

## Significant Analysis for Rules Concerning

**WAC 246-853-640** Non-Surgical Medical Cosmetic Procedures. –  
(Osteopathic Physician)

**WAC 246-854-230** Non-Surgical Medical Cosmetic Procedures –  
(Osteopathic Physician Assistants)

### **Section 1. What is the scope of the rule?**

Chapter 18.57 RCW regulates the practice of osteopathic medicine in the state of Washington by establishing the Board of Osteopathic Medicine and Surgery (board). Under RCW 18.57.005 (2), the board has the power to make such rules and regulations as are not inconsistent with the laws of this state as may be deemed necessary or proper to carry out the purposes of this chapter. One of the purposes of the board is to regulate the competency and quality of professional health care providers under its jurisdiction by establishing consistent standards of practice. To do this, the board may develop a rule that promotes the delivery of quality health care to the residents of Washington State.

The number of offices and clinics nationwide providing non-surgical medical cosmetic procedures is increasing at a rapid rate.<sup>1</sup> More consumers are demanding medical cosmetic procedures, and more osteopathic physicians and non-physicians are entering this lucrative field, many without adequate training or an appropriate health care license<sup>2</sup>. The board is concerned that in these offices and clinics individuals with little or no training, without an appropriate license, or without adequate supervision, are injecting medications or substances into patients, or are using prescription devices on patients.<sup>3</sup> The injection of medication or substances into the human body, and the use of prescriptive devices, is deemed the “practice of medicine” and must only be performed by those with prescriptive authority.

The medication and substances being injected include botulinum toxin, autologous fat, calcium hydroxylapatite (synthetic form of material found in bone and teeth), collagen, and hyaluronic acid. Offices and clinics are offering procedures such as sclerotherapy, involving injection of a sclerosing solution into veins which cause them to scar and occlude; mesotherapy, the controversial practice of injecting a combination of substances to break down body fat; and liposuction. Offices and clinics are using prescription devices to do such things as remove hair, resurface the skin, and break down cellulite.

The Federal Food and Drug Administration (FDA) and state laws regulate the manufacture of certain medications and medical devices because those medications and medical devices are too dangerous to be available without the prescription of a licensed practitioner. According to the FDA web site, these prescription medications and devices are available for sale only to licensed practitioners with prescriptive authority as determined by state law.

Potential complications from these non-surgical medical cosmetic procedures include infections, bleeding, nerve damage, liver and kidney toxicity, droopy eyelids, weak neck, respiratory paralysis, fat embolisms, skin loss at injection areas, perforation of the eye, blindness, formation of blood clots, severe inflammation, adverse allergic reaction, and possible scarring.<sup>4</sup>

There is no state law specifically regulating non-surgical medical cosmetic procedures. The board wishes to clarify this area of the practice of medicine and set minimum standards for the performance and the delegation of non-surgical medical cosmetic procedures by osteopathic physicians and osteopathic physician assistants in our state. The board wants to ensure that osteopathic physicians and osteopathic physician assistants apply the same standards of good medical practice to the performance and delegation of non-surgical medical cosmetic procedures.

**Briefly describe the proposed rule.**

The proposed rules:

