

WAC 246-919-605 Use of laser, light, radiofrequency, and plasma devices as applied to the skin. (1) For the purposes of this rule, laser, light, radiofrequency, and plasma devices (hereafter 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; and

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

(2) Because an LLRP device penetrates and alters human tissue, the use of an LLRP device is the practice of medicine under RCW 18.71.011. 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 the purpose set forth in subsection (1) of this section constitutes surgery and is outside the scope of this section.

PHYSICIAN RESPONSIBILITIES

(4) A 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) A physician must use an LLRP device in accordance with standard medical practice.

(6) Prior to authorizing treatment with an LLRP device, a 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 physician is ultimately responsible for the safety of the patient.

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

(9) The 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 untoward 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 physician supervising practices; and

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

PHYSICIAN DELEGATION OF LLRP TREATMENT

(10) A physician who meets the above requirements may delegate an LLRP device procedure to a properly trained and licensed professional, whose licensure and scope of practice allow the use of an LLRP 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 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) A 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 physician authorized to use the 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 physician concerning specific decisions made;

(e) The supervised professional has appropriate training in, at a minimum, application techniques of each LLRP device, cutaneous medicine, indications and contraindications for such procedures, preprocedural and postprocedural care, potential complications and infectious disease control involved with each treatment;

(f) The delegating 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 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 physician provided that there is a local back-up physician 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. The local 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 a physician assistant is covered by WAC 246-918-125.

[Statutory Authority: RCW 18.71.017, 18.71A.020 and 18.130.050(12). WSR 07-03-177, § 246-919-605, filed 1/24/07, effective 3/1/07.]