## GLOBAL AESTHETIC GUIDELINES FOR INJECTABLES IN FACIAL AESTHETICS

BOTULINUM TOXIN & DERMAL FILLERS FOR COSMETIC INDICATIONS ARE GLOBALLY ACCEPTED FOR:

- GENERAL PHYSICIANS
- DERMATOLOGIST
- ✤ PLASTIC SURGEONS
- ✤ GENERAL NURSE

{DISCLAIMER KINDLY REFER WITH GOVERING COUNCIL OF YOUR RESPECTIVE COUNTRY PRACTISE SUBJECTIVE TO CHANGE }

ADDITIONAL CPD OR CDE TRAINING REQUIRED

## **GLOBAL STANDARDS FOR DENTIST**

#### SINGAPORE:

- Chemical peel/ pressurized gas. (perioral region).
- Botulinum toxin. (perioral region).
- ✓ Dermal filler (perioral region).

REF: (Singapore dental council).

#### AUSTRALIA:

- Botulinum toxin. (for therapeutic dental indications and enhancement within perioral region).
- Dermal filler (for therapeutic dental indications and enhancement within perioral region).
- Threads. (for therapeutic dental indications and enhancement within perioral region).
- ✓ Chemical peels.

#### REF: (Dental board of australia).

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### LONDON:

- ✓ Botulinum toxin.
- ✓ Dermal filler.
- ✓ PDO threads.

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory.)

#### SCOTLAND

- ✓ Botulinum toxin.
- ✓ Dermal filler.
- ✓ Threads.

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### NEWYORK

- ✓ Botulinum toxin. (Oral and maxillofacial region)
- ✓ Dermal filler. (Oral and maxillofacial region)
- ✓ Threads. (Oral and maxillofacial region)

#### CANADA

- ✓ Botulinum toxin.
- ✓ Dermal filler.

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### GERMANY

- ✓ Botulinum toxin.
- ✓ Dermal filler.

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### PARIS

- ✓ Botulinum toxin. (perioral region)
- ✓ Dermal filler. (perioral region)

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### AFRICA

- ✓ Botulinum toxin. (perioral region)
- ✓ Dermal filler. (perioral region)

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### ITALY

- Botulinum toxin. (perioral region)
- ✓ Dermal filler. (perioral region)

#### INDIA

- Botulinum toxin & dermal filler for cosmetic enhancement indications : Dermatologist / plastic surgeon / maxillofacial surgeon ,
- ✓ botulinum toxin & fillers in the periroal region within the scope of dentistry for dentist

#### THAILAND

- Botulinum toxin. (perioral region)
- ✓ Dermal filler. (perioral region)

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### KOREA

- Botulinum toxin. (perioral region)
- Dermal filler. (perioral region)

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### RUSSIA

- Botulinum toxin. (perioral region)
- Dermal filler. (perioral region)

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### IRELAND

- ✓ Botulinum toxin. (perioral region)
- ✓ Dermal filler. (perioral region)

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### SWEDEN

- ✓ Botulinum toxin.
- ✓ Dermal filler.
- ✓ Threads

(Additional professional indemnity insurance compulsory & CPD/ CDE accredited training compulsory)

#### TURKEY

- ✓ Botulinum toxin.
- ✓ Dermal filler.

# State by State Dental Botox Regulations (United States)

Botulinum Toxin – A (Botox<sup>®</sup>) injections for cosmetic purposes by dentists is growing at a rapid pace especially with the advent of cosmetic dentistry. These cosmetic injections however have state boards having to create regulations and opinions for members – no state board has promulgated Botox<sup>®</sup> regulations for dentists. State boards have been issuing policy statements and guidance regarding the cosmetic use of Botulinum Toxin – A and its administration they have not legislated changes to the laws of these states. Most states are allowing general dentistry practices to administer Botox<sup>®</sup> to patients if they have received formal training from continuing medical education organizations. The Board of Dentistry in states of question that have created guidance for dentists have not created the regulations to enforce their policies.

Not all states are friendly to dentists and is the reason for the summary statement by state below. The laws limiting dentists concern the ability to purchase the product legally from the drug manufacturers. Botulinum Toxin Products (Botox<sup>®</sup>, Xeomin<sup>™</sup>, and Dysport<sup>™</sup>) are schedule 4 drugs which can limit the purchase of these drugs by general dentists, however the administration of these products in many cases is not limited by the individual states.

#### So what does all this mean?

The issue is to determine what states are truly regulating general dentists and other dental specialties (Oral and Maxillofacial Surgeons) and which states do not give guidance to general dentists and if so what are the requirements. It sounds confusing in that the states differ from one to another with policy statements and regulations in many cases without rhyme or reason. Many of the states have antiquated laws from 5-10 years ago and other states do not address the issue at all or are still debating the issue of general dentists administering Botulinum Toxin.

The Dental Quality Assurance Commission (DQAC) of Washington has released an interpretive statement effective July 26, 2013, which now affirms the ability of general dentists to use Botox and dermal fillers when "used to treat functional or aesthetic dental conditions and their direct aesthetic consequences and the treating dentist has appropriate, verifiable training and experience."

Be careful about what other general dentists in your states are doing and understand the administrative rulings associated with your state. Many states do allow general dentists to perform the procedure but with stipulations such as additional training initiatives and incorporating these treatments into a dental plan for the patient. There are other limitations in certain states as to the areas of the face that can be treated as well as the use of Botox<sup>®</sup> for medical dental reasons and/or for cosmetic applications.

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates the use of Botulinum Toxin-A and is in charge of interpreting state laws. The following analysis of state laws is partially based on the MHRA as well as administrative rulings by individual state dental boards and possible repercussions to dentists:

#### Alaska

The Dental Board of Alaska does not regulate licensed dentists in the State of Alaska as long as these cosmetic procedures provided are part of a dental plan for the patient and not performed as standalone procedures. The Dental Board determined there was no statutory or regulatory prohibition to administering Botox, and again chose to refer back to the scope of practice in statutes and regulations (2007).

In essence, the State of Alaska does not limit how a dentist practices other than to state that it must be safe and is within normal standard of care practices. Cosmetic procedures are allowed part of dental treatment plan but are not allowed as standalone procedures. Dentists should be trained in the procedures offered and should be within the scope of practice as it relates to the face and neck regions.

## Arizona

The Arizona Dental Association (<u>www.azda.org</u>) in August, 2012 states "Dentists in Arizona can administer Botox and dermal fillers as long as it is part of a dental treatment plan", according to a Substantive Policy Statement update issued in June by the Arizona State Board of Dental Examiners.

According to the updated statement, "a dentist may inject pharmacological agents such as Botulinum, Toxin Type A, or dermal fillers as supportive therapy in conjunction with a dental treatment plan consistent with the scope of practice." The statement also makes it clear that such agents cannot not be administered outside a dental treatment plan.

One key thing to note is that this update on ruling allows Arizona dentists to do these treatments as part of their treatment plans, however they can't advertise the use of Botox to the general public or treat patients just for those purposes. Facial Aesthetics is a rapidly evolving niche market within dentistry, and with many states now offering aesthetic and therapeutic treatments, this update that allows dentists in Arizona to provide their patient these beneficial treatments."

Although dentists in Arizona are limited to injecting for therapeutic uses, it's important to acknowledge that the same area and same dosage is used for aesthetic outcomes as well. The aesthetic effects of therapeutic treatments need to be taken into consideration because it's

impossible to separate the two uses and your patient could end up with results they were not prepared for."

#### Arkansas

The Arkansas State Board of Dental Examiners (<u>www.dentalboard.arkansas.gov</u>) have not created guidance or regulations for restorative and cosmetic dentistry procedures relating to licensed dentists. Therefore, Dentists may perform such procedures as they fall under the scope relating to their dental practice and for which they are adequately trained. There are no special requirements given by the board and Botulinum Toxin, dermal fillers, and dental materials are presently unregulated. According to the Arkansas State Board of Dental Examiners the definition of dentistry as per the Dental Practice Act. April 2012. Section 17-82-102; (<u>http://www.dentalboard.arkansas.gov/licensure/Documents/April%202012%20Dental%20Practice%20Act.pdf</u>) is as follows:

- (1)(A) "Practicing dentistry" means:
  - (i) The evaluation, diagnosis, prevention and treatment by nonsurgical, surgical or related procedures of diseases, disorders and conditions of the oral cavity, maxillofacial area and the adjacent and associated structures and their impact on the human body, but not for the purpose of treating diseases, disorders and conditions unrelated to the oral cavity, maxillofacial area and the adjacent and associated structures; and
  - (ii) The sale or offer for sale of those articles or services of dentistry enumerated in §17-82-105(a).
  - (B) "Practicing dentistry" shall include, but not be limited to, the administration of anesthetics for the purpose of or in connection with the performance of any of the acts, services, or practices enumerated or described in this section.

## California

The Dental Board of California (<u>www.dbc.ca.gov/</u>) has begun taking disciplinary action against dentists who are providing Botox<sup>®</sup>/Dysport<sup>™</sup> or dermal filler treatments to patients for cosmetic purposes or teaching courses to dentists to do so. The website of the Dental Board of California is pretty clear on the matter: "Botox or any related agents can only be used for the diagnosis and treatment of TMD/myosfacial conditions as part of a comprehensive treatment plan. Use for isolated cosmetic purposes is illegal, unless privileged under the Facial Cosmetic Surgery Permit."

California law, Business and Professions Code, Section 1638.1 states that only an oral and maxillofacial surgeon with appropriate training and a board-issued permit may provide elective facial cosmetic treatments.

## Connecticut

The Connecticut State Dental Commission (<u>http://www.ct.gov/dph/cwp</u>) is the dental board for the state of Connecticut. Connecticut General Statutes, Chapter 379 states "dentists only to perform procedures related to the mouth, structures in the mouth, and the jaw". Specifically, procedures outside the area of the mouth or jaw may not be performed by dentists. For more information please visit <u>https://www.cga.ct.gov/2015/pub/Chap\_379.htm</u>.

## Delaware

The Delaware Board of Dentistry and Dental Hygiene has no regulations concerning the application of Botulinum Toxins and dermal fillers as they believe they do not have the authority to make rules related to the same. The Delaware Board of Dentistry has not completely ignored the issue but states that neither licensing law nor the Board of Dentistry rules and regulations do not address such treatments. Because of this any potential violation concerning the use of Botulinum Toxins and dermal fillers must be made on a case by case basis based on facts of the alleged violation that are presented to the Board.

In essence, The Delaware Board of Dentistry and Dental Hygiene have not created guidance or regulations for restorative and cosmetic dentistry procedures relating to licensed dentists. Therefore, Dentists may perform such procedures as they fall under the scope of practice relating to their dental practice and for which they are adequately trained.

From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

## Florida

Training is demanded by dentists prior to incorporating cosmetic Botulinum Toxin –A in the state of Florida. Dentists are allowed to prescribe medications within legal limitations (face and neck); they can perform surgical procedures that are part of his or her practice in which he or she has been trained as it relates to their dental practice. Cosmetic dentistry is now an integral part of many dental practices that would include the use of such prescriptions, devices and appliances associated to their dental practices.

In essence, the State of Florida does not limit how a dentist practices other than to state that it must be safe and is within normal standard of care practices. Dentists should be trained in the procedures offered and should be within the scope of practice as it relates to the face and neck regions.

#### Hawaii

The Hawaii State Board of Dental Examiners have not regulated the use of Botox<sup>®</sup> or dermal fillers by dentists, nor has the state regulated licensed dentists in the State of Vermont through related rules or regulations. From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

"The use of Botox is within the scope of practice of dentistry as defined in Chapter 448, Hawaii Revised Statutes ("HRS"). Licensed dentists in Hawaii are allowed to utilize Botox specifically for the treatment of TMD/myofacial pain or other conditions affecting the oral cavity and associated structures as specified in §448.1, HRS. Dental practitioners are advised to receive appropriate training and acquire the necessary knowledge, skills, and expertise to provide this service in a safe and efficacious manner. Additionally, they should confer with their dental insurance carrier to determine if malpractice coverage for this procedure exists.

The use and placement of dermal fillers by licensed dentists in Hawaii is also within the scope of practice of dentistry. Dermal fillers may be utilized to treat conditions affecting the oral cavity and associated structures. Licensed dentists should confer with their dental insurance carrier to determine if malpractice coverage for this procedure exists.

## Idaho

The Idaho Board of Dentistry (<u>isbd.idaho.gov</u>) has given the opinion that the bylaws regarding the practice of dentistry are broad enough to permit general dentists to administer Botox<sup>®</sup> and FDA Approved dermal fillers as part of their continuing dental practice. They have also pronounced and given guidance that all dentists have an implicit duty to obtain adequate training from other organizations to ensure competence in any procedure they would perform in relationship to the practice of dentistry.

From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

## Illinois

The Illinois State Board of Dentistry, Department of Financial & Professional Regulation works in conjunction with Illinois State Dental Society in establishing concerning education, legislation and communication to dentists licensed in the state. Botox<sup>®</sup> and other cosmetic dental procedures are all be considered part of the practice of dentistry as defined in the Illinois Dental Practice Act, "Dentistry' means the healing art which is concerned with the examination, diagnosis, treatment planning and care of conditions within the human oral cavity and its adjacent tissues and structures." 225 ILCS 25/4(k). Furthermore to the Illinois Dental Practice

act it is the requirement of the dentist in performing any of these procedures that he/she be qualified to do so through advanced education, training and experience.

It is left to the professional judgment of the dentist to make sure that he or she obtains the appropriate education for any given procedure offered. The state offers an Illinois's specialty licensure for dentists but is only for title protection, any licensed general dentist is licensed in all branches of dentistry.

Finally, the Attorney General of the State of Illinois is the only person empowered to render formal opinions concerning the laws of this State and there has been no additional opinions offered as of this date.

#### lowa

lowa Dental Board defines the scope of dentistry in Iowa Code section 153.13(2) as duties that include, "examination, diagnosis, treatment, and attempted correction by any medicine, appliance, surgery, or other appropriate method of any disease, condition, disorder, lesion, injury, deformity, or defect of the oral cavity and maxillofacial area, including teeth, gums, jaws, and associated structures and tissue, which methods by education, background experience, and expertise are common to the practice of dentistry".

Licensed dentists have the authority to prescribe, administer, or dispense prescription medications 650-IAC16.2(1). However, this authority is granted only "if the use is directly related to the practice of dentistry within the scope of the dentist-patient relationship." This statute also requires that a dental exam be conducted and a medical history taken before a dentist prescribes, administers, or dispenses medication to a patient.

Given the information within the statutes, it has been determined that a dentist may administer botox and other derma fillers if the use of those medications is directly related to the practice of dentistry, but only if the dentist has successfully completed appropriate education and training. The Board further stipulated that, "the only dentists who have completed appropriate education and training to use these medications in the practice of dentistry are dentists who have completed an ADA-accredited residency program which included within the scope of its education and training the administration of Botox and other dermal fillers".

