

COUNCIL OF OPTOMETRY REGISTRATION AUTHORITIES Inc.

Incorporation No. A0049268P
ABN 13758851575

Secretariat Office: 15 Hillandale Road, Warragul, Victoria 3820
Executive Officer: Ph. 03 5623 1787 Fax. 03 56 23 5677
Email: leunig@dcsi.net.au

29 October 2008

Ms Bronwyn Nardi
Chair
Practitioner Regulation Subcommittee
Health Workforce Principal Committee

REGISTRATION ARRANGEMENTS SUBMISSION

This submission is being furnished on behalf of the Council of Optometry Registration Authorities Inc (CORA).

In the main, CORA supported the majority of proposals contained within the consultation paper. For ease of reference, Appendix A reflects the views of CORA in relation to each of the proposals.

However, there were some policy directions with which CORA expressed strong disapproval on the grounds that if included in national legislation, they would potentially compromise the health and safety of the Australian public. Specifically, I refer to proposals 8.4.1 and 8.4.2 respectively, on the question of including plano cosmetic contact lenses in the definition of "optical appliance" and exempting orthoptists from a prohibition relating to performing refractions.

With regard to plano contact lenses, CORA endorses the paper marked as Attachment A, which was prepared by the Optometrists Board of Queensland. Additionally, I am sure the Health Workforce Committee is aware of a number of recent cases where the misuse of plano contact lenses, supplied without prescription or proper examination, have led to severe corneal damage requiring corneal transplantation.

The proposal to extend prescribing rights to orthoptists, yet exempt them statutory regulation, runs contrary to the due process registration and accreditation objectives expressed within the Intergovernmental Agreement. The proposal also raises health and safety issues that are addressed in dot point form at Appendix B.

CORA appreciates having been given an opportunity to lodge this submission.

Yours faithfully

Mark Feltham
PRESIDENT
CORA Inc

President
Dr Mark Feltham

Executive Officer
Mr Geoff Leunig

APPENDIX A

To CORA SUBMISSION
29 OCTOBER 2008

PROPOSAL	DESCRIPTOR	COMMENTS
2.1	Framing of registration provisions	Supported
4.1.1	Applications for registration	Supported
4.2.1	Information on initial application	Supported (but in (c) add "or other" after "previous")
4.3.1	Criminal History Checks	Option 3 Supported
5.1	Qualifications for registration	Supported
5.2	Recognition of equivalent qualifications	Supported
5.3	Qualifications "approved" by boards	Supported
6.1.1	Express powers of boards	Supported
6.1.2	Terminology: "health assessment"	Supported
6.2.1	Empowering a committee	Supported BUT also provide authority for a quorum to sit
6.2.2	Delegation of power to register	Supported
6.3.1	Professional Indemnity Insurance	Supported But also provide option for new grads etc to <u>undertake</u> to obtain PII coverage prior to commencing practice (eg clause 7(1)(e) of Health Care Liability Regulation 2007 NSW)
6.3.2	PII guidelines issued by boards	Supported
6.4.1	Power to refuse registration	Supported
6.4.2	Fraudulent applications	Supported
6.5.1	Refusal process – issuing notice of intent to refuse registration or impose conditions	Supported
6.5.2	Refusal process	Supported
6.6.1	Review of decisions mechanism	Supported
7.1	Sub-types of registration	Supported
7.3.1	Non-practising registration	Supported
7.3.2	Non-practising registration	Supported
7.4.1	Student registration legislation	Option 2 Supported BUT fees are problematical
7.5	Corporate registration	Supported
8.1.1	Courtesy titles	Supported
8.3.1	Dentistry practice restrictions	Supported
8.4.1	Prohibiting unregistered persons from prescribing optical appliances	Supported (BUT cosmetic plano contact lenses need to be included in the definition of optical appliance – refer to Attachment A)
8.4.2	Exempting registered orthoptists	Not Supported Refer to Appendix B
9.2.1	Continuing practitioner competence	Supported
9.2.2	Legislate boards' powers	Supported
9.3.1	Annual reporting obligations	Supported
9.4.1	Monitoring professional competence	Supported
9.4.2	Power to issue standards guidelines	Supported

