

RULE ADOPTION
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LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
NEW JERSEY BOARD OF DENTISTRY

Adopted Amendment: N.J.A.C. 13:30-8.1

Adopted New Rule: N.J.A.C. 13:30-8.4A

Fee Schedules; Administration of Injectable Pharmacologics

Proposed: November 1, 2010 at 42 N.J.R. 2575(a).

Adopted: February 2, 2011 by the New Jersey Board of Dentistry, Herbert Dolinsky, D.D.S., President.

Filed: October 18, 2011 as R.2011 d.281, **without change**.

Authority: N.J.S.A. 45:1-15.1 and 45:6-3.

Effective Date: November 21, 2011.

Expiration Date: January 5, 2018.

Summary of Public Comments and Agency Responses:

The New Jersey State Board of Dentistry (Board) received comments from the following:

1. Louis Malcmacher, D.D.S., M.A.G.D., President, American Academy of Facial Esthetics;
2. Lawrence Downs, Esq., General Counsel, Medical Society of New Jersey;
3. Bruce G. Freund, D.D.S., CEO, and Zev Schulhof, D.M.D., M.D., President, American Academy of Facial Cosmetics;
4. Phillip C. Haeck, M.D., F.A.C.S., President, American Society of Plastic Surgeons, and Gary Smotrich, M.D., F.A.C.S., President, New Jersey Society of Plastic Surgeons;
5. William D. James, M.D., F.A.A.D., President, American Academy of Dermatology Association;
6. Sandra E. Vause, M.D., President, Dermatological Society of New Jersey;
7. Richard G. Bennett, M.D., President, American Society of Dermatologic Surgery Association; and
8. Michael D. Maves, M.D., M.B.A., Executive Vice President, CEO, American Medical Association.

1. COMMENT: Dr. Vause, on behalf of the Dermatological Society of New Jersey, expressed concern about the proposed new rule, noting that there are certain risks associated with the use of dermal fillers and neurotoxins. The commenter noted that mild to severe complications may result when such injections are administered by individuals who do not have proper training in recognizing pre-existing conditions, selecting and preparing the proper product, and utilizing a specialized injection technique. The commenter believes that permitting dentists to administer such injections with only 21 hours of training may endanger patients. The commenter observed that the Dermatological Society of New Jersey has great respect for dentists' ability to perform dental procedures that are within dentists' scope of practice. The commenter, however, believes that the Board has exceeded its statutory authority in proposing the new rule because the rule authorizes dentists to engage in the practice of medicine.

RESPONSE: Proposed new rule N.J.A.C. 13:30-8.4A does not authorize dentists to engage in the practice of medicine.

N.J.A.C. 13:30-8.4A(m) expressly provides that nothing in the rule shall be construed to authorize a dentist to treat diseases, disorders or conditions that are outside of the scope of the practice of dentistry as defined in N.J.S.A. 45:6-19 of the Dental Practice Act. N.J.S.A. 45:6-19 defines the practice of dentistry to include "being able to diagnose, treat, prescribe or operate for any disease, pain, deformity, deficiency, injury, or physical condition of the human tooth, teeth, alveolar process, gums, cheek, or jaws, or oral cavity and associated tissues." Therefore, dentists are authorized by statute to diagnose, treat, prescribe or operate on teeth, the alveolar process, gums, cheek, jaws, or the oral cavity and associated tissue. Consistent with this statutory authority, the Board notes, some dentists are currently providing services that involve the administration of injectable pharmacologics. The Board's intention in proposing the new [page=3097] rule is to establish standards for the proper administration of such medications in order to help ensure the health, safety, and welfare of New Jersey consumers who seek such services from licensed dentists. Under the new rule, a dentist may only administer injectable pharmacologics for the cosmetic or functional enhancement of the peri-oral area, which is defined in N.J.A.C. 13:30-8.4A(a) as the gums, cheeks, jaws, lips, and oral cavity and associated tissue. This definition is consistent with the statutory parameters established under N.J.S.A. 45:6-19. Moreover, the new rule expressly limits a dentist's authority with respect to injectable pharmacologics to administrations of such medications in dental treatment settings under N.J.A.C. 13:30-8.4A(c), and only after the dentist has conducted an appropriate physical examination, obtained a completed medical history, and made an assessment of the patient's dental needs under N.J.A.C. 13:30-8.4A(i).

The Board notes that prior to the proposal of the new rule, it consulted with representatives from the State Board of Medical Examiners (Board of Medical Examiners) to ensure that the new rule did not create unintended ambiguity with respect to the type of treatment dentists were authorized to provide. A Committee of the Board of Medical Examiners reviewed the proposed new rule and was satisfied that the rule adequately identified relevant areas of education and was consistent with the scope of dental practice. The Board also notes that the Board of Medical Examiners did not submit a comment expressing any concerns about the new rule in response to the formal notice of proposal.

The Board disagrees with the commenter's assertion that dentists who complete the Board-approved training course mandated under the new rule will lack appropriate training to safely administer injectable pharmacologics. Dentists completing a Board-approved post-doctoral training course will receive supplemental instruction in the anatomy of the head and neck, neurophysiology, including facial tissues, parasympathetic, sympathetic, and peripheral nervous systems relative to peri-oral tissue, and facial architecture, as well as patient assessment, product selection, pharmacological effects and contraindications, and management of complications. Moreover, the Board notes that completion of this 21-hour Board-approved training course does not represent the totality of a dentist's education and training in the areas covered in the new rule. Rather, dentists receive extensive training in dental school in facial anatomy, physiology, neurophysiology, pharmacology, and injection technique. Indeed, the Board notes that the curriculum for first- and second-year students at dental schools is virtually identical to the curriculum used to instruct first- and second-year medical students. The 21-hour Board-approved training course is intended to refresh and/or supplement the education dentists receive in dental school in the areas of study relevant to the administration of injectable pharmacologics in the peri-oral area. Completion of this course will help ensure that dentists administering injectable pharmacologics do so in a safe and effective manner.

2. COMMENT: Dr. Malcmacher, on behalf of the American Academy of Facial Esthetics (AAFE), objected to the new rule's requirement that an approved training course be 21 hours in length and that it must be offered at an accredited dental school or in a hospital-based program. The commenter noted that the AAFE is an educational organization that has worked with a number of dental boards in developing educational guidelines for the training of dentists in the use of neurotoxins and dermal fillers. The commenter noted that the current educational standard for neurotoxin and dermal filler training in North America for all healthcare professionals is 16 hours of training, including didactic and live patient hands-on training. The commenter observed that training requirements comparable to those being proposed for dentists are not imposed on any other healthcare professionals in New Jersey who wish to provide this treatment. In addition, the commenter noted that the Board has not required dentists desiring to provide other more invasive dental treatments, such as implant therapy, to complete additional Board-approved training. The commenter recommended that the Board amend the rule to require dentists to complete a 16-hour continuing education course on neurotoxins and dermal fillers certified by either the American Dental Association or the Academy of General Dentistry.

RESPONSE: The Board proposed the 21-hour training course requirement in the new rule following its review of various factors, including the number of content areas the Board believes must be covered as part of this training and the complexity of these areas of instruction. The Board disagrees with the commenter's assertion that 16 hours of training is sufficient, and notes that the Board is not obligated to establish training requirements for dentists that are comparable to the requirements imposed on other healthcare providers by their respective licensing boards. It is a reasonable exercise of the Board's statutory authority to require dentists to obtain additional instruction in order to perform certain procedures if the Board determines that the protection of the public health, safety, and welfare necessitates such heightened training. For example, existing Board rules N.J.A.C. 13:30-8.2 and 8.4 require dentists who seek to administer parenteral conscious sedation or enteral sedation to complete Board-approved post-doctoral coursework of 80 hours and 40 hours, respectively. Training in these areas must be completed at an accredited dental school, in a hospital-based program, or in a college or university setting, consistent with the training requirements the Board has proposed for dentists seeking to administer injectable pharmacologics. Moreover, the Board notes that whether a course has been certified as an approved continuing education program by the American Dental Association or the Academy of General Dentistry is irrelevant for purposes of determining whether the course meets the express content requirements imposed under the rule. The Board must review the course outline, course content, and objectives, and the instructor's qualifications to determine whether the course meets these requirements. The Board, therefore, declines to amend the training requirements in N.J.A.C. 13:30-8.4A as suggested by the commenter.

