



# RULE-MAKING ORDER

**CR-103 (June 2004)**  
**(Implements RCW 34.05.360)**

**Agency:** Department of Health- Board of Osteopathic Medicine and Surgery.

**Permanent Rule**  
 **Emergency Rule**

**Effective date of rule:**  
**Permanent Rules**  
 31 days after filing.  
 Other (specify) (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

**Effective date of rule:**  
**Emergency Rules**  
 Immediately upon filing.  
 Later (specify)

**Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?**  
 Yes  No If Yes, explain:

**Purpose:** The adopted rules will clarify that the use of laser, light, radiofrequency, and plasma (LLRP) devices classified as prescriptive medical devices by the Food and Drug Administration are the practice of osteopathic medicine. The adopted rules define delegation and supervision for the use of LLRP devices by osteopathic physicians and osteopathic physician assistants.

**Citation of existing rules affected by this order:**  
Repealed: None  
Amended: None  
Suspended: None

**Statutory authority for adoption:** RCW 18.57.005, RCW 18.57A.020, RCW 18.130.050

**Other authority:**

**PERMANENT RULE ONLY (Including Expedited Rule Making)**

Adopted under notice filed as WSR 08-13-093 on 06/18/2008 (date).  
Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: Erin Obenland phone (360)236-4945  
Address: Board of Osteopathic Medicine and Surgery fax (360)236-2406  
PO Box 47866 e-mail erin.obenland@doh.wa.gov

**EMERGENCY RULE ONLY**

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding:

**Date adopted:** 07/25/2008

**NAME (TYPE OR PRINT)**  
Blake Maresh

**SIGNATURE**

**TITLE**  
Executive Director

**CODE REVISER USE ONLY**

CODE REVISER'S OFFICE  
STATE OF WASHINGTON  
FILED

1 2008

8:47  
08.20.125

AM  
PM

(COMPLETE REVERSE SIDE)

Filed Oct 1, 2008

**Note: If any category is left blank, it will be calculated as zero.  
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.  
A section may be counted in more than one category.**

**The number of sections adopted in order to comply with:**

<b>Federal statute:</b>	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
<b>Federal rules or standards:</b>	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
<b>Recently enacted state statutes:</b>	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

**The number of sections adopted at the request of a nongovernmental entity:**

	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
--	-----	----------	---------	----------	----------	----------

**The number of sections adopted in the agency's own initiative:**

	New	<u>2</u>	Amended	<u>0</u>	Repealed	<u>0</u>
--	-----	----------	---------	----------	----------	----------

**The number of sections adopted in order to clarify, streamline, or reform agency procedures:**

	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
--	-----	----------	---------	----------	----------	----------

**The number of sections adopted using:**

<b>Negotiated rule making:</b>	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
<b>Pilot rule making:</b>	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
<b>Other alternative rule making:</b>	New	<u>2</u>	Amended	<u>0</u>	Repealed	<u>0</u>

NEW SECTION

WAC 246-853-630 Use of laser, light, radiofrequency, and plasma devices as applied to the skin. (1) For the purposes of this section, laser, light, radiofrequency, and plasma (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 prescriptive devices.

(2) Because an LLRP device is used to treat disease, injuries, deformities, and other physical conditions in human beings, the use of an LLRP device is the practice of osteopathic medicine under RCW 18.57.001. 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 those in subsection (1) of this section constitutes surgery and is outside the scope of this section.

OSTEOPATHIC PHYSICIAN RESPONSIBILITIES

(4) An osteopathic 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) An osteopathic physician must use an LLRP device in accordance with standard medical practice.

(6) Prior to authorizing treatment with an LLRP device, an osteopathic 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 an allied health care professional 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 osteopathic physician is ultimately responsible for the safety of the patient.

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

(9) The osteopathic 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 problematic effects of treatment and to determine their cause;
- (b) A mechanism to review the adherence of supervised allied health care professionals to written protocols;
- (c) A mechanism to monitor the quality of treatments;
- (d) A mechanism by which the findings of the quality assurance program are reviewed and incorporated into future protocols required by subsection (10) (d) of this section and osteopathic physician supervising practices; and
- (e) Ongoing training to maintain and improve the quality of treatment and performance of the treating allied health care professionals.