9.4.3	Registrants' reporting obligations	Supported (BUT replace "medical" with "professional" at point (b))
10.1.1	Specialist endorsement	Supported
10.1.3	Protection of specialist titles	Supported
10.2.1	Endorsement to prescribe medicines	Supported
10.3.1	Other endorsements	Supported
11.1.1	Duration of Registration	Supported
11.2.1	Registration Certificates	Supported
11.2.2	Practising certificate	Supported
11.2.3	Surrender of registration certificate	Supported
11.2.4	Notification of change of address	Alternative option Supported
11.2.5	Notification of employment address	Option 1 Supported
11.3.1	Period of grace	Option 1 Supported
11.4.1	Reinstatement to the register	Option 1 Supported
11.5.1	Removal from the register	Supported
12.1	Transition provisions	Supported

APPENDIX B
To CORA SUBMISSION
29 OCTOBER 2008

PROPOSAL 8.4.2 - OPTOMETRY PRACTICE RESTRICTIONS

If the prescribing of optical appliances is to be a restricted act under the legislation, then it is proposed that an orthoptist who is listed with the Australian Orthoptic Board (not a statutory board in this scheme) be exempted from committing an offence for prescribing spectacle lenses in the normal course of their practice.

- Restrictions of practice that are contained within current legislation are intended to address the significant risk of asymptomatic eye disease associated with the dispensing of an ophthalmic appliance, optical appliance or ophthalmic medical device, without the first step of a diagnosis by a registered health practitioner. This is clearly enunciated in the *Guidelines for the Operation of Restricted Activities under the Health Practitioners Competence Assurance Act 2003 (NZ)*, which recognised a clear risk of serious or permanent harm if the activity (refracting and prescribing) is done by anyone other than a registered health practitioner;
- The exclusion of orthoptists is unlikely to reduce the level of service to the community as:

the majority of orthoptists are supervised by ophthalmologists;
the number of orthoptists in rural regions is very low;
(source: AHWAC Report 2006.1. March 2006:.)

Orthoptists by ASGC-remoteness

Major city	Inner regional	Outer regional	Remote	Very remote	Total	Major city (%)
382	46	6	0	0	434	88.0

- Protection of the public is not feasible through an unconstituted body;
- Accountability is only achievable through governance by a properly constituted and regulated body;
- There is no requirement in the proposal that the patient be examined by an ophthalmologist or optometrist prior to the orthoptist prescribing spectacle lenses;
- The proposal presents an irresistible commercial opportunity to large spectacle dispensing corporations to offer free refraction and prescribing services (by orthoptists), heightening the risk of serious eye pathology remaining undetected.



Optometrists Board of Queensland

SALE OF COSMETIC CONTACT LENSES

This document has been produced by the Optometrists Board of Queensland in response to the Legislative proposal for the regulation of the sale of cosmetic plano contact lenses.

Background

In recent years in Queensland there has been an increase in unregulated sale of plano cosmetic contact lenses, especially those with opaque peripheral tints. These have been sold in a variety of outlets (e.g. the Ekka, flea-markets and in beauty therapy shops).

Current legislative framework.

Contact lenses sales are regulated under the Optometrists Registration Act, 2001 under Part 4, Division 1 A, which states:

120A Restriction

- (1) A person who is not a registrant or medical practitioner must not prescribe an optical appliance to a person.

Maximum penalty –1,000 units

- (2) In this section-

“optical appliance” means spectacles, contact lenses or other appliance for correcting, remedying or relieving a defect of sight.

Plano cosmetic lenses are not currently included in the restrictions covered by the Optometrists Registration Act, 2001, because they do not correct, remedy, or relieve a defect of sight. This a legislative anomaly because plano cosmetic contact lenses carry similar risks to other cosmetic contact lenses, and possibly greater risks than non-cosmetic contact lenses.

Section 1. Need for regulation

1 a. Current good clinical practice for contact lens dispensing.

The health of the eye does not differentiate between a cosmetic or corrective contact lens. In both cases, a person is placing a large foreign object on the cornea. This object, if not properly assessed and fitted by a professional and cared for by the individual wearer, has the potential to damage the eye.

