



Medical Law Perspectives

LAW AND MEDICINE PUBLICATIONS FOR LITIGATION SUCCESS



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What Principles and Regulations Govern Non-Physician Use of Lasers?

The risk of complications from properly performed medical laser and related technology procedures is very low. However, complications including permanent loss of pigment, scarring, infection, loss of vision and even death (related to improper topical anesthetic application) have been reported. These are medical procedures that have to be taken seriously. Members of the American Society for Laser Medicine and Surgery (ASLMS) are reporting that they are seeing increasing numbers of patients that have undergone laser procedures outside the traditional physician office setting, such as in med-spas, presenting with complications related to improper technique, incorrect device for an incorrect indication, and poor patient selection. Often these patients have no recourse to the legal system as the device operator does not have professional liability insurance, so no attorney is willing to take on the case. In many states, they have no recourse with the medical licensing board as the board often only regulates physicians, and non-physician operator regulations are inadequate.

With the explosion in the number of medical lasers and related energy devices along with the number of indications, there has been a dramatic increase in the number of non-physician device operators being sued for malpractice. From 2008 to 2011 alone, the percentage of non-physician operator laser-related lawsuits increased from 36% to 78% of the total with 64% arising in situations outside the traditional medical setting. See Jalian HR, Jalian CA, Avram MM. [Increased risk of litigation associated with laser surgery by nonphysician operators](#). JAMA Dermatol. 2014 Apr;150(4):407-11

The American Society for Laser Medicine and Surgery (ASLMS) recommends that laser operators adhere to certain principles of training and supervision to maximize patient safety: (1) The delegating physician should have appropriate training in the use of the device and procedure along with knowledge of complications and their management. (2) A medical professional employed by the physician to perform the laser procedure must have documented training and education in the procedure and device, state licensure, and malpractice insurance. (3) The properly trained licensed medical professional may deliver the laser procedures only under direct, on-site, physician supervision following written procedures and protocols all done in compliance with state laws and regulations.

The regulation of medical laser and related technology resides with the states, their legislatures and medical licensing boards. These regulations range from no regulation whatsoever (6 states and DC) to very tight guidelines (MD, PA, or APRN (advanced practice registered nurses) only in 7 states), and govern who can and cannot operate lasers and related energy-based technology and the degree of supervision necessary. When developing laser regulation, patient safety must be of paramount importance. It is key that state legislatures recognize that any medical device that has the capability of causing injury (cell death) in skin should fall under the rubric of the practice of medicine and surgery.

Physician organizations, including the ASLMS, with the help of injured patients and patient advocacy groups, have been able to achieve meaningful laser use regulations to protect patients. There are now 32 states that require at least some physician supervision of laser operators. Progress requires the concerted effort of state, local, and national dermatology organizations working together with state medical societies and medical licensing boards to introduce and push for sensible laser use legislation and subsequent regulation by legislators and governors. Once regulations are in place, there is often very spotty enforcement of the

rules. However, at least when patients are injured by a laser device, they may now have some recourse with state regulators in states with laser regulations.

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Dr. Hruza received his medical degree from New York University, completed his dermatology residency at New York University Medical Center followed by a laser surgery fellowship at Harvard Medical School's Wellman Laboratory for Photomedicine and a Mohs and dermatologic surgery fellowship at the University of Wisconsin-Madison. Dr. Hruza is a Diplomate of the American Board of Dermatology, Treasurer of the Missouri State Medical Association and Past President of the St. Louis Metropolitan Medical Association.

He has contributed more than 140 publications to the medical literature including three textbooks on laser surgery and has lectured extensively on four continents on lasers in dermatology, Mohs surgery, skin cancer, cosmetic surgery, and dermatologic surgery.

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