PROPOSED RULE MAKING



Other: naturopathy@doh.wa.gov

By (date) 04/04/2022

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

Do NOT use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER STATE OF WASHINGTON FILED

DATE: February 23, 2022

TIME: 8:42 AM

WSR 22-06-025

Agency: Department	t of Health- B	soard of Naturopathy	
⊠Original Notice			
□Supplemental No	tice to WSR		
☐Continuance of W	/SR		
⊠Preproposal State	ement of Inc	uiry was filed as WSR 21-16-030;	or
☐Expedited Rule M	lakingProp	osed notice was filed as WSR ; or	
☐Proposal is exem	pt under RC	SW 34.05.310(4) or 34.05.330(1).	
☐Proposal is exem	-		
hydrotherapists and \(\) (board) is proposing a	NAC 246-830 a new chapte profession. T	er of rule and two new sections of rule	Chapter 246-836A WAC (New), Colon ns), Naturopathic physicians. The Board of Naturopathy e to implement Senate Bill 5124 which created the sh the education, training, affiliation relationship, and
Hearing location(s)			
Date:	Time:	Location: (be specific)	Comment:
04/08/2022	1:00 pm	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the Board of Naturopathy will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. A virtual public hearing, without a physical meeting space, will be held instead. Register in advance for this webinar: https://attendee.gotowebinar.com/register/4522694167139040781 After registering, you will receive a confirmation email containing information about joining the webinar.	
	-	2022 (Note: This is NOT the effective	ve date)
Submit written com	ments to:		
	x 47852 VA 98504-78 .wa.gov/doh/		

Assistance for p	ersons with disabilities:					
Contact Susan Gr						
Phone: 360-236-4						
Fax: 360-236-290 TTY: 711	1					
Email: naturopath	v@doh wa gov					
Other: N/A	y @ don.wa.gov					
By (date) <u>04/01/20</u>	022					
		effects, including any changes in existing rules:				
implement Senate Bill (SB) 5124 (chapter 179, Laws of 2021) which created a new profession in the State of Washington, known as colon hydrotherapists. The board is proposing rules that establish the new profession's education and examination requirements, standards for affiliation relationships between colon hydrotherapists and supervising naturopathic physicians, and certification requirements.						
Reasons supporting proposal: The board proposes these rules to align with the requirements of chapter 18.36A RCW and legislative intent of SB 5124. Rules are needed to establish the regulatory framework for regulating colon hydrotherapists. In addition, the board proposes rules establishing standards for patient referral, the provision of supervision, patient care communication, the use of appropriate equipment, safety and consent procedures, and transfer for patients needing a higher level of care.						
Statutory author	ity for adoption: RCW 18.36/	A.160 and 18.36A.095				
Statute being im	plemented: SB 5124 (chapter	179 Laws of 2021)				
	promonioni ob o : 2 i (enapter	1. o, Lawo o. 2021)				
Is rule necessary	because of a:					
Federal Lav	w?		☐ Yes ⊠ No			
Federal Co	urt Decision?		☐ Yes ⊠ No			
State Court			☐ Yes ⊠ No			
If yes, CITATION:						
matters: N/A	its or recommendations, if a	ny, as to statutory language, implementation, e	morcement, and fiscal			
Name of propone	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 If yes, insert state		equired under RCW 28A.305.135?	☐ Yes ⊠ No			
The public may Name: Address Phone: Fax: TTY: Email:		listrict fiscal impact statement by contacting:				

Other:	
Is a cost-benefit analy	sis required under RCW 34.05.328?
Yes: A prelimin	ary cost-benefit analysis may be obtained by contacting:
Name: Susar	ı Gragg
Address: PC) Box 47852
Oly	ympia, WA 98504-7852
Phone: 360-2	36-4941
Fax: 360-236	-2901
TTY: 711	
Email: naturo	pathy@doh.wa.gov
Other:	
□ No: Please ex	plain:

Regulatory Fairness Act Cost Considerations for a Small Business 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 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.							
	e proposal, or portions of the proposal, is exer	mpt under F	RCW 19.85.025(3). Check all that apply:				
Гп	RCW 34.05.310 (4)(b)	· 🗆	RCW 34.05.310 (4)(e)				
	(Internal government operations)		(Dictated by statute)				
	RCW 34.05.310 (4)(c)	П	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				
☐ Thio mul	a proposal or partiana of the proposal is ever	mnt under F	or permit)				
	e proposal, or portions of the proposal, is exer	npt under R	CVV.				
Explanation	n of exemptions, if necessary:						
	COMPLETE THIS SECTION	N ONLY IF	NO EXEMPTION APPLIES				
If the propo	sed 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 sho	wing how c	osts were calculated. The proposed rules do not apply to				
busines		wing now c	osts were calculated. The proposed raies do not apply to				
Yes	Calculations show the rule proposal likely im	poses more	e-than-minor cost to businesses, and a small business				
econom	ic impact statement is required. Insert statement	ent here:					
	public may obtain a copy of the small business acting:	s economic	impact statement or the detailed cost calculations by				
N	ame:						
Address:							
Phone:							
Fax:							
	TY:						
	mail: hther:						
Date: 02/23		Signati	ure:				
Name: Renee Fullerton			D 211-				
Title: Executive Director			Revertubleaton				

- WAC 246-836-300 Affiliation relationships for colon hydrotherapy. (1) A naturopathic physician must establish an affiliation relationship with a colon hydrotherapist to allow the colon hydrotherapist to perform colon hydrotherapy on a patient of the naturopathic physician. Such affiliation relationships must be registered with the board on forms provided by the board and will remain in effect until rescinded by either practitioner.
- (2) A naturopathic physician who has a registered affiliation relationship with a colon hydrotherapist and desires to terminate such relationship must provide a minimum of 60 days' notice prior to submitting documentation to the board rescinding that relationship.
- (3) A naturopathic physician may enter into registered affiliation relationships with up to a maximum of 20 colon hydrotherapists but may petition the board for a waiver of this limit.
- (4) Affiliation relationships must be fully documented, signed by both practitioners with copies maintained by each practitioner, and available upon request by the board or its designee. Such affiliation relationship documentation must include, at a minimum:
- (a) Communication of a patient's plan of care to include the methods and process for shared documentation of treatment;
- (b) Standards for patient referral, to include an expiration date of the referral or the total number of colon hydrotherapy treatments to be provided within a specified time frame. Unless otherwise stated, such referral shall not exceed 24 treatments within six months;
- (c) Policy and procedures for transfer of patient care in the event a higher level is indicated;
- (d) Acknowledgment that contraindications for a patient prohibit performing colon hydrotherapy including, but not limited to:
 - (i) Gastrointestinal cancer;
 - (ii) Acute or severe abdominal pain;
 - (iii) Gastrointestinal bleed within the past six weeks;
- (iv) Surgery within the previous six weeks of the following types:
 - (A) Abdominal;
 - (B) Gastrointestinal;
 - (C) Colon;
 - (v) History of gastrointestinal hemorrhage or perforation;
 - (vi) Complicated abdominal hernia;
 - (vii) Severe anemia;
 - (viii) Acute diverticulitis;
 - (ix) Severe or painful hemorrhoids;
 - (x) Severe or painful fissures or fistula;
 - (xi) Acute ulcerative colitis;
 - (xii) Acute Crohn's disease;
 - (xiii) Recent myocardial infarction;
 - (xiv) Congestive heart failure;
 - (xv) Uncontrolled hypertension;
 - (xvi) Vascular or aortic aneurysm;
 - (xvii) Kidney failure or renal insufficiency;
 - (xviii) Acute cirrhosis; and
 - (xix) Pregnancy that is:
 - (A) First trimester;
 - (B) Third trimester;
 - (C) Complicated; or

- (D) High risk; and
- (e) A plan for inspection and maintenance of the colon hydrotherapy equipment, which must be registered FDA equipment and utilize disposable rectal nozzles or speculae. However, if the equipment utilizes reusable materials, such materials must be cleaned and sterilized within manufacturer's specifications. Any disposable materials shall not be reused or repurposed.