In April 23-24, 2015 The lowa Dental Board took up the issue of allowing general dentists to perform and administer Botox<sup>®</sup> and dermal filler injections. The board agreed to revisit the matter at their next meeting as questions arose as to the type of training would be needed to approve a revision in the statutes.

#### Kansas

The Kansas Dental Board through announcement has determined that injections intended to reduce appearance of aging or cosmetic in nature is not appropriate to the practice of dentistry by any dentist regardless of specialty. Any dental practice or dental practitioner who performs injections other than for dental purposes are not observing proper standards of dental care and are subject to disciplinary action - it's as simple as that.

#### Louisiana

The Louisiana State Board of Dentistry (<u>http://www.lsbd.org</u>) have not created guidance or regulations for restorative and cosmetic dentistry procedures relating to licensed dentists. Therefore, Dentists may perform such procedures as they fall under the scope relating to their dental practice and for which they are adequately trained. There are no special requirements given by the board and Botulinum Toxin, dermal fillers, and dental materials are presently unregulated.

The board of dental examiners however has outlined requirements for the use of Botulinum Toxins and dermal fillers as outlined in LAC 46:XXXIII.1615. In order to administer Botulinum Toxin - A or dermal fillers, dentists must complete a course of training from either a dental institution approved by the Commission on Dental Accreditation of the American Dental Association or a continuing education course that includes instruction on:

- Consulting with and assessing patients for the use of Botulinum Toxin A and dermal fillers;
- Uses and contraindications for these treatments;
- Safety and risks associated with botulinum toxins and injectable dermal filler treatments;
- How to prepare and administer the products for the best results;
- How to use dermal fillers to augment and conclude esthetic dental treatment;
- Using botulinum toxin to treat disorders of the temporomandibular joint (TMJ) and teeth grinding (Bruxism);
- · How to recognize and manage adverse reactions and treat potential complications;
- How to evaluate the patient for the best outcomes, both therapeutic and esthetic;
- How to incorporate Botulinum Toxin A and dermal fillers into dental and esthetic treatment plans;
- Hands on training on live patients, including diagnosing, planning treatments, dosing and administering Botulinum Toxin A and dermal fillers;

The administration of Botulinum Toxin and dermal fillers in a dental office environment must observe universal precautions set forth by the Federal Centers for Disease Control and may only be administered by dentists – other dental staff are prohibited from administering these procedures.

#### Maine

The State of Maine Board of Dental Examiners have pronounced the use of Dermal Fillers (including Botulinum Toxin - A) for non-dentally-related procedures is considered professional misconduct and is subject to disciplinary action. However, the administration of dermal filler(s) (including Botulinum Toxin - A) is allowed to be performed by Maine licensed dentists for dental related procedures (i.e. Bruxism, TMJ or other maxillofacial pain) as part of a treatment plan for patients.

## Maryland

The Maryland State Board of Dental Examiners state allow Dentists to prescribe medications for treatments that are within the scope of a dental practice and must have adequate training in administration of Botulinum Toxin - A and other medications in compliance with the Code of Maryland Regulations (COMAR).

## Massachusetts

In 2008, the Board enacted a policy stating that only Oral & Maxillofacial Surgeons can administer Botox treatments (MGL Chapter 112, Section 45). However, The Massachusetts Board of Registration in Dentistry (<u>www.mass.gov/eohhs/gov/departments/dph/</u>) have not created guidance or regulations for restorative and cosmetic dentistry procedures relating to licensed dentists just a policy statement.

In 2013 The Massachusetts Board of Registration in Dentistry clarified this ruling by stating "Massachusetts dentists who want to administer Botox and fillers must be board certified in oral and maxillofacial surgery or have completed a minimum of eight hours of training in the administration of botulinum toxins and/or derma fillers that includes instruction in the anatomy of head and neck, neurophysiology, patient selection, pharmacological effects and contraindications, management of complications, informed consent and hands-on training on the administration of the agents. The training must be offered by a continuing education provider approved by the ADA's Continuing Education Recognition Program, the Academy of General Dentistry's Program Approval for Continuing Education or another nationally recognized and accredited entity approved by the dental board".

From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

## Michigan

The Michigan Board of Dentistry in a statement released on 2/29/11 that "general dentists may not use Botox<sup>®</sup>, dermal fillers or any other neurotoxin for cosmetic purposes". In March of 2012 The Michigan Board of Dentistry further clarified the definition of dentistry to read "treat areas of the face that are reasonably identified as dependent tissue of the teeth".

The board understands the medical use in dentistry for Botox® and dermal fillers for TMJ, Bruxism (teeth grinding), trigeminal neuralgia and other conditions, however the board also recognized the consequences of the improper administration of Botox® and dermal fillers. Therefore, the Michigan Board of Dentistry has taken the position that dentists who do not undergo proper training or who are practicing outside their scope of practice are placing patients at risk. This statement specifically addresses those general dentistry in stating that "the general practice of dentistry does not include injections of these substances for cosmetic pruposes".

In essence, the Michigan Board of Dentistry has empowered itself to self-regulate general dentists in Michigan and limit the ability of dentists to obtain malpractice insurance or legal standing in doing such procedures.

