

Dear Member:

It has very recently come to the College's attention that on July 25, 2019 Health Canada released an advisory to members of the public and health professionals regarding the use of laser based medical devices to treat fungal nail infections.

The advisory can be found at <u>https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70553a-eng.php#media-medias</u>. It is <u>important</u> that you read the notice.

The College has since been in direct contact with Health Canada regarding this matter to seek clarification about their position. We have been informed that although the advisory is directed more towards spas and unregulated professionals, it is also applicable to regulated health professionals.

**SOME** laser-based medical devices are approved in Canada to <u>temporarily increase</u> <u>the clarity of the nail in patients with a fungal nail infection</u>. **HOWEVER**, these devices will only change the appearance of the nail and will have **NO** impact on treating the underlying pathogens that cause it.

Health Canada has not received enough evidence to support claims that laser treatments could be used to treat a fungal nail infection. Health Canada is concerned that members of the public maybe misled that the laser device will eradicate the infection itself. Unmanaged fungal nail infections could cause pain, damage to or loss of nails, and skin infections. Some patients, such as those with diabetes or weakened immune systems, may be at greater risk of developing serious complications, including bacterial skin infections and conditions that threaten the limbs.

## What Members Should Do

In order to address the matters raised in the Health Canada advisory members utilizing a laser medical device in the management of fungal nails MUST:

• inform patients that the use of the laser device may temporarily increase the clarity of the nail



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- inform patients that the use of the laser device <u>does not</u> treat the underlying infection.
- discuss the full range of treatment options available for managing the fungal infection;
- ensure that the laser medical device is approved by Health Canada for this application (as per COCOO Guidelines); and
- review advertising (website, patient literature, etc.) to accurately reflect the findings of the Health Canada advisory.

## College Follow-up

The College will provide Health Canada with this communique along with the College's Guideline entitled *Guidelines for the Safe Use of Lasers by Members of the College of Chiropodists of Ontario* found at : http://www.cocoo.on.ca/pdf/guidelines/use of the lasers.pdf

If you have any questions, please feel free to contact the College.

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