

Shifting Standards: Washington's Regulation of Nonsurgical Cosmetic Procedures

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The administration of Botulinum Toxin Type A (more commonly known as Botox) was the most frequently performed nonsurgical cosmetic procedure in 2011, with over 2.6 million procedures performed by physicians in the United States.¹ Factor in the number of Botox injections performed not only by physicians, but also by physician assistants and nurse practitioners, and this number skyrockets to 4 million.² The injection may remain the same, but in Washington, the

type of practitioner performing the procedure can have a major impact on policies and procedures relating to its administration.

Background

In 2007, the Medical Quality Assurance Commission ("MQAC") began drafting the state's first, and still only, regulation specifically relating to the administration of Botox. The rules were a result of an increasing number of complaints regarding the

administration by individuals with little or no training and without proper licensure.³ Commentators questioned whether the proposed regulation was simply a reiteration of the standard of care. In response, MQAC asserted that, regardless of the standard of care, it was still receiving complaints demonstrating that the standard was not being met. It stated that "while it is true that these requirements are the standard of care in our state, [MQAC] wants to make these requirements explicit in this area of medicine."⁴

In 2010 the rules became effective. Although commentators questioned why the rules did not address advanced registered nurse practitioners ("ARNPs"), and urged that the rules be rewritten to include them, ultimately MQAC had to decline.⁵ MQAC has no authority to create and adopt rules regarding ARNPs; such authority rests with the Nursing Care Quality Assurance Commission ("NCQAC"). Thus, the rules adopted in 2010 apply to only two types of practitioners: physicians and physician assistants.

Physician Regulations⁶

The injection of medication or sub-

stances for cosmetic purposes, or the use of prescriptive devices for cosmetic purposes, constitutes the practice of medicine under Washington law. In addition to requiring that a physician be fully and appropriately trained in performing nonsurgical cosmetic medical procedures, the regulations also require the physician to:

- Keep a record on his or her training in the office and available for review;
- Take a history;
- Perform an appropriate physical examination;
- Make an appropriate diagnosis;
- Recommend appropriate treatment;
- Obtain a patient's informed consent;
- Provide instructions for emergency and follow-up care; and
- Prepare an appropriate medical record.

The physician is also required to ensure that there is a quality assurance program at the facility regarding the selection and treatment of patients.

Once a physician has met these requirements, he or she may delegate the procedure to a properly trained physician assistant, registered nurse ("RN"), or licensed practical nurse ("LPN"). Among other delegation requirements, the physician must maintain a written protocol for the delegation and must ensure that the patient signs a consent form before the procedure that, among other information, identifies the delegate performing the procedure. The physician must be reachable by phone and able to respond within 30

minutes when delegating the procedures using medications approved by the Food and Drug Administration (the "FDA") and approved for the particular purpose for which they are used. If the procedure calls for substances not approved by the FDA, or not approved for the particular purpose for which they are being used, the physician must be on site.

Regardless of who performs the procedure, the physician is ultimately responsible for the safety of the patient.

Physician Assistant Regulations⁷

Physician assistants may perform a nonsurgical medical cosmetic procedure only after MQAC approves a practice plan permitting the physician assistant to perform the procedure. Further, among other requirements such as specific training, the physician assistant must ensure that the supervising or sponsoring physician is in full compliance with regulations governing physician practice found at WAC 246-919-606. Additional requirements are set forth in WAC 246-918-126.

ARNP Regulations

In contrast to physicians and physician assistants subject to MQAC's regulations, ARNPs performing the same procedures are not subject to specific regulations regarding the administration of Botox. NCQAC has declined to create and adopt rules and regulations governing an ARNP's performance and delegation of nonsurgical cosmetic procedures.⁸

ARNPs are authorized to "perform specialized and advanced levels of

nursing as recognized jointly by the medical and nursing professions,"⁹ and may "perform procedures or provide care services that are within the scope of practice according to the [NCQAC] approved certification program."¹⁰ Although the administration of Botox can fall within the scope of practice for ARNPs, these practitioners are left with less explicit care requirements regarding performance and delegation. ARNPs are guided by the general principle that an "ARNP functions within his or her scope of practice according to the [NCQAC] approved certification program and standards of care developed by professional organizations."¹¹

Conclusion

Although the nonsurgical cosmetic procedure itself does not vary, the rules and regulations regarding its performance are vastly different depending on the practitioner involved. Whereas physicians and physician assistants are highly regulated, an ARNP's performance is guided only by more general standard-of-care principles. To ensure legal compliance in the performance of any nonsurgical cosmetic procedure, practitioners need to be aware of their specific licensure requirements. It will be interesting to see whether, as time passes, the MQAC regulations became the standard of practice for all practitioners engaged in the administration of nonsurgical cosmetic procedures.

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Notes:

¹American Society for Aesthetic Plastic Surgery, 2011 Statistics on Cosmetic Surgery.

²*Id.*

³Concise Explanatory Statement for WAC 246-919-606 and WAC 246-918-126, Nonsurgical Medical Cosmetic Procedures.

⁴*Id.*

⁵*Id.*

⁶Regulations pertaining to physicians' duties in the administration and delegation of nonsurgical cosmetic procedures are found at WAC 246-919-606.

⁷Regulations pertaining to physician assistants' duties in the administration of nonsurgical cosmetic procedures are found at WAC 246-919-126.

⁸NCQAC has, however, released a position statement regarding the administration of Botox by RNs and LPNs. The position statement makes it clear that the administration of Botox is within the scope of practice for RNs and LPNs so long as certain guidelines are met. WAC 246-246-919-606 makes clear that a physician may delegate the procedure to either a RN or an LPN; however, the position statement points out that the administration of Botox does not authorized to diagnose or prescribe.

⁹RCW 18.79.250.

¹⁰WAC 246-840-300(6)(h).

¹¹WAC 246-840-300(4).

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