- State that the purpose of the proposed rules are to set forth the duties and responsibilities of an osteopathic physician who delegates the injection of medications or substances for cosmetic purposes or the use of prescription devices for cosmetic purposes;
- State that the performance of these procedures is the practice of osteopathic medicine;
- State that the proposed rules do not apply to surgery, the use of lasers or similar light devices, the practice of a profession under a method within the scope of that profession, the use of non-prescription devices, and intravenous therapy;
- Require an osteopathic physician or physician assistant to be appropriately trained in a non-surgical medical cosmetic procedure prior to performing these procedures;
- Require an osteopathic physician to be appropriately trained in a nonsurgical medical cosmetic procedure prior to delegating the procedure;
- Require an osteopathic surgeon or osteopathic physician assistant, prior to authorizing a nonsurgical medical cosmetic procedure to take a history, to perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent, provide instructions for emergency and follow-up care, and prepare an appropriate medical record;
- Provide that regardless of who performs the procedure, the osteopathic physician is ultimately responsible for the safety of the patient and for documenting the treatment in the medical record;
- Require an osteopathic physician to establish a quality assurance program for non-surgical medical cosmetic procedures;
- Prohibit an osteopathic physician or osteopathic physician assistant from selling or giving a prescription device to an individual who does not possess prescriptive authority in the state in which the individual resides or practices;
- Require an osteopathic physician or an osteopathic physician assistant to ensure that all equipment used for procedures covered by the proposed rules is inspected, calibrated, and certified as safe according to the manufacturer's specifications;
- Permit an osteopathic physician to delegate a non-surgical medical cosmetic procedure to an osteopathic physician assistant, registered nurse or licensed practical nurse, provided that the procedure does not involve surgery, the delegation is within the delegate's lawful scope of practice, the delegate is appropriately trained, the delegate follows a written office protocol, each patient gives informed consent, and the delegate is readily identified by a name tag;
- Require an osteopathic physician who delegates the performance of a procedure that uses a medication or substance that is not approved by the FDA for the particular purpose for which it is used to be on site during the entire duration of the procedure;

- Permit an osteopathic physician to be temporarily absent to supervise a delegate as long as the physician makes arrangements for an alternate physician to provide the necessary supervision; the alternate physician must be familiar with the protocols in use at the site, accountable for adequately supervising the treatment pursuant to the protocols, and have comparable training.
- Restrict an osteopathic physician from allowing a delegate to further delegate the performance of a nonsurgical medical cosmetic procedure to another individual;
- Provide that before an osteopathic physician assistant performs a non-surgical medical cosmetic procedure, the sponsoring osteopathic physician must be trained to perform that procedure;
- Prohibit an osteopathic physician assistant from delegating a non-surgical medical cosmetic procedure.

**Section 2. What are the general goals and specific objectives of the proposed rule’s authorizing statute?**

One of the purposes of the board is to regulate the competency and quality of professional health care providers under its jurisdiction by establishing consistent standards of practice. RCW 18.57.005 states the board shall make rules and regulation as are not inconsistent with the laws of this state as may be deemed necessary or proper to carry out the purposes of chapter develop must promote the delivery of quality health care to the residents of our state. There are no specific laws or rules in our state for the delegation or practice of non-surgical medical cosmetic procedures. The goal of the proposed rules is to promote patient safety by 1) clarifying that the injection of medication or substances into the human body, and the use of prescriptive devices, is deemed the “practice of medicine and 2) by establishing the conditions under which an osteopathic physician or osteopathic physician assistant may practice or delegate the performance of non-surgical medical cosmetic procedures.

Currently, there are offices and clinics in the state that are providing these procedures without the direct supervision of an osteopathic physician or osteopathic physician assistant. Some of the offices and clinics have an osteopathic physician act as a “medical director.” However, some of these offices and clinics do not require this osteopathic physician to:

- (1) Be trained in this area of expertise,
- (2) Examine the patient to determine whether treatment is appropriate for the patient’s condition,
- (3) Make sure the person administering the treatment is appropriately trained,
- (4) Ensure the device is used in accordance with standard medical practice,
- (5) Be on site for any treatments or have a back-up physician available to treat complications,
- (6) Establish a quality assurance program, or
- (7) Provide appropriate follow-up care.

The proposed rules specifically address each of these areas and meet the objective of RCW 18.57.005.

**Section 3. What is the justification for the proposed rule package?**

The Department of Health (department) has had multiple unlicensed cases involving improper delegation for non-surgical medical cosmetic procedures. Many cases involved unlicensed individuals performing non-surgical medical cosmetic procedures, or licensed individuals performing procedures

that were beyond the scope of practice of their license. The department has received reports from specialists complaining that they have had to treat patients who were injured after undergoing these procedures.

