal and mitigation strategies

The Board is a risk based regulator and the following risks and risk mitigating strategies have been considered.

1. Risks of prescribing errors, poly pharmacy, fragmentation of care and adverse events

Although appropriate use of medicines can improve eye health, medicines can be associated with harm. The main risk of the proposal is related to the prescribing of oral medicines, where oral medicines have more systemic risks compared to topical medicines.

The use of scheduled medicines, regardless of route of administration, carries an inherent risk for all patients. All prescribing health professionals, including optometrists risk medicinal misadventure, prescribing errors, drug interactions, adverse effects, poly pharmacy and potential for fragmentation of care leading to harm to the patient. Errors associated with the use of medicines may occur at any point in the medicines management cycle, including the prescribing, dispensing, administration and monitoring of medicines. Adverse drug reactions contribute significantly to morbidity and mortality in the acute care setting. Medicines can contribute to 2–3% of admissions to hospital in Australia.¹⁶

Risk mitigations

The Board's proposed guidelines mitigate this risk by strengthening and outlining the Board's expectations of the prescribing process, appropriate use of scheduled medicines, patient-centred approaches, the application of the Quality Use of Medicines principles, adverse event reporting, anti-microbial resistance, working with other practitioners and ensuring appropriate and timely referrals. Optometrists are trained, educated and skilled to safely prescribe medicines and recognise when to refer.

The current OCANZ accreditation standards state that education providers should be able to demonstrate having regard to the 2021 framework in aspects of the program concerning prescribing. ¹⁷ The OCANZ report highlights that the existing curriculum in approved programs of study ensures a foundational knowledge of medicine errors. This includes types, causes and risks of medicines errors and where they are most likely to happen, for example due to prescribing the wrong route, dose, time, dosing frequency for the medicine, or drug interactions. It is important to note that the report found this foundational knowledge to be embedded regardless of route of prescribing.

The accreditation standards also state that education providers should also reference within their programs, as appropriate, the work of the Australian Commission on Safety and Quality in Health Care (ACSQHC), including the Primary and Community Healthcare Standards. These provide expectations of the systems in place to support safe, appropriate and effective use of medicines, reduce the risks associated with medicine-related events and improve the safety and quality of medicine use.¹⁸

The Optometry Australia Entry-Level Competency Standards for Optometry 2022 has alignment with the framework and set clear expectations about how to safely prescribe medicines, including how to reduce the risk of medicine errors and how to recognise, monitor and manage adverse events. The entry level competency standards also state that optometrists must comply with relevant standards of care, legislative and regulatory frameworks.¹⁹ Optometry Australia also provides practice and professional support materials on prescribing, risk management checklists for optometry practices and is a continuing education provider that already provides education for its members regarding oral medicines and medicine safety.²⁰

The <u>Therapeutic Goods Administration</u> is responsible for monitoring medicinal adverse events and taking action on medicine safety issues. It monitors the continuing safety, quality, and efficacy of medicines in Australia through adverse event reporting by consumers and health professionals. It also enforces Australian pharmaceutical manufacturer standards and licensing, where the manufacturer 'sponsor' has legal pharmacovigilance responsibilities to monitor, meet legislative requirements for reporting serious adverse reactions and update their product labels and product information with new safety information in a timely way.

The Board encourages quality CPD on prescribing medicines. It regularly meets with the professional association, CPD providers, and optometry schools, including at its annual meeting, to highlight the importance of relevant and high-standard CPD on prescribing and associated topics. The Board would work with CPD providers and approved programs of study to ensure that endorsed optometrists and new

¹⁶ Cardiff, L and Nissen L, <u>Enabling competence in prescribing medicines across multiple healthcare disciplines through systematic assessment practices</u>, Queensland University of Technology, p7, 11–18, research-repository.uwa.edu.au, 2017, accessed 20 April 2022.

¹⁷ Optometry Council of Australia and New Zealand, Accreditation, ocanz.org/accreditation/standards, accessed 25 January 2023

¹⁸ Australian Commission on Safety and Quality in Health Care, <u>National Safety and Quality Primary and Community Healthcare Standards</u>, safetyandquality.gov.au, 2021, accessed 25 January 2023

¹⁹ Optometry Australia, Entry-level Competency Standards for Optometry revised to reflect current best practice, optomety.org.au, 2022, accessed 13 February 2024

²⁰ Optometry Australia, Oral therapeutic prescribing by Australia Optometrists, 2022

graduates understand the new standards and guidelines. The Board expects the optometry curriculum in approved programs of study and CPD material to evolve as practice evolves.

Pharmacists act as a safeguard and final check, by making sure prescriptions are legal, within the optometrist's authority and safe for the patient by checking for prescribing errors and medicine interactions.

