

STATE OF COLORADO

BARBER AND COSMETOLOGY LICENSURE

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POLICY 2 – Director’s Policy on Medical Devices for Esthetic Services

Medical spas and advanced esthetic services are becoming more popular and commonplace in cosmetology salons and medical offices. There are several machines being used to improve the esthetic appearance and health of one’s skin. The most common machines are microdermabrasion, electrolysis, intense pulse light (IPL) therapy, LED light, extreme super-luminous LEDs, and lasers. However, depending on the machine’s classification by the U.S. Food and Drug Administration (FDA), all of these devices have different restrictions on who can use such device and under what circumstances. This policy sets some basic parameters regarding the use of medical devices for esthetic services.

The FDA’s Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and import medical devices sold in the United States. Medical devices are classified into categories of Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. A description of device classification and a link to the Product Classification Database can be found at: <http://www.fda.gov/cdrh/devadvice/313.html>.

In conjunction with the Colorado Board of Medical Examiners, the Director deems it appropriate for licensed cosmetologists and estheticians to use any Class I device such as electrolysis, red light LED, and microdermabrasion. Class II devices such as intense pulse light (IPL), blue light LED, and laser are more invasive than Class I, and as a result, the risk of injury is greater. Medical knowledge is needed in order to appropriately use the machine. Therefore, the Director determines that Class II devices are beyond the scope for licensed cosmetologists and estheticians. Cosmetologists and estheticians can only use a Class II device when under the delegation of a Colorado-licensed physician in compliance with Medical Board Rule 800, which can be found at <http://www.dora.state.co.us/medical/rules/800.pdf>.

All medical device manufacturers have a FDA manufacturer and product number. Cosmetologists and estheticians can only use Class I devices properly registered with the FDA. Device and manufacturer registration numbers can be found and verified at the FDA Web site, <http://www.fda.gov/cdrh/>, or by contacting the FDA at 1-800-638-2041 or via Email at DSMICA@cdrh.fda.gov.

The Director warns that the failure to comply with this policy may subject a licensee to disciplinary action pursuant to section 12-8-132(1)(c), C.R.S., for being incompetent to practice a profession licensed under the Barbers and Cosmetologists Practice Act, “which shall include performing services outside of person’s area of training, experience, or competence.” In addition, licensees may be subject to an injunction initiated by the Colorado Board of Medical Examiners for practicing medicine without a license as well as criminal prosecution for violating state law.

Adopted on May 8, 2006