## Mississippi

The Mississippi State Board of Dental Examiners at its 10/19/2007 meeting determined that only Oral and Maxillofacial surgeon are allowed to administer Botulinum Toxin - A and dermal fillers for cosmetic extra-oral procedures. Oral and maxillofacial surgeons must also complete an American Dental Association accredited residency or fellowship training or further training as adopted by the Mississippi State Dental Board of Dental Examiners, Board Regulation 7.

On 04/21/2015 the Board of Dental Examiners revisited the issue to rescind the restrictions for cosmetic procedures to include all licensed Mississippi dentists including general dentistry. The Board of Dental Examiners voted to reaffirm its prior determination (Miss. Code Ann. §73-9-3 and Board Regulation 7) to exclude general dentists from performing these cosmetic procedures.

## Missouri

The Missouri State Dental Board defines as the appropriate scope of dental practice involves treating disease, deformity, injury or condition of the teeth or mouth and related structures, including lesions in the oral area. No guidelines currently exist regarding administration of Botulinum Toxin-A or similar medications.

The Missouri State Dental Board have not created guidance or regulations for restorative and cosmetic dentistry procedures relating to licensed dentists. Missouri Dental Board does not provide express guidance on whether dentists may administer Botox or other injectables.

From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

#### Nevada

The Nevada State Board of Dental Examiners have expressed the opinion that Botulinum Toxin -A and dermal fillers for cosmetic uses (not medical purposes) are outside the appropriate scope of practice for a dentist and therefore general dentists are not permitted to perform these injections for cosmetic or aesthetic purposes.

Furthermore, the Board finds that administration of Botox<sup>®</sup>, dermal fillers and like substances for cosmetic purposes is not within the scope of practice of a dentist." The Nevada State Board of Dental Examiners ordered that the use of these substances by dentists for cosmetic purposes is a violation of NRS 631.3475 and NRS 631.215.

## **New Hampshire**

The New Hampshire Board of Dental Examiners have not created guidance or regulations for restorative and cosmetic dentistry procedures relating to licensed dentists. Therefore, Dentists may perform such procedures as they fall under the scope as defined by NH RSA 317-A:20 relating to their dental practice and for which they are adequately trained.

From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

#### **New Jersey**

The New Jersey State Board of Dentistry in 2011 adopted a rule that permits licensed dentists to administer injectable pharmacologics if they were to satisfy certain training and education requirements. The Board of Dentistry has set forth the following minimum requirements to ensure the safety, health and welfare of patients:

- 1. "Peri-oral area" means the gums, cheeks, jaws, lips and oral cavity and associated tissues.
- 2. No dentist shall administer an injectable pharmacologic unless the minimum standards of training and procedure set forth in this section are satisfied.
- 3. A dentist may administer an injectable pharmacologic for the cosmetic or functional enhancement of peri-oral tissue only in a dental treatment setting.

- 4. A dentist may administer an injectable pharmacologic only after having completed a Board-approved post-doctoral course that is sufficient to prepare a dentist to satisfactorily administer injectable pharmacologics safely and effectively, as provided in (f) below. The course shall be offered at an accredited dental school, in a hospital-based program or in a college or university clinical setting.
- 5. Notwithstanding (d) above, a dentist who holds a specialty permit in oral and maxillofacial surgery issued by the Board pursuant to N.J.A.C. 13:30-6.1 shall not be required to complete the Board-approved course set forth in (f) below prior to administering injectable pharmacologics.
- 6. In order to obtain Board approval for a course on injectable pharmacologics, a course provider shall submit a course outline, including course content and objectives and the curriculum vitae of the instructor(s), for Board review and approval. The course outline shall indicate whether the training is visual, hands-on or lecture. An approved course shall be at least 21 hours in length and shall include instruction in the following:
  - a. Anatomy of head and neck;
  - b. Neurophysiology, including facial tissues, parasympathetic, sympathetic and Peripheral nervous systems relative to peri-oral tissue, and facial architecture;
  - c. Patient selection, including indications and contraindications;
  - d. Pharmacological effects and contraindications, including potential drug interactions; management of complications; and Informed Consent.
- 1. The course administrator shall issue a certificate of completion to a dentist who successfully completes the approved course.
- 2. A dentist who desires to administer injectable pharmacologics shall submit to the Board, within 30 days of completing the course, a certified true copy of the certificate of course completion provided to the dentist by the course administrator.
  - (i) Prior to administering, dispensing or prescribing injectable pharmacologics to a patient, the dentist shall conduct an appropriate physical examination within the scope of dental practice, obtain a complete medical history, including the patient's previous medications, allergies and sensitivities and comprehensively pass the dental needs of the patient. The patient history shall be maintained in the patient's record for a period of not less than seven years. Specific notations on the use of injectable pharmacologics, including the type of agent, dosage, duration and any untoward reactions, shall be recorded in the patient record.
- 3. (j) A dentist shall not delegate the administration of an injectable pharmacologic, except to a licensed health care professional who is authorized pursuant to the laws and/or rules in this State governing the professional's healthcare practice to provide injections under the direction of a dentist.
- 4. (k) The use of injectable pharmacologics without first having met the minimum standards for training and the procedures contained in this section shall constitute a deviation from the acceptable standards of practice required of a licensee and may subject a dentist to the penalties set forth in N.J.S.A. 45:1-21 et seq.