Risk assessment

Australian optometrists have demonstrated safe topical prescribing under the National Scheme. Optometry is a relatively small and safe profession, with a low rate of notifications compared to other professions within the National Scheme. In the 2023/24 reporting period, only 0.3% of total notifications were about optometrists, despite optometrists making up 0.8% of practitioners in the Scheme. Of all the notifications about optometrists between 2012/13 and 2022/23, only four optometrists received a notification related to scheduled medicines. None of the notifications required any further action to keep the public safe.

The Board anticipates the uptake of endorsed optometrists wanting to expand their scope of practice to prescribe oral medicines to be slow, conservative and safe, similar to the New Zealand experience. For more information refer to Appendix K *Existing international precedents*.

Overall, the Board believes these mitigations minimise the risk of prescribing errors and adverse events of the proposal. The Board would consult and work with OCANZ, Optometry Australia, education providers and CPD providers to encourage further ongoing opportunities to educate both students and the profession about understanding risks and strategies to reduce prescribing errors and adverse events in the context of oral medicines.

2. Risks related to prescribing out of scope

By proposing to remove the existing regulatory restrictors of 'topical' from the endorsement, there is a risk that stakeholders including the medical profession will have a concern that optometrists could potentially prescribe out of scope. The particular concern is that prescribing out of scope has a potential to cause harm to the patient through medical error.

Risk mitigation

The Boards' shared Code of conduct and proposed guidelines provide specific guidance regarding referrals. The section in the proposed guidelines have been strengthened under 'Working with other practitioners and referrals' and states that optometrists have the responsibility to recognise and work within the limits of their skills and competence and refer a patient to another practitioner when it is the best interest of the patient. Furthermore, these skills are included in the Entry-Level Competency Standards and accreditation standards for the profession, ensuring that this skill is taught by the accredited schools.

The proposed standard and guidelines also link to the Boards' shared Code of Conduct, Registration standard: Continuing professional development, Registration standard: Professional indemnity insurance arrangements and Registration standard: Recency of practice which set the specific expectations that endorsed optometrist must practice within their scope and maintain ongoing competence in their scope. To monitor adherence to standards, the Board has existing compliance and monitoring safeguards under the National Scheme, such as auditing of its standards (such as Continuing Professional Development), refer to Appendix K Standard setting and practice monitoring arrangements.

The Board would publish the medicine lists on its website as supporting guidance to make it clear for everyone to see what an optometrist is qualified to prescribe. For enforceability, the standard and guidelines would still refer to there being approved lists of scheduled medicines. The Board believes its proposal with the existing safeguards in the system would mitigate the risk of prescribing out of scope.

The lists do not include higher-risk Schedule 8 or Schedule 4 Restricted medicines (medicines that are considered to have a higher risk of patient abuse or dependence). It is proposed that the lists be reviewed annually and as required. Relevant stakeholders would continue to be consulted. The Board has mature, established governance structures where the Board's <u>Scheduled Medicines Advisory Committee</u>, that includes an ophthalmologist, a medical practitioner, a pharmacist, a pharmacologist and optometrists will continue to review and advise the Board on scheduled medicines that are suitable for optometrists.

The proposed standard states that the authorisation for endorsed optometrists to use scheduled medicines to practice optometry must be in the scope provided by state and territory legislation. The jurisdictional legislation is the final barrier to prescribing for all practitioners and additional safeguard for consumers. Pharmacists also act as another safeguard, they ensure prescriptions are lawful and within the optometrist's authority.

²¹ Australian Health Practitioner Regulation Agency, Annual reports, www.ahpra.gov.au, accessed 05 August 2025

²² Australian Health Practitioner Regulation Agency Research Unit prepared for the Optometry Board of Australia, Research Report,
December 2023

It's important to highlight that the National Boards under the National Law do not regulate scope of practice in Australia, they regulate title protection. The Board expects the profession to practice within their scope of practice, influenced by a combination of the optometrist's authorisation, competence and accountability. ²³

Should the Board and Ministerial Council approve the proposal, the Board would provide comprehensive communications to relevant stakeholders emphasising the importance that endorsed optometrists must prescribe within scope.