Safe wearing of contact lenses requires that the practitioner assess the dimensions and shape of the anterior eye, tear film quality, anterior eye ocular health, fit and movement of the contact lens on the eye. This requires specialist equipment such as keratometers and slit-lamp biomicroscopes. If patients are found to be suitable for contact lens wear, then they need to be carefully instructed in contact lens insertion and removal, and care, hygiene and maintenance of contact lenses, and on the appropriate wearing schedule to build up daily wearing times. During this adaptation period, patients need to be reviewed by the practitioner, again using appropriate equipment. After the adaptation period, patients should be reviewed at regular intervals to ensure that asymptomatic complications do not develop.

If contact lenses are not appropriately fitted they may be either too loose or too tight on the eye. Both have the potential to disrupt the surface of the cornea, a factor which allows microorganisms to colonize the cornea and cause infections. (Young and Coleman). The board notes that the role of contact lens fitting has been previously ignored in the legislative proposal.

Professional dispensing and prescribing reduces the risk of ocular health incidences and ocular injury. When dealing with other medical devices and pharmaceutical agents, professional dispensing is mandatory. Eye-care should not be any different from any other aspect of primary health care. There must be a consistent regulatory regime in place for both corrective and cosmetic contact lenses. It is in the public interest to ensure that eye injury risk is minimised via regulations that result in professional prescribing and dispensing.

COMPLICATIONS

We have reviewed literature on the optical, pathological and physiological complications of plano cosmetic contact lenses. This is contained in Appendix 1, but summarized below.

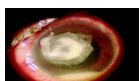


Figure 1. from Steinemann, et al, 2005. Corneal infection induced by plano opaque tint cosmetic contact lenses.

In summary

1. These complications range from corneal distortion and optical blur in the majority of cases, differing levels of irritation, to severe slight threatening corneal infections (see Figure 1). There is *prima facie* evidence that the unrestricted sale of plano cosmetic contact lenses poses a significant risk of damage to eyes and vision to wearers.

2. There is evidence that risk of severe infection arises from a combination of

- a. poor or non-existent pre-wear assessment (which can lead to poorly fitting lenses, lenses being fitted to patients who are not suitable for contact lens wear).
 - b. poor or non-existent instruction on lens care and poor lens hygiene. (possibly lack of knowledge of insertion and removal techniques)
3. Anecdotal evidence from local practitioners and in the literature suggests that teenagers constitute a substantial proportion of users of these products.

Section 2. Regulation and Options and Board's recommendation.

Given the available evidence, the board recommends that the sale of cosmetic contact lenses be regulated. The board's position is that cosmetic soft contact lenses pose risks similar to, if not greater than, conventional lens soft contact lenses, which are currently regulated under the Optometrists Registration Act, 2001.

Good contact lens practice includes the following:

1. All contact lenses should only be dispensed after proper assessment of eye health
2. and should be properly fitted.
3. Patients need to be adequately instructed on contact lens insertion and removal.
4. Patients need to be adequately monitored after lenses are dispensed.

This means that, for all types of contact lenses, supply of contact lenses needs to take place with involvement from an appropriate eye-care practitioner.

2 A OPTION 1

Sale of contact lenses is restricted to supply in accordance with a prescription. Like Option 2, this option will restrict supply to those circumstances where adequate assessment of eye health and contact lens fitting has been performed and adequate instruction has been provided for care and use of contact lenses. The proposal from the legislative policy unit does not specify who would be eligible to write the prescriptions, nor does it specify who would have ability to dispense the prescriptions, and some consideration should be given to this. The board's position is that writing of such prescriptions should be limited to Optometrists and Medical Practitioners in line with the current Optometrists Registration Act. Those eligible to supply contact lenses in accordance with prescriptions should include Optometrists and Medical Practitioners, but it might be worthwhile considering other professions as in option 3.

- i. Option 1 may require further legislative and policy development in a number of areas. In Queensland there is currently no legislation on what would constitute a valid contact lens prescription and this would need to be discussed in broader detail, and might involve significant legislative development. While a model might be the Health (Drugs and Poisons) Regulation 1996 (currently used to control prescription of medicines) there are also important differences between contact lenses and prescription medicines in how they are described and how they are used.
- ii. The term "prescribe" in the Optometrists Registration Act does not have a definition in the act and may not preclude supply without a prescription. Thus it may be that if a street vendor supplies a contact lens to a patient, it might not be considered "prescribing". This is likely to remain unclear until tested in a court of law. It might therefore be useful to include a sanction in the act against "supplying" optical appliances and plano cosmetic contact lenses

without a prescription. It should be 1000 penalty units, in line with the current penalty for prescribing without a prescription.

