

WAC 246-919-606 Nonsurgical medical cosmetic procedures. (1)

The purpose of this rule is to establish the duties and responsibilities of a physician who delegates the injection of medication or substances for cosmetic purposes or the use of prescription devices for cosmetic purposes. These procedures can result in complications such as visual impairment, blindness, inflammation, burns, scarring, disfiguration, hypopigmentation and hyperpigmentation. The performance of these procedures is the practice of medicine under RCW 18.71.011(3).

(2) This rule does not apply to:

(a) Surgery;

(b) The use of prescription lasers, noncoherent light, intense pulsed light, radiofrequency, or plasma as applied to the skin; this is covered in WAC 246-919-605 and 246-918-125;

(c) The practice of a profession by a licensed health care professional under methods or means within the scope of practice permitted by such license;

(d) The use of nonprescription devices; and

(e) Intravenous therapy.

(3) Definitions. These definitions apply throughout this section unless the context clearly requires otherwise.

(a) "Nonsurgical medical cosmetic procedure" means a procedure or treatment that involves the injection of a medication or substance for cosmetic purposes, or the use of a prescription device for cosmetic purposes. Laser, light, radiofrequency and plasma devices that are used to topically penetrate the skin are devices used for cosmetic purposes, but are excluded under subsection (2)(b) of this section, and are covered by WAC 246-919-605 and 246-918-125.

(b) "Physician" means an individual licensed under chapter 18.71 RCW.

(c) "Prescription device" means a device that the federal Food and Drug Administration has designated as a prescription device, and can be sold only to persons with prescriptive authority in the state in which they reside.

PHYSICIAN RESPONSIBILITIES

(4) A physician must be fully and appropriately trained in a nonsurgical medical cosmetic procedure prior to performing the procedure or delegating the procedure. The physician must keep a record of his or her training in the office and available for review upon request by a patient or a representative of the commission.

(5) Prior to authorizing a nonsurgical medical cosmetic procedure, a physician must:

(a) Take a history;

(b) Perform an appropriate physical examination;

(c) Make an appropriate diagnosis;

(d) Recommend appropriate treatment;

(e) Obtain the patient's informed consent;

(f) Provide instructions for emergency and follow-up care; and

(g) Prepare an appropriate medical record.

(6) Regardless of who performs the nonsurgical medical cosmetic procedure, the physician is ultimately responsible for the safety of the patient.

(7) Regardless of who performs the nonsurgical medical cosmetic procedure, the physician is responsible for ensuring that each treatment is documented in the patient's medical record.

(8) The physician must ensure that there is a quality assurance program for the facility at which nonsurgical medical cosmetic proce-

dures are performed regarding the selection and treatment of patients. An appropriate quality assurance program must 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 health care 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 supervised health care professionals.

(9) A physician may not sell or give a prescription device to an individual who does not possess prescriptive authority in the state in which the individual resides or practices.

(10) The physician must ensure that all equipment used for procedures covered by this section is inspected, calibrated, and certified as safe according to the manufacturer's specifications.

PHYSICIAN DELEGATION

(11) A physician who meets the above requirements may delegate a nonsurgical medical cosmetic procedure to a properly trained physician assistant, registered nurse or licensed practical nurse, 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) The physician delegates procedures that are within the delegate's lawful scope of practice;

(c) The delegate has appropriate training in, at a minimum:

(i) Techniques for each procedure;

(ii) Cutaneous medicine;

(iii) Indications and contraindications for each procedure;

(iv) Preprocedural and postprocedural care;

(v) Recognition and acute management of potential complications that may result from the procedure; and

(vi) Infectious disease control involved with each treatment.

(d) The physician has a written office protocol for the delegate to follow in performing the nonsurgical medical cosmetic procedure. A written office protocol must include, at a minimum, the following:

(i) The identity of the physician responsible for the delegation of the procedure;

(ii) Selection criteria to screen patients for the appropriateness of treatment;

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

(iv) A statement of the activities, decision criteria, and plan the delegate 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 physician ensures that the delegate performs each procedure in accordance with the written office protocol;

(f) Each patient signs a consent form prior to treatment that lists foreseeable side effects and complications, and the identity and license of the delegate or delegates who will perform the procedure; and

(g) Each delegate performing a procedure covered by this section must be readily identified by a name tag or similar means so that the patient understands the identity and license of the treating delegate.

(12) If a physician delegates the performance of a procedure that uses a medication or substance that the federal Food and Drug Administration has not approved, or that the federal Food and Drug Administration has not approved for the particular purpose for which it is used, the physician must be on-site during the entire duration of the procedure.

(13) If a physician delegates the performance of a procedure that uses a medication or substance that is approved by the federal Food and Drug Administration for the particular purpose for which it is used, the physician need not be on-site during the procedure, but must be reachable by phone and able to respond within thirty minutes to treat complications.

(14) If the physician is unavailable to supervise a delegate as required by this section, the physician must make arrangements for an alternate physician to provide the necessary supervision. The alternate supervisor must be familiar with the protocols in use at the site, will be accountable for adequately supervising the treatment under the protocols, and must have comparable training as the primary supervising physician.

(15) A physician performing or delegating nonsurgical cosmetic procedures may not sponsor more than three physician assistants at any one time.

(16) A physician may not permit a delegate to further delegate the performance of a nonsurgical medical cosmetic procedure to another individual.

[Statutory Authority: RCW 18.71.017, 18.71A.020 and 18.130.050(4). WSR 10-11-001, § 246-919-606, filed 5/5/10, effective 6/5/10.]