3. COMMENT: Mr. Downs, on behalf of the Medical Society of New Jersey (MSNJ), opposed the new rule, believing that it expands the scope of dental practice beyond what the Legislature authorized in N.J.S.A. 45:6-19 of the Dental Practice Act. The commenter does not believe that the New Jersey Legislature contemplated "dental practice" to include the administration of injectable pharmacologics for cosmetic purposes. The commenter also objected to the definition of "peri-oral area" in the proposed new rule, believing that the inclusion of the word "lips" in the definition is indicative of the Board's attempt to expand the term "associated tissues" in order to allow dentists to provide cosmetic procedures that are currently performed by medical doctors. The commenter notes that such expansion is not permitted through rulemaking, but is the province of the Legislature.

The commenter also expressed concern that the proposed new rule will endanger patient safety, noting that the 21 hours of training mandated under the rule cannot replace the years of clinical training required to understand the pharmacologic issues and anatomical structures implicated by the rule. The commenter believes that the proposed new rule will jeopardize public health by permitting lesser trained professionals to provide medical procedures. The commenter also objected to the Board's classification of the administration of injectable pharmacologics as "dental services" in the Economic Impact statement of the notice of proposal, and observed that the Economic Impact statement fails to acknowledge the economic impact on patients for mistakes in the administration of toxic pharmacologic agents by inadequately trained individuals.

RESPONSE: The Board disagrees with the commenter's assertion that the new rule expands the scope of dental practice in violation of the Dental Practice Act. As noted above, in the Response to Comment 1, N.J.S.A. 45:6-19 of the Dental Practice Act defines the practice of dentistry to include "being able to diagnose, treat, prescribe or operate for any disease, pain, deformity, deficiency, injury, or physical condition of the human tooth, teeth, alveolar process, gums, cheek, or jaws, or oral cavity and associated tissues." Therefore, dentists are authorized by statute to diagnose, treat, prescribe, or operate on teeth, the alveolar process, gums, cheek, jaws, or the oral cavity and associated tissue. The new rule limits a dentist's administration of injectable pharmacologics to the "peri-oral" area, as defined in N.J.A.C. 13:30-8.4A(a), the definition of which, including its reference to "lips," is consistent with N.J.S.A. 45:6-19. The Board believes that it is reasonable to interpret the statutory reference to gums, cheek, jaws, or oral cavity and associated tissue to also include "lips." Interpreting the statutory reference to these areas to exclude the treatment of lips would lead to absurd results. For example, the Board notes that in a case of a patient who has sustained traumatic injury to the mouth, a dentist could treat the patient's teeth, gums, cheeks, [page=3098] and jaw, but could not suture or otherwise treat the patient's injured lips under the commenter's interpretation of the statute. Moreover, the Board notes that its express reference to "lips" in the definition of peri-oral area is supported by the express reference to "lips" in N.J.S.A. 45:6-19, in relation to the use of artificial restorations and other dental appliances. In relevant part, the statute provides that artificial restorations and other dental appliances may be used to correct diseases or injury to "the jaws, teeth, lips, gums, cheeks, [and] palate ..."

The Board strongly disagrees with the commenter's assertion that dentists are not adequately trained to administer injectable pharmacologics. As noted above in the Response to Comment 1, dentists receive extensive training in dental school in facial anatomy, physiology, neurophysiology, pharmacology, and injection technique. Dentists completing the Board-approved post-doctoral training course will receive supplemental instruction in the anatomy of the head and neck, neurophysiology, including facial tissues, parasympathetic, sympathetic, and peripheral nervous systems relative to peri-oral tissue, and facial architecture, as well as patient assessment, product selection, pharmacological effects and contraindications, and management of complications. Completion of this training will help ensure that dentists administering injectable pharmacologics do so in a safe and effective manner.

The new rule does not authorize dentists to provide medical procedures or to engage in the practice of medicine, as the commenter suggests. As noted above in the Response to Comment 1, N.J.A.C. 13:30-8.4A(m) expressly provides that nothing in the rule shall be construed to authorize a dentist to treat diseases, disorders, or conditions that are outside of the scope of the practice of dentistry as defined in N.J.S.A. 45:6-19 of the Dental Practice Act. Dentists are authorized by statute to diagnose, treat, prescribe, or operate on the peri-oral area. The administration of injectable pharmacologics for the enhancement of peri-oral tissue is within the scope of dental practice and, therefore, may appropriately be referred to as a "dental service." Lastly, the Board disagrees with the commenter's assertion that the administration of injectable pharmacologics by licensed dentists will result in economic harm to patients. As noted above, the Board believes that the training mandated under the new rule will help to ensure that dentists administering injectable pharmacologics do so in a safe and effective manner.

4. COMMENT: Dr. Bennett, on behalf of the American Society for Dermatologic Surgery Association (ASDSA) believes that the training requirements in the new rule fail to offer sufficient patient safety protections. The commenter expressed concern about the number of non-physicians practicing medicine and the resulting impact on patient safety, and noted that the injection of dermal fillers and neurotoxins requires extensive, specialized physician knowledge in order to ensure the highest level of care. The commenter noted that complications resulting from the use of neurotoxins and dermal fillers, while rare, are frequently caused by poor injection technique. The commenter observed that proper management of complications requires experience with wound healing on the skin and, therefore, requires a medical, rather than dental, background.

The commenter expressed concern that the training required under the rule will not adequately prepare dentists to administer these agents, noting that appropriate training should include instruction in: normal facial anatomy and the changes that occur with aging and illness; the location, thickness, and properties of the soft tissue layers, and the location and course of major arteries and nerves; injection techniques; post-operative care; and potential complications and their management. The commenter noted that medical specialties such as dermatology, plastic surgery, otolaryngology, and ophthalmology, include training in these areas as part of their residency curriculum.

The commenter also noted that injectable fillers are not classified as "injectable pharmacologics" by the Food and Drug Administration (FDA), but rather as "medical devices." As such, the commenter believes that the definition of "injectable pharmacologic" in new rule N.J.A.C. 13:30-8.4A(a) contradicts the FDA classification of these products.

The commenter believes that the Board has exceeded its statutory authority by authorizing dentists to practice medicine, noting that the injections of dermal fillers and neurotoxins do not constitute the practice of dentistry. The commenter notes that the Dental Practice Act defines "dental practice" to include treatment of the teeth and its associated oral cavity tissues. The commenter noted that the ASDSA is not aware of any use of dermal fillers, either FDA-approved or off-label, beyond the treatment of, and immediately below, the dermis of the skin. In addition, the commenter noted that neurotoxins are only approved to treat wrinkles between the eyebrows.

RESPONSE: The Board disagrees with the commenter's assertions that dentists are not adequately trained to administer injectable pharmacologics in a safe manner, and that only physicians should be permitted to provide such services. As noted above in the Response to Comment 1, dentists receive extensive training in dental school in facial anatomy, physiology, neurophysiology, pharmacology, and injection technique. Dentists completing a Board-approved post-doctoral training course will receive supplemental instruction in the anatomy of the head and neck, neurophysiology, including facial tissues, parasympathetic, sympathetic, and peripheral nervous systems relative to peri-oral tissue, and facial architecture, as well as patient assessment, product selection, pharmacological effects and

contraindications, and management of complications. The Board believes that completion of this training will help ensure that dentists administering injectable pharmacologics do so in a safe and effective manner.

The Board also disagrees with the commenter's assertion that the definition of "injectable pharmacologic" in N.J.A.C. 13:30-8.4A(a) contradicts the Federal classification of the products referenced in the rule. The definition of "injectable pharmacologics" in N.J.A.C. 13:30-8.4A(a) provides that dentists may administer medications or similar products that have been "approved by the Federal Food and Drug Administration." The Board's definition is designed to capture medications that are classified as "injectable pharmacologics," as well as other products, such as injectable fillers, that the FDA classifies as medical devices. In addition, the new rule does not authorize dentists to practice medicine, as the commenter suggests. As noted above in the Response to Comment 1, N.J.A.C. 13:30-8.4A(m) expressly provides that nothing in the rule shall be construed to authorize a dentist to treat diseases, disorders, or conditions that are outside of the scope of the practice of dentistry as defined in N.J.S.A. 45:6-19 of the Dental Practice Act. N.J.S.A. 45:6-19 defines the practice of dentistry to include "being able to diagnose, treat, prescribe or operate for any disease, pain, deformity, deficiency, injury, or physical condition of the human tooth, teeth, alveolar process, gums, cheek, or jaws, or oral cavity and associated tissues." Under the new rule, a dentist may only administer injectable pharmacologics for the cosmetic or functional enhancement of the peri-oral area, which is defined in N.J.A.C. 13:30-8.4A(a) as the gums, cheeks, jaws, lips, and oral cavity and associated tissue. This definition is consistent with the statutory parameters established under N.J.S.A. 45:6-19. Lastly, as noted above in the Response to Comment 1, the Board consulted with the Board of Medical Examiners about the new rule prior to the publication of the notice of proposal, and the Board of Medical Examiners does not object to the rule.