The proposed rules set clear standards for the performance of non-surgical medical cosmetic procedures, and the delegation of these procedures by osteopathic physicians and osteopathic physician assistants, thereby promoting the delivery of quality health care to the residents of our state. If rules are not adopted, there will continue to be almost no regulation in this area. More offices and clinics will offer non-surgical medical cosmetic treatments with little, if any, physician supervision. It was estimated in 2005 that less than half of the medical spas in the United States have physician involvement.<sup>5</sup> This will likely result in some patients receiving non-surgical medical cosmetic procedures from unqualified staff, which may have resulted in the patient being harmed during treatment.

**Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?**

The goal of the proposed rules is to improve the safety of patients undergoing non-surgical medical cosmetic procedures. The proposed rules will clarify that the injection of medication or substances into the human body, and the use of prescriptive devices, is deemed the “practice of medicine”, and thus only osteopathic physicians or osteopathic physician assistants may perform these tasks. The proposed rules will also clarify that the standards of care that apply to the rest of their practice apply to the performance or supervision of these procedures. Although the proposed rules apply only to osteopathic physicians and osteopathic physician assistants, the proposed rules could potentially affect cosmetic spas, beauty salons, and other businesses where customers could receive non-surgical medical cosmetic procedures. If these businesses elect to offer non-surgical medical cosmetic procedures, they will have to ensure they have qualified staff to perform these procedures.

The benefit of implementing these proposed rules is that only properly trained medical staff are performing these medical procedures. By assuring that only qualified medical staff performs these medical procedures there will likely be a reduction in the number of complications resulting from non-surgical medical cosmetic procedures.

Although the proposed rules establish standards for the safe practice of non-surgical medical cosmetic procedures, most of the applicable requirements are considered “standard of care”, a term used to reflect how a reasonably prudent osteopathic physician or osteopathic physician assistant is expected to practice medicine. For those sections where we identified requirements as the “standard of care”, we estimate costs, when possible, but our assumption is the requirement will not impose “new” costs because most practitioners are already satisfying these requirements.

There are, however, a few sections that have new requirements that will impose a minor economic impact on medical offices and clinics in the state of Washington who have chosen to provide non-surgical cosmetic medical procedures. The following table identifies the significant sections of the proposed rules and the potential impact to the applicable parties:

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Requirements	Impact (board's assumptions) Existing Requirement, Standard of Care, New Requirement
<p>1. Osteopathic physicians and osteopathic physician assistants who elect to perform or delegate non-surgical medical cosmetic procedures will have to be properly trained.</p>	<p>This requires practitioners to be properly trained in procedures they are performing or delegating. The cost will vary due to the training they choose to obtain. Training for these procedures could include post-training courses required for initial licensure or continuing medical education. The CME courses range from \$500 to \$1,500 each, for a typical (4 to 16) hour class.</p> <p>The board's assumption is that the training component should not increase the cost to most of the practitioners because osteopathic physicians and osteopathic physician assistants should be able to obtain the required training within the existing continuing medical education hours to maintain their license, as follows:</p> <ol style="list-style-type: none"> <li>1. Osteopathic physicians are required to complete 150 hours of continuing medical education (CME) every 3 years;</li> <li>2. Osteopathic physician assistants are required to take 50 hours of CME every year.</li> </ol>
<p>2. Requires that a osteopathic physician or osteopathic physician assistant, prior to authorizing a non-surgical medical cosmetic procedure, perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent, provide instructions for emergency and follow-up care, and prepare an appropriate medical record.</p>	<p>This requirement is already considered a standard of care in the practice of medicine. This requires practitioners to see and examine each and every patient at the hourly examination cost of \$180 - \$250. The time it takes varies with each patient. Therefore, the board's assumption is that there will be no new costs associated with these rules.</p>
<p>3. The osteopathic physician is ultimately responsible for the safety of a patient, regardless of who performs the non-surgical medical procedure</p>	<p>This requires osteopathic physicians to be ultimately responsible for the safety of the patient, regardless if they perform the procedure or delegate the procedure. This requirement is already considered a standard of care in the practice of medicine. The board's assumption is that there are no new costs associated with these rules.</p>
<p>4. Requires the osteopathic physician or osteopathic physician assistant to ensure that each treatment is documented in the patient's medical record, regardless of</p>	<p>This requires osteopathic physicians to document each treatment in the patient's record, which could vary depending on the type of treatment and patient. This requirement is considered the standard of care in the</p>

