PROPOSED RULE MAKING



CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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DATE: July 02, 2018 TIME: 12:11 PM

WSR 18-14-087

Agency: Department of Health- Board of Naturopathy							
⊠Original Notice							
☐ Supplemental Notice to WSR							
☐Continuance of WSR							
☑Preproposal Statement of Inquiry was filed as WSR <u>13-22-059</u> ; or							
Expedited Rule MakingProposed notice was filed as WSR; or							
Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).							
Proposal is exempt under RCW.							
Title of rule and other identifying information: (describe subject) WAC 246-836-210 Authority to use, prescribe, dispense and order (amending) and WAC 246-836-212 Non-surgical medical cosmetic procedures (new section) - The Board of Naturopathy (board) is proposing an amendment to an existing rule and proposing to add a new section of rule to address the practice of non-surgical cosmetic procedures performed by naturopathic physicians.							
Hearing location(s):							
Date:	Time:	Location: (be specific)	Comment:				
09/07/2018	1:00 pm	Department of Health Town Center 2 (TC2) Room 145 111 Israel Road SE Tumwater, WA 98501					
Date of intended ado	ption: <u>09/07</u>	7/2018 (Note: This is NOT the effe	ctive date)				
Submit written comm	ents to:						
Name: Susan Gragg Address: PO Box 47852 Olympia, WA 98504-7852 Email: https://fortress.wa.gov/doh/policyreview Fax: 360-236-2901 Other: By (date) 08/31/2018							
Assistance for persons with disabilities:							
Contact Susan Gragg Phone: 360-236-4941 Fax:							
TTY: (360) 833-6388 d							
Email: susan.gragg@c	ion.wa.gov						
Other: By (date) <u>08/31/2018</u>							
Purpose of the proposal and its anticipated effects, including any changes in existing rules: The board is							
proposing an amendment to an existing rule and proposing to add a new section of rule to clarify the practice of non-surgical cosmetic procedures performed by naturopathic physicians, and adds training and practice requirements for those naturopathic physicians who choose to perform them.							

Reasons supporting proposal: The proposed rule is necessary to set minimum standards for the performance of non-surgical cosmetic procedures by naturopathic physicians and ensure that naturopathic physicians performing these							
procedures apply the same, consistent standard of good medical practice as a similar, prudent health care practitioner.							
Statutory author	ity for adoption: RCW 18.36A	A.160					
Statute being im	plemented: Chapter 18.36A F	RCW					
Is rule necessary	y because of a:						
Federal La	☐ Yes ☒ No						
Federal Co State Cour	☐ Yes ⊠ No ☐ Yes ⊠ No						
If yes, CITATION	1c3						
Agency commer matters: Non		ny, as to statutory language, implementation, o	enforcement, and fiscal				
mattere.	.						
Name of propen	ent (norman or organization)	Washington State Board of Naturanathy	☐ Private				
Name of propon	ent: (person or organization)	Washington State Board of Naturopathy	☐Private ☐Public				
			⊠Governmental				
Name of agency	personnel responsible for:						
	Name	Office Location	Phone				
Drafting:	Susan Gragg	111 Israel Road SE, Tumwater, WA 98501	360-236-4941				
Implementation:	Susan Gragg	111 Israel Road SE, Tumwater, WA 98501	360-236-4941				
Enforcement:	Susan Gragg	111 Israel Road SE, Tumwater, WA 98501	360-236-4941				
Is a school distri	-	equired under RCW 28A.305.135?	☐ Yes ⊠ No				
ii yes, iiiseri state	anent nere.						
•	y obtain a copy of the school d	listrict fiscal impact statement by contacting:					
Name: Address	. .						
Phone:	o.						
Fax:							
TTY:	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: Susan Gragg							
Address: PO Box 47852							
Olympia, WA 98504-7852 Phone: 360-236-4941							
Fax: 360-236-4941							
TTY: (360) 833-6388 or 711							
Email: susan.gragg@doh.wa.gov							
Other:							
☐ No: Plea	☐ No: Please explain:						

