PROPOSED RULE MAKING

CR-102 (June 2004)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: Department of Health- Medical Quality Assurance Commission

☑ **Preproposal Statement of Inquiry was filed as WSR 05-01-079 WSR 06-07-019 ; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR ; or**
☐ **Proposal is exempt under RCW 34.05.310(4).**

☑ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

Title of rule and other identifying information: (Describe Subject)
WAC 246-919-605 Use of Lasers, Light, Radiofrequency, and Plasma as Applied to the Skin (Physician) and WAC 246-918-125 Use of Lasers, Light, Radiofrequency and Plasma Devices as Applied to the Skin. (Physician Assistants)

Hearing location(s):
Red Lion River Inn
700 North Division
Spokane WA 99202

Date: August 25, 2006 **Time:** 8:00 a.m.

Submit written comments to:
Name:Beverly A. Thomas, Program Manager
Address:
PO Box 47866
Olympia Washington 98504

Web site: http://www3.doh.wa.gov/policyreview/
fax: 360-236-4768 **by (date)** 08/04/2006

Date of intended adoption: 08/25/2006
(Note: This is NOT the effective date)

Assistance for persons with disabilities: Contact Beverly A. Thomas by 08/04/2006
TTY (800) 833-6388 or ( ) 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
In 2004, the Medical Quality Assurance Commission (Commission) began rule making to develop rules to clarify the use of laser, light, radiofrequency and plasma devises (LLRP). A policy was adopted by the Commission in 2003, but rules need to be adopted to establish minimal standards for the use of such devices by physicians and physician assistants in Washington State. This proposal defines the use of LLRP devices, specfies who can operate a device and under what circumstances, specifies who can delegate the use of a device and under what circumstances, and outlines the degree of supervision required after delegationl The proposed new sections will protect the public from being harmed by unsupervised and untrained persons using LLRP devices.

Reasons supporting proposal:
Many offices and clinics in Washington are providing skin treatment or hair removal using 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 and other offices and clinics have cosmetologists, estheticians, and unlicensed persons administering the treatment. The Commission is concerned that unlicensed or inadequately trained persons are using prescriptive devices.

Statutory authority for adoption:
RCW 18.71.017 and RCW 18.71A.020

Statute being implemented:
RCW 18.130.050 (12)

Is rule necessary because of a:

Federal Law?	☐ Yes	☑ No
Federal Court Decision?	☐ Yes	☑ No
State Court Decision?	☐ Yes	☑ No

If yes, CITATION:

DATE
7/17/06

NAME (type or print)
Blake T. Maresh

SIGNATURE
Blake T. Maresh

TITLE
Executive Director

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CODE REVISER'S OFFICE
STATE OF WASHINGTON
FILED

JUL 19 2006

TIME 10:10 AM PM
WSR 06-15-130

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None

Name of proponent: (person or organization)
Department of Health Medical Quality Assurance Commission

☐ **Private**
☐ **Public**
☑ **Governmental**

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Beverly A. Thomas	310 Israel Road SE, Tumwater WA 98501	360-236-4788
Implementation	Beverly A. Thomas	310 Israel Road SE, Tumwater WA 98501	360-236-4788
Enforcement	Beverly A. Thomas	310 Israel Road SE, Tumwater WA 98501	360-236-4788

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

☑ Yes. Attach copy of small business economic impact statement.
A copy of the statement may be obtained by contacting:
Name:Beverly A. Thomas
Address:
PO Box 47866
Olympia WA 98501

phone: 360-236-4788
fax: 360-236-4768
e-mail: beverly.thomas@doh.wa.gov

☐ No. Explain why no statement was prepared.

Is a cost-benefit analysis required under RCW 34.05.328?

☑ Yes. A preliminary cost-benefit analysis may be obtained by contacting:
Name:Beverly A. Thomas, Program Manager
Address:
PO Box 47866
Olympia WA 98501

phone: 360-236-4788
fax: 360-236-4768
e-mail: beverly.thomas@doh.wa.gov

☐ No. Please explain:

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

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. Some offices and clinics have physician assistants and registered nurses using the devices; others have cosmetologists and estheticians; others have persons who hold no license administering the treatment. The Commission is concerned that unlicensed or inadequately trained persons are using prescriptive devices on patients.

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 and set minimal standards for the use of such devices by physicians and physician assistants in our state.

The proposed rule:

- Defines 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;
- Provides that a physician or physician assistant must use an LLRP device in accordance with standard medical practice;
- States that the use of an LLRP device is the practice of medicine;
- Requires 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;
- Requires 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;

- Permits a physician or physician assistant to delegate use of the device to a properly trained and licensed professional under certain circumstances, but requires the physician or physician assistant to develop a specific protocol for the licensed professional to follow;
- Prohibits a physician from delegating an LLRP for use on globe of the eye;
- Requires the delegating physician to be on the immediate premises during the initial treatment to treat complications, if indicated;
- Permits 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;
- Requires the delegating physician assistant to be on the premises during all treatment with an LLRP device.
- Provides that regardless of who operates the device, the physician is ultimately responsible for the safety of the patient.
- Requires the physician to establish a quality assurance program.
- Provides 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 proposed rules will affect medical offices and clinics in the state of Washington providing treatment with LLRP devices as applied to the skin. Although the proposed rules apply only to physicians and physician assistants, the proposed rules potentially could affect beauty salons, boutiques, spas and other small cosmetic businesses that use LLRP devices without physician or physician assistant supervision. If these businesses choose to comply with the rule, they will have to hire a physician to provide supervision.