<p>who perform the non-surgical medical procedure.</p>	<p>practice of medicine. Therefore, the board’s assumption is that there will be no new costs associated with these rules.</p>
<p>5. Requires the osteopathic physician to ensure that there is a quality assurance program in place. Requires the osteopathic physician assistant to participate in the quality assurance program.</p>	<p>This requires osteopathic physicians to provide for appropriate review of the quality of care being provided within an office or clinic offering these procedures. This requirement is considered standard of care in the practice of medicine.</p> <p>Osteopathic physicians can create their own quality assurance program by developing and using a checklist for monitoring routine events (e.g. medical records review, safety and accident review, credentials review, policies and procedures update review, etc.). Small health groups of five or more (physician and employees) can consider using the Department of Health Coordinated Quality Improvement Program created in law in 1993. The purpose of this voluntary program is to improve the quality of health care services by identifying and preventing health care malpractice under RCW <a href="#">43.70.510</a>.</p> <p>An osteopathic physician who chooses to create a quality assurance program through the department will have to have a staff person complete the documents, coordinate and implement the program and mail the application which could take a number of hours to complete. The board assumes that the physician’s staff can complete this work during normal work hours at an estimated medical receptionist pay rate of \$13.00 an hour. The cost is \$250 for the application fee to submit a plan and \$65 for modification, if necessary.</p> <p>The board’s assumption is that there are no costs associated with the osteopathic physician assistant’s requirement to participate in a quality assurance program because this is already considered the standard of care in the osteopathic physician and osteopathic physician assistant working relationship.</p>
<p>6. Prohibits a osteopathic physician or osteopathic physician assistant from selling or giving a prescription device to people who do not have prescriptive authority</p>	<p>Federal law defines a prescription device as a device that is not considered safe except under the supervision of a practitioner licensed to use such a device. Providing a prescriptive device to a person without prescriptive authority is prohibited by federal law and is dangerous to the public. The board’s assumption is that there are no new costs associated with these rules.</p>

<p>7. Requires an osteopathic physician or osteopathic physician assistant to ensure that all equipment used for the procedures are inspected, calibrated, and certified as safe according to the manufacture's specifications.</p>	<p>This requires practitioners to ensure all equipment used for procedures are safe. This task would normally be done by staff or periodically by the companies under the equipment warranty. This requirement is considered a standard of care and is already being completed in the practice of medicine. The board's assumption is that there are no new costs associated with these rules.</p>
<p>8. Permits osteopathic physicians to delegate a nonsurgical medical cosmetic procedure to a properly licensed and trained staff.</p>	<p>This section does not have any requirements that will result in compliance costs. It identifies what an osteopathic physician must do to delegate his or her authority to another qualified staff. This is already identified in RCW 18.57A.030, RCW 18.79.260 and RCW 18.79.270.</p>
<p>9. Requires an osteopathic physician to be onsite if they delegate a procedure that uses a medication or substance that is or is not approved by the federal food and drug administration (FDA) for a particular purpose (procedure).</p>	<p>Performing a procedure using a medication other than one approved by the FDA carries a potential risk to patients. These rules will provide enforceable standards for an osteopathic physician response if there is a complication due to using a medicine or substance that is not approved for that purpose by the FDA. This requirement is currently considered the standard of care. By requiring physicians to be at the facility, the cost of these rules would be the cost of the time required in the office which is estimated to be \$77.26 an hour based on the procedure.</p>
<p>10. Requires an osteopathic physician to make arrangements with an alternate physician to provide necessary supervision when unable to supervise a delegate. The alternate physician must have comparable training as the primary supervising physician and must also be familiar with the protocols in use at the site</p>	<p>This is considered the standard of care for providing medical treatment to a patient.</p> <p>Most osteopathic physicians routinely provide back-up coverage for each other within their specialty. The board's assumption is that there are no new costs associated with these rules. If a physician had to contract with another physician to provide coverage when the physician is absent, the average hourly rate for a physician is \$77.26<sup>6</sup> or \$618 per day.</p>
<p>11. Restricts an osteopathic physician to permit a delegate to further delegate the performance of a nonsurgical medical cosmetic procedure to another individual.</p>	<p>The rules allow an osteopathic physician to delegate certain procedures, but do not allow further delegation by a non-physician, as that would create too much distance between the osteopathic physician and the person doing the procedure. The board's assumption is that there are no new costs associated with these rules.</p>