WAC 246-836-310 Training affiliation relationships for colon hydrotherapy. (1) A supervising naturopathic physician providing a colon hydrotherapy training program must establish a training affiliation relationship with a colon hydrotherapist trainee. Such training affiliation relationships must:

- (a) Be registered with the board on forms provided by the board; and
- (b) Include a training schedule for the trainee to complete a colon hydrotherapy practicum component. The trainee must successfully complete a minimum of 30 colon hydrotherapy procedures within six months. If the colon hydrotherapist trainee is unable to successfully complete the full training program requirements within six months, the training is null and void and a new training affiliation relationship must be initiated and registered with the board. The supervising naturopathic physician shall be allowed to register the same colon hydrotherapy trainee for a total of two training programs.
- (2) The supervising naturopathic physician is responsible for ensuring the competency of the trainee in the performance of colon hydrotherapy procedures. Such competency must also include successful completion of education in:
- (a) The history, theory, and practice of colon hydrotherapy to include risks and contraindications;
- (b) Anatomy and physiology, a portion of which must include the anatomy and physiology of the alimentary tract as well as the function and disfunction of intestinal health;
 - (c) Professional ethics and patient boundaries;
 - (d) Business ethics and office procedures; and
- (e) Equipment safety, infection prevention and control, and the handling and disposal of used equipment.
- (3) For purposes of this section, "licensed supervising naturo-pathic physicians" has the same meaning as that term is defined in WAC 246-836A-010.

Chapter 246-836A WAC COLON HYDROTHERAPIST

NEW SECTION

- WAC 246-836A-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.
- (1) "Affiliation relationship" means documentation of affiliation between a colon hydrotherapist and a naturopathic physician as set forth in WAC 246-836-300.
 - (2) "Board" means the board of naturopathy.
- (3) "Colon hydrotherapist" means a person certified under chapter 18.36A RCW and this chapter to perform colon hydrotherapy pursuant to an affiliation relationship with one or more naturopathic physicians.
- (4) "Colon hydrotherapy" means the performance of enemas or colonic irrigation.
 - (5) "Department" means the department of health.
- (6) "Direct visual supervision" means the supervising naturopathic physician is physically present and within visual range of the colon hydrotherapist.
- (7) "GPACT" means the global professional association for colon hydrotherapy.
- (8) "I-ACT" means the international association for colon hydrotherapy.
- (9) "Licensed supervising naturopathic physicians" means a naturopathic physician licensed under chapter 18.36A RCW that enters into a training affiliation relationship with a colon hydrotherapist trainee for purposes of fulfilling the education and training requirements in WAC 246-836A-020.
 - (10) "NBCHT" means the national board for colon hydrotherapy.

NEW SECTION

- WAC 246-836A-020 Colon hydrotherapist—Education and training. An applicant for a colon hydrotherapy credential must successfully complete a colon hydrotherapy training program approved by the board.
- (1) The colon hydrotherapy training program must be administered by a licensed supervising naturopathic physician under a training affiliation relationship. Such training affiliation relationship must also meet the requirements in WAC 246-836-310 (1)(a) through (c). The supervising naturopathic physician is responsible for verifying the content of the training and for ascertaining the proficiency of the trainee.
- (a) The colon hydrotherapy training program must provide evaluation and assessment of knowledge and skills in the following areas:
- (i) The history, theory, and practice of colon hydrotherapy to include risks and contraindications;