SIC Industry Code and Title	# of Businesses	# of Employees	Average # of Employees for Smallest Businesses	Average # of Employees for 10% of Largest Businesses
8011 Offices and Clinics of Doctors of Medicine	2,821	43,659	7.9	70.6
7231 Beauty Shops	1,598	9,191	4.7	21.1
8049 Offices and Clinics of Health Practitioners, Not Elsewhere Classified	913	5,450	4.5	27.4

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?

The clear qualitative 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 injures, and legal costs as a result of lawsuits to determine wrongdoing in the absence of clear regulatory guidance.

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. Their staff will have to be trained to use the device properly. 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.

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

The proposed rules do impose a disproportionate impact on small businesses. The rule will require possible additional training that is usually provided by the marketing companies offering at no cost training regarding the devices. The physician may also take a continuing medical education course which costs an average of $225 for one course. However, the physicians and physician assistants are required at least 200 hours of continuing medical education every four years which may include the training required for these devices, so this does not impact the cost.

The proposed rules will require the physician or physician assistant to complete the initial physical and history of the patient prior to initiating any treatment. This cost will be charged to the patient or the patient's insurer.

The proposed rules will require the practitioner to delegate procedures to trained and licensed professionals. The cost impact to a physician's office may potentially increase by adding a physician assistant 2 days per week at $354 to supervise when the physician is not available, do medical examination and create treatment plans. A large clinic may add a physician assistant for 4 days a week that costs $708. Training for staff is generally offered by the laser companies at the time of purchase. The addition of the physician assistant's cost would ultimately fall on the client/patient who the procedure was performed.

The proposed rule will require physician assistants to be on-site during any treatment whether delegated or not. There is a cost to the physician assistant for the increase of the physician's supervision time. The cost for a supervising physician's time per hour is on average $100 to $400 per hour to be present. The supervising physician would be present at least 2 additional hours per week costing $800. A large practice would potentially increase the additional hours of the supervising physician time to 4 hours per week costing $1600. This cost would ultimately fall on the patient for whom the procedure is being performed.

Beauty salons, spas, boutiques or other small cosmetic businesses may be impacted by the proposed rules. At present, these businesses should not be using the devices defined by the FDA as medical prescriptive devices; and are considered practicing medicine without a license by the Department of Health (DOH). DOH will respond to any complaint received regarding unlicensed practice of medicine. After the completion of an investigation the result could be in a cease and desist order and payments of fines. This practice will continue after the rules are in place for those practicing medicine without a license.

The most reasonable solution for beauty salons, spas, boutiques or other cosmetic small businesses to comply with the proposed rules will be to hire a physician assistant with an approved practice plan to supervise, complete the history and physician examination, and direct all medical laser procedures. The physician assistant would need to be present on the days and when the lasers are used. The calculation for hiring of a physician assistant to be present 2 days per week costs $354. A large beauty salon may need to hire a physician assistant to be present 4 days per week costing $708. The beauty salon, spas, boutiques or other cosmetic small business would ultimately pass the cost onto the client/patient who the procedure is performed on.

The Medical Commission does not have a sense of how many lasers 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 proposed rule will require a backup physician for a physician if not available. This is a common practice among physicians.

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
8011 Offices and Clinics of Doctors of Medicine	7.9	70.6	$354	$708	$44.81	$9.99
7231 Beauty Shops	4.7	21.1	$354	$708	$75.32	$33.55
8049 Offices and Clinics of Health Practitioners, Not Elsewhere Classified	4.5	27.4	$800	$1600	$177.78	$58.39

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 Medical Commission's significantly reduced the regulatory requirements of the first proposed draft that 1) required only health care practitioners to use the devices, 2) required a physician assistant to be directly supervised, 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) estheticians 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 to 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 small as possible while still promoting safe medical care.

The Medical Commission has included the Department of Licensing Cosmetology Board during its rule process. Estheticians have attended the public meetings to provide comments. The proposed rules were modified to allow physicians or physician assistants to delegate to a licensed professional rather than a licensed health care provider, in order to include estheticians currently working with physicians.

NEW SECTION

WAC 246-918-125 Use of laser, light, radiofrequency, and plasma devices 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

(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.

(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.

PHYSICIAN ASSISTANT RESPONSIBILITIES

(4) A physician assistant must be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such a device, and must remain competent for as long as the device is used.

(5) A physician assistant may use an LLRP device so long as it is with the consent of the sponsoring or supervising physician, it is in compliance with the practice arrangement plan approved by the commission, and it is in accordance with standard medical practice.

(6) Prior to authorizing treatment with an LLRP device, a physician assistant must take a 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 nonphysician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record.