Regulatory	Fairness Act Cost Considerations for a Smal	l Busine	ss Economic Impact Statement:					
This rule proposal, or portions of the proposal, may be exempt from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). 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	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								
	a referendum.		o promoter a contract (2) a contract in mass					
☐ This rule	proposal, or portions of the proposal, is exempt	under R	CW 19.85.025(3). Check all that apply:					
	RCW 34.05.310 (4)(b)		RCW 34.05.310 (4)(e)					
	(Internal government operations)		(Dictated by statute)					
	RCW 34.05.310 (4)(c)		RCW 34.05.310 (4)(f)					
	(Incorporation by reference)		(Set or adjust fees)					
	RCW 34.05.310 (4)(d)		RCW 34.05.310 (4)(g)					
	(Correct or clarify language)		((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 R	CW.					
Explanation	of exemptions, if necessary:							
	COMPLETE THIS SECTION O	MIVE	NO EXEMPTION APPLIES					
COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES If 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 analysis showing how costs were calculated. No SBEIS is required because although the proposed rules do have a more-than-minor cost, that cost is a one-time cost, is only for those practitioners choosing to perform the non-surgical cosmetic procedures, and will be more than offset by the expected new revenue that will come in to providers through being able to offer these additional health care services. The cost of the one-time training is expected to be approximately \$1,700; this is more than the threshold of \$1,138 but the new expected income would be a new on-going revenue stream. The cost impact threshold is calculated as follows: Payroll-based threshold for an average establishment in this NAICS code 621399 (Offices of All Other Miscellaneous Health Practitioners) that would be affected by these proposed rules is \$1,138 (103,873*1000/913)*(0.01) = \$1,138 where 108,873*1000 is Annual payroll and 913 is Total Establishments for this NAICS. Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert 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:								
Ot	her:	r = -						
Date: 07/02/	2018	Signatu	re:					
Name: Blake Maresh			Blk 7. Much					
Title: Executive Director			DUL 1. MING					

AMENDATORY SECTION (Amending WSR 12-13-104, filed 6/20/12, effective 7/21/12)

WAC 246-836-210 Authority to use, prescribe, dispense and order.

- (1) Naturopathic medical practice includes the prescription, administration, dispensing, and use of:
- (a) Nutrition and food science, physical modalities, minor office procedures, homeopathy, hygiene, and immunizations/vaccinations;
 - (b) Contraceptive devices;
- (c) Nonlegend medicines including vitamins, minerals, botanical medicines, homeopathic medicines, and hormones;
- (d) Legend drugs as defined under RCW 69.41.010 ((with the exception of Botulinum Toxin (commonly known as, among other names, Botox, Vistabel, Dysport, or Neurobloc) and inert substances used for cosmetic purposes)); and
- (e) Codeine and testosterone products that are contained within Schedules III, IV, and V in chapters 69.50 RCW and 246-887 WAC.
- (2) In accordance with RCW 69.41.010(13), all prescriptions must be hand-printed, typewritten, or generated electronically.
- (3) Prior to being allowed to administer, prescribe, dispense, or order controlled substances, a naturopathic physician must meet the requirements in WAC 246-836-211 and have obtained the appropriate registration issued by the Federal Drug Enforcement Administration.
- (4) Naturopathic physicians may not treat malignancies except in collaboration with a practitioner licensed under chapter 18.57 or 18.71 RCW.

NEW SECTION

WAC 246-836-212 Nonsurgical medical cosmetic procedures. (1) Prior to performing a nonsurgical cosmetic procedure, a naturopathic physician must establish a physician/patient relationship which includes, but is not limited to:

- (a) Taking a history;
- (b) Performing an appropriate physical examination;
- (c) Making an appropriate diagnosis;
- (d) Recommending appropriate treatment;
- (e) Obtaining the patient's informed consent;
- (f) Providing instructions for emergency and follow-up care; and
- (g) Preparing an appropriate medical record.
- (2) The naturopathic physician is responsible for:
- (a) The safety of the patient;
- (b) Performing the nonsurgical medical cosmetic procedure in accordance with standard medical practice; and
- (c) Ensuring that each treatment is documented in the patient's medical record.
- (3) Prior to being allowed to prescribe and administer botulinum toxins (commonly known as, among other names, Botox, Vistabel, Dysport, or Neurobloc) and inert substances consistent with naturopathic scope of practice used for cosmetic purposes, naturopathic physicians must be appropriately trained in aesthetic injectable techniques. Such training must:

[1] OTS-9334.3

- (a) Be obtained through a certifying body or organization that is:
 - (i) Accredited or nationally recognized;
 - (ii) A recognized entity as defined in WAC 246-836-080;
- (iii) Part of a council on naturopathic medical education (CNME) accredited residency; or
- (iv) Conducted through in-person training substantially equivalent to those trainings in (a)(i) through (iii) of this subsection by a qualified individual holding an active license that includes the authority to prescribe and administer botulinum toxins and inert substances.
- (b) Be a combination of hands-on training and training in pharma-cology that pertains to aesthetics and must also include:
 - (i) Criteria for the selection and treatment of patients;
 - (ii) Indications and contraindications for each procedure;
 - (iii) Preprocedural and postprocedural care;
- (iv) Recognition and acute management of potential complications; and
 - (v) Infectious disease control.