[1] OTS-3513.2

- (ii) Anatomy and physiology, a portion of which must include the anatomy and physiology of the alimentary tract as well as the function and disfunction of intestinal health;
 - (iii) Professional ethics and patient boundaries;
 - (iv) Business ethics and office procedures; and
- (v) Equipment safety, infection prevention and control, and the handling and disposal of used equipment.
- (b) The colon hydrotherapy training program must include a colon hydrotherapy practicum component for which the supervising naturopathic physician shall provide direct visual supervision to the trainee. Such practicum must include at a minimum 30 colon hydrotherapy procedures performed by the trainee within six months.
- (c) The supervising naturopathic physician is responsible for ensuring the competency of the trainee in the performance of colon hydrotherapy procedures.
- (2) Documentation of all colon hydrotherapy training, duties, and responsibilities of the trainee must be completed, signed by the supervising naturopathic physician and the trainee, and placed in the trainee's file. Such documentation must be retained for two years.
- (3) Training programs that meet the requirements described in subsection (1) of this section are approved by the board.
- (4) A trainee must submit their completed application, with a copy of the documentation required in subsection (2) of this section, and all required fees, to the board within 90 days of completing the colon hydrotherapy training program to be approved to sit for the state colon hydrotherapy examination as set forth in WAC 246-836A-030.
- (5) A colon hydrotherapist who is currently certified, registered, or otherwise credentialed by GPACT, I-ACT, or NBCHT is considered to have met the education and training requirements in this section.

- WAC 246-836A-030 Colon hydrotherapist—Examination. (1) Applicants for a colon hydrotherapist credential shall successfully pass the state board examination administered by the NBCHT, unless they are currently certified under subsection (3) of this section. Applicants taking the state examination must meet the education and training requirements in WAC 246-836A-020 and submit the application, supporting documentation, and application fee set in WAC 246-836A-990 to the department for approval prior to being authorized to take the examination. Once authorized, applicants then contact the NBCHT to be scheduled for the Washington state examination and pay the examination fee set by NBCHT directly to NBCHT. The examinations shall be conducted in accordance with the NBCHT security measures and contract.
- (2) Examination candidates shall be advised of the results of their examination in writing by the NBCHT.
- (3) A colon hydrotherapist who is currently certified, registered, or otherwise credentialed by GPACT, I-ACT, or NBCHT is considered to have met the examination requirement in this section.

[2] OTS-3513.2

- WAC 246-836A-040 Colon hydrotherapist—Application. An applicant for a colon hydrotherapist credential shall submit the following to the board:
 - (1) Completed application on forms provided by the department;
- (2) Proof of successful completion of education, training, and examination required in WAC 246-836A-020;
- (3) Proof of an affiliation relationship with a naturopathic physician as required in WAC 246-836-300;
- (4) Proof of current certification in cardiopulmonary resuscitation (CPR);
 - (5) Any fee required in WAC 246-836A-990; and
- (6) Fingerprint cards for national fingerprint-based background check pursuant to RCW 18.130.064(2), if requested by the department; and
- (7) Any additional documentation or information requested by the board.

NEW SECTION

- WAC 246-836A-050 Colon hydrotherapist—Affiliation relationships. (1) A colon hydrotherapist may perform colon hydrotherapy only under an affiliation relationship with a naturopathic physician as required in WAC 246-836-300. Such affiliation relationships must be registered with the board before a colon hydrotherapist may perform colon hydrotherapy services on patients referred from that naturopathic physician. A registered affiliation relationship will remain in effect until rescinded by either practitioner.
- (2) A colon hydrotherapist who has a registered affiliation relationship with a naturopathic physician and desires to terminate such relationship must provide a minimum of 60 days' notice to that naturopathic physician prior to submitting documentation to the board rescinding that relationship.
- (3) If a colon hydrotherapist desires to become affiliated with additional naturopathic physicians, he or she must enter into an additional affiliation relationship with each naturopathic physician as set forth in WAC 246-836-300. Such additional affiliation relationships must also be registered with the board before a colon hydrotherapist may perform colon hydrotherapy services on patients referred to them from the additional naturopathic physicians.
- (4) There is no limit to the number of affiliation relationships a colon hydrotherapist may have with naturopathic physicians.
- (5) A colon hydrotherapist's certification is considered inoperable when there is no registered affiliation relationship on file with the board.

