



Virginia
Regulatory
Town Hall

Proposed Regulation Agency Background Document

Agency Name:	Board of Dentistry/Department of Health Professions
VAC Chapter Number:	18 VAC 60-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Dentistry and Dental Hygiene
Action Title:	Oral & Maxillofacial Surgery
Date:	05/17/02

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Board of Dentistry has taken action to replace emergency regulations in compliance with Chapter 662 of the 2001 Acts of the Assembly requiring the Board to promulgate regulations establishing rules for the registration and profiling of oral and maxillofacial surgeons and for the certification of such persons to perform certain cosmetic procedures.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the

Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

- 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
- 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
- 4. To establish schedules for renewals of registration, certification and licensure.*
- 5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*
- 6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 and Chapter 25 of this title.*
- 7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*
- 8. To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*
- 9. To take appropriate disciplinary action for violations of applicable law and regulations.*
- 10. To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv)*

reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.

11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*
12. *To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.*

In addition to the general authority for the Board to promulgate regulations and levy fees, the specific authority for the registration and certification of oral and maxillofacial surgeons is found in the following sections:

§ 54.1-2700. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Dentistry;

"Dental hygiene" means cleaning and polishing teeth and assisting the members of the dental profession in providing oral health care and oral health education to the public;

"Dental hygienist" means a person trained in the practice of and practicing dental hygiene;

"Dentist" means a person who has been awarded a degree in and is licensed to practice dentistry;

"Dentistry" means the evaluation, diagnosis, prevention, and treatment, through surgical, nonsurgical or related procedures, of diseases, disorders, and conditions of the oral cavity and the maxillofacial, adjacent and associated structures and their impact on the human body;

"License" means the document issued to an applicant upon completion of requirements for admission to practice dentistry or dental hygiene in this Commonwealth or upon registration for renewal of license to continue the practice of dentistry or dental hygiene in this Commonwealth;

"Maxillofacial" means pertaining to the jaws and face, particularly with reference to specialized surgery of this region.

"Oral and maxillofacial surgeon" means a person who has successfully completed an oral and maxillofacial residency program, approved by the Commission on Dental Accreditation of the American Dental Association, and who holds a valid license from the Board.

§ 54.1-2706. Revocation or suspension; other sanctions.

A. The Board may refuse to admit a candidate to any examination, refuse to issue a license to any applicant, suspend for a stated period or indefinitely, or revoke any license or censure or reprimand any licensee or place him on probation for such time as it may designate for any of the following causes:

1. *Fraud, deceit or misrepresentation in obtaining a license;*
2. *The conviction of any felony or the conviction of any crime involving moral turpitude;*
3. *Use of alcohol or drugs to the extent that such use renders him unsafe to practice dentistry or dental hygiene;*
4. *Any unprofessional conduct likely to defraud or to deceive the public or patients;*
5. *Intentional or negligent conduct in the practice of dentistry or dental hygiene which causes or is likely to cause injury to a patient or patients;*
6. *Employing or assisting persons whom he knew or had reason to believe were unlicensed to practice dentistry or dental hygiene;*
7. *Publishing or causing to be published in any manner an advertisement relating to his professional practice which (i) is false, deceptive or misleading, (ii) contains a claim of superiority, or (iii) violates regulations promulgated by the Board governing advertising;*
8. *Mental or physical incompetence to practice his profession with safety to his patients and the public;*
9. *Violating, assisting, or inducing others to violate any provision of this chapter or any Board regulation;*
10. *Conducting his practice in a manner contrary to the standards of ethics of dentistry or dental hygiene or in a manner presenting a danger to the health and welfare of his patients or to the public;*
11. *Practicing outside the scope of the dentist's or dental hygienist's education, training, and experience;*
12. *(See Editor's note) Performing a procedure subject to certification without such valid certification required by the Board pursuant to § 54.1-2709.1 and Board regulations; however, procedures performed pursuant to the provisions of subdivision 5 of § 54.1-2712 as part of an American Dental Association accredited residency program shall not require such certification;*
13. *The revocation, suspension or restriction of a license to practice dentistry or dental hygiene in another state, possession or territory of the United States or foreign country; or*
14. *The violation of any provision of a state or federal law or regulation relating to manufacturing, distributing, dispensing or administering drugs.*

B. The Board may direct any licensee under a disciplinary order to furnish it at such intervals as it may require, evidence that he is not practicing his profession in violation of this chapter. In addition, when the Board has probable cause to believe the licensee is unable to practice dentistry with reasonable skill and safety to patients because of excessive use of alcohol or drugs or physical or mental illness, the Board, after preliminary investigation by informal conference, may direct that the licensee submit to a mental or physical examination. Failure of the licensee to submit to the examination shall constitute grounds for disciplinary action. Any licensee affected by this subsection shall be afforded reasonable opportunity to demonstrate that he is competent to practice dentistry or dental hygiene with reasonable skill and safety to patients.

§ 54.1-2709.1. (For effective date /- See Editor's note) Certain certification required.

A. The Board of Dentistry shall promulgate regulations establishing criteria for certification of board certified or board eligible oral or maxillofacial surgeons to perform certain procedures within the definition of dentistry that are unrelated to the oral cavity or contiguous structures, provided such services (i) are not for the prevention and treatment of disorders, diseases, lesions and malpositions of the human teeth, alveolar process, maxilla, mandible, or adjacