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May 21, 2014

Court of Appeals
Division III
State of Washington

NO. 32055-3-III

**COURT OF APPEALS, DIVISION III
OF THE STATE OF WASHINGTON**

TYLER ARNOLD and JASON SWANSON,

Petitioners,

v.

WASHINGTON STATE DEPARTMENT OF HEALTH,

Respondent.

RESPONSE TO PETITIONERS' OPENING BRIEF

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I. INTRODUCTION

The Washington State Department of Health (DOH) issued a Final Order requiring Tyler Arnold and Jason Swanson (Petitioners) to permanently cease and desist from removing tattoos using a laser device. The Final Order found that Petitioners' use of the laser constituted the unlicensed practice of medicine. DOH's decision was affirmed by the Spokane County Superior Court on October 29, 2013. The Petitioners now seek judicial review of the Final Order in this Court.

II. COUNTER ASSIGNMENTS OF ERROR

1. Did DOH err in concluding that a person who uses a laser to penetrate the skin and remove tattoos engages in the practice of medicine?
2. Does substantial evidence support DOH's Finding that using a laser to remove tattoos penetrates the skin and alters human tissue?

III. STATEMENT OF THE CASE

Petitioner Arnold and Petitioner Swanson are owners of the business Bullet Proof Tattoo located in Spokane, Washington. Administrative Record (AR) at 106. Petitioner Arnold is licensed as a tattoo artist and body piercer by the Department of Licensing. AR at 245-46. Petitioner Swanson is licensed as a tattoo artist by the Department of Licensing. AR at 261. Neither Arnold nor Swanson hold

any health care credential from DOH or have any health care training.
AR at 245, 260-61.

DOH issued individual Notices of Intent to Issue Cease and Desist Orders to Arnold and Swanson on April 24, 2012, alleging their use of a laser to remove tattoos was the unlicensed practice of medicine. AR at 4-17, 26-39. Because the two cases involved the same issues, witnesses, and exhibits, they were consolidated. AR at 85-86.

A consolidated adjudicative hearing was held on November 13, 2012, before an administrative Health Law Judge. AR at 227. Petitioners participated in the consolidated hearing and were represented by the same attorney. At hearing, both Petitioners admitted they use the Palomar Q YAG 5 (Palomar) laser to remove tattoos from their customers' skin. AR at 219-219 (Final Order Findings of Fact 1.3, 1.8)¹, AR at 246, 261.

The exhibits admitted at the hearing included, among others, the operator's manual for the Palomar laser (AR at 184-194), forms used by the Petitioners to inform patients of the side effects of laser treatment and skin care instructions following treatment (AR at 165, 167, 173), and documents used by Petitioners for laser use and treatment training (AR at 179).

¹ For the court's convenience, a copy of the Final Order is attached as Appendix A.

The operator's manual for the laser states that common side effects of laser treatments include pain, purpura (discoloration of skin), blisters/scabs, hyper/hypo pigmentation, swelling, infection, scarring, persistence of tattoo, and allergic reactions. AR at 194. The Petitioners' consent form for laser tattoo removal warns their customers that many of these common side effects occur. AR at 173.

In addition, both Petitioners testified at the hearing that tattoo ink is deposited within or underneath the dermis. AR at 258, 283. Petitioners' witness, Mr. Patrick Clark (Clark), testified that "a medical laser would be something that would send light into tissue to respond to a single, specific target." AR at 293. He also testified that, "a laser is designed to look through healthy tissue to seek out something that does not belong in tissue" AR at 294.

Following the hearing, the Health Law Judge found that the use of lasers penetrates the skin and alters tissue, and for that reason the laser is considered a prescriptive device. AR at 220. The Health Law Judge concluded that Petitioners' use of the laser for tattoo removal was the unlicensed practice of medicine, in violation of RCW 18.71.011, RCW 18.71.021 and WAC 246-919-605, and ordered Petitioners to permanently cease and desist from the unlicensed practice of medicine and to pay a fine of \$1,000 each. AR at 221-224.

Petitioners sought judicial review of the Final Order in the Spokane County Superior Court. Clerk's Papers (CP) at 1. The superior court affirmed DOH's Final Order. CP at 13. Petitioners then filed a Notice of Appeal and Motion to Stay the Final Order in this court. The Commissioner denied the stay, finding that Petitioners were unlikely to prevail on appeal. Commissioner's Ruling March 20, 2014 (applying RCW 34.05.550(3)).

IV. ARGUMENT

A. Standard of Review

Judicial review of the administrative adjudication in this case is governed by the Administrative Procedure Act (APA), Chapter 34.05 RCW. RCW 34.05.510. The burden is on the Petitioners to demonstrate the invalidity of the agency action and that they were substantially prejudiced by that action. RCW 34.05.570(1)(a), (d). *King Cnty. Pub. Hosp. Dist. No. 2 v. Wash. State Dep't of Health*, 178 Wn.2d 363, 372, 309 P.3d 416 (2013)(agency decision is presumed correct and the challenger bears burden of proof). This court sits in the same position as the superior court and applies the APA standards directly to the record before the agency. *King Cnty. Pub. Hosp. Dist.*, 178 Wn.2d at 372 (citing *Tapper v. Employment Sec. Dep't*, 122 Wn.2d 397, 402, 858 P.2d 494 (1993)).

The Petitioners do not cite the APA, but their arguments appear to invoke two subsections of RCW 34.05.570(3). They appear to allege that the Health Law Judge erroneously interpreted or applied the law and that the Final Order is not supported by “evidence that is substantial when viewed in light of the whole record before the court.” RCW 34.05.570(3)(d), (e).

Alleged errors of law are reviewed de novo. *Ames v. Wash. State Health Dep’t Med. Quality Health Assurance Comm’n*, 166 Wn.2d 255, 260, 208 P.3d 549 (2009). Although the court may substitute its judgment for that of an administrative agency, the court accords substantial weight to the agency’s interpretation of the law it administers—especially when the issue falls within the agency’s expertise. *Id.* at 260-61. Courts also give substantial weight to the agency’s interpretation of its own rules. *Lang v. Wash. State Dep’t of Health*, 138 Wn. App. 235, 243, 156 P.3d 919 (2007) (citing *Federated Am. Ins. Co. v. Marquardt*, 108 Wn.2d 651, 656, 741 P.2d 18 (1987)).

Substantial evidence is that which is sufficient “to persuade a fair-minded person of the truth of the declared premises.” *Id.* at 261 (quoting *Heinmiller v. Dep’t of Health*, 127 Wn.2d 595, 607, 903 P.2d 433, (1995)) (internal quotation marks omitted). The evidence is reviewed in the light most favorable to “the party who prevailed in the highest

forum that exercised fact-finding authority,” in this case DOH. *University of Wash. Med. Ctr. v. Wash. State Dep’t of Health*, 164 Wn.2d 95, 104-05, 187 P.3d 243 (2008) (quoting *City of Univ. Place v. McGuire*, 144 Wn.2d 640, 652, 30 P.3d 453 (2001)) (internal quotation marks omitted). The court will accept the fact-finder’s determinations of witness credibility and the weight to be given to reasonable but competing inferences. *City of Univ. Place*, 144 Wn.2d at 652. If there are sufficient facts in that record from which a reasonable person could make the same finding as the agency, the agency’s finding should be upheld, even if the reviewing court would make a different finding from its reading of the record. *Callecod v. Wash. State Patrol*, 84 Wn. App. 663, 676 n.9, 929 P.2d 510, review denied, 132 Wn.2d 1004 (1997).

B. DOH Correctly Interpreted And Applied The Law When It Concluded That Petitioners Engaged In the Unlicensed Practice of Medicine

DOH brought these actions against the Petitioners under the Secretary’s statutory authority to protect the public from unregulated and unlicensed individuals practicing medicine. RCW 18.130.190.²

² The Medical Quality Assurance Commission regulates the practice of medicine by licensed physicians and physician assistants, chapters 18.71 and 18.71A RCW, but it does not regulate the unlicensed practice of medicine. RCW 18.13.190 delegates to the Secretary of Health the authority to investigate alleged unlicensed practice and to issue cease and desist orders against unlicensed persons found to be practicing a health care profession for which a license is required.

A person is prohibited from practicing medicine unless licensed to do so. RCW 18.71.021. The practice of medicine has been defined by the legislature to include “[s]ever[ing] or penetrat[ing] the tissues of human beings.” RCW 18.71.011(3). In 2007, the Medical Quality Assurance Commission (MQAC) adopted a rule³ clarifying that the use of lasers and other similar medical devices to penetrate human tissue is the practice of medicine:

(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.

.....
WAC 246-919-605.

³ The MQAC was concerned that unlicensed individuals without prescriptive authority were operating the prescriptive lasers. Even though existing law does not permit the use by estheticians or others without prescriptive authority, the MQAC found that the use was widespread. Appendix (App.) A-Final Small Business Economic Statement for Rules Concerning WAC 246-919-605 and WAC 246-918-125.

The rule also sets out the requirements for use of a prescriptive laser device, including licensure, training, physician supervision, and record keeping. WAC 246-919-605. These requirements ensure a patient receives proper treatment from competent practitioners. Patients must be properly screened by a physician for medical issues and medication. AR at 185-189; WAC 246-919-605(6). A physician must be ultimately responsible for the patient's treatment so that any complications, such as infection, can be effectively managed. AR at 187, WAC 246-919-605.

The Petitioners do not hold any recognized license or certification related to laser treatment, as required in WAC 246-919-605(10). AR at 247-248, 263-264. They have no medical training or medical credentials. AR at 245, 260-261. Although the Petitioners claim they are trained and certified in the use of the laser, Pet'rs' Op. Br. at 2, the record reflects that their only training was an eight-hour course in 2008 taught by a nurse licensed in California. AR at 247-248, 263-264. Even if they had been properly trained and licensed, their use of the laser is neither delegated nor supervised by a qualified physician, as required in WAC 246-919-605(10). AR at 248, 250, 253.

Instead, the Petitioners argue that the Palomar laser they used does not penetrate and alter human tissue and therefore is not the practice of medicine. Petitioners do not refute DOH's evidence that the Palomar laser

used by the Petitioners is classified by the United States Food and Drug Administration as a prescriptive device.⁴

Petitioners attempt to argue that because RCW 18.71.011 uses the phrase “severs or penetrates,” there is connection between sever and penetrate. They argue that this connection requires a “complete physical penetration of tissue by some object.” Pet’rs’ Op. Br. at 9. Their argument fails, for at least two reasons.

First, the plain language of the statute treats severing and penetrating tissue as alternatives, not a single connected thing. *See Lake v. Woodcreek Homeowners Ass’n*, 169 Wn.2d 516, 528, 243 P.3d 1283 (2010) (“The dictionary describes ‘or’ as a ‘function word’ indicating ‘an alternative between different or unlike things.’”) (quoting *Webster’s Third New International Dictionary* 1585 (2002) (emphasis added by the court)); *Tesoro Ref. & Mktg. Co. v. State, Dep’t of Revenue*, 164 Wn.2d 310, 319, 190 P.3d 28 (2008) (“As a default rule, the word ‘or’ does not mean ‘and’ unless legislative intent clearly indicates to the contrary.”). Petitioners

⁴ Health Care Investigator Dwight Correll testified at hearing that he had examined the Petitioners’ laser and that it is a Palomar Q-YAG 5 laser, Model No. 5226, Serial No. 21-002. AR at 240. He further testified that it is categorized by the federal Food and Drug Administration as a prescriptive device. AR at 241. The operator training materials for this laser that were admitted into evidence state that, “[i]n the United States, federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by state law to use or order the use of this device.” AR at 185, 21 C.F.R. § 801.109. Petitioner Swanson testified that he purchased the laser second-hand from an individual in Texas. AR at 262. The transaction occurred over the phone. AR at 263. A physician was not involved in the sale. AR at 247, 262.

have not cited any legislative history or any other authority to demonstrate the legislature meant to somehow connect the words “sever” and “penetration.” The plain language of the statute does not support their suggested interpretation.

Second, the MQAC rules regarding the use of prescriptive lasers supports DOH’s interpretation. The MQAC rules use the phrase “topically penetrate” when defining what constitutes the practice of medicine when using a laser device. WAC 246-919-605(1)(a). The official rule-making file demonstrates that MQAC intended for these rules to apply to “LLRP devices applied to the skin.” App. B at 2, App. C at 4. In addition, a great deal of the discussion and comments during the rule-making process related to the fact that the rule applied to laser hair removal. App. B at 1, App. C at 2. Laser hair removal is done in the same manner as tattoo removal, with the laser applied to the skin. AR at 188-194. Petitioners’ Palomar laser is approved for use in hair removal. AR at 191. Therefore, contrary to Petitioners’ argument, the MQAC considers a laser applied to the skin, with no physical penetration by an object, to be sufficient to meet the definition of the practice of medicine. The Health Law Judge correctly interpreted and applied the statute and pertinent rule concluding that Petitioners engaged in the unlicensed practice of medicine. Petitioners have not demonstrated any error of law.

C. There Is Substantial Evidence In The Record To Support The Findings Of Fact In The Final Order

In this case, after considering all of the testimony and evidence and evaluating the credibility of each witness, DOH specifically found that the Petitioners were engaged in the practice of medicine by using the Palomar laser to remove tattoos. Finding of Fact 1.11; Conclusions of Law 2.4 and 2.5. Petitioners argue that Finding of Fact 1.11, finding that tattoo ink lies beneath the skin and that the laser penetrates the skin and alters tissue, is not supported by substantial evidence. AR at 220. Petitioners' argument fails because there is substantial evidence to support these findings.

