



# PROPOSED RULE MAKING

## CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

**Agency:** Department of Health- Medical Quality Assurance Commission

- Preproposal Statement of Inquiry was filed as WSR 07-08-103 ; or
- Expedited Rule Making--Proposed notice was filed as WSR    ; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

**Title of rule and other identifying information:** (Describe Subject)

WAC 246-919-606 Non-Surgical Medical Cosmetic Procedures (Medical physicians) and WAC 246-918-126 Non-Surgical Medical Cosmetic Procedures (Medical physician assistants)

**Hearing location(s):** Holiday Inn  
One South Grady Way  
Renton Washington

Date: January 14, 2010

Time: 7:00 p.m.

**Submit written comments to:**

Name: Beverly Teeter, Deputy Executive Director

Address: P.O. Box 47866

Olympia Washington 98504

beverly.teeter@doh.wa.gov

Website: <http://www3.doh.wa.gov/policyreview/>

fax 360-236-2795 by (date) 01/04/2010

**Assistance for persons with disabilities:** Contact

Julie Kitten, Program Manager by 01/04/2010

TTY (800) 833-6388 or () 711

**Date of intended adoption:** 01/14/2010

(Note: This is **NOT** the **effective** date)

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:**

There is no state law specifically regulating non-surgical medical cosmetic procedures, specifically the injection of medication or substances into humans or the use of prescription devices for cosmetic purposes. Rules are needed to clarify this area of medicine and set minimum standards for the performance and the delegation of non-surgical medical cosmetic procedures by physicians and physician assistants in our state. The proposed rules will establish standards so that physicians and physician assistants apply the same standards of good medical practice to the performance and delegation of non-surgical medical cosmetic procedures.

**Reasons supporting proposal:**

The number of offices and clinics nationwide providing non-surgical medical cosmetic procedures is increasing at a rapid rate. More consumers are demanding medical cosmetic procedures, and more physicians and non-physicians are entering this lucrative field, many without adequate training or an appropriate health care license. The Commission is concerned that in these offices and clinics individuals with little or no training, without an appropriate license, or without adequate supervision, are injecting medication or substances into patients, or are using prescription devices on patients.

**Statutory authority for adoption:**

RCW 18.71.017 and RCW 18.71A.020

**Statute being implemented:**

RCW 18.130.050(4)

**Is rule necessary because of a:**

Federal Law?

Yes

No

Federal Court Decision?

Yes

No

State Court Decision?

Yes

No

If yes, CITATION:

**CODE REVISER USE ONLY**

**OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED**

**DATE: December 02, 2009**

**TIME: 9:41 AM**

**WSR 09-24-107**

**DATE** 12/1/2009

**NAME** (type or print)

Maryella Jansen

*Maryella E. Jansen*

**TITLE**

Executive Director

(COMPLETE REVERSE SIDE)

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**

None

**Name of proponent: (person or organization)**

Commission

Department of Health Medical Quality Assurance

- Private  
 Public  
 Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Beverly A. Teeter	243 Israel Road SE, Tumwater WA 98501	360-236-2758
Implementation.... Beverly A. Teeter	243 Israel Road SE, Tumwater WA 98501	360-236-2758
Enforcement..... Beverly A. Teeter	243 Israel Road SE, Tumwater WA 98501	360-236-2758

**Has a small business economic impact statement been prepared under chapter 19.85 RCW?**

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name: Beverly A. Teeter

Address: PO Box 47866  
Olympia Washington 98504

phone 360-236-2758

fax 360-236-2795

e-mail [beverly.teeter@doh.wa.gov](mailto:beverly.teeter@doh.wa.gov)

No. Explain why no statement was prepared.

A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

**Is a cost-benefit analysis required under RCW 34.05.328?**

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Beverly A. Teeter

Address: PO Box 47866  
Olympia Washington 98501

phone 360-236-2758

fax 360-236-2795

e-mail [beverly.teeter@doh.wa.gov](mailto:beverly.teeter@doh.wa.gov)

No: Please explain:

NEW SECTION

**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 procedures 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 is not approved by the federal Food and Drug Administration 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.

NEW SECTION

**WAC 246-918-126 Nonsurgical medical cosmetic procedures.** (1)

The purpose of this rule is to establish the duties and responsibilities of a physician assistant who injects medication or substances for cosmetic purposes or uses 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.

(2) This section 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) "Physician assistant" means an individual licensed under chapter 18.71A RCW.

(d) "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 ASSISTANT RESPONSIBILITIES

(4) A physician assistant may perform a nonsurgical medical cosmetic procedure only after the commission approves a practice plan permitting the physician assistant to perform such procedures. A physician assistant must ensure that the supervising or sponsoring physician is in full compliance with WAC 246-919-606.

(5) A physician assistant may not perform a nonsurgical

cosmetic procedure unless his or her supervising or sponsoring physician is fully and appropriately trained to perform that same procedure.

(6) Prior to performing a nonsurgical medical cosmetic procedure, a physician assistant must have appropriate training in, at a minimum:

- (a) Techniques for each procedure;
- (b) Cutaneous medicine;
- (c) Indications and contraindications for each procedure;
- (d) Preprocedural and postprocedural care;
- (e) Recognition and acute management of potential complications that may result from the procedure; and
- (f) Infectious disease control involved with each treatment.

(7) The physician assistant 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.

(8) Prior to performing a nonsurgical medical cosmetic procedure, either the physician assistant or the delegating 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 including disclosing the credentials of the person who will perform the procedure;
- (f) Provide instructions for emergency and follow-up care; and
- (g) Prepare an appropriate medical record.

(9) The physician assistant must ensure that there is a written office protocol for performing the nonsurgical medical cosmetic procedure. A written office protocol must include, at a minimum, the following:

(a) A statement of the activities, decision criteria, and plan the physician assistant must follow when performing procedures under this rule;

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

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

(d) A statement of the activities, decision criteria, and plan the physician assistant must follow if performing a procedure delegated by a physician pursuant to WAC 246-919-606, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made.

(10) A physician assistant may not delegate the performance of a nonsurgical medical cosmetic procedure to another individual.

(11) A physician assistant may perform a nonsurgical medical cosmetic procedure that uses a medication or substance that the federal Food and Drug Administration has not approved for the particular purpose for which it is used so long as the physician assistant's sponsoring or supervising physician is on-site during the entire procedure.

(12) A physician assistant may perform a nonsurgical medical cosmetic procedure at a remote site. A physician assistant must comply with the established regulations governing physician assistants working in remote sites, including obtaining commission approval to work in a remote site under WAC 246-918-120.

(13) A physician assistant must ensure that each treatment is documented in the patient's medical record.

(14) A physician assistant 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.

(15) A physician assistant 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.

(16) A physician assistant must participate in a quality assurance program required of the supervising or sponsoring physician under WAC 246-919-606.