5. COMMENT: Drs. Haeck and Smotrich, on behalf of the American Society of Plastic Surgeons (ASPS) and the New Jersey Society of Plastic Surgeons (NJSPS), believe that the new rule relates to the practice of medicine and is, therefore, outside the purview of the Board to regulate. The commenters believe that there are no uses for dermal fillers that relate, in any manner, to the maintenance of oral and dental health. Although the commenters note that there have been isolated instances when Botox<(R)> has been used by dentists in an off-label context for the treatment of TMJ disorders, they do not believe that this product has practical applications related to oral health.

The commenters believe that injectable pharmacologics should only be administered by a licensed medical doctor or doctor of osteopathy. The commenters note that there are many injectable pharmacologics and fillers that would be covered under the proposed new rule, with each product presenting its own unique set of potential complications, including severe allergic or neurotoxic reactions, infection, granulomas, and disfiguring keloid or other scar formations. The commenters note that such complications, although rare, require the treating provider to have the extensive training and education that only medical schools provide.

[page=3099] The commenters note that although some state laws permit properly trained non-medical personnel to perform minimally invasive medical procedures, such procedures must be performed under the direct supervision of a licensed physician, and the physician must maintain direct responsibility for all treatments being delegated to non-physicians. The commenters, therefore, objected to proposed new rule N.J.A.C. 13:30-8A.4(j), which would allow non-physician dentists to supervise and delegate the administration of injectable pharmacologics to other licensed health care professionals. The commenters also observed that the Board of Medical Examiners currently prohibits physicians with a medical degree from delegating the administration of Botox<(R)> and dermal fillers to non-physicians.

RESPONSE: The Board disagrees with the commenters' assertions that the administration of injectable pharmacologics may only be performed by physicians and that dentists lack appropriate training to administer such medications in a safe and effective manner, and reiterates the Response provided above to Comment 1. The new rule authorizes appropriately trained dentists to administer injectable pharmacologics for the enhancement of peri-oral tissue, consistent with the scope of dental practice authorized pursuant to N.J.S.A. 45:6-19 and is, therefore, within the Board's statutory purview to regulate. In addition, the Board disagrees with the commenter's assessment of the new rule's delegation provision in N.J.A.C. 13:30-8.4A(j). N.J.A.C. 13:30-8.4A(j) does not allow a dentist to delegate the administration of an injectable pharmacologic to any licensed health care professional as the commenter suggests. The rule expressly provides that a dentist may only delegate such administrations to a licensed healthcare professional who is authorized by his or her scope of practice to provide injections at the direction of a dentist. Moreover, the new rule

does not create any inconsistency or conflict with any rules or guidelines issued by the Board of Medical Examiners with respect to the delegation of such services to non-physicians because the administration of injectable pharmacologics for the functional enhancement of peri-oral tissue by licensed and appropriately trained dentists is squarely within the scope of dental practice. As noted above in the Response to Comment 1, the Board of Dentistry consulted with the Board of Medical Examiners about the new rule prior to the publication of the notice of proposal, and the Board of Medical Examiners does not object to the rule.

6. COMMENT: Drs. Freund and Schulhof, on behalf of the American Academy of Facial Cosmetics, which provides training for healthcare professionals in injectable pharmacologics, expressed support for the new rule, noting that dentists have more expertise than other healthcare professionals in facial anatomy and injecting techniques. The commenters, however, expressed concern regarding the requirement that the training course be offered at an accredited dental school, in a hospital-based program, or in a college or university clinical setting. The commenters observed that offering training programs in hospitals and universities may prove difficult because certain medical professionals view dentists as competitors for viable professional revenue. The commenters note that many healthcare professionals who are presently injecting these agents were primarily taught the procedures from a private trainer or from a product sales representative. The commenters, therefore, recommend that the Board amend the new rule to eliminate the requirement that the training course be offered at an accredited dental school, in a hospital-based program, or in a college or university clinical setting.

The commenters also expressed concern regarding the new rule's restriction of injections to the peri-oral area. The commenters noted that most botulinum treatments are given further away than the direct peri-oral area. The commenters believe that dentists should be permitted to administer these agents to treat the full facial region, just as physicians are authorized to do.

RESPONSE: The Board thanks the commenters for their support of the new rule. The Board, however, declines to amend the rule to eliminate the requirement that approved training courses must be offered at accredited dental schools, in hospital-based programs, or in college or university settings, as the commenters suggest. The Board believes that training courses offered in these settings provided licensees with a more structured learning experience than would be possible in less formal, non-academic, or non-clinical settings. The Board also notes that the new rule's requirement that the training course be offered at an accredited dental school, in a hospital-based program, or in a college or university clinical setting is consistent with the training requirements currently imposed by the Board on dentists seeking to administer parenteral conscious sedation or enteral sedation, as set forth in existing Board rules N.J.A.C. 13:30-8.2 and 8.4.

As noted above in the Response to Comment 1, the new rule limits a dentist's administration of injectable pharmacologics to the peri-oral area consistent with the scope of dental practice established in N.J.S.A. 45:6-19 of the Dental Practice Act. Therefore, the Board cannot amend the rule to permit dentists to administer injectable pharmacologics outside of the peri-oral area, as the commenters suggest.

7. COMMENT: Dr. James, on behalf of the American Academy of Dermatology Association (AADA), believes that the use of injectable pharmacologics is the practice of medicine, specifically within the scope of dermatologic practice. The commenter noted that the practice of dermatology includes, but is not limited to, performing any act or procedure that can alter or cause biologic change or damage to the skin and subcutaneous tissue. Any procedure using any approved device that can alter or cause biologic change or damage, therefore, should be performed only by an appropriately trained physician or by non-physician personnel under the direct, on-site supervision of an appropriately trained physician. The commenter also believes that the rule's training requirements in N.J.A.C. 13:30-8.4A(d) and (f) will not ensure patient safety. The commenter noted that training to inject dermal fillers, which can damage living tissue, requires specific, long-term training, such as a residency, in cutaneous dermatologic procedures. The commenter does not believe that a dentist's education includes appropriate training in the use of dermal fillers, nor does he believe that the new rule's 21-hour training program will adequately prepare general dentists to use these products. The commenter notes that the focus of a general dentist's education in dental school is oral health, rather than the skin and soft tissue. The commenter noted that dentists are not required to demonstrate competency in procedures involving skin and soft tissue augmentation involving products that can alter or damage living tissue, such as dermal fillers. The commenter believes that the basic training authorized under the rule is not equivalent to a physician's

training and understanding of this medical procedure.

The commenter also noted that the use of FDA-approved injectable fillers in the dermis or mid-to-deep dermis require extensive knowledge of facial anatomy to ensure proper placement of the injections. In addition, the commenter noted that the FDA's Consumer Health Information materials suggest that patients should discuss the use of dermal fillers with a doctor who can refer the patient to a specialist in the fields of dermatology or aesthetic plastic surgery.

RESPONSE: The Board disagrees with the commenter's assertions that the administration of injectable pharmacologics may only be performed by physicians and that dentists lack appropriate training to administer such medications in a safe and effective manner, and reiterates the Response provided above to Comment 1. The new rule authorizes appropriately trained dentists to administer injectable pharmacologics for the enhancement of peri-oral tissue in a dental treatment setting, consistent with the scope of dental practice authorized pursuant to N.J.S.A. 45:6-19. The new rule does not authorize a dentist to perform medical procedures. The Board also notes that the Federal Food and Drug Administration has not adopted any regulations, nor issued any pronouncements or guidelines, that preclude a dentist from administering injectable pharmacologics consistent with the scope of dental practice established in N.J.S.A. 45:6-19.

8. COMMENT: Dr. Maves, on behalf of the American Medical Association (AMA), noted that medical school students receive comprehensive training in all organ systems, but dental students are trained in oral health. The commenter also noted that medical students received a broad-based, comprehensive education that enables them, as future physicians, to understand how different interventions, such as those contemplated in the new rule might affect a patient's overall health. The commenter also noted that in a medical student's education, pharmacology is integrated into the comprehensive content of biomedical sciences, whereas a dental student's pharmacology training is limited to [page=3100] oral health. The commenter believes that the "peri-oral area" created in the new rule is beyond the scope of a dentist's education and training.