#### OSTEOPATHIC PHYSICIAN DELEGATION OF LLRP TREATMENT

(10) An osteopathic physician who meets the requirements in subsections (1) through (9) of this section may delegate an LLRP device procedure to a properly trained allied health care professional licensed under the authority of RCW 18.130.040, whose scope of practice allows the use of a prescriptive LLRP medical 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 osteopathic medicine;
- (b) Such delegated use falls within the supervised allied health care professional's lawful scope of practice;
- (c) The LLRP device is not used on the globe of the eye;
- (d) An osteopathic physician has a written office protocol for the supervised allied health care 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 osteopathic physician authorized to use the LLRP device and responsible for the delegation of the procedure;
  - (ii) A statement of the activities, decision criteria, and plan the supervised allied health care 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 allied health care professional shall follow when performing delegated procedures, including the method for documenting decisions made and a plan for communication or feedback to the authorizing osteopathic physician concerning specific decisions made;
- (e) The supervised allied health care professional has appropriate training including, but not limited to:
  - (i) Application techniques of each LLRP device;

- (ii) Cutaneous medicine;
  - (iii) Indications and contraindications for such procedures;
  - (iv) Preprocedural and postprocedural care;
  - (v) Potential complications; and
  - (vi) Infectious disease control involved with each treatment;
- (f) The delegating osteopathic physician ensures that the supervised allied health care 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 osteopathic 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 allied health care 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 osteopathic physician provided there is a local back-up physician, licensed under chapter 18.57 or 18.71 RCW, 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. In case of an emergency the delegating osteopathic physician or a 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 an osteopathic physician assistant is covered by WAC 246-854-220.
- (12) This section only applies to the use of LLRP devices by osteopathic physicians and osteopathic physician assistants.

## NEW SECTION

**WAC 246-854-220 Use of laser, light, radiofrequency, and plasma devices as applied to the skin.** (1) For the purposes of this section, laser, light, radiofrequency, and plasma (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 prescriptive devices.

(2) Because an LLRP device is used to treat disease, injuries, deformities and other physical conditions of human beings, the use of an LLRP device is the practice of osteopathic medicine under RCW 18.57.001. 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 those in subsection (1) of this section constitutes surgery and is outside the scope of this section.

### OSTEOPATHIC PHYSICIAN ASSISTANT RESPONSIBILITIES

(4) An osteopathic physician assistant may use an LLRP device with the consent of the sponsoring or supervising osteopathic physician who meets the requirements under WAC 246-853-630, is in compliance with the practice arrangement plan approved by the board, and in accordance with standard medical practice.

(5) An osteopathic 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.

(6) Prior to authorizing treatment with an LLRP device, an osteopathic 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 an allied health care practitioner may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record.

### OSTEOPATHIC PHYSICIAN ASSISTANT DELEGATION OF LLRP TREATMENT

(7) An osteopathic physician assistant who meets the above requirements may delegate an LLRP device procedure to a properly trained allied health care professional licensed under the authorization of RCW 18.130.040, whose scope of practice allows the use of a prescriptive LLRP medical 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 allied health care professional's lawful scope of practice;

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

(d) The supervised allied health care professional has appropriate training including, but not limited to:

(i) Application techniques of each LLRP device;

(ii) Cutaneous medicine;

(iii) Indications and contraindications for such procedures;

(iv) Preprocedural and postprocedural care;

(v) Potential complications; and

(vi) Infectious disease control involved with each treatment;

(e) The delegating osteopathic physician assistant has written office protocol for the supervised allied health care 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 osteopathic 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 allied health care 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 allied health care professional shall follow when performing delegated procedures, including the method for documenting decisions made and a plan for communication or feedback to the authorizing osteopathic physician assistant concerning specific decisions made. Documentation shall be recorded after each procedure on the patient's record or medical chart;

(f) The osteopathic physician assistant is responsible for ensuring that the supervised allied health care 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 osteopathic 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.

October 9, 2008

TO: Mary C. Selecky  
Secretary

FROM: Erin Obenland, Program Manager

SUBJECT: **CONCISE EXPLANATORY STATEMENT FOR WAC 246-853-630 Use of laser, light, radiofrequency, and plasma devices as applied to the skin (Osteopathic Physicians); WAC 246-854-220 Use of laser, light, radiofrequency, and plasma devices as applied to the skin (Osteopathic physician assistants)**

1. Identify the agency's reasons for adopting this rule.

The use of a laser, light, radiofrequency, and plasma (LLRP) device penetrates and alters human tissue and can result in complications such as visual impairment, blindness, inflammation, burns, scarring, hypopigmentation, and hyperpigmentation. The Board of Osteopathic Medicine and Surgery is concerned that individuals who have little or no formal medical training may be using the devices inappropriately and without adequate medical oversight and supervision. The adopted rules clarify the use of LLRP devices and define delegation and supervision for the use of LLRP devices by osteopathic physicians and osteopathic physician assistants.

2. Is the adopted rule different from the text of the proposed rule as published in the Washington State Register? YES  or NO   
If yes, explain why the rule was changed.

3. By category or subject matter, summarize all comments received since filing the CR-102 regarding the proposed rule, program's responses, and either how the final rule reflects agency consideration of those comments or why the agency cannot use those comments.

There were no comments received regarding the proposed rule.

4. Describe any remaining public opposition to the rule.

There was no opposition.

Any questions regarding this rule adoption should be directed to Erin Obenland at (360) 236-4945.

Attachments:

CR-103 form

Final OTS copy of rule

Rule Implementation Plan (for significant rules only)

Final Cost of Rulemaking