PHYSICIAN ASSISTANT DELEGATION OF LLRP TREATMENT

(7) A physician assistant who meets the above requirements may delegate an LLRP device procedure to a properly trained and licensed professional, whose licensure and scope of practice allow the use of an LLRP device provided all the following conditions are met:

(a) The treatment in no way involves surgery as that term is understood in the practice of medicine;

(b) Such delegated use falls within the supervised professional's lawful scope of practice;

(c) The LLRP device is not used on the globe of the eye; and

(d) The supervised professional has appropriate training in, at a minimum, application techniques of each LLRP device, cutaneous medicine, indications and contraindications for such procedures, preprocedural and postprocedural care, potential complications and infectious disease control involved with each treatment.

(e) The delegating physician assistant has written office protocol for the supervised professional to follow in using the LLRP device. A written office protocol must include at a minimum the following:

(i) The identity of the individual physician assistant authorized to use the device and responsible for the delegation of the procedure;

(ii) A statement of the activities, decision criteria, and plan the supervised professional must follow when performing procedures delegated pursuant to this rule;

(iii) Selection criteria to screen patients for the appropriateness of treatments;

(iv) Identification of devices and settings to be used for patients who meet selection criteria;

(v) Methods by which the specified device is to be operated and maintained;

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

(vii) A statement of the activities, decision criteria, and plan the supervised professional shall follow when performing delegated procedures, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician assistant concerning specific decisions made. Documentation shall be recorded after each procedure, and may be performed on the patient's record or medical chart.

(f) The physician assistant is responsible for ensuring that the supervised professional uses the LLRP device only in accordance with the written office protocol, and does not exercise independent medical judgment when using the device.

(g) The physician assistant shall be on the immediate premises during any use of an LLRP device and be able to treat complications, provide consultation, or resolve problems, if indicated.

NEW SECTION

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

(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.

(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.

PHYSICIAN RESPONSIBILITIES

(4) A physician must be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such a device, and must remain competent for as long as the device is used.

(5) A physician must use an LLRP device in accordance with standard medical practice.

(6) Prior to authorizing treatment with an LLRP device, a physician must take a 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 nonphysician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record.

(7) Regardless of who performs LLRP device treatment, the physician is ultimately responsible for the safety of the patient.

(8) Regardless of who performs LLRP device treatment, the physician is responsible for assuring that each treatment is documented in the patient's medical record.

(9) The physician must ensure that there is a quality assurance program for the facility at which LLRP device procedures are performed regarding the selection and treatment of patients. An appropriate quality assurance program shall include the following:

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

(b) A mechanism to review the adherence of supervised

professionals to written protocols;

(c) A mechanism to monitor the quality of treatments;

(d) A mechanism by which the findings of the quality assurance program are reviewed and incorporated into future protocols required by subsection (10)(d) of this section and physician supervising practices; and

(e) Ongoing training to maintain and improve the quality of treatment and performance of treating professionals.

PHYSICIAN DELEGATION OF LLRP TREATMENT

(10) A physician who meets the above requirements may delegate an LLRP device procedure to a properly trained and licensed professional, whose licensure and scope of practice allow the use of an LLRP device, provided all the following conditions are met:

(a) The treatment in no way involves surgery as that term is understood in the practice of medicine;

(b) Such delegated use falls within the supervised professional's lawful scope of practice;

(c) The LLRP device is not used on the globe of the eye;

(d) A physician has a written office protocol for the supervised professional to follow in using the LLRP device. A written office protocol must include at a minimum the following:

(i) The identity of the individual physician authorized to use the device and responsible for the delegation of the procedure;

(ii) A statement of the activities, decision criteria, and plan the supervised professional must follow when performing procedures delegated pursuant to this rule;

(iii) Selection criteria to screen patients for the appropriateness of treatments;

(iv) Identification of devices and settings to be used for patients who meet selection criteria;

(v) Methods by which the specified device is to be operated and maintained;

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

(vii) A statement of the activities, decision criteria, and plan the supervised professional shall follow when performing delegated procedures, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made;

(e) The supervised professional has appropriate training in, at a minimum, application techniques of each LLRP device, cutaneous medicine, indications and contraindications for such procedures, preprocedural and postprocedural care, potential complications and infectious disease control involved with each treatment;

(f) The delegating physician ensures that the supervised professional uses the LLRP device only in accordance with the written office protocol, and does not exercise independent medical judgment when using the device;

(g) The delegating physician shall be on the immediate premises during the patient's initial treatment and be able to treat complications, provide consultation, or resolve problems, if indicated. The supervised professional may complete the initial treatment if the physician is called away to attend to an

emergency;

(h) Existing patients with an established treatment plan may continue to receive care during temporary absences of the delegating physician provided that there is a local back-up physician who satisfies the requirements of subsection (4) of this section. The local back-up physician must agree in writing to treat complications, provide consultation or resolve problems if medically indicated. The local back-up physician shall be reachable by phone and able to see the patient within sixty minutes.

(11) The use of, or the delegation of the use of, an LLRP device by a physician assistant is covered by WAC 246-918-125.