The commenter also noted that following medical school, medical residents typically enter into one of several specialty fields, which build on this comprehensive medical education with further emphasis on the treatment and management of disease, including how those treatments may affect other systems in the human body. Such specialties require an additional three-to-seven years of training before the resident is ready to independently perform procedures such as those identified in N.J.A.C. 13:30-8.4A. The commenter noted that dental students receive no such additional training, and that the procedures authorized under the rule require much more than the basic training in oral health that dental students receive. The commenter does not believe that the 21-hour course outlined in the new rule will adequately educate or train dentists to administer injectable pharmacologics. The commenter contends that the new rule seeks to provide legal authority for dentists to perform procedures that they are not legally authorized to perform.

RESPONSE: The Board strongly disagrees with the commenter's assertion that a dental student's education is limited to "oral health." As noted above in the Response to Comment 1, dentists receive extensive training in dental school in facial anatomy, physiology, neurophysiology, pharmacology, and injection technique. In addition, dentists completing the Board-approved post-doctoral training course will receive supplemental instruction in the anatomy of the head and neck, neurophysiology, including facial tissues, parasympathetic, sympathetic, and peripheral nervous systems relative to peri-oral tissue, and facial architecture, as well as patient assessment, product selection, pharmacological effects and contraindications, and management of complications. Completion of this training will help ensure that dentists administering injectable pharmacologics do so in a safe and effective manner. Moreover, the Board disagrees with the commenter's assertion that dentists are not legally authorized to provide the services authorized under the rule and reiterates the Response provided above to Comment 1. Dentists are authorized under N.J.S.A. 45:6-19 of the Dental Practice Act to diagnose, treat, prescribe, or operate on teeth, the alveolar process, gums, cheek, jaws, or the oral cavity and associated tissue. The new rule authorizes appropriately trained dentists to administer injectable pharmacologics for the enhancement of peri-oral tissue, consistent with the scope of dental practice authorized pursuant to N.J.S.A. 45:6-19. Therefore, dentists are legally authorized to provide such services.

The Board received no comments on its proposal to amend N.J.A.C. 13:30-8.1.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendment and new rule are governed by N.J.S.A. 45:6-1 et seq., and are not subject to any Federal requirements or standards.

Full text of the adoption follows:

SUBCHAPTER 8. GENERAL PROVISIONS

13:30-8.1 Fee schedules

(a)-(c) (No change.)

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Reinstatement
fee:

1. Dentists. . . \$200.00

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2. Dental \$100.00

hygienists,
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(e)-(f) (No change.)

13:30-8.4A Administration of injectable pharmacologics

(a) For purposes of this section, the following words and terms shall have the following meanings, unless the context clearly indicates otherwise.

"Injectable pharmacologic" means any medication classified as a neurotoxin, adjuvant or therapeutic agent including, but not limited to, hyaluronic acid (such as Restylane<(R)>), fillers (such as collagen), Botulinum Toxin Type A (such as Botox<(R)>) or similar products that have been approved by the Federal Food and Drug Administration.

"Peri-oral area" means the gums, cheeks, jaws, lips and oral cavity and associated tissues.

(b) No dentist shall administer an injectable pharmacologic unless the minimum standards of training and procedure set forth in this section are satisfied.

(c) A dentist may administer an injectable pharmacologic for the cosmetic or functional enhancement of peri-oral tissue only in a dental treatment setting.

(d) 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.

(e) 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.

(f) 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:

1. Anatomy of head and neck;
2. Neurophysiology, including facial tissues, parasympathetic, sympathetic and peripheral nervous systems relative to peri-oral tissue, and facial architecture;
3. Patient selection, including indications and contraindications;
4. Pharmacological effects and contraindications, including potential drug interactions;
5. Management of complications; and
6. Informed consent.

(g) The course administrator shall issue a certificate of completion to a dentist who successfully completes the approved course.

(h) 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 assess 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.

(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 health care practice to provide injections under the direction of a dentist.

(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.

(l) 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.

(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.

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