1. The Laser Used By Petitioners Penetrates Human Tissue

Petitioners argue that the use of the laser for tattoo removal does not penetrate the skin. Their argument fails because the laser light must pass through and penetrate the skin in order to reach the tattoo ink located within the skin. Petitioner Arnold testified that the laser is designed to break up the tattoo ink molecule so that the body can carry away the ink. AR at 258. When asked where the tattoo ink is located he stated that "it would be beneath the skin." AR at 258. Petitioner Swanson testified that tattoo ink is applied "underneath the dermis" and "under the skin." AR at 283. Petitioners' witness, Clark, stated at the hearing that, "[a] medical laser would be something that would send light into tissue to

respond to a single, specific target.” AR at 293. He also stated that, “[a] laser is designed to look through healthy tissue to seek out something that does not belong in tissue” AR at 294. Further, in Petitioners’ training materials which were entered into evidence, it is stated that the use of certain spot sizes⁵ “offer greater penetration with less chance of epidermal damage.” AR at 179. Additionally, the operator’s manual states that. [f]or tattoo removal the target is the embedded ink.” AR at 186. In fact, even in Petitioners’ brief they admit that the laser penetrates the outer layer of skin. Pet’rs’ Op. Br. at 7. The record contains substantial evidence to support the finding that the laser light penetrates human tissue.

2. The Laser Used By Petitioners Alters Human Tissue

Second, Petitioners argue the laser does not alter human tissue. They argue that the laser interacts only with the tattoo ink and does not interact with surrounding tissue. This argument fails because the evidence presented at hearing shows that the use of the Palomar laser to remove tattoos can and has changed and altered the Petitioners’ customers’ skin.

The evidence shows that common side effects from the use of this laser include pain, purpura (discoloration of skin), blisters/scabs,

⁵ Spot sizes refer to certain settings on the laser machine. The Palomar Q-YAG 5 laser machine has three spot size settings, 6mm, 4mm and 2mm. AR at 270. The 6mm setting is the lowest setting. *Id.*

hyper/hypo pigmentation, swelling, infection, scarring, persistence of tattoo, and allergic reactions. AR at 194. Petitioner Swanson testified that some of his patients have suffered from these side effects, including pain, swelling, blistering and scabbing. AR at 268 and 273-274. In addition, the Petitioners' own consent form for clients undergoing laser tattoo removal states,

It has also been explained that for all skin types there is a chance that hyper-pigmentation (skin becoming darker) or hypo-pigmentation (skin becoming lighter) may occur. These conditions may become permanent in rare instances It has also been explained to me that there can be redness, bleeding, swelling, blistering, and/or very rarely infection or scarring of the areas being treated Occasionally, brown/gray dark areas may occur at the sites of the laser exposure, especially if you expose the skin to sunlight while healing. These occur rarely but can be unsightly and last for months to a year or more.

AR at 173.

The Petitioners warn their patients that these skin changes and alterations can occur from the treatment they provide in removing the unwanted tattoo. AR at 171, 173. The warning also states that these alterations in the skin can be long-term or permanent. AR at 173. In fact, on cross examination, the Petitioners' witness, Clark, was asked if any of the side effects result from the actual alteration of the tissue surrounding the ink. His response was, "yeah." AR at 298. Blistering, scabbing, scarring and hypo/hyper pigmentation are changes to the skin caused as

direct result of the laser treatment. There is substantial evidence that the laser does alter human tissue.

V. CONCLUSION

The Health Law Judge correctly interpreted and applied the law when he found that the use of the Palomar laser by Petitioners to remove a tattoo constituted the unlicensed practice of medicine because it penetrates and alters human tissue. Viewed in light of the whole record before the court, there is substantial evidence—evidence in sufficient quantum to persuade a fair minded person of the truth of the declared premise—to support the Findings of Fact in the Final Order. DOH respectfully requests the Final Order be affirmed.

RESPECTFULLY SUBMITTED this 21st day of May, 2014.

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APPENDIX A

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

ATTORNEY GENERAL'S OFFICE
AGRICULTURE & HEALTH DIVISION

In the Matter of:

JASON SWANSON,
TYLER ARNOLD,

Respondents.

Master Case Nos. M2009-736
M2009-737

CORRECTED
FINDINGS OF FACT,
CONCLUSIONS OF LAW,
AND FINAL ORDER

APPEARANCES:

Respondent, Jason Swanson, by
Richard D. Will, P.S., per
Richard D. Wall, Attorney at Law

Respondent, Tyler Arnold, by
Richard D. Will, P.S., per
Richard D. Wall, Attorney at Law

Department of Health Unlicensed Practice Program (Program), by
Office of the Attorney General, per
Heather Carter, Assistant Attorney General

PRESIDING OFFICER: Jerry D. Mitchell, Health Law Judge

A hearing was held in this matter on November 13, 2012, regarding allegations of the unlicensed practice of medicine. The Respondents are ordered to permanently cease and desist the unlicensed practice of medicine by engaging in the removal of tattoos using a laser device and are ordered to pay a fine.

ISSUES

- A. Did the Respondents engage in unlicensed practice alleged under RCW 18.71.011, RCW 18.71.021, RCW 18.130.050 and WAC 246-919-605?

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- B. If the Program proves unprofessional conduct, what are the appropriate sanctions under RCW 18.130.190?

SUMMARY OF PROCEEDINGS

At the hearing, the Program presented the testimony of Tyler Arnold, the Respondent; Jason Swanson, the Respondent; and Dwight Correll, Department of Health (DOH) Investigator. The Respondents presented the testimony of Jason Swanson, the Respondent; Tyler Arnold, the Respondent; and Patrick J. Clark.

The Presiding Officer admitted the following Program exhibits:

- P-1: Department of Licensing, License Query System, License Detail on Bullet Proof Tattoo Valley, printed May 12, 2009;
- P-2: U.S. Food and Drug Administration, Center for Devices and Radiological Health 510(l) Premarket Notification Database for Palomar Q-Yag-5 Nd: YAG Laser System, dated May 20, 2009;
- P-3: Summary of Safety and Effectiveness for K 061436, Palomar Q-Yag-5 laser, filed December 6, 2006;
- P-4: DOH and Human Services Letter to Palomar Med Tech, dated December 6, 2006; and
- P-5: Indications for Use Statement K 061436 Q-Yag-5 laser system.

The Presiding Officer admitted the following Respondent exhibits:

- R-1: Laser Tattoo Session – Post Laser Skin Care Instructions;
- R-2: Releaser from Palomar A-YAG-5;
- R-3: Laser Tattoo Session – Information and Consent;
- R-4: Laser Tattoo Session Applications for Skin Conditions Gen. Information;
- R-5: Consent form;

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- R-6: Treatment Chart;
- R-7: Patient Invoice Record;
- R-9: Chapter 6, Clinical Application; and
- R-10: Palomar Q-YAG-5 Clinical Update Number One.

I. FINDINGS OF FACT

1.1 The Respondents, Jason Swanson and Tyler Arnold, do not currently hold credentials to practice as physicians and surgeons in the state of Washington, and have never held such credentials.

1.2 "Tattooing" is the indelible marking of the skin produced by introducing minute amounts of pigments into the skin. The Respondents are owners of a tattooing business in Spokane, Washington, and work as licensed tattoo artists in that business. The business has a website that advertises "tattoo removal". While an individual can provide tattooing services without a health care license, it requires a health care license or a physician's license to remove a tattoo using a laser.

1.3 On or about May 12, 2009, DOH Investigator **Tony Pizzillo** conducted a site visit to the business and spoke with Tyler Arnold (Arnold). Arnold identified himself as an owner of the business and also as a tattoo artist. Arnold informed the Investigator that the business used a laser device to remove tattoos. Arnold admitted that he used the device to remove tattoos from customers.