As discussed previously, the table above illustrates that a majority of the requirements in the proposed rules are considered “standard of care.” The board assumes that a majority of osteopathic physicians are already completing the required tasks. The proposed rules will have a minor cost impact on osteopathic physicians.

There are, however, impacts to businesses that are performing these procedures without proper licenses or authority. These businesses are violating the law and are subject to a Cease and Desist Order issued by the department. Businesses that are currently performing these procedures without qualified licensed personnel will have to hire qualified staff to perform non-surgical medical cosmetic procedures.

The board believes improvement in the safety of patients undergoing non-surgical medical cosmetic procedures will outweigh any potential increase in the cost of providing treatment.

### **Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?**

The board’s staff worked with the Medical Quality Assurance Commission (MQAC) and with constituents and the public to minimize the burden of this proposed rules. For example, both the Washington State Medical Association and the Department of Licensing Cosmetology Board provided input to MQAC. Though the board did not receive comments, MQAC did receive comments from individual physicians, nurses, estheticians, and other licensed practitioners. MQAC carefully reviewed all the comments, discussed the issues with interested parties, and modified the proposed rules in several respects. The board reviewed several versions of the MQAC rules, knowing that they were receiving feedback.

*Alternative version #1: Definition:* Non-surgical cosmetic procedures. A procedure or treatment that uses a device or product for a cosmetic purpose that penetrates the skin and affects living tissue (anything below the stratum corneum).

There were many comments from estheticians who perform non-invasive treatments that penetrate the stratum corneum, such as the application of lotions and creams. Estheticians were concerned the proposed rules would limit their legal scope of practice. To alleviate this concern, the board, as well as MQAC decided to limit the application of the proposed rules to a narrow and easily definable range of procedures: the injection of a medication or substance, or the use of prescription device.

The proposed rules are clear and understandable, and do not affect the practice of estheticians or licensed health care providers.

*Alternative version #2: Physician delegation:* If an osteopathic physician delegates the performance of a procedure that uses a medication or substance, not approved by the federal Food and Drug Administration for the particular purpose for which it is used, the osteopathic physician must be on-site during the procedure. If the procedure uses a medication or substance that is approved by the federal Food and Drug Administration the osteopathic physician can be off-site during the procedure.

The Board of Osteopathic Medicine and Surgery discussed at length that they felt it is best for patient safety that the osteopathic physician be on-site if a procedure that uses a medication approved or not approved by the federal Food and Drug Administration is delegated.

**Section 6. Did you determine that the rule does not require anyone to take an action that violates another federal or state law?**

The proposed rules do not require those to whom it applies to take an action that violates requirements of federal or state law.

**Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?**

The proposed rules do not impose more stringent performance requirements on private entities than on public entities.

**Section 8. Did you determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?**

The proposed rules do not differ from any applicable federal regulation or statute.

**Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?**

There are no other applicable laws. The Department of Licensing, through the Cosmetology Board, licenses estheticians. The board worked closely with MQAC who received feedback from estheticians and the Cosmetology Board, and modified the proposed rules to eliminate any overlap between the scope of practice of an esthetician and the scope of practice of a physician or physician assistant, thus an osteopathic physician and osteopathic physician assistant.