- iii. The appropriate sections of the Optometrist's Registration Act would need to be amended to incorporate plano cosmetic contact lenses into the definition "optical appliances"
- iv. The amended act would add some administrative burden on the board. It has the potential to broaden the pool of professions controlled and supervised by the board, if the act were to specify who dispensers could be.

2. B OPTION 2

Supply of contact lenses is restricted to supply by, or under the supervision of, an optometrist or medical practitioner. This option will restrict sale to those circumstances where adequate assessment of eye health and contact lens fitting has been performed and adequate instruction has been provided on care and use of contact lenses.

i. This option would require small legislative change, with the appropriate section of the Optometrists Registration Act, 2001 being amended to include additional restrictions. For example:

120A Restriction

- (1) A person who is not a registrant or medical practitioner must not prescribe an optical appliance to a person.
Maximum penalty –1,000 units
- (2) A person who is not a registrant or medical practitioner must not prescribe or supply a contact lens to a person.
Maximum penalty –1,000 units

(3) In this section-
"optical appliance" means spectacles, or other appliance for correcting, remedying or relieving a defect of sight..

"Contact lens" means a lens designed to be worn in contact with a person's cornea.

ii. The amended act would require a minimum additional administrative burden on the board. The board's task would be to ensure that sellers of contact lenses had the registration credentials currently scrutinized by the board.

2.C OPTION 3

Restrict the sale of cosmetic contact lenses to by, or under the supervision of, registered health practitioners or registered nurses. Practitioners which are covered by this list include: *Registered Nurses, Chiropractors, Dental Practitioners, Dental Technicians and Dental Prosthetists, Medical Radiation Technologists, Occupational Therapists, Optometrists, Osteopaths, Pharmacists, Physiotherapists, Podiatrists, Psychologists, Speech Pathologists.*

The stated purpose of Option 3 is to ensure that "persons with appropriate training and expertise in infection control will be available to explain use and care."

The board contends that the list of practitioners covered by this proposal is largely comprised of practitioners without training in contact lens infection control, and with inadequate knowledge of insertion and removal techniques, and with inadequate knowledge of patient assessment and contact lens fitting techniques. We also think that the list also means that the lenses are likely to be dispensed in circumstance where inadequate equipment will be available to assess lenses. The proposal suggests that this list be restricted to certain health professionals (e.g. Registered nurses, pharmacists, medical practitioners, optometrists) if necessary to exclude practitioners who may not have the same level of knowledge in relation to lens care and use. The board contends that the necessary restrictions to ensure safe contact lens wear, will mean that only optometrists and medical practitioners will be included in this list, effectively turning Option 3 into Option 2.

i. If a broad list of practitioners is included in Option 3 then there would need to be some monitoring of practitioner contact lens training and skill. There may also need to be some determination of what training is adequate. Option 3 does not outline how such training would be given, nor how it would be assessed. Such monitoring would be necessary to prevent practitioners from engaging in procedures in which they are not adequately skilled.

ii. Option 3 will impose a more complicated administrative burden on the Optometrist's board. Whereas the board currently administers the prescription of optical appliances by two professions, (optometrists and medical practitioners), Option 3 will mean that the board will have regulatory duties involving some 15 professions. Checking appropriate qualifications in some retail situations (e.g. flea markets) would pose particular practical problems. More-over Option 3 creates a situation where the practice of some professions is administered by more than one board, and this may lead to areas of confusion in disciplinary matters.

The board believes Option 3 will not provide sufficient safeguards in terms of patient assessment, contact lens fitting, after care or hygiene.

2d. Option 4

Incorporate the sale of cosmetic contact lenses into the definition of 'beauty therapy' in the Public Health (Infection Control for Personal Appearance Services) Act 2004 to administer appropriate control standards.

The board agrees with the legislative proposal's assessment that this option offers no guarantee that sellers will have an understanding of contact lens care, use, and hygiene and will not be able to provide specific assistance to customers. The board's view is that this option will not provide adequate protection to the public.

Section 3. Other considerations

The legislative proposal lists 4 or 5 main requirements for a regulatory model. The board contends that requirement A is incomplete.