1.4 On or about May 20, 2009, the DOH Investigator visited the business again. The DOH Investigator handed Jason Swanson (Swanson) a letter notifying him that the use of the laser device to remove tattoos constituted the unlicensed practice of

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medicine. Swanson received the letter and signed the document as evidence of receipt.

1.5 Swanson called the DOH Investigator on or about May 21, 2009. Swanson told the Investigator that he would continue to use the laser.

1.6 On or about February 24, 2012, DOH Investigator **Pizzillo** visited Arnold at his tattoo business. **Pizzillo** did not identify himself as a DOH investigator. **Pizzillo** showed Arnold a tattoo on his arm and asked if they could remove it using their laser device. Arnold affirmed that he would use the laser to remove the tattoo. Arnold said he is trained to use the device and that he or another technician at the business would use the laser. Arnold gave the Investigator a business card and **Pizzillo** left the premises.

1.7 On or about February 27, 2012, DOH Investigator Correll visited the Respondents' tattoo business. The DOH Investigator identified himself to Swanson as a DOH Investigator. The DOH Investigator asked to see the laser that was used to remove tattoos. Swanson showed the Investigator a laser device that said it was used to remove tattoos.

1.8 The device used by both the Respondents to remove tattoos is the Palomar Q-Yag 5 (Palomar). On the back of the device is a caution that federal law restricts the use of this device by anyone other than a physician.

1.9 Swanson and Arnold (jointly the Respondents) each received eight hours of hands-on training for use of the laser from Laurie Haney, a registered nurse in California. Ms. Haney has no Washington credentials. The Palomar operator guidelines (Exhibit P-6, p. 4) provide that all use of the laser equipment is based on the

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physician's knowledge and experience; and a physician is responsible for correct diagnosis and for all treatment results. The physician should carefully screen all potential candidates for laser treatment. The screening should include the physician's assessment of the patient's skin type.

1.10 Mr. Arnold and Mr. Swanson did not refer their customers/patients for screening by a physician prior to the use of the laser on the customers/patients. Neither of the Respondents held any health care credentials in the state of Washington during the relevant period and was not qualified to perform diagnoses or assess the customer's/patient's skin type.

1.11 Tattoo ink lies beneath the skin. Mr. Swanson testified that a safety device only allows the laser to go a certain distance, but he admitted that the laser does penetrate the skin. The use of lasers penetrates the skin, alters tissues, and for that reason the laser is considered a prescriptive device. See WAC 246-919-605.

1.12 Mr. Arnold and Mr. Swanson have no medical training and hold no health certifications. The unlicensed use of the laser by the Respondents creates a risk of harm to the Respondents' patients/clients. The use of a laser device to remove tattoos can result in complications such as visual impairment, blindness, inflammation, burns, scarring, hypopigmentation (diminished pigment in a tissue) and/or hyperpigmentation (increased pigmentation, especially of the skin).

II. CONCLUSIONS OF LAW

2.1 The Secretary of Health (and by designated authority, the Presiding Officer) has jurisdiction over the Respondents and the subject of this proceeding. Chapter 18.130 RCW.

2.2 Except as otherwise required by law, the Program bears the burden of proving the allegations set forth in the Notice of Intent to Issue Cease and Desist Order by a preponderance of the evidence. WAC 246-10-606.

2.3 It is the purpose of the Medical Quality Assurance Commission to regulate the competency and quality of professional health care providers under its jurisdiction by establishing, monitoring, and enforcing qualifications for licensing, consistent standards of practice, continuing competency mechanisms, and discipline. Rules, policies, and procedures developed by the Commission must promote the delivery of quality health care to the residents of the state of Washington. RCW 18.71.002. Anyone practicing medicine in the state of Washington must possess a valid current license. RCW 18.71.021.

2.4 In the Jason Swanson matter, assigned Master Case No. M2009-736, the Program proved by a preponderance of the evidence that the Respondent committed the unlicensed practice of medicine in violation of RCW 18.71.011, RCW 18.71.021, and WAC 246-919-605.

2.5 In the Tyler Arnold matter, assigned Master Case No. M2009-737, the Program proved by a preponderance of the evidence that the Respondent committed

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the unlicensed practice of medicine in violation of RCW 18.71.011, RCW 18.71.021, and WAC 246-919-605¹, which state:

RCW 18.71.011 Definition of practice of medicine-Engaging in practice of chiropractic prohibited, when. A person is practicing medicine if he or she does one or more of the following:

- (1) Offers or undertakes to diagnose, cure, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, by any means or instrumentality;
- (2) Administers or prescribes drugs or medical preparations to be used by any other person;
- (3) Severs or penetrates the tissues of human beings;
- (4) Uses on cards, books, papers, signs, or other written or printed means of giving information to the public, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human disease or conditions the designation : doctor of medicine," "physician", "surgeon", "m.d.", or any combination thereof unless such designation additionally contains the description of another branch of the healing arts for which a person has a license: PROVIDED HOWEVER, That a person licensed under this chapter shall not engage in the practice of chiropractic as defined in RCW 18.25.005.

RCW 18.71.021 License required. No person may practice or represent himself or herself as practicing medicine without first having a valid license to do so.

WAC 246-919-605 Use of laser, light, radiofrequency, and plasma devises 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

¹ See RCW 18.130.050. Authority of disciplining authority and RCW 18.130.190 Practice without license-Investigation of complaints-Cease and desist orders-Injunctions-Penalties.

- (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 hyper pigmentation.
- (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.

2.6 Pursuant to RCW 18.130.190 of the Uniform Disciplinary Act, after due and proper notice, the Secretary of Health is authorized to issue a cease and desist order against a person upon a determination that such person has engaged in or is engaging in unlicensed practice of medicine and may impose a fine of up to \$1,000 for each day of unlicensed practice.

2.7 The Program requested a cease and desist order and \$1,000 fine be entered against the Respondent Swanson and a cease and desist order and \$1,000 fine be entered against the Respondent Arnold. The Respondents each request that the Statement of Charges be dismissed.

2.8 Safeguarding the public's safety is the paramount responsibility of every disciplining authority. In considering the sanction, the Presiding Officer notes the following aggravating factors: medical risk to patients. The Presiding Officer notes the following mitigating factor: there is no evidence to indicate that any patient suffered physical harm.

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III. ORDER

3.1 The Respondent, Jason Swanson, Master Case No. M2009-736, is ORDERED TO PERMANENTLY CEASE AND DESIST the unlicensed practice of medicine by engaging in the removal of tattoos using a laser device. The Respondent, Jason Swanson is further ORDERED TO PAY a fine of \$1,000 to the Unlicensed Practice Program in the state of Washington.

3.2 The Respondent, Tyler Arnold, Master Case No. M2009-737, is ORDERED TO PERMANENTLY CEASE AND DESIST the unlicensed practice of medicine by engaging in the removal of tattoos using a laser device. Respondent, Tyler Arnold is further ORDERED TO PAY a fine of \$1,000 to the Unlicensed Practice Program in the state of Washington.

3.3 The fines shall be made payable to the Washington State Department of Health and sent to the following address:

Unlicensed Practice Program
PO Box 1099
Olympia, WA 98507

Dated this 24 day of January, 2013.



