WSR 23-14-122 PROPOSED RULES DEPARTMENT OF HEALTH (Board of Naturopathy) [Filed July 5, 2023, 10:34 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 20-24-042. Title of Rule and Other Identifying Information: Naturopathic nonsurgical cosmetic procedure rules. WAC 246-836-210 Authority to use, prescribe, dispense and order and new 246-836-212 Botulinum toxin nonsurgical cosmetic procedures. The board of naturopathy (board) is proposing the standards for naturopathic physicians to administer cosmetic purpose Botox injections.

Hearing Location(s): On August 11, 2023, at 8:45 a.m., at Labor and Industry Office Building, 7273 Linderson Way S.W., Room S130, Tumwater, WA 98501; or virtual. Please use the following link to register for the virtual hearing https://us02web.zoom.us/webinar/register/ WN_CL9eL-IET_CWQPB500cfPA. The board will provide a virtual and a physical location for this hearing to promote social distancing and the safety of the citizens of Washington state.

Date of Intended Adoption: August 11, 2023.

Submit Written Comments to: Lana Crawford, P.O. Box 47852, Olympia, WA 98504-7852, email https://fortress.wa.gov/doh/policyreview/, fax 360-236-2850, by August 4, 2023.

Assistance for Persons with Disabilities: Contact Lana Crawford, phone 360-236-4760, fax 360-236-2901, TTY 711, email naturopathic@doh.wa.gov, by August 4, 2023.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The board is proposing the standards for naturopathic physicians to administer cosmetic purpose Botox injections. This proposal is based on feedback received and research into training requirements for each of the nonsurgical cosmetic procedures being considered. The board determined that it is appropriate to focus on Botox injections for cosmetic purposes in this rule making and not those cosmetic procedures that are considered tissue altering, such as fillers and sclerosing substances. Typical training sessions for Botox injections for advanced level health care practitioners involve weekend courses lasting approximately 16 hours. The topic of other, more invasive nonsurgical cosmetic procedures may be the subject a future rule project. This change in rule will promote patient safety by establishing the training and conditions required to administer Botox and allows naturopaths to provide treatment once requirements are met.

Reasons Supporting Proposal: One of the purposes of the board is to regulate the competency and quality of naturopathic physicians by establishing consistent standards of practice. There are no specific laws or rules in Washington state for the practice of nonsurgical cosmetic procedures by naturopathic physicians. RCW 18.36A.020(12) defines "naturopathic medicines" as those substances "... those legend drugs and controlled substances consistent with naturopathic medical practice in accordance with rules established by the board." RCW 18.36A.160 provides that the board shall determine the education and experience requirements for licensure. The goal of the proposed rules is to promote patient safety by identifying Botox as an approved legend drug, identifying allowable nonsurgical cosmetic procedures in naturopathic practice and establishing the training required and conditions under which naturopathic physicians perform nonsurgical cosmetic procedures. Statutory Authority for Adoption: RCW 18.36A.160. Rule is not necessitated by federal law, federal or state court decision. Name of Proponent: Department of health, board of naturopathy, governmental. Name of Agency Personnel Responsible for Drafting: Lana Crawford, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4760; Implementation and Enforcement: Harold Wright, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2850. A school district fiscal impact statement is not required under RCW 28A.305.135. A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Lana Crawford, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-236-4760, fax 360-236-2901, TTY 711, email naturopathic@doh.wa.gov. This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal: Is exempt under RCW 19.85.025(4). Explanation of exemptions: The proposed rule does not affect small businesses. These rules only apply to providers. Scope of exemption for rule proposal: Is fully exempt. July 5, 2023

July 5, 2023 Harold Wright, Jr. M. Ed. Executive Director

OTS-4228.2

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)) 246-945 WAC.

(2) In accordance with RCW 69.41.010(((13))) <u>(14)</u>, 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

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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 Botulinum toxin nonsurgical cosmetic procedures. (1) Prior to utilizing botulinum toxin (commonly known as, among other names, Botox, Vistabel, Dysport, or Neurobloc) for nonsurgical cosmetic procedures, a naturopathic physician shall 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 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 for cosmetic purposes, naturopathic physicians must be appropriately trained in aesthetic injectable techniques. Such training must be a combination of hands-on training and training in pharmacology that pertains to aesthetics and must also include:

- (a) Criteria for the selection and treatment of patients;
- (b) Indications and contraindications for each procedure;
- (c) Preprocedural and postprocedural care;

(d) Recognition and acute management of potential complications;

and

(e) Infectious disease control.