

August 22, 2018

Susan Gragg
Program Manager
Washington Department of Health
P.O. Box 47852
Olympia, WA 98504

RE: Proposed Amendments to WAC 246-836-210 and Proposed New Rule WAC 246-836-212

Dear Ms. Gragg:

On behalf of the Washington Society of Plastic Surgeons (WSPS) and American Society of Plastic Surgeons (ASPS), we are writing in opposition to the proposed amendments to WAC 246-836-210 and the proposed new rule WAC 246-836-212. The Washington Society of Plastic Surgeons is the largest association of plastic surgeons in the state, and in conjunction with our national affiliates ASPS, represents 139 board-certified plastic surgeons in the state. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

ASPS's policy statement on the administration of botulinum toxin neuromodulators – enclosed for your review – goes into great detail on the background of the development of injecting botulinum toxins and other similar therapies. It took over 30 years of research and development to derive clinical uses of botulinum toxins to treat serious medical conditions, such as cervical dystonias, cranial nerve VII disorders, benign essential blepharospasm, general spasticity, strabismus, migraine headaches, hyperhidrosis, vocal cord dysfunction, anal fissures, urinary incontinence, bruxism, vasospastic disorders of the hand, and other conditions. Botulinum toxins are now an established component of facial rejuvenation.

These injections are not “minor” procedures, but rather are surgical and carry serious consequences. The American College of Surgeons defines surgery as follows¹:

*Surgery is performed for the purpose of structurally altering the human body by incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transportation of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. **Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery** (this does not include administration by*

¹State of the states: Defining surgery. The Bulletin. <http://bulletin.facs.org/2012/05/state-of-the-states-defining-surgery>. Published June 6, 2016. Accessed December 19, 2017.

nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel. Patient safety and quality of care are paramount, and the College therefore believes that patients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards.

While some injections are intended for cosmetic use, the risk of surgical error listed above is of serious concern. In order to ensure patient safety, it takes a deeper understanding of the clinical uses and corresponding dangers of injecting botulinum toxins, dermal fillers, and other similar injectable therapies. This understanding is developed through a core medical and surgical education – which plastic surgeons attain – followed by seven to ten years of training (and thus 12-15 years of education). Board-certified plastic surgeons must: (1) earn a medical degree; (2) complete three to six years of full-time experience in a residency training program accredited by the Accreditation Council for Graduate Medical Education (ACGME); and (3) the last three years of training must be completed in the same program.

This clinical experience and medical education allows for plastic surgeons to safely administer injections because they have a comprehensive understanding of the neuromuscular and facial anatomy, facial aging and aesthetics, as well as the potential neurotoxicity of botulinum toxins and dermal fillers. Unlike naturopaths, plastic surgeons understand the indicators for individuals who are not candidates for these cosmetic treatments, including patients who are sensitive to the ingredients, patients with neuromuscular diseases and pregnant women.

Ultimately, plastic surgeons will train as much as four-times-as-long as naturopaths in order to join this critical knowledge and clinical experience. Expertise in managing these types of serious complications cannot be obtained by going to naturopathy school, as the naturopathic training curriculum does not provide the sufficient training to perform these injections safely, or through an “add-on” weekend training course. Neither of these options provide the medical expertise to determine whether injected medication is even the proper treatment for medical conditions or whether the patient is a candidate for injectable surgical procedures. Moreover, the state Board of Naturopathy has voiced its own concerns – which echo those of the medical community – in the cost-benefit analysis that was prepared for this rule. That document includes the following statement²:

Potential complications from these non-surgical medical cosmetic procedures include infections, bleeding, nerve damage, liver and kidney toxicity, droopy eyelids, weak neck, respiratory paralysis, fat embolisms, skin loss at injection areas, perforation of the eye, blindness, blood clot formation, severe inflammation, adverse allergic reaction, and possible scarring.

It is clear that the Board of Naturopathy agrees with the medical community that allowing this scope expansion would be a patient safety risk.

²https://fortress.wa.gov/doh/policyreview/Documents/Significant_Analysis_BON_AuthoritytoPrescribe.pdf

Furthermore, revised Code of Washington (RCW) 18.36A.040 defines naturopathic medicine scope of practice as:

"...the art and science of the diagnosis, prevention, and treatment of disorders of the body by stimulation or support, or both, of the natural processes of the human body."

The American Association of Naturopathic Physicians' definition of naturopathy reads as³:

"Naturopathic medicine is a distinct primary health care profession, emphasizing prevention, treatment, and optimal health through the use of therapeutic methods and substances that encourage individuals' inherent self-healing process."

As cosmetic injections and fillers are neither "natural" nor "inherent self-healing processes," these procedures clearly fall outside of the profession's own state and national definitions.

The Washington State Legislature has not granted additional scope expansions since the passage of the 1987 law, nor has it amended naturopaths' scope of practice in statute to include the administration of injections for cosmetic purposes. The Washington Board of Naturopathic Medicine lists duties⁴ notably does not include the ability to pass scope of practice expansions for the practice of naturopathic medicine. That duty rests with the legislative branch of government, and – just as the ability to administer botulinum toxins, dermal fillers, or inert substances is outside of naturopathic scope of practice – this scope expansion is outside the purview of the Board of Naturopathy. To be clear, the will of the legislature – and ergo the will of the people of Washington – is that naturopaths have not been granted expansion of scope of practice of a non-natural treatment.

Given the above – as well as the fact that naturopaths are not trained surgeons – expanding the scope of practice of naturopaths to allow them to administer botulinum toxin injections, dermal fillers, or other inert substances is extremely concerning. ASPS members are all too familiar with the nightmarish stories of patients who fall victim to undertrained individuals who perform procedures that fall squarely outside of their scope of practice. For example, a patient named Carol went to a provider for a common cosmetic procedure – the kind that thousands of women and men have every day. However, she made the mistake that many people make: she didn't consult a board-certified plastic surgeon. The provider injected substances into Carol's face that were not FDA approved. She had a severe, adverse reaction that caused her face to become permanently distorted. Worse still, the provider had no idea what caused the reaction or how to treat it. Carol's life changed forever.

Unfortunately, individuals such as Carol have to deal with life-altering consequences such as disfigurement and loss of vision following botched surgical procedures, including those administered by injection only. We encourage you to watch Carol's story yourselves at <https://www.plasticsurgery.org/video-gallery/carols-story-who-to-trust-with-your-plastic-surgery-journey>.

The aforementioned potentially devastating effects coupled with the fact that naturopaths are insufficiently-trained are reason enough to maintain their current scope and not allow them to administer

³<https://www.naturopathic.org/content.asp?contentid=59>

⁴<https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/NaturopathicPhysician/BoardInformation>

Botox injections. Therefore, we strongly urge you not to make the changes to WAC 246-836-210 and thus not to introduce the new rule WAC 246-836-212.

Thank you for your consideration of our position on this important issue. Please do not hesitate to contact Patrick Hermes, Director of Advocacy and Government Relations, at phermes@plasticsurgery.org or (847) 228-3331 with any questions or concerns.

Sincerely,

Handwritten signature of Jeffrey E. Janis in black ink.

Jeffrey E. Janis, MD, FACS
President, American Society of Plastic Surgeons

Handwritten signature of Shannon Colohan in black ink.

Shannon Colohan, MD, MSc, FRCSC, FACS
President, Washington Society of Plastic Surgeons