- 5. (I) A dentist shall not advertise, offer or otherwise represent the provision of treatment or services related to injectable pharmacologics unless the dentist has completed the Board-approved course outlined in (f) above.
- 6. (m) Nothing in this section shall be construed to authorize a dentist to treat diseases, disorders or conditions that are outside the scope of the practice of dentistry, as defined in N.J.S.A. 45:6-19.

#### **New Mexico**

The Board of Dental Health Care oversees the practice of dentistry and expanded function dental auxiliary in New Mexico. The Board of Dental Health Care has not regulated the use of Botox<sup>®</sup> or dermal fillers by dentists. However, though the state does not regulate licensed dentists in the State of New Mexico the national standard by the ADA should be considered which requires training and as long as these cosmetic procedures provided are part of a dental plan for the patient and not performed as standalone procedures.

#### **New York**

The New York State Board of Dentistry does not prohibit the administration of Botulinum Toxin and dermal fillers as long it is part of a dental treatment plan. Using or offering Botox<sup>®</sup> as a standalone treatment is not permitted and is outside the dentist's scope of practice.

## **North Carolina**

The North Carolina Board of Dental Examiners through their opinion on elective cosmetic procedures has ruled that "the use of cosmetic facial procedures and/or drug or cosmetic chemical facial enhancement for purely cosmetic and/or dermatological applications is outside the scope of practice as defined by the Dental Practice Act and its attendant rules".

North Carolina has said as recently as February 2012 that chemical enhancement for cosmetic purposes may be outside what dentists are allowed to do. While this is an opinion and does not yet carry the weight of a regulation, the implication for dentists in the state is clear: don't offer additional assistance to your patients, even if you're completely trained and qualified.

If any dentist does not have formal training through their accredited dental school or residency program within the scope of NC General Statute §90-29(b)(1) they are subject to discipline by the Board of Dental Examiners on a case by case basis.

## **North Dakota**

The North Dakota State Board of Dental Examiners Policy, adopted April 2006, states "the prescription, dispensing or administration of drugs or materials or the delivery of services by a

licensed dentist for purposes other than those required for accepted dental therapeutic purposes shall be considered unprofessional conduct with the exception of those services for which advanced specialty training recognized and accredited by the ADA has been acquired."

## Ohio

The Ohio State Dental Board in 2007 expressed an opinion (guidance) and determined that the use of Botulinum Toxin-A and dermal fillers by licensed dentists can be considered within the scope of dentistry. However, the board also stipulated that treatments could only be performed in the oral and maxillofacial areas. In addition, the Ohio State Dental Board stressed and created further limitations about the specific training of the dentist providing these services.

The Dental Board requires that the training received by dentists be equal to that would be provided by ADA accredited programs as part of residency programs.

## Oregon

The Oregon Board of Dentistry (www.oregondentistry.org/) has issued a policy statement saying only Oral Surgeons can administer Botulinum Toxin-A medications and only if they have successfully completed a residency in Oral and Maxillofacial Surgery accredited by the American Dental Association, Commission on Dental Accreditation (CODA), and have successfully completed a clinical fellowship, of at least one continuous year in duration, in esthetic (cosmetic) surgery recognized by the American Association of Oral and Maxillofacial Surgeons or by the American Dental Association Commission on Dental Accreditation, or to treat a condition that is within the scope of the practice of dentistry after completing a minimum of 16 hours in a hands on clinical course(s) in which the provider is approved by the Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) or by the American Dental Association Continuing Education Recognition Program (ADA CERP).

## Pennsylvania

The State Board of Dentistry in Pennsylvania has not regulated the use of Botox<sup>®</sup> or dermal fillers by dentists. However, though the state does not regulate licensed dentists in the State of Pennsylvania. There are currently no regulations regarding the use of Botulinum Toxins relating to dentists. From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

SBOD drafted regulations in response to inquiries about when dentists are allowed to administer botox injections and dermal fillers. The regulations allow for dentists to administer botox and dermal fillers as long as:

- The dentist takes a medical history, performs an examination and renders a treatment plan prior to administering botox or dermal fillers.
- The dentist discusses risks, options and benefits with the patient prior to the procedure.
- The dentist obtains written informed consent from the patient and documents such in his or her record.
- Administering botox or dermal fillers occurs on structures associated with the human teeth, jaws or associated structures.
- The dentist is properly trained to competently administer botox and dermal fillers.
- The dentist makes note of any procedures performed in the patient's record.

