



Comments and Request of the Contact Lens Institute To Delay Implementation Of BC Regulations Eliminating Prescription Verification Requirements For Contact Lenses

The Contact Lens Institute (CLI) is a trade association of research-based manufacturers of contact lenses and contact lens care products. CLI members include Abbott Medical Optics, Alcon, Bausch + Lomb, CIBA Vision, CooperVision and Vistakon – manufacturers of the overwhelming majority of the contact lenses and lens care products sold in Canada and the United States.

CLI recently became aware of new regulations, currently scheduled to take effect on May 1, 2010, which make a number of significant changes in the manner in which contact lenses are fitted, prescribed and dispensed in British Columbia (BC).¹ CLI had previously been unaware of these new regulations and has been unable to identify any notice proposing to adopt these changes published prior to March 19, 2010. Therefore, CLI has had only limited opportunity to review and begin to assess the significance of these new regulations and the potential consequences of their adoption.

Upon initial review, CLI is highly concerned that the new regulations effectively eliminate prescription controls over the dispensing of contact lenses to consumers in BC, in contravention of the federally-mandated prescription-only status of these products. For this reason, and as elaborated below, CLI respectfully requests and recommends that the Ministry of Health delay implementation of these new regulations until they can be more carefully considered based on input from all affected parties.

¹ Optometrists Regulation, Consultation Draft March 19, 2010 (REV), at www.health.gov.bc.ca/leg/pdfs/Consultation_Draft_Optometrists_Regs_March_19_2010_REV.pdf and Opticians Regulation, Consultation Draft March 19, 2010 at www.health.gov.bc.ca/leg/pdfs/Consultation_Draft_Opticians_Regs_March_19_2010.pdf.

The Safe and Effective Use of Contact Lenses Depends Upon Their Regulation as Prescription Medical Devices

Corrective contact lenses are regulated in Canada (as in the United States) as medical devices, subject to premarket clearance requirements under which federal authorities review clinical test data and other data and information before the products may be cleared for commercial distribution. Under these federal standards, corrective contact lens products have been cleared for distribution to patients only pursuant to the prescription of a qualified practitioner.

There are numerous critically important reasons for requiring a valid prescription prior to distributing contact lenses. These include, but are not limited to:

- 1) the need for expert, professional selection and fitting of contact lenses in order to assure safe and effective vision correction;
- 2) the need for regular monitoring of changes in eye health and vision, potentially requiring changes in contact lens parameters and/or the selection of a different lens type, material, brand, or wear modality; and
- 3) the need to protect against the risk of a patient selecting and using lenses without a prescription or that differ from those specifically chosen for them by their prescriber.

The consequences of a patient receiving lenses without a prescription or that differ from the specific lenses that have been prescribed for them include, but are not limited to:

- 1) compromised vision correction (which may or may not be readily apparent to the patient) due to, e.g., incorrect parameters, sub-optimal fit, or differences in optical design (particularly for toric or multifocal lenses); and
- 2) compromised ocular health due to sub-optimal fit, differences in lens materials and surface characteristics, or differences in oxygen permeability and other lens characteristics that affect patient compatibility and/or the patient's safe wear times, cleaning and/or replacement schedules.

As the Canadian Association of Optometrists has recently observed:

“Recent studies confirm increased risks associated with purchasing contact lenses online. The risk of serious infection was found to be nearly five

times higher. As well, consumers who bought contact lenses from sources other than their eye care practitioner were found to be less likely to comply with recommended contact lens care practices.”²

Eliminating BC’s requirement that contact lenses be dispensed only pursuant to valid, verified prescriptions would clearly exacerbate these risks.

Although a valid prescription may be issued in various forms based on applicable professional standards (such as, where appropriate, handwritten, computer-generated, faxed, electronic or verbal forms), the essential feature of a prescription is that it be in an authentic form generated by the prescriber or otherwise communicated directly by the prescriber to the dispensing party. Except in an emergency situation, if at all, we are unaware of any circumstance in which the assertion by a patient that he or she has received a prescription from an authorized practitioner is considered, without direct verification by the dispenser, a sufficient basis on which to dispense any prescription drug or device.³ The new BC regulations would eliminate this requirement for contact lenses in most cases and would therefore appear directly to contradict the status of contact lenses as prescription devices under Canadian federal law.

The fact that the BC regulations would maintain the requirement that initial lens fittings be performed by qualified practitioners would not address any of the documented risks

² CAO Position on Proposed Amendments to Optometry and Optician Regulations, available at www.opto.ca/media/docs/en/optometry-in-media/CAO%20Backgrounder%20and%20Position%20Statement.pdf. See also the March 31, 2010 letter to Honorable Kevin Foster, Minister Health Services, from Randolph E. Brooks, O.D., President of the American Optometric Association, available at www.opto.ca/media/docs/en/optometry-in-media/BC-BOA%20Comments%20Regarding%20Proposed%20Changes%20March%2031%202010.pdf.

³ In the United States, the Federal Fairness to Contact Lens Consumers Act modified historical prescription verification requirements for contact lenses with a so-called “passive” verification requirement, which requires that a seller of contact lenses make specified efforts to verify prescriptions directly with the prescriber. The FCLCA, however, clearly and explicitly upholds the requirement for prescription verification and does not eliminate those requirements as the new BC regulation would do. See FTC, The Contact Lens Rule: A Guide for Prescribers and Sellers, October 2004, available at www.ftc.gov/bcp/edu/pubs/business/health/bus62.shtm.

described above because the regulations would not require dispensers to verify that there was a valid initial fitting and because all of the cited risks are implicated whenever lenses are not dispensed in accordance with a valid prescription, whether deliberately or in error.

The BC Regulation Changes Eliminating Prescription Verification Requirements for Contact Lenses are Unjustified

The only apparent impetus for the BC regulation changes that eliminate the prescription verification requirements for contact lenses is to facilitate the sale of contact lenses by internet sellers who, in the absence of these changes, would be required by an October 2009 court injunction either to comply with existing verification requirements or to stop selling lenses.⁴ However, internet sellers, who typically distribute in the United States as well as Canada, have proven fully capable of implementing prescription verification systems adequate to meet the current BC regulations and required by the October 2009 injunction. For instance, internet sellers such as Coastal Contacts and 1800-Contacts have implemented prescription verification systems that purport to comply with the United States FCLCA. As an example, Coastal Contacts provides the following instructions to patients regarding its prescription verification procedures:

“To Purchase your lenses

1. After you find your lenses, enter your prescription information using the drop down boxes provided.

⁴ See the BC Court of Appeals decision in *College of Opticians of British Columbia v. Coastal Contacts Inc.*, 2009 BCCA 459, October 26, 2009. We also note with concern the March 20, 2010, report in The Province that “[t]he provincial government wanted to update the laws to keep Coastal Contacts from moving to another jurisdiction,” and the erroneous statement, attributed to the Minister of Health Services, that “it is only in British Columbia where we have the regulation that ... does restrict them from dispensing contacts or glasses unless they receive a physical copy of the prescription.” (www.theprovince.com/story_print.html?id=2706327.) Such comments indicate a misunderstanding of the status of contact lens prescription requirements outside of BC and of the fact that changing those requirements in BC would create new public health risks both within and outside of BC.

2. You will be prompted to **provide us with your eye doctor's contact information or with a copy of your prescription**. Select whichever method that you prefer from the list of options.
3. You will then see a confirmation page with an order number. This will let you know your order has been received and is on its way. You will be sent an email copy of this confirmation.
4. **We will verify your prescription**. Then you will receive an email letting you know when your order has shipped and when to expect delivery.
5. Payment options will be described on your invoice. You can pay online, by phone, or by mail using a credit card or check.”

www.coastalcontacts.com/new-visitors.ep (emphasis added). Such systems could easily be adapted and applied to meet the verification requirements of existing Canadian regulations (including BC regulations) as well.⁵

For these reasons, CLI respectfully requests and recommends that the Ministry of Health delay implementation of new BC regulations that would exempt the dispensing of contact lenses, in any case, from requirements for prescription verification. Such a delay should be for a period of time sufficient to allow for due consideration of input from additional affected and concerned parties. Prior to implementing the regulations,

⁵ The BC Court of Appeals found that existing BC regulations require affirmative verification of contact lens prescriptions and not the type of “passive” verification permitted under the United States FCLCA. However, each type of verification requires the dispenser to contact the prescriber unless the dispenser receives an actual written prescription issued by the prescriber. In lieu of eliminating verification requirements altogether, the Ministry of Health should consider adopting a “passive” verification requirement for dispensing contact lenses to patients in BC. In that context, however, the Ministry should also consider seriously the objections that have been lodged by many professional organizations to the adequacy of “passive” verification systems such as those currently in effect in the United States (see, e.g., Recommendations for Improving Contact Lens Safety, published by The American Academy of Ophthalmology, the Contact Lens Association of Ophthalmologists, the Cornea Society and the American Society of Cataract and Refractive Surgery at www.corneasociety.org/pdf/cl-070708.pdf), and the history of violations by internet sellers of the United States “passive” verification requirements (see., e.g., www.ftc.gov/opa/2006/08/walsh.htm and the materials available at www.1800contacts.com/compliance).

the Ministry should also assess the potentially significant consumer safety risks associated with the proposed regulatory changes, the apparent inconsistency between the new regulations and the federally-mandated prescription status of contact lenses, and the apparent ability of internet sellers to comply with existing and potential alternate systems of prescription verification that do not altogether eliminate those important verification requirements.

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