LEGAL UPDATE

Staying Abreast of Light Therapy Regulations

Laser and intense light treatments may be subject to numerous state regulations that change constantly

BY ANDREA NADAI, M.H.P.

The aesthetic light therapy industry has experienced exponential growth over the past 10 years. According to the American Society for Aesthetic Plastic Surgery, more than 2.2 million aesthetic laser procedures were performed nationwide in 2006, reflecting an 8 percent increase from 2005. Private clinics and medical spas throughout the United States have been increasing in number and in the scope of services offered to a growing population seeking new and improved light-based treatments.

Laser and intense light (LIL) treatments may be subject to numerous state regulations that change constantly, frustrating and confusing manufacturers of LIL devices and providers of LIL treatments. Following a number of high-visibility lawsuits, patients' complaints and media reports, many states have increased the level of scrutiny of health and safety issues related to the use of LIL devices for aesthetic treatments. New statutes and regulations are being proposed and task forces to study these issues are being formed almost on a daily basis.

The pace of activity is noticeable around the country. In the last few months, new statutes and regulations have been enacted in a number of states, including Washington, Idaho, and Virginia. In Massachusetts, the Board of Medicine has convened a task force to study medical spas and the use of related procedures, and in California, the boards of medicine and nursing are in process of developing regulations related to training and supervision of laser users. Other initiatives are underway in many other states, making it essential for those looking to add aesthetic procedures to their practice to understand what is permitted and required in their state and adapt to new regulations, when enacted.

Researching state and federal regulations can be onerous. It can consume valuable time and most practitioners do not possess the knowledge to locate and decipher the pertinent information in this constantly changing regulatory environment. Ignoring the laws and rules could have costly consequences, so more providers are seeking information from one of the consulting companies that specialize in this area or retaining a health care attorney to address specific legal issues. Practitioners and operators may also elect to devote their time and resources to research these regulations and stay current.

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STATE REGULATIONS

States enforce both statutes and regulations. Statutes are the laws enacted by the state legislature whereas regulations are sets of rules created by individual state professional licensing boards based on the statutes. The level of detail included in statutes and regulations varies widely among the states. Regulations are sometimes written quite broadly, so licensing boards also have a mechanism in place to address specific areas of practice. This is done through the issuance of advisory opinions and/or declaratory statements, which often provide a more detailed interpretation of the regulations.

The first step in searching for regulations is to identify the relevant licensing boards. LIL services are primarily regulated by the boards of medicine, nursing, cosmetology and electrology. Other professions that may use lasers are dentists, acupuncturists, and chiropractors. Not all states license electrologists and acupuncturists, so a licensing board might not be found for these professions. Additionally, some states regulate the actual facility where the LIL device is used, generally entrusting such oversight to the state's public health or environmental protection department.

Most states publish their statutes and regulations on their web sites. A search may start with visiting the individual professional licensing board's home page, which in most instances can be reached through the state's home page at www.state. 'state abbreviation'.us (such as www.state.va.us). Most state government sites provide links to various agencies. Once finding the appropriate page, a specific department or board can be identified. Alternatively, a search engine such as Google can be used to locate the specific licensing board by simply entering the state name and the relevant licensing board, such as Virginia Board of Medicine. Once the desired licensing board is reached the search for statutes and regulations can begin. If this information is not found on the licensing board's web site, it may be located through the Secretary of State site. When conducting a search, it is important to review advisory opinions and declaratory statements, which may be posted on the professional licensing board's web site.

Reading and interpreting statutes and regulations can represent a considerable challenge to those unfamiliar with such codes. Some states specifically identify LIL devices within these documents, but most do not. Often, reviewing the definitions and scope of practice sections provides information on the type of services/procedures permitted for that profession. The information will be clearly documented if an advisory opinion or declaratory statement on LIL device use has been issued.

Moreover, information can be gathered by contacting the licensing board directly to request clarification on LIL device use or reviewing minutes of past board meetings. Unfortunately, while some boards provide clear information, others could decline to provide any interpretation of statutes and regulations, requiring assistance from a health care attorney or consultant.

FEDERAL REGULATIONS

In addition to understanding state regulations, practitioners must comply with federal regulations related to LIL devices. The Occupational Safety and Health Administration (OSHA) oversees workplace safety and publishes regulations that address personnel training and safety, as well as facility management. The Food and Drug Administration (FDA) regulates the marketing and interstate commerce of medical devices. Light-based devices are usually classified by the FDA as prescriptive devices, although some over-the-counter (OTC) clearances for light-based devices recently have been approved. FDA regulations require that prescriptive devices are sold to or on the prescription or order of a licensed practitioner for use in the course of his/her professional practice. OSHA and FDA regulations can be found on their respective websites.

SUMMARY

Although researching the numerous state and federal regulations can be daunting, it is essential before opening a new practice or expanding an existing LIL service. As state professional licensing boards expand their oversight and involvement in the use of lasers and intense light devices for aesthetic procedures, providers will need to keep abreast of the ever-changing regulatory landscape.

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