[3] OTS-3513.2

WAC 246-836A-060 Colon hydrotherapist—Activities allowed or prohibited. A colon hydrotherapist is authorized to perform colon hydrotherapy services. Such services shall only include the administration of substances ordered or prescribed by the referring naturopathic physician for the specific patient receiving the colon hydrotherapy procedure. A colon hydrotherapist is prohibited from administering any controlled substance or experimental medication.

NEW SECTION

- WAC 246-836A-070 Minimum standards of practice for colon hydrotherapy. (1) A colon hydrotherapist shall:
- (a) Allow a patient privacy to dress or undress except as may be necessary in emergencies or custodial situations; and
- (b) Always provide the patient a gown or draping except as may be necessary in emergencies.
- (2) A colon hydrotherapist shall use safe, functional, and hygienic coverage and draping practices during the practice of colon hydrotherapy when the patient is disrobed. Safe, functional, and hygienic coverage and draping means:
- (a) The colon hydrotherapist explains and maintains coverage and draping boundaries; and
- (b) Movement of the body does not expose the patient's gluteal cleft and perineum beyond that needed to perform the colon hydrotherapy procedure.
- (3) The colon hydrotherapist shall use hygienic, safe, and sanitary practices, including:
 - (a) Wearing gloves during insertion of the speculae;
 - (b) Using fresh gloves for every patient during insertion;
 - (c) Being physically present with the patient during insertion;
 - (d) Not reusing or repurposing disposable materials; and
- (e) Cleaning and sterilizing any reusable materials within manufacturer's specifications.

NEW SECTION

- WAC 246-836A-080 Recordkeeping and retention. (1) Documentation. A colon hydrotherapist providing colon hydrotherapy services to a patient must document services provided. Documentation should be in sufficient detail to support and enable anticipated continuity of care. The documentation must include:
- (a) Patient name and contact information or name and contact information of a parent or guardian if a patient is under 18 years of age;
 - (b) Age of patient;
 - (c) Date the colon hydrotherapy service is provided;

- (d) Written informed consent to treat, which is considered valid for the duration of the treatment referral or one year unless revoked; and
- (e) For colon hydrotherapy where the focus is on treating a health condition, the documentation must also include symptoms and expected outcome measures as reported by the referring naturopathic physician and the treatment plan for future sessions, if applicable.
 - (2) Patient records.
- (a) Colon hydrotherapist records for patients shall comply with record retention requirements and be secured with properly limited access consistent with chapter 70.02 RCW and the Health Insurance Portability and Accountability Act (HIPAA).
- (b) A colon hydrotherapist shall ensure the patient record is legible, permanent, and recorded within 24 hours of treatment. Documentation that is not recorded on the date of service must designate both the date of service and the date of the chart note entry.
- (c) The colon hydrotherapist shall retain in the patient record correspondence relating to any referrals by a naturopathic physician concerning the diagnosis, evaluation, or treatment of the patient.
- (d) Patient records should clearly identify the referring naturopathic physician and the colon hydrotherapist providing the colon hydrotherapy service.
- (e) Records for clients or patients 18 years of age and older must be retained by or be otherwise accessible to the colon hydrotherapist for at least three years from the date of last treatment, or for patients under the age of 18 years old, at least three years after the patient reaches 18 years old.
- (f) After the retention period, records may be disposed of pursuant to this subsection. Disposal must be done in a secure and confidential manner in compliance with chapter 70.02 RCW and HIPAA and must include, as appropriate:
 - (i) Shredding;
 - (ii) Deleting, erasing, or reformatting electronic media; or
- (iii) Rendering other readable forms of media unusable or unreadable.

WAC 246-836A-100 Mandatory reporting. Mandatory reporting requirements under chapter 246-16 WAC apply to a person who holds a colon hydrotherapist credential.

NEW SECTION

WAC 246-836A-110 Sexual misconduct. The sexual misconduct rules under WAC 246-836-500 and 246-836-510 apply to a person who holds a colon hydrotherapist credential.