A. that the product is sold with appropriate instructions on use, cleaning, and storage to avoid eye infection and injury. There is sufficient evidence from Steinemann et al, (2003, 2005) that inadequate fitting of contact lenses is implicated in the serious complications listed. Thus *requirement A* should also include that: eye health and lens fit is appropriately assessed to avoid eye infection and injury.

In these circumstances Options 1 and 2 will ensure that requirement A is met. Options 3 and 4 will not.

B. That the product sold is of a safe quality.

This is likely to be met by Options 1,2 3.

C. That the restrictions may be monitored and enforced within existing regulatory regimes to minimize cost and further administrative burden.

From the board's point of view Option 2 would be the easiest to administer, because it represents the smallest change to the existing legislative framework. Option 1 is more more complicated, because it requires some discussion about what will constitute an adequate contact lens prescription, may need additional legislation to proscribe supply without a prescription, and if there is limitation on the professions which can dispense contact lenses, there may be additional professions to administer. Option 3 as discussed above has the potential to be quite complicated in its administration, given the large number of professions which could be administered, and the additional requirements to ensure adequate practitioner training.

D. That the restrictions only limit competition and the operations of businesses to the extent necessary to protect the health of the public.

Only Options 1 and 2 address good fitting and pre-sale assessment of patient health and suitability. These represent the safest options. Option 3 is likely to result in poorly fitting lenses being dispensed to unsuitable candidates, although appropriate hygiene instructions given under this option are likely to partly decrease the risk of infections. Option 4 is likely to result in poorly fitting lenses being dispensed to unsuitable candidates and poor lens hygiene and have the highest rates of complications. The board recognises that Options 1 and 2 restrict competition, but contends that only Options 1 and 2 provide sufficient public safety.

E. That the restrictions not be so onerous or costly as to promote unrestricted internet sales and sharing of cosmetic contact lenses.

This final requirement is difficult to assess. Sharing of contact lenses is likely to occur in circumstances where users do not view the product as a medical device and have not been properly educated in the risks of sharing. In this regard Options 1,2 and perhaps 3 are likely to decrease the risks of sharing. Option 4 may well increase sharing, with users trading readily available colours and designs. There will also be patient groups for whom sharing is more likely; on anecdotal evidence, teenage girls. Options 1 and 2 are likely to limit access to cosmetic contact lenses by this group and decrease overall rates of sharing. A targeted health education campaign may also decrease sharing in this group.

Purchasing lenses via the internet is likely to occur with all four options, and again may not be driven only by the impetus of cost reduction. Again, trivializing the product by lower levels of regulation may drive internet sales. Regulating contact lens sales through Options 1 and 2 is likely to decrease the incidence of impulse buying through traditional sources.

APPENDIX 1

Complications arising from wearing cosmetic opaque tint plano contact lenses.

1b. Cosmetic contact lenses. Soft contact lenses are made from flexible materials which have some gas permeability, to allow oxygen to pass from atmosphere to the cornea, and for respired gases to pass out of the cornea into the atmosphere. Transparent tints can be added to the lens, which have little effect on the physiological interaction between lens and eye.

The un-regulated sale of plano cosmetic contact lenses has been largely in the area of opaque tinted soft contact lenses. Opaque tint cosmetic contact lenses have additional pigment added to their surfaces, to give an altered appearance to the underlying iris. These effects can mimic natural irises of different colours, and have a therapeutic role in restoring normal appearance to irises which have an abnormal appearance due to deformity or trauma. Opaque tinted contact lenses can, however be made with almost any pattern as “special effects” lenses.

1c. Optical Performance

Incorrectly fitted contact lenses (cosmetic or not) may fit too loosely and have the potential to move excessively on the eye. This can blur and impair vision, and may be a hazard when driving.

When opaque tint cosmetic contact lenses are placed on the eye in the majority of cases they cause circular zones of corneal distortion which can lead to wearers perceiving “haloes” and “ghosting” around objects, sometimes for several hours after the lenses have been removed. (Voetz et al 2004). Even in the absence of complications, opaque tint cosmetic contact lenses have been found to decrease visual acuity, decrease peripheral vision, decrease the ability to see low contrast objects in high medium and low light levels. (Spraul et al, 1998)

1d. Physiological Complications from cosmetic contact lenses.

