

**JOINT ADVISORY OPINION OF THE SOUTH CAROLINA STATE BOARDS OF DENTISTRY, MEDICAL EXAMINERS AND NURSING REGARDING THE ADMINISTRATION OF NEUROMODULATORS, INCLUDING BOTOX<sup>1</sup>**

The South Carolina State Board of Nursing first issued its Advisory Opinion #39 regarding whether certain cosmetic procedures, including administration of Botox and collagen injections, fall within the scope of a registered nurse on January 24, 2002. The State Board of Medical Examiners issued its guidance regarding Botox injections at its July 28-31, 2002 meeting. The State Board of Dentistry issued its policy Botox and Other Injectables on August 20, 2009. In the years following the issuance of these three separate guidance documents, a number of public safety concerns have been identified that involve licensees regulated by these three professional regulatory boards. All three boards are concerned regarding the increasing number of events where neuromodulators are being injected without appropriate supervision or training outside of an appropriate clinical setting and without resuscitative capabilities. Accordingly, representatives from all three boards met on June 9, 2017, to determine whether uniform standards applicable to all licensees should be established and, if so, what the prevailing standards should be in order to allow authorized licensees to practice to the full extent of their training and experience while promoting and preserving patient safety. This Joint Advisory Opinion is intended to provide guidance to licensees performing injections of neuromodulators, including Botox, for both cosmetic and non-cosmetic purposes, which include, but are not limited to, problems with the Temporomandibular joint (TMJ), overactive bladders, cervical dystonia, chronic migraines, muscle spasms and hyperhidrosis. Each board retains the exclusive authority and responsibility to evaluate the conduct of its licensees within the context of individual facts presented in any disciplinary matter in order to determine whether conduct complained of constitutes a violation of the respective profession's applicable statutory<sup>2</sup> and regulatory requirements for professional conduct.

First, a practitioner must be actively licensed to practice dentistry, medicine, or nursing in South Carolina in order to inject neuromodulators for either cosmetic or non-cosmetic purposes. Additionally, any licensee must have documented special education and training regarding the pharmacology of injectable neuromodulators, including but not limited to, contraindications, potential side effects, injection techniques and appropriate injection sites for the condition being treated, applicable storage and sterility requirements, and necessary resuscitative techniques and equipment in the event of an unexpected adverse outcome. Continuing education and competency demonstrated for these procedures is ongoing and must be documented.

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<sup>1</sup> The Board of Medical Examiners approved this Joint Advisory Opinion on August 7, 2017. The Board of Dentistry approved this Joint Advisory Opinion on August 25, 2017. The Board of Nursing approved this Joint Advisory Opinion on September 28, 2017.

<sup>2</sup> Dentists are regulated by Chapter 15 of Title 40 of the South Carolina Code of Laws and Chapter 39 of the Code of Regulations. Nurses are regulated by Chapter 33 of Title 40 of the South Carolina Code of Laws and Chapter 91 of the Code of Regulations. Physicians and Physician Assistants are regulated by Chapter 47 of Title 40 of the South Carolina Code of Laws and Chapter 81 of the Code of Regulations. Additional statutes applicable to all professions are set forth in Chapter 1 of Title 40 of the South Carolina Code of Laws.

Second, it is necessary to establish a bona fide physician-practitioner relationship prior to the injection of any neuromodulator for either cosmetic or non-cosmetic purposes. A medical record must be created for each patient and should include, at a minimum, the following information for each injection: informed consent, diagnosis or description of condition to be treated, record of anatomical location of injection site(s) either via photograph or diagram, dosage, and manufacturer's lot number.

Third, practitioners should adhere to the FDA and manufacturer's guidelines for storage, reconstitution, administration, and management of unused product to ensure patient safety.

Fourth, neuromodulators should only be injected in an appropriate clinical setting that ensures sterility and resuscitative capabilities. Each facility where neuromodulators will be injected should have written policies and procedures in place governing these procedures.

Fifth, cosmetic use is a delegable act to an appropriately qualified licensed person pursuant to state law and the physician or dentist must be on site and readily available for any problems that may occur. If a physician assistant is performing the injection, it must be done pursuant to the practice guidelines executed by and established with the supervising physician. If an advanced practice registered nurse (APRN) is performing the injection, it must be done pursuant to the written protocol executed by and established with the supervising physician or dentist. If a registered nurse is performing the injection, it must be done with the on-site supervision of a physician or APRN.

Non-cosmetic use is non-delegable and must be performed by either the physician or the dentist.

Finally, patient safety is the responsibility and priority for any licensed practitioner engaged in the injection of neuromodulators, whether for cosmetic or non-cosmetic purposes.