JERRY D. MITCHELL, Health Law Judge
Presiding Officer

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CLERK'S SUMMARY

<u>Charge</u>	<u>Action</u>
RCW 18.71.011	VIOLATED
RCW 18.71.021	VIOLATED
WAC 246-919-605	VIOLATED

NOTICE TO PARTIES

This Order is subject to the reporting requirements of RCW 18.130.110, Section 1128E of the Social Security Act, and any other applicable interstate or national reporting requirements. If discipline is taken, it must be reported to the Healthcare Integrity Protection Data Bank.

Either party may file a **petition for reconsideration**. RCW 34.05.461(3); 34.05.470. The petition must be filed within ten days of service of this Order with:

Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Unlicensed Practice Program
PO Box 47874
Olympia, WA 98504-7874

The petition must state the specific grounds for reconsideration and what relief is requested. WAC 246-10-704. The petition is denied if the Presiding Officer does not respond in writing within 20 days of the filing of the petition.

A **petition for judicial review** must be filed and served within 30 days after service of this order. RCW 34.05.542. The procedures are identified in Chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed, the above 30-day period does not start until the petition is resolved. RCW 34.05.470(3).

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The order is in effect while a petition for reconsideration or review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This order is "served" the day it is deposited in the United States mail. RCW 34.05.010(19).

For more information, visit our website at:

<http://www.doh.wa.gov/PublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/Hearings.aspx>

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APPENDIX B

Final Small Business Economic Impact Statement for Rules Concerning

**WAC 246-919-605 Use of Lasers, Light, Radiofrequency, and Plasma Devices
as Applied to the Skin by Physicians**

and

**WAC 246-918-125 Use of Lasers, Light, Radiofrequency, and Plasma Devices
as Applied to the Skin by Physician Assistants**

1. Briefly describe the proposed rule.

There are many offices and clinics in the state of Washington providing skin treatment or hair removal using laser, light, radiofrequency and plasma (LLRP) devices. Some offices and clinics have a physician on site, some have a physician off-site, and some have no physician involvement at all. Since the Commission's authority is limited to governing physicians and physician assistants, the Commission has no authority over clinics that do not employ a physician or physician assistant. The Commission understands that some physicians employ appropriately licensed persons, such as physician assistants or registered nurses, to use the devices. The Commission is concerned that some physicians are employing persons whose legal scope of practice does not include the use of prescriptive devices on patients. This is analogous to an unlicensed person dispensing prescription medications.

The Commission believes when used appropriately, these devices are generally safe and relatively easy to operate. But the potential for patient injury with untrained, inappropriate, or negligent operation is significant. Several states have created rules regulating the use of LLRP devices. The Commission wishes to clarify this area of medicine, set minimal standards for the use of such devices by physicians and physician assistants in our state, and ensure that persons using these devices are operating within their legal scope of practice.

The adopted rules:

- Provide an effective date of March 1, 2007 giving individuals time to come into compliance with adopted rules.
- Define Laser, Light, Radiofrequency, and Plasma Devices (hereafter LLRP devices) as medical devices (a) that use a laser, non-coherent 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 (FDA) as prescription devices;
- Provide that a physician or physician assistant must use an LLRP device in accordance with standard medical practice;
- State that the use of an LLRP device is the practice of medicine;
- Require a physician or physician assistant to be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such a device, and to remain competent for as long as the device is used;
- Require a physician or physician assistant to, prior to authorizing treatment with such a device, take the patient's medical 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 non-physician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record;

- Permit a physician or physician assistant to delegate use of the device to a properly trained and licensed professional whose scope of practice permits the use of a prescriptive device
- Require the physician or physician assistant to develop a specific protocol for the licensed professional to follow;
- Prohibit a physician or physician assistant from delegating an LLRP for use on globe of the eye;
- Require the delegating physician to be on the immediate premises during the initial treatment to treat complications, if indicated;
- Permit the physician to be temporarily absent during treatment of patients with established treatment plans provided a local back-up physician agrees in writing to treat complications, is reachable by telephone, and can see the patient within sixty minutes;
- Require the delegating physician assistant to be on the premises during all treatment with an LLRP device;
- Provide that regardless of who operates the device, the physician is ultimately responsible for the safety of the patient;
- Require the physician to establish a quality assurance program; and
- Provide that the use of devices to penetrate and alter human tissue for a purpose other than to topically penetrate the skin constitutes surgery and is outside the scope of these rules.

2. Is a Small Business Economic Impact Statement (SBEIS) required for this rule?

Yes.

3. Which industries are affected by this rule?

The adopted rules will directly affect medical offices and clinics in the state of Washington providing treatment with LLRP devices as applied to the skin in which a physician or physician assistant is involved. The adopted rules regulate a physician and physician assistant's use and delegation of LLRP devices.

Although the proposed rules apply only to physicians and physician assistants, the proposed rules will affect beauty salons, boutiques, spas and other small cosmetic businesses that use LLRP devices without physician or physician assistant supervision. Existing law does not permit estheticians or any person without prescriptive authority to operate these devices. DOH has taken action against estheticians and others for operating these devices. Despite this, the use of these devices by persons without prescriptive authority appears to be widespread. The adopted rules have brought attention to the fact that these people are operating outside the bounds of the law.

In response to the Commission's adopted rules, the Department of Licensing is in the process of adopting a rule that will permit estheticians to use these devices only under the supervision and delegation of a physician or physician assistant licensed under Chapter

18.71, 18.71A, 18.57, or 18.57A RCW. If the Department of Licensing rule is adopted, beauty salons, boutiques, spas and other small cosmetic businesses that use LLRP devices will have to hire a physician or physician assistant to examine each patient, set up a treatment plan, and supervise the treatment.

SIC Industry Code and Title	# of Businesses	# of Employees	Average # of Employees for Smallest Businesses	Average # of Employees for Largest Businesses
			< 50 Employees	>= 50 Employees
8011 Offices and Clinics of Doctors of Medicine	2,821	43,659	7.9	154.2
8093 Specialties outpatient clinic	245	7530	9.3	113.5
8049 Offices and Clinics of Health Practitioners, Not Elsewhere Classified	913	5,450	4.5	102.9
7231 Beauty Shops	1,598	9,191	4.7	106.2
7299 Miscellaneous Personal Services	530	2668	6.0	No Large businesses

4. What are the costs of complying with this rule for small businesses (those with 50 or fewer employees) and for the largest 10% of businesses affected?

There are potential costs due to the implementation of this rule. Practitioners who have an LLRP device in their office or clinic will have to be trained to use the device properly. The staff who is a licensed professional in which the use of LLRP devices are within their scope of practice will have to be trained to use the device properly if not already trained. A physician or physician assistant will have to see and examine each and every patient who wishes to undergo treatment with an LLRP device. The physician will have to contract with a back-up physician to provide treatment if there are complications. If a physician assistant delegates the use of an LLRP device, the physician assistant will have to be on site for each treatment. Each of these requirements may add to the cost of treatment with an LLRP device. On the other hand, the rules should decrease the cost of healthcare by reducing the severity or number of complications to patients.