## South Carolina

The South Carolina Board of Dentistry has not regulated the use of Botox<sup>®</sup> or dermal fillers by dentists. However, though the state does not regulate licensed dentists in the State of South Carolina. There are currently no regulations regarding the use of Botulinum Toxins relating to dentists. From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

## South Dakota

The South Dakota Board of Dentistry has not regulated the use of Botox<sup>®</sup> or dermal fillers by dentists. However, though the state does not regulate licensed dentists in the State of South Dakota. There are currently no regulations regarding the use of Botulinum Toxins relating to dentists. From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

## Tennessee

The Tennessee Board of Dentistry has given guidance and has determined that the use of Botulinum Toxins for cosmetic facial treatments is not within the scope of practice of general Dentistry, but is limited to the practice of oral and maxillofacial surgery. The Tennessee Board of Dentistry determined that the dental practice of Oral and Maxillofacial Surgery includes the following procedures which the Board finds are included in the curricula of dental schools accredited by the American Dental Association. Commission on Dental Accreditation, postgraduate training programs or continuing education courses - rule 0460-2-.06(8):

- Rhinoplasty;
- Blepharoplasty;
- Rylidectomy;

- Submental liposuction;
- Laser resurfacing;
- Browlift. either open or endoscopic technique;
- Platysmal muscle plication;
- Dermabrasion;
- Otoplasty;
- Lip augmentation; and
- Botulinum Toxin-A injections or future FDA approved neurotoxins.

The State of Tennessee Office of the Attorney General has approved the use of Botox injections, other neurotoxins approved by the federal Food and Drug Administration (FDA), and dermal fillers into a patient's oral cavity, maxillofacial area, and/or adjacent and associated structures by a general dentist who is properly trained, whether for therapeutic or cosmetic purposes.

#### Texas

The Texas State Board of Dental Examiners have no regulations concerning cosmetic procedures performed by dental practices. However, the Texas Dental Practice Act defines the scope of dentistry to be limited to "human teeth, oral cavity, alveolar process, gums, jaws, or directly related and adjacent masticatory structures" Tex. Occ. Code §251.003(a).

Based upon interpretation of the statute, the Texas State Board concluded that the aesthetic and cosmetic procedures outside of the stomatognathic system consisting of the mouth, jaws, and closely associated structures are outside the scope of general dentistry. The Board further pronounced that only dentists that have a specialty in oral and maxillofacial surgery may perform these injections and only if the diagnosis and adjunctive treatment involved the functional and aesthetic aspects of tissues in the oral and maxillofacial region Tex. Occ. Code § 251.003(c).

## Virginia

The Virginia Board of Dentistry (<u>https://www.dhp.virginia.gov/dentistry/</u>) has regulations (§ 54.1-2706, § 54.13408, § 54.1-2709.1 and 18VAC60-20-190) defining the use of Botulinum Toxin-A medications for cosmetic facial treatments as outside the scope of practice for dentistry. Oral and maxillofacial surgeons may administer Botox<sup>®</sup> in a limited manner as it relates to the diagnosis and adjunctive treatment involved the functional and aesthetic aspects of tissues in the oral and maxillofacial region.

## Vermont

The Vermont Board of Dental Examiners have not regulated the use of Botox<sup>®</sup> or dermal fillers by dentists, nor has the state regulated licensed dentists in the State of Vermont through related rules or regulations. From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

#### Washington

The Washington State Dental Board have not regulated dentists regarding Botulinum Toxin-A or dermal fillers, but rather have issued an interpretive statement from the Dental Quality Assurance Commission affirming that general dentists have the privileges to administer Botox<sup>®</sup> and dermal fillers for functional and aesthetic dental conditions relating to their direct aesthetic consequences (WAC 246-817-360). Dentists need to show that they have received adequate training before administering Botulinum Toxin–A products and dermal fillers and must be verifiable to the state.

The Dental Quality Assurance Commission has issued an interpretive statement about <u>Dentist</u> <u>Scope of Practice – Use of Botulinum Toxin Injections/Dermal Fillers (PDF)</u>. The interpretive statement was approved by the commission on July 26, 2013, and filed by the Office of the Code Reviser on August 20, 2013, as WSR 13-17-090.

The use of botulinum toxin injections or dermal fillers in the soft tissues throughout the face can be within the scope of practice of a dentist licensed under chapter 18.32.020 RCW when:

- Used to treat functional or esthetic dental conditions and their direct esthetic consequences; and
- The treating dentist has appropriate, verifiable training and experience.

The use of botulinum toxin injections or dermal fillers outside the treatment of dental-related conditions for purely cosmetic purposes isn't within the scope of practice of dentists not specialty trained as an oral and maxillofacial surgeon.

## West Virginia

The West Virginia Board of Dental Examiners has issued a policy statement saying only Oral Surgeons can administer Botulinum Toxin-A medications and dermal fillers only if they have successfully completed a residency in Oral and Maxillofacial Surgery accredited by the American Dental Association and only in the oral and maxillofacial region

#### Wisconsin

The Wisconsin Dentistry Examining Board have not regulated the use of Botox\* or dermal fillers by dentists, nor has the state regulated licensed dentists in the State of Wisconsin through related rules or regulations. Botulinum Toxin-A and dermal fillers may be administered for medical and aesthetic treatments that fall within the practice of dentistry as outlined in s. 447.01.08 of the Wisconsin Statutes which states:

- "Dentistry" means the examination, evaluation, diagnosis, prevention, or treatment, including surgery, of diseases, disorders, or conditions of the human oral cavity or its adjacent or associated tissues and structures, or of the maxillofacial area, and their impact on the human body.
- A dentist licensed under this chapter may not perform dental services that are outside the scope of the dentist's relevant education, training, and experience. Such training shall be provided by organizations or institutions recognized to provide continuing education courses in accordance with s. 447.056 of the Wisconsin Statutes.

From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers or other services they have not been specifically trained in.

#### Wyoming

The Wyoming Board of Dental Examiners have not regulated the use of Botox® or dermal fillers by dentists, nor has the state regulated licensed dentists in the State of Wyoming through related rules or regulations. From a practical standpoint, dentists need to show that they have received adequate training before administering Botulinum Toxin – A products and dermal fillers.

# FDA APPROVALS FOR BOTULINUM TOXIN & DERMAL FILLERS

Filler	Properties	FDA-Approved Indications	Company
Restylane <sup>®</sup>	Non-animal-derived hyaluronic acid; immediate results that last ~6 mo	Moderate to severe wrinkles around the nose and mouth	Medicis Pharmaceutical Corporation, Scottsdale, AR
Perlane	Non-animal-derived hyaluronic acid; immediate results may last up to 1 y	Not approved in the U.S.	Medicis Pharmaceutical Corporation, Scottsdale, AR
Captique <sup>TM</sup>	Non-animal-derived hyaluronic acid; immediate results that last up to 1 y	Moderate to severe glabellar lines, facial wrinkles and folds around the nose and mouth	Inamed Aesthetics, Inc., Santa Barbara, CA
Hylaform <sup>®</sup>	Hyaluronic acid derived from rooster combs; results may last up to 6 mo	Moderate to severe wrinkles around the nose and mouth	Inamed Aesthetics, Inc., Santa Barbara, CA
Hylaform Plus <sup>®</sup>	Large hyaluronic gel acid derived from rooster combs; results may last longer than 4–6 mo	Moderate to severe wrinkles around the nose and mouth	Inamed Aesthetics, Inc., Santa Barbara, CA
Artefill <sup>®</sup>	Bovine collagen with polymethylmethacrylate microspheres; immediate and permanent results; wait 3 mo between injections	Facial wrinkles and scars. contraindication for lip augmentation	Artes Medical, San Diego, CA
Radiesse <sup>™</sup>	Microspheres of calcium hydroxylapatite suspended in an aqueous gel carrier; immediate results last 1–2 y	Vocal cord paralysis, radiographic tissue marking, and maxillofacial augmentation	Bioform Inc., Franksville, WI
Sculptra	Synthetic polylactic acid contained in microspheres that must be reconstituted prior to injection; immediate results last typically 2 y		Sanofi Aventis, Bridgeton, NJ

\*Clinical uses typically go well beyond the FDA-approved indications. FDA, Food and Drug Administration.

## Table I: Medical Indications for Botulinum Toxin.

FDA Approved			
Detrusor overactivity associated with a neurologic condition			
Chronic migraine			
Upper limb spasticity			
Cervical dystonia			
Primary axillary hyperhidrosis			
Blepharospasm and strabismus			
Off-Label Uses for Pain			
Osteoarthritis			
Myofascial pain			
Peripheral neuropathy			

Material	Year of Approval	FDA-Approved Indications
Collagen	1981	Correction of contour deficiencies in the dermis
Hyaluronic acid (HA)	2003	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (eg, nasolabial folds); injection into facial tissue to smooth wrinkles and folds, especially around the nose and mouth; lip augmentation in patients aged ≥21 y
Modified HA derived from an avian source	2004	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (eg, nasolabial folds)
Poly-L-lactic acid (PLLA)	2004	Restoration and/or correction of facial lipoatrophy associated with HIV; correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles
Hydroxylapatite	2006	Restoration and/or correction of facial lipoatrophy associated with HIV; subdermal implantation to correct volume loss in the dorsum of the hands
Polymethyl methacrylate (PMMA) microspheres suspended in bovine collagen with lidocaine	2006	Soft tissue augmentation of the face and mouth
HA with lidocaine	2006	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (eg, nasolabial folds); correction of moderate to severe facial folds and wrinkles or facial volume loss in patients aged $\geq$ 21 y; lip augmentation and dermal implantation for correction of perioral rhytids in patients aged $\geq$ 21 y; deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid face in patients aged $\geq$ 21 y

## Filler Materials Approved by the US Food and Drug Administration for Soft Tissue Augmentation $^{\rm 3}$

Abbreviation: FDA, US Food and Drug Administration; HIV, human immunodeficiency virus.

TABLE. ONABOTULINUMA TOXIN INDICATIONS				
Approved	Indication			
1989	Strabismus			
1989	Blepharospasm, seventh cranial nerve disorders			
2000	Cervical dystonia			
2002	Glabellar lines			
2004	Axillary hyperhidrosis			
2010	Upper limb spasticity			
2010	Chronic migraine			
2011	Neurogenic overactive bladder			
2013	Lateral canthal lines			
2013	Idiopathic overactive bladder			
2016	Lower limb spasticity			
2017	Frontalis muscle overactivity			



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