Scope of practice and environment to support safe effective prescribing

Authorisation

- State and territory medicines and poisons legislation
- Commonwealth
 Pharmaceutical Benefits
 Scheme

Competency

- National law
 - the Board only registers and renews suitably trained, qualified & competent optometrists with an endorsement for scheduled medicines
- Optometry Council of Australia and New Zealand accreditation standards
- Optometry Australia competency standards

Accountability

- Optometrists are ultimately accountable and expected to practise within their scope.
- Supported by:
 - Optometry Australia competency standards, clinical practice guides and practice support advice
- Boards' shared Code of conduct, registration standards and guidelines e.g. Endorsement for scheduled medicines, Continuing Professional Development, Recency Of Practice

Figure 3 Scope of practice and environment to support safe effective prescribing

Authorisation

The authorisation for an optometrist to legally administer, obtain, possess, prescribe, supply or use scheduled medicines is highly regulated and would continue to be provided by or under state and territory medicines and poisons legislation. The Board would seek input and work closely with jurisdictions to harmonise the authorisation of optometrists to prescribe oral medicines for the purposes of the practice of optometry in addition to the current authorisation for topical medicines. For more information refer to Appendix K Legislative arrangements.

The authorisation for an optometrist to legally prescribe medicines included in the PBS will continue to be provided by the Commonwealth government. It is the professional association's role to advocate for the profession to add medicines to the PBS. The Board expects that Optometry Australia would advocate to add oral and contemporary topical medicines to the PBS, and they would be able to do so if this proposal is approved. However, the additions to the PBS are not guaranteed as it's a decision for the federal government and its delegates.

Where a stakeholder is unsure of what medicines an optometrist would be able to prescribe, they may check the lists on the Board's website to see what medicines optometrists are qualified to prescribe. Stakeholders may continue to obtain advice from their local state or territory medicines and poisons regulation unit contact about what an optometrist is authorised to prescribe. This is also stated in the Board's proposed guidelines. Furthermore, Optometry Australia's submission to the Board has indicated that they are well placed to provide prescribing support advice, given their ownership of the Entry-Level Competency Standards and their current provision of clinical practice guides. It's important to highlight that what is described in jurisdictional medicines and poisons legislation takes precedence over the Board's medicine lists.

Competence

The Board ensures optometrists who are suitably trained and qualified to practise in a competent, safe, and ethical manner are registered, and only renew the registration of those who continue to maintain their competence. The OCANZ accreditation standards provides the Board with assurance that those who enter the

²³ Optometry Council of Australia and New Zealand and Queensland University of Technology, Prescribing oral medicines by optometrists A mapping of current education programs and professional practice standards to demonstrate the preparation of optometrists to prescribe medicines for oral administration, December 2020

profession are competent with the knowledge, skills and behaviours to practise to contemporary standards set by the profession. The Entry Level Competency Standards for Optometry developed by Optometry Australia determines the skills, knowledge, abilities and attributes needed to perform safe and competent optometry practice, including safe optometry prescribing.

Accountability

Accountability and professional responsibility is supported by professional standards, but ultimately the accountability of prescribing within scope lies with the optometrist. Professional standards for optometry include the Optometry Australia Entry-Level Competency Standards for Optometry and the Boards' shared Code of conduct, registration standards and guidelines.

Optometry Australia develops evidence based clinical practice guides to support optometrists, provides practice support and is also a CPD provider. Optometry Australia's report highlights that it is well placed to provide optometrists with comprehensive guidance and practical support in relation to prescribing medicines.²⁴

The Board would consult and work with Optometry Australia to ensure endorsed optometrists have the ongoing support to meet emerging needs of the profession should Ministerial Council approve the proposal.

Risk assessment

The Board believes the risk of prescribing out of scope is mitigated by the existing system. The OCANZ/QUT report provides evidence that Australian optometrists remain aware of and practice according to their recognised scope of practice.²⁵

The Board also believes that the Australian experience would be similar to the New Zealand experience, where ODOB have not been alerted to any out of scope prescribing during their monitoring and compliance functions. Refer to Appendix K *Existing international precedents* for more information.

Should the medicines be added to the PBS optometric list, any PBS non-compliance and suspected fraud may be reported to the Provider Benefits Integrity Hotline.²⁶

Should an optometrist prescribe out of scope, this may be reported to the Board. The Board's Registration and Notifications Committee will continue to monitor prescribing notifications or concerns as part of its established regulatory function.

3. Other non-clinical risks

With any discussion of scope of practice, there is a risk that the proposal may not be accepted by medical stakeholders. The Board would consult with stakeholders including key medical stakeholders to test the proposal, to identify any issues and to address any unintended consequences.

²⁴ Optometry Australia, Oral therapeutic prescribing by Australia Optometrists, 2022

²⁵ Optometry Council of Australia and New Zealand and Queensland University of Technology, Prescribing oral medicines by optometrists A mapping of current education programs and professional practice standards to demonstrate the preparation of optometrists to prescribe medicines for oral administration, December 2020

²⁶ Department of Health and Aged Care, Report suspected fraud, www.health.gov.au, Australian Government, accessed 27 September 2024