The therapeutic use of cosmetic contact lenses is associated with complications including conjunctivitis and keratitis in 40% of patients. (Kanemoto et al, 2007), although most of these complications are mild.



Figure 2. Severe bilateral corneal infections caused by opaque tint cosmetic contact lenses in an immuno-compromised patient (Colin et al, 2006).

Use of opaque tint cosmetic contact lenses, without adequate practitioner involvement, has been associated with serious corneal infections which have the potential to blind patients (Steinemann et al 2003; Connell et al, 2004; Steinemann et al, 2005 (Figure 1.), Lee et al, 2007.), including progression to perforation (Colin et al, 2006) in an immuno-compromised patient (Figure 2). In a significant proportion (1/6 to 1/3) of cases of serious

complications from opaque tint cosmetic contact lens wear (from unlicensed providers), there was evidence that poorly fitting lenses (tight lens syndrome and limbal indentation) may have been a contributing factor and the reported levels of poor fitting are likely to underestimate the true levels of poor fits. (Steinmann, et al 2003, Steinmann, et al 2005). As a consequence of these complications, the US Food and Drug administration issued a warning against obtaining decorative contact lenses without proper prescription and fitting by a qualified eye care professional. (FDA News October 21, 2002)

In Australia, opaque tinted plano cosmetic contact lens use in a 13 year-old female, resulted in a painful necrotic cornea ulcer which resolved with corneal scarring and thinning and the eye losing sight to beyond the level for legal blindness. (Li et al 2006). In this case the wearer had not been properly fitted or instructed in contact lens wear and had borrowed the lenses from a friend. Anecdotal evidence is that, locally, teenagers make up a significant proportion of wearers purchasing opaque tint cosmetic contact lenses through unregulated sources, which appears to be also the case in other countries (Lee et al, 2007.) with 33% of patients with serious complications in one case series being teenagers, (Steinmann et al, 2005).

References

- Colin J, Aitali F, Malet F, Touboul D, Feki J. 2006 Keratite infectieuse bilatérale chez une patiente porteuse de lentilles souples cosmétiques (Bilateral infectious keratitis in a patient wearing cosmetic soft contact lenses). *J Fr Ophtalmol.* 29:665-7.
- Connell BJ, Tullo A, Morgan PB, Armstrong M. 2004 Pseudomonas aeruginosa microbial keratitis secondary to cosmetic coloured contact lens wear. *Br J Ophthalmol.* 88:1603-4.
- FDA News October 21, 2002 FDA warns consumers against using decorative contact lenses without a prescription or professional fitting.
(www.fda.gov/bbs/topics/news/2002/new00846.html.)
- Kanemoto M, Toshida H, Takahiro I, Muramaki A. 2007 Prosthetic soft contact lenses in Japan. *Eye Contact Lens* 33: 111-117
- Lee JS, Hahn TW, Choi SH, Hak SY, Lee, J-E. 2007 Acanthamoeba Keratitis related to cosmetic contact lenses. *Clin Exp Ophthalmol.* 775-777.
- Li Y-C, Zeldovitch A, Chua BJ, Rowe NJ, Martin FJ, McClellan K. Hazardous contact: a case of visual loss following Pseudomonas keratitis from novelty contact lens wear *Med J Aust, 185, 3; 173-4*
- Spraul CW, Roth HJ, Gackle H, Lang GE, Lang GK. 1998 Influence of special effect contact lenses (Crazy Lenses) on visual function. *CLAO J.* 24-32.
- Steinmann TL, Fletcher M, Bonny AE, Harvey RA, Hamlin D, Zloty P, Besson M, Walter K, Gagnon M. 2005 Over-the-counter decorative lenses: cosmetic or medical devices? A case series. *Eye Contact Lens* 31: 194-200.
- Steinmann TL, Pinninti U, Szczotka LB, Eiferman RA, Price FW Jr. 2003 Ocular complications associated with the use of cosmetic contact lenses from unlicensed vendors. *Eye Contact Lens* 29:196-200.
- Voetz SC, Collins MJ, Lingelbach B. 2004, Recovery of corneal topography and vision following opaque-tinted contact lens wear. *Eye Contact Lens* 30: 111-117
- Young G, Coleman S. 2001, Poorly fitting soft lenses affect ocular integrity. *CLAO J.* 27: 68-74.