During the rules process, public comments were made regarding the small business economic impact which required further review and research on the wages of physicians and physician assistant. This final SBEIS reflects those findings.

The rule will require additional training for the licensed professional using the LLRP devices. The manufacturer of the device frequently provides training at no cost to the purchasers of the device at the time of the initial sale. After the sale, new employees will need additional training. The cost of the training for physicians, physician assistants or new employed license professional is in the range of \$1250 to \$2500¹ depending on the

¹ Based on a sample of advertisements for laser training courses:

- o Esthetic Skin Institute, Inc (www.esiw.com)
- o Empire Medical Training (www.empiremedicaltraining.com)
- o Aesthetic Enhancement Institute (www.aeinstitute.biz)
- o CeLibre Medical Corporation (www.celibre.com)

type of devices. The rules also require the physician or physician assistant to be not only trained on the prescriptive devices, but also appropriately trained in physics, safety and techniques of the LLRP devices prior to using them. In order to maintain a Washington state license, physician or physician assistants are required to obtain continuing medical education every two (PAs) or four years (MDs). The assumption is that the cost for training of the physician or physician assistant is included in the cost of maintaining licensure and therefore has little or no impact to the practitioner.

The adopted rules will require the physician or physician assistant to complete the initial physical and history of the patient prior to initiating any treatment. The Commission believes it is the standard of care for a physician or physician assistant to examine a patient before developing any medical treatment plan. This medical cost will be borne by the patient or the patient's insurer.

The adopted rules require physicians and physician assistants to supervise the use of LLRP devices, which ultimately increases the cost for the treatments. A physician who delegates the use of an LLRP device must be on the immediate premises during the initial treatment. For subsequent treatments, the licensed professional may perform the treatments during "temporary absences" of the physician, so long as there is a back-up physician available by phone and accessible to see the patient within 60 minutes. When supervising, physician assistants must be on the "immediate premises" at all times.

The adopted rules will require the practitioner to delegate procedures only to trained and licensed professionals whose scope of practice allows for the use of the LLRP devices. A physician's office costs may increase by adding one physician assistant for 32 hours per week at a pay range from \$36.97² to \$48.76³ an hour. The physician assistant would be available to supervise other licensed personnel when the physician is not available or to be responsible for the initial patient history and physical examinations and create the appropriate treatment plans. The cost may potentially increase an additional \$1,183 to \$1,560 per week. For large physician clinics with physicians on site most of the patient hours, the clinic may need two additional physician assistants for 32 hours each which will increase the costs approximately \$2,366 to \$3,120.

The adopted rules may indirectly affect beauty salons, spas, boutiques or other small cosmetic businesses. The rules apply only to physicians and physician assistants. Other entities may take action against persons who are not physicians or physician assistants. The DOH has taken the position that the use of LLRP devices is the practice of medicine, and has issued cease and desist orders against licensed estheticians and persons with no license who are operating these devices without the supervision of a physician or physician assistant. The adopted rules will not affect DOH's ability to respond to complaints of unlicensed practice of medicine and issuing cease and desist orders and fines. However, the adopted rules, along with the rule under consideration by the Department of Licensing, will provide a pathway for estheticians to operate LLRP devices.

² Based on the U.S. Department of Labor May 2005 WA State Occupational Employment and Wage Estimates

³ Based on the American Academy of Physician Assistant 2005 Physician Assistant Income.

Beauty salons, spas, boutiques or other small cosmetic businesses who employ estheticians to use the LLRP devices without the supervision of a physician or physician assistants may come into compliance with the current law and the adopted rules by:

- Hiring a full time physician for 32 hours per week at a cost of \$135,250⁴ to \$204,672⁵ annual pay; or
- Hiring a part time physician to supervise 1-2 physician assistants. The assumed total cost for a small clinic opened 6 days per week may increase to \$4,350 per week. This includes:
 - A physician to be present to supervise the physician assistants and other personnel for 5-10 hours per week at \$65⁶ to \$123⁷ per hour for an average of \$650 to \$1,230 per week
 - Each physician assistant may overlap a 32 hour work week to supervise licensed professionals, complete histories and physicals, and direct all medical laser procedures increases the cost an additional \$2,366 to \$3,120.

The Commission does not have a sense of how many LLRP devices are being used by individuals without a professional license. Although the FDA requires prescriptive authority to purchase the medical laser devices, the unlicensed individuals are able to obtain the equipment through the second hand market. The FDA is focused on the manufacturers and not the regulation or enforcement of the end users.

The adopted rule will require a backup physician for a physician if not available. This is already a common practice among physicians.

5. Does the rule impose a disproportionate impact on small businesses?

The adopted rules do impose a disproportionate impact on small businesses as the table shows. The cost per average employee is much higher for small businesses as compared to large businesses.

SIC Industry Code and Title	Average # of Employees for Smallest Businesses	Average # of Employees for 10% of Largest Businesses	Costs of Rule Change Small Businesses	Costs of Rule Change Large Businesses	Average Cost Per Employees Small Businesses	Average Cost Per Employees Large Businesses
	< 50	>= 50	< 50	>= 50	< 50	>= 50
8011 Offices and Clinics of Doctors of Medicine	7.9	154.2	\$1,560	\$3,120	\$197.50	\$20.23
8093 Specialty outpatient clinics, nec	9.3	113.5	\$1,560	\$3,129	\$167.74	\$27.49
8049 Offices and Clinics of Health Practitioners, Not	4.5	102.9	\$1,560	\$3,120	\$346.67	30.32

⁴ Based on the U.S. Department of Labor May 2005 WA State Occupational Employment and Wage Estimates

⁵ Based on Salaries.com for physicians-family practice in Seattle, Washington.

⁶ Based on the U.S. Department of Labor May 2005 WA State Occupational Employment and Wage Estimates

⁷ Based on Salaries.com for physicians-family practice in Seattle, Washington.

Elsewhere Classified						
7231 Beauty Shops	4.7	106.2	\$4,350	\$4,350	\$925.53	40.69
7299 Misc. Personal Care Services	6.0	No large businesses	\$4,350	No large businesses	\$725.00	No large businesses

6. If the rule imposes a disproportionate impact on small businesses, what efforts were taken to reduce that impact (or why is it not “legal and feasible” to do so) by

The Commission’s significantly reduced the regulatory requirements of the first proposed draft that 1) required only licensed health care practitioners to use the devices, 2) required a physician assistant to be directly supervised during the use of the LLRP devices 3) required a physician to remain on site at all times, and 4) required only a physician to do the history and physical of the patient. The Commission collaboratively worked with the Department of Licensing, Washington State Medical Association, estheticians, and practitioners who employ individuals to do laser procedures. The proposed rules allows for 1) licensed professionals whose scope of practice includes the use of the LLRP prescriptive devices and who are supervised by a physician or physician assistant to perform procedures, 2) a physician assistant supervision as defined by the practice plan, 3) physicians may be temporarily absent if called away for an emergency under certain conditions, and 4) physician assistants to do history and physicals and treatment plans because this is already in their current scope of practice.