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<sup>1</sup> Berke R., *Laser Surgery in the Wrong Hands can be Dangerous*, CNN.com web site: <http://www.cnn.com/2007/HEALTH/09/20/berke.lasersurgery/>. (the medical spa industry has grown 160 percent between 2004 and 2007).

Goldberg, D., *The Future of Medical Spas*, Manuscript presented at conference on May 19, 2005, at New York Hilton (10 million women spend over \$3.5 billion per year on laser hair removal; number of men seeking laser hair removal is increasing; laser hair removal is expected to double over the next five years; there are over 6500 med spas in the U.S.).

Beil L., *Doctors Cashing in on Cosmetic Work, Saying it Keeps Practices Afloat*, Dallas Morning News, September 3, 2006 (number of medical spas doubled between 2002 and 2004).

Pressler M., *Medspas Profit on Facials and Facelifts*, The Washington Post, November 13, 2005 (growing number of physicians are opening spas to reach a wider patient base and boost income lost to managed care. The number of non-surgical cosmetic procedures increased eight-fold from 1997 to 2005, to nearly one billion).

<sup>2</sup> Beil L., *Doctors Cashing in on Cosmetic Work, Saying it Keeps Practices Afloat*, Dallas Morning News, September 3, 2006 (Treatments are increasingly delivered by physicians schooled in something else or by unskilled physicians with little medical background; society should be concerned about this trend.)

<sup>3</sup> This concern is shared by physicians across the country. See Lazo A., *Washingtonians Tuck into Medical Spas*, The Washington Post, March 31, 2008.

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<sup>4</sup> U.S. Food and Drug Administration, *Early Communication about an Ongoing Safety Review Botox and Botox Cosmetic (Botulinum toxin Type A) and Myobloc (Botulinum toxin Type B)*, [http://www.fda.gov/cder/drug/early\\_comm/botulinium\\_toxins.htm](http://www.fda.gov/cder/drug/early_comm/botulinium_toxins.htm) .

U.S. Food and Drug Administration, Executive Summary, Dermal Filler Devices, November 18, 2008, <http://www.fda.gov/OHRMS/DOCKETS/ac/08/briefing/2008-4391b1-01%20-%20FDA%20Executive%20Summary%20Dermal%20Fillers.pdf> .

Berke R., *Laser Surgery in the Wrong Hands can be Dangerous*, CNN.com web site:

<http://www.cnn.com/2007/HEALTH/09/20/berke.lasersurgery/> (“botched laser skin procedures increased 41 percent from 2005 to 2006”).

The American Board of Plastic Surgeons lists the potential complications from the administration of Botulinum Toxic Type A Injections (Botox), as headaches, respiratory infections, flu like syndrome, temporary eyelid droop and nausea. The United Kingdom Department of Health reports risks of fat injections include infections, bleeding, nerve damage, skin irregularity or waviness, swelling, aching, itching and bruising. The Canadian Society for Aesthetic Plastic Surgery reports potential risks of autologous fat (fat taken from your own body) as discomfort, bruising, and the same risks that are present for liposuction procedures. The American Society for Aesthetic Plastic Surgery reports potential risks of mesotherapy to include infections, disfiguring masses of inflamed tissues, and tissue death. The Consumer Guide to Plastic Surgery reports the liquefied fat could be filtered through the liver creating a fatty liver, inflammation and possible scarring and liver failure. In addition, the liquefied fat may wind up in the blood vessels, adding to fatty plaque and increase the risk of heart attack and stroke.

<sup>5</sup> Pressler M., *Medspas Profit on Facials and Facelifts*, The Washington Post, November 13, 2005 (Of the estimated 1500 medical spas in 2005, only 500 to 600 were owned or operated by physicians).

<sup>6</sup> Salary.com at [swz.salary.com](http://swz.salary.com) the average salary for a typical physician – generalist in the United States. 5-27-2009.