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What You Need to Know about Botox Treatments

During their office visits in recent months, our Risk Management & Patient Safety Specialists have found that many physicians are now supplementing their primary practice with cosmetic services. Most common among these services are Botox treatments. This week's Risk E-Note addresses some of the requirements and risks associated with the provision of this particular service.

New Black Box Warning

On April 30, 2009, the Food and Drug Administration (FDA) announced that it will require black box labeling on Botox and similar products warning of a rare but potentially life-threatening complication when the effects of the toxin spread far beyond the injection site. The new black box warning pertains specifically to the use of Botox to reduce spasticity or excessive muscular contractions. No serious side effects related to the distant spread of the toxin have been confirmed among people who have used Botox and the related product Myobloc for cosmetic purposes.

Do you administer a new Botox-type product?

The new black box warnings pertain to all Botox-type products including two new products: Myobloc and Dysport. The FDA also warns of the risks associated with substituting one botulism product for another. The products have different dosing units, which are incompatible, so switching products can result in dangerous overdosing.

Who may administer Botox to your patients?

The Medical Board of California (MBC) states that physicians may inject Botox. Physicians may direct registered nurses or physician assistants to perform the injection under their supervision **and with written/approved Standardized Procedures or Delegation of Services Agreements**. An unlicensed person, such as a medical assistant, may not inject Botox. The above persons should be employees of the physician, not contract employees.

Have you been asked by a nurse to be her "sponsoring physician" for his/her Botox practice?

According to the MBC, there is no such thing as a "sponsoring physician." Under California law, nurses may not contract with a physician for supervision. A nurse may not have a private practice without actual supervision. Nurses may only perform medical functions under "standardized procedures."

In their spring 2003 newsletter, the California Board of Registered Nursing published California regulations regarding the administration of Botox by Registered Nurses. Specifically, RNs are authorized to perform Botox injections by approved standardized procedures in an organized health care system. Health spas and private residences do not meet the requirement of an organized health care system for the performance of standardized procedures.

For more information on these issues, go to:

http://www.medbd.ca.gov/allied/medical_assistants_lasers.html

or <http://www.rn.ca.gov/pdfs/forms/brnspring2003.pdf> (BRN Newsletter Spring 2003, Pge 8).

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