

RULE §193.17. Nonsurgical Medical Cosmetic Procedures.

(a) Purpose. The purpose of this section is to establish the duties and responsibilities of a physician who performs or who delegates the performance of a nonsurgical medical cosmetic procedure (hereafter referred to as "Procedure"). These procedures can result in complications and the performance of these procedures is the practice of medicine. This rule shall not be interpreted to allow individuals to perform procedures without either a physician or midlevel practitioner being onsite, or a physician being available for emergency consultation or appointment in the event of an adverse outcome.

(b) Definitions.

(1) Midlevel practitioner--A physician assistant or advanced practice registered nurse.

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

(3) Procedure--A nonsurgical medical cosmetic procedure, including but not limited to the injection of medication or substances for cosmetic purposes, the administration of colonic irrigations, and the use of a prescription medical device for cosmetic purposes.

(c) Applicability. This section does not apply to:

(1) surgery as defined under Texas Occupations Code, §151.002(a)(14);

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

(3) the use of nonprescription devices;

(4) intravenous therapy;

(5) procedures performed at a physician's practice by the physician or midlevel practitioners acting under the physician's supervision; or

(6) laser hair removal procedures performed in accordance with Texas Health and Safety Code, Chapter 401, Subchapter M.

(d) Physician Responsibilities.

(1) A physician must be appropriately trained, including hands-on training, in a Procedure prior to performing the Procedure or delegating the performance of a Procedure. The physician must keep a record of his or her training in the office and have it available for review upon request by a patient or a representative of the board.

(2) Prior to authorizing a Procedure, a physician, or a midlevel practitioner acting under the delegation of a physician, must:

(A) take a history;

(B) perform an appropriate physical examination;

(C) make an appropriate diagnosis;

(D) recommend appropriate treatment;

(E) develop a detailed and written treatment plan;

(F) obtain the patient's informed consent;

(G) provide instructions for emergency and follow-up care;

(H) prepare and maintain an appropriate medical record;

(I) have signed and dated written protocols as described in paragraph (7) of this subsection that

are detailed to a level of specificity that the person performing the Procedure may readily follow; and

(J) have signed and dated written standing orders.

(K) The performance of the items listed in subparagraphs (A) - (J) of this paragraph must be documented in the patient's medical record.

(3) After a patient has been evaluated and diagnosed, as described in paragraph (2) of this subsection, qualified unlicensed personnel may perform a procedure only if:

(A) a physician or midlevel practitioner is onsite during the procedure; or

(B) a delegating physician is available for emergency consultation in the event of an adverse outcome, and if the physician considers it necessary, be able to conduct an emergency appointment with the patient.

(4) Regardless of who performs the Procedure, the physician is ultimately responsible for the safety of the patient and all aspects of the Procedure.

(5) Regardless of who performs the Procedure, the physician is responsible for ensuring that each Procedure is documented in the patient's medical record. A Procedure performed by unlicensed personnel must be timely co-signed by a supervising physician.

(6) The physician must ensure that the facility at which Procedures are performed, there is a quality assurance program pertaining to Procedures that includes the following:

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

(B) a mechanism to review the adherence to written protocols by all health care personnel;

(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; and

(E) ongoing training to maintain and improve the quality of treatment and performance of Procedures by health care personnel.

(7) A physician may delegate Procedures only at a facility at which the physician has either:

(A) approved in writing the facility's written protocols pertaining to the Procedures; or

(B) developed his own protocols for the Procedures as described in paragraph (2)(I) of this subsection.

(8) The physician must ensure that a person performing a Procedure has appropriate training in, at a minimum:

(A) techniques for each Procedure;

(B) cosmetic or cutaneous medicine;

(C) indications and contraindications for each Procedure;

(D) pre-procedural and post-procedural care;

(E) recognition and acute management of potential complications that may result from the Procedure; and

(F) infectious disease control involved with each treatment.

(9) The physician has a written office protocol for the person performing the Procedure to follow in performing Procedure delegated. A written office protocol must include, at a minimum, the following:

(A) the identity of the physician responsible for the delegation of the Procedure;

- (B) selection criteria to screen patients by the physician or midlevel practitioner for the appropriateness of treatment;
 - (C) a description of appropriate care and follow-up for common complications, serious injury, or emergencies;
 - (D) a statement of the activities, decision criteria, and plan the physician, or midlevel practitioner, shall follow when performing or delegating the performance of a Procedure, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician or midlevel practitioner concerning specific decisions made; and
 - (E) a description of what information must be documented by the person performing the Procedure.
- (10) The physician ensures that each person performs each Procedure in accordance with the written office protocol.
- (11) Each patient signs a consent form prior to treatment that lists potential side effects and complications, and the identity and titles of the individual who will perform the Procedure.
- (12) Each person performing a Procedure must be readily identified by a name tag or similar means that clearly delineates the identity and credentials of the person.
- (13) Any time a Procedure is performed, at least one person trained in basic life support must be onsite.

(e) Notice Provisions

(1) Each facility providing Nonsurgical Medical Cosmetic Procedures must post a Notice Concerning Complaints in compliance with Chapter 178.

(2) Each facility providing Nonsurgical Medical Cosmetic Procedures must post in the each public areas and treatment room or area a Notice in the format found in Rule 178.3 including the name(s) of the delegating physician(s) for that facility including their Texas Medical License Number.