7. How are small businesses involved in the development of this rule?

Department staff worked closely with the Medical Commission, the Washington State Medical Association, persons using these devices, both licensed and non-licensed, and people associated with companies marketing devices to minimize the burden of these proposed rules. Several owners of affected businesses submitted written comments or attended Commission meetings to discuss the potential impact the proposed rules would have on their businesses. The Commission modified the proposed rules so that the impact would be as minimal as possible while still promoting safe medical care.

The Medical Commission has included the Department of Licensing Cosmetology Board during its rule process and continues to work with DOL staff to ensure public safety by both agencies. Licensed estheticians provided written comments during the rules process and attended the Commission’s public meetings to provide oral comments. There were multiple professions represented at the rules hearing and provided oral testimony.

APPENDIX C

**Final Significant Analysis for Rules Concerning
WAC 246-919-605 Use of Lasers, Light, Radiofrequency, and Plasma
Devices by Physicians
WAC 246-918-125 Use of Lasers, Light, Radiofrequency, and Plasma
Devices by Physician Assistants**

Background

Chapter 18.71 RCW regulates the practice of medicine in Washington State by establishing the Medical Quality Assurance Commission (Commission). Under RCW 18.71.002, one of the purposes of the Commission 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 Commission may develop rules that promote the delivery of quality health care to the residents of Washington State.

The Federal Food and Drug Administration (FDA) and state laws regulate the manufacture of certain medications because those medications are considered too dangerous to be available without the prescription of a licensed practitioner, and without certain restrictions on this prescribing. Similarly, the FDA regulates medical lasers and similar devices due to the risk of complications from their use. According to the FDA web site, medical lasers are prescription devices available for sale only to licensed practitioners with prescriptive authority as determined by state law. Complications from the use of lasers for skin care and treatment include visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation. Yet, there is no state law regulating the use of such devices.

There are many offices and clinics in the state of Washington providing treatment with Lasers, Light, Radiofrequency, and Plasma (LLRP) devices. Some offices and clinics have a physician on site, some have a physician off-site, and some have no physician involvement at all. Some offices and clinics have physician assistants and registered nurses using the devices; other offices and clinics have licensed estheticians; while others have persons who hold no license such as laser technicians and or electrologists administering the treatment. The Commission is concerned that unlicensed or inadequately trained persons are using prescriptive devices on patients. This is analogous to an unlicensed person dispensing prescription medications.

The Commission and its staff have received numerous inquiries in the past few years concerning these offices and clinics and the regulation of LLRP devices. Most of the questions concern who can use LLRP devices, whether such use can be delegated, and whether a physician has to be on site during the procedure. The Commission has also received complaints from patients and physicians that specific offices and clinics do not have appropriate safeguards to ensure patient safety. Physicians have come to the Commission meetings to discuss the proposed rules and reported that they have treated patients who have had complications from treatment in offices and clinics of unlicensed individuals or with no physician supervision.

The Department of Health (DOH) processes all complaints received regarding the unlicensed practice of medicine. DOH has received seven complaints in which a patient was injured by an untrained person using an LLRP device. DOH has issued cease and desist orders in seven cases and is investigating eight more cases of unlicensed practice. Existing law defining scope of practice does not permit estheticians or others to operate these devices. DOH has taken action against estheticians and others for operating these devices. In 1995, the Commission received a complaint against a physician where an inappropriate delegation to an unlicensed staff where a patient was burned during the procedure. The case resulted in disciplinary action.

In 2004, the Commission was informed of a young lady who received laser treatment at a mall salon in Washington to have some hair removed. The unlicensed individual treated the spot of hair with a laser. The spot was later diagnosed as malignant melanoma. Using a laser on a melanoma is only one of the potential risks when untrained or unsupervised individuals are deciding a medical treatment plan. Using a laser on a malignant melanoma may increase the rate at which the cancer spreads significantly and obscure the diagnosis and treatment of the malignant melanoma.

The Commission attempted to clarify the use of prescriptive lasers by adopting a policy in 2003 entitled "The Use of Lasers in Skin Care and Treatment." Since the adoption of the policy, numerous non-laser prescriptive devices have entered the market. The number of inquiries about the use of lasers and similar devices has increased since the policy took effect. The Commission wishes to clarify this area of medicine and set minimal standards for the use of such devices by physicians and physician assistants in our state. A number of other states have enacted statutes or adopted rules covering this area.

Briefly describe the proposed rule.

The proposed rules

- Provide an effective date of March 1, 2007, giving individuals' time to come into compliance with adopted rules.
- Define Laser, Light, Radiofrequency, and Plasma Devices (hereafter LLRP devices) as medical devices (a) that use a laser, non-coherent light, intense pulsed light, radiofrequency, or plasma to topically penetrate skin and alter human tissue and (b) are classified by the FDA as prescription devices;
- Provide that a physician or physician assistant must use an LLRP device in accordance with standard medical practice;
- State that the use of an LLRP device is the practice of medicine;
- Require a physician or physician assistant to be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such a device, and to remain competent for as long as the device is used;
- Require a physician or physician assistant to, prior to authorizing treatment with such a device, take the patient's medical 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 non-

- physician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record;
- Permit a physician or physician assistant to delegate use of the device to a properly trained and licensed professional under certain circumstances, but require the physician or physician assistant to develop a specific protocol for the licensed professional to follow;
 - Prohibit a physician from delegating an LLRP for use on the globe of the eye;
 - Require the delegating physician to be on the immediate premises during the initial treatment to treat complications, if indicated;
 - Permit the physician to be temporarily absent during treatment of patients with established treatment plans provided a local back-up physician agrees in writing to treat complications, is reachable by phone, and can see the patient within sixty minutes;
 - Require the delegating physician assistant to be on the premises during all treatment with an LLRP device.
 - Provide that regardless of who operates the device, the physician is ultimately responsible for the safety of the patient.
 - Require the physician to establish a quality assurance program.
 - Provide that the use of devices to penetrate and alter human tissue for a purpose other than to topically penetrate the skin constitutes surgery and is outside the scope of these rules.

Is a Significant Analysis required for this rule?

Yes.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

Under RCW 18.71.002, one of the purposes of the Commission is to regulate the competency and quality of professional health care providers under its jurisdiction by establishing consistent standards of practice. RCW 18.71.002 states that the Commission may develop rules to promote the delivery of quality health care to the residents of our state. There are no regulations or standards in our state for the use of these devices. The goal of the proposed rules is to promote patient safety by 1) clarifying this area of medicine and 2) by setting forth the conditions under which a physician or physician assistant may operate LLRP devices.

Currently, there are many offices and clinics around the state that use LLRP devices without the direct supervision of a physician or physician assistant. Some of the offices and clinics have a physician act as a "medical director." However, some of these offices and clinics do not require this physician to (a) be trained in the use of an LLRP device, (b) examine the patient to determine whether treatment with an LLRP device is appropriate for the patient's condition, (c) make sure the person administering the treatment is appropriately trained, (d) ensure the device is used in accordance with standard medical practice, (e) be on site for any treatments or have a back-up physician available to treat complications, (f) establish a quality assurance program, or (g) provide appropriate follow-up care. The rules specifically address each of these areas. This meets

the objective of RCW 18.71.002 by promoting the delivery of safe health care to our residents.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

In 2003, the Commission adopted a Policy on the Use of Lasers in Skin Care and Treatment. Since then, numerous energy-based, prescription devices have entered the market. The field is rapidly changing. The Commission has learned that many more offices and clinics using LLRP devices have opened since 2003. Some of them are not complying with the policy.

