



PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: June 21, 2024

TIME: 9:31 AM

WSR 24-14-013

Agency: Health Care Authority

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

- Preproposal Statement of Inquiry was filed as WSR 24-10-047 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or
- Proposal is exempt under RCW _____.

Title of rule and other identifying information: (describe subject) 182-543-3300, Covered – Osteogenesis electrical stimulator (bone growth stimulator)

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
August 6, 2024	10:00 AM	The Health Care Authority holds public hearings virtually without a physical meeting place	To attend the virtual public hearing, you must register in advance: https://us02web.zoom.us/webinar/register/WN_I CtK0VXGQXCIK3UtUFFypw If the link above opens with an error message, please try using a different browser. After registering, you will receive a confirmation email containing information about joining the public hearing

Date of intended adoption: Not sooner than August 7, 2024 (Note: This is **NOT** the effective date)

Submit written comments to: Name HCA Rules Coordinator Address PO Box 42716, Olympia WA 98504-2716 Email arc@hca.wa.gov Fax 360-586-9727 Other Beginning (date and time) <u>June 25, 2024, 8:00 AM</u> By (date and time) <u>August 6, 2024, by 11:59 PM</u>	Assistance for persons with disabilities: Contact Johanna Larson Phone 360-725-1349 Fax 360-586-9727 TTY Telecommunication Relay Service (TRS): 711 Email Johanna.Larson@hca.wa.gov Other By (date) <u>July 26, 2024</u>
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Purpose of the proposal and its anticipated effects, including any changes in existing rules: The agency is amending WAC 182-543-3300 to update medical necessity criteria based on evidence review(s).

Reasons supporting proposal: See Purpose

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Statute being implemented: RCW 41.05.021, 41.05.160

Is rule necessary because of a:

- Federal Law? Yes No
- Federal Court Decision? Yes No
- State Court Decision? Yes No

If yes, CITATION:

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

Name of proponent: (person or organization)
Type of proponent: Private. Public. Governmental.

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Brian Jensen	PO Box 42716, Olympia, WA 98504-2716	360-725-0815
Implementation	Dani Crawford	PO Box 45502, Olympia, WA 98504-5502	360-725-0983
Enforcement	Dani Crawford	PO Box 45502, Olympia, WA 98504-5502	360-725-0983

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No
 If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name
 Address
 Phone
 Fax
 TTY
 Email
 Other

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

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

Name
 Address
 Phone
 Fax
 TTY
 Email
 Other

No: Please explain: RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

Regulatory Fairness Act and Small Business Economic Impact Statement
 Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:
 This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.
 Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

- This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:
- | | |
|---|---|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input type="checkbox"/> RCW 34.05.310 (4)(g)
(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

- This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#). (Does not affect small businesses).
- This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: This rule proposal updates the criteria under which the medicaid agency pays for a client's bone growth stimulator. This rule proposal does not impose costs on businesses.

(2) Scope of exemptions: *Check one.*

- The rule proposal: Is fully exempt. (*Skip section 3.*) Exemptions identified above apply to all portions of the rule proposal.
- The rule proposal: Is partially exempt. (*Complete section 3.*) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):
- The rule proposal: Is not exempt. (*Complete section 3.*) No exemptions were identified above.


(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs. _____
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

- Name
- Address
- Phone
- Fax
- TTY
- Email
- Other

Date: June 24, 2024	Signature: 
Name: Wendy Barcus	
Title: HCA Rules Coordinator	

WAC 182-543-3300 Covered—Osteogenesis electrical stimulator (bone growth stimulator)—Noninvasive. (1) The medicaid agency covers, with prior authorization, noninvasive osteogenesis electrical stimulators, also known as bone growth stimulators, limited to one per client, in a five-year period.

(2) The agency pays for the purchase of nonspinal bone growth stimulators, only when:

(a) The stimulators have pulsed electromagnetic field (PEMF) ~~((simulation))~~ stimulation; and

(b) The client meets one or more of the following clinical criteria:

(i) Has a nonunion of a long bone fracture (which includes clavicle, humerus, phalanx, radius, ulna, femur, tibia, fibula, metacarpal and metatarsal) where three months have elapsed since the date of injury without healing; or

(ii) Has a failed fusion of a joint, other than in the spine, where a minimum of nine months has elapsed since the last surgery; or

(iii) Diagnosed with congenital pseudarthrosis.

(3) The agency pays for the purchase of spinal bone growth stimulators, when:

(a) Prescribed by a neurologist, an orthopedic surgeon, or a neurosurgeon; and

(b) The client meets one or more of the following clinical criteria:

(i) Has a failed spinal fusion where a minimum of nine months ~~((have))~~ has elapsed since the last surgery; or

(ii) Is post-op from a multilevel spinal fusion surgery; or

(iii) Is post-op from spinal fusion surgery and there is a history of a previously failed spinal fusion.

(4) The agency pays for the purchase of ultrasonic noninvasive bone growth stimulators when:

(a) Prescribed by a neurologist, an orthopedic surgeon, or a neurosurgeon; and

(b) The client meets all the following clinical criteria:

(i) Nonunion confirmed by two radiographs minimum 90 days apart;
and

(ii) Physician statement of no clinical evidence of fracture healing.