WAC 246-853-630 Use of laser, light, radiofrequency, and plasma devices as applied to the skin. (1) For the purposes of this section, laser, light, radiofrequency, and plasma (LLRP) devices are medical devices that:

(a) Use a laser, noncoherent light, intense pulsed light, radiofrequency, or plasma to topically penetrate skin and alter human tissue, or use high frequency ultrasound or other technologies to deliver energy to or through the skin; and

(b) Are classified by the federal Food and Drug Administration as prescriptive devices.

(2) Because an LLRP device is used to treat disease, injuries, deformities, and other physical conditions in human beings, the use of an LLRP device is the practice of osteopathic medicine under RCW 18.57.001. The use of an LLRP device can result in complications such as visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation.

(3) Use of medical devices using any form of energy to penetrate or alter human tissue for a purpose other than those in subsection (1) of this section constitutes surgery and is outside the scope of this section.

OSTEOPATHIC PHYSICIAN RESPONSIBILITIES

(4) An osteopathic physician must be appropriately trained in the physics, safety, and techniques of using LLRP devices prior to using such a device, and must remain competent for as long as the device is used.

(5) An osteopathic physician must use an LLRP device in accordance with standard medical practice.

(6) Prior to authorizing treatment with an LLRP device, an osteopathic physician must take a history, perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent (including informing the patient that a nonphysician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record.

(7) Regardless of who performs LLRP device treatment, the osteopathic physician is ultimately responsible for the safety of the patient.

(8) Regardless of who performs LLRP device treatment, the osteopathic physician is responsible for assuring that each treatment is documented in the patient's medical record.

(9) The osteopathic physician must ensure that there is a quality assurance program for the facility at which LLRP device procedures are performed regarding the selection and treatment of patients. An appropriate quality assurance program shall include the following:

(a) A mechanism to identify complications and problematic effects of treatment and to determine their cause;

(b) A mechanism to review the adherence of supervised professionals to written protocols;

(c) A mechanism to monitor the quality of treatments;

(d) A mechanism by which the findings of the quality assurance program are reviewed and incorporated into future protocols required by subsection (10)(d) of this section and osteopathic physician supervising practices; and

(e) Ongoing training to maintain and improve the quality of treatment and performance of the treating professionals.

OSTEOPATHIC PHYSICIAN DELEGATION OF LLRP TREATMENT

(10) An osteopathic physician who meets the requirements in subsections (1) through (9) of this section may delegate an LLRP device procedure to a properly trained and licensed professional, whose licensure and scope of practice allows the use of a prescriptive LLRP medical device, provided all the following conditions are met:

(a) The treatment in no way involves surgery as that term is understood in the practice of osteopathic medicine;

(b) Such delegated use falls within the supervised professional's lawful scope of practice;

(c) The LLRP device is not used on the globe of the eye;

(d) An osteopathic physician has a written office protocol for the supervised professional to follow in using the LLRP device. A written office protocol must include at a minimum the following:

(i) The identity of the individual osteopathic physician authorized to use the LLRP device and responsible for the delegation of the procedure;

(ii) A statement of the activities, decision criteria, and plan the supervised professional must follow when performing procedures delegated pursuant to this rule;

(iii) Selection criteria to screen patients for the appropriateness of treatments;

(iv) Identification of devices and settings to be used for patients who meet selection criteria;

(v) Methods by which the specified device is to be operated and maintained;

(vi) A description of appropriate care and follow-up for common complications, serious injury, or emergencies; and

(vii) A statement of the activities, decision criteria, and plan the supervised professional shall follow when performing delegated procedures, including the method for documenting decisions made and a plan for communication or feedback to the authorizing osteopathic physician concerning specific decisions made.

(e) The supervised professional has appropriate training including, but not limited to:

(i) Application techniques of each LLRP device;

(ii) Cutaneous medicine;

(iii) Indications and contraindications for such procedures;

(iv) Preprocedural and postprocedural care;

(v) Potential complications; and

(vi) Infectious disease control involved with each treatment.

(f) The delegating osteopathic physician ensures that the supervised professional uses the LLRP device only in accordance with the written office protocol, and does not exercise independent medical judgment when using the device;

(g) The delegating osteopathic physician shall be on the immediate premises during the patient's initial treatment and be able to treat complications, provide consultation, or resolve problems, if indicated. The supervised professional may complete the initial treatment if the physician is called away to attend to an emergency;

(h) Existing patients with an established treatment plan may continue to receive care during temporary absences of the delegating osteopathic physician provided there is a local back-up physician, licensed under chapter 18.57 or 18.71 RCW, who satisfies the requirements of subsection (4) of this section. The local back-up physician must agree in writing to treat complications, provide consultation or resolve problems if medically indicated. In case of an emergency the

delegating osteopathic physician or a back-up physician shall be reachable by phone and able to see the patient within sixty minutes.

(11) The use of, or the delegation of the use of, an LLRP device by an osteopathic physician assistant is covered by WAC 246-854-220.

[Statutory Authority: RCW 18.57.005, 18.130.050, and 18.340.020. WSR 20-09-025, § 246-853-630, filed 4/6/20, effective 5/7/20. Statutory Authority: RCW 18.57.005, 18.57A.020, and 18.130.250. WSR 15-16-085, § 246-853-630, filed 7/31/15, effective 8/31/15. Statutory Authority: RCW 18.57.005, 18.57A.020, 18.130.050. WSR 08-20-125, § 246-853-630, filed 10/1/08, effective 11/1/08.]