The rules are needed because the Commission's current policy is outdated and does not have the force of law. The Commission cannot take action against a practitioner based solely on a violation of the policy. The rules set clear standards for the safe use of LLRP devices, thereby promoting the delivery of quality health care to the residents of our state.

If no rules were adopted, there would continue to be almost no regulation in this area. More and more offices and clinics would offer treatment with LLRP devices with little, if any, physician supervision. The number of unlicensed, inadequately trained and unsupervised persons administering potentially dangerous treatment to patients would increase. This would undoubtedly result in patients being harmed during treatment.

Unlike in other states, the only recourse for patients who are harmed by unlicensed persons would be to sue the unlicensed persons. Thus, the decisions on who uses the devices and under what circumstances would be determined by market economics or the civil court system, rather than by what is best for patient safety.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The clear benefit of the rule is enhanced safety of patients undergoing treatment with an LLRP device, as explained above. Quantitative benefits may include avoided costs of patients who are harmed by LLRP devices and are required to undergo medical treatment to recuperate from injuries, and legal costs as a result of lawsuits to determine wrongdoing in the absence of clear regulatory guidance. Calculating quantitative benefits (costs averted / savings) of the proposed rule, i.e., the possible avoided costs of injuries, pain and suffering as a result of using LLRP devices is difficult and resource intensive.

The adopted rules will affect medical offices and clinics in the state of Washington providing treatment with LLRP devices as applied to the skin. Although the adopted rules apply only to physicians and physician assistants, the proposed rules potentially could indirectly affect beauty salons, boutiques, spas and other small cosmetic businesses that use LLRP devices without physician or physician assistant supervision because existing law defining scope of practice does not permit estheticians or others to operate these devices. However, the Department of Licensing is in the process of adopting a rule that will permit estheticians to use these devices only under the supervision and delegation of

a physician or physician assistant licensed under Chapter 18.71, 18.71A, 18.57, or 18.57A RCW. If the Department of Licensing rule is adopted, beauty salons, boutiques, spas and other small cosmetic businesses will have to hire at minimum a part time physician and a physician assistant to examine each patient, set up a treatment plan, and supervise the treatment. If they do not comply with the rules, they risk an investigation and the issuance of a Cease and Desist Order and a fine.

There are potential costs due to the implementation of this rule. Practitioners who have an LLRP device in their clinics will have to be trained to use the device properly if not already trained. The staff who is a licensed professional in which the use of LLRP devices are within their scope of practice will have to be trained to use the device properly if not already trained. A physician or physician assistant will have to see and examine each and every patient who wishes to undergo treatment with an LLRP device. The physician will have to contract with a back-up physician to provide treatment if there are complications. If a physician assistant delegates the use of an LLRP device, the physician assistant will have to be on site for each treatment. Each of these requirements may add to the cost of treatment with an LLRP device. On the other hand, the rules should decrease the cost of healthcare by reducing the severity or number of complications to patients.

The Commission believes improvement in the safety of patients undergoing treatment with LLRP devices will outweigh any potential increase in the cost of treatment.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

During the rules process, Department staff worked closely with the Commission, the Washington State Medical Association, the Department of Licensing (DOL) Cosmetology Program, persons using these devices, both licensed and non-licensed, and people associated with companies marketing devices to minimize the burden of these rules. This coordination also included working jointly with DOL staff as that program revises its cosmetology rules.

In the course of these efforts, the rules went through numerous drafts. One previous draft required the physician to be on site during each and every treatment with an LLRP device. This was modified to require the physician to be on site for the important initial treatment, to allow the initial treatment to continue if the physician is called away for an emergency, and to permit physicians to be temporarily absent during treatment for patients with established treatment plans so long as a back-up physician agrees to be reachable by phone and to respond to treat complications within sixty minutes.

Another proposal did not permit a physician assistant to delegate the use of the devices. The physician assistant rule was created to permit physician assistants to authorize the treatment and provide the same services as a physician, with the exception that the physician assistant must be on site for each and every treatment.

The Commission also considered an objection that the definition of devices was too broad, and should not include devices that use infrared, "or other forms of energy." The rules were modified to eliminate these devices from the scope of the rules.

There was objection to a provision in a prior draft that would have required the physician to use the device in accordance with the Intended Use Statement on file with the Food and Drug Administration. The objector believed this would preclude appropriate off-label uses of the device. The current rules merely require the physician to use the device "in accordance with standard medical practice."

The Commission has modified the proposed rules in response to feedback provided by persons who use these devices to make them less burdensome for those required to comply with it. It is noteworthy, that according to the Federation of State Medical Boards document on "Use of Lasers and Delegation of Medical Functions Regulations by State" the rules are less burdensome than the rules in most of the other states that regulate this area by permitting delegation to a broad range of licensed professionals, and not requiring on site supervision.

The current rules are the least burdensome to practitioners while still preserving necessary patient safety measures.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

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

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determines that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The first section of the rule states that it applies to devices that have been classified by the Federal Food and Drug Administration as prescription devices. The FDA regulates the manufacture of medical devices and enforcement is geared toward manufacturers

rather than end users. The FDA for the most part leaves the regulation of the use of the prescription devices to state law.

The use of prescriptive medical lasers in this state is largely unregulated. The few regulations that identify laser are found in RCW 18.53.010(8) optometrists may use laser instruments for diagnostic purposes. Both WAC 246-855-010 (Osteopathic physicians' acupuncture assistants) and WAC 246-918-310 (Physician assistants-MQAC) define acupuncture as including laser puncture. WAC 246-855-090 prohibits an osteopathic physician acupuncture assistant from performing laser puncture. And WAC 246-918-230 (Physician assistants-Surgical assistants -MQAC) states that a number of procedures are considered the practice of medicine, including assisting surgeons in opening incisions by use of any surgical method including laser, scalpel, scissors or cautery.

NO. 32055-3-III

**COURT OF APPEALS, DIVISION III
OF THE STATE OF WASHINGTON**

TYLER ARNOLD and
JASON SWANSON,

Petitioners,

v.

WASHINGTON STATE
DEPARTMENT OF HEALTH,

Respondent.

CERTIFICATE OF
SERVICE

I, TASHA G. DUSENBERY, state and declare as follows:

I am a citizen of the United States of America and over the age of 18 years and I am competent to testify to the matters set forth herein. On May 21, 2014, I served a true and correct copy of this **RESPONSE TO PETITIONERS' OPENING BRIEF** and this **CERTIFICATE OF SERVICE** by electronic mail and U.S. mail service to the following parties of this case:

RICHARD D. WALL, P.S.
505 W. RIVERSIDE AVE, STE 400
SPOKANE, WA 99201

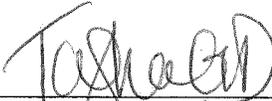
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US Mail Postage Prepaid
via Consolidated Mail Svc

Email

I certify under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct.

Dated this 21st day of May, 2014, at Tumwater, Washington.



TASHA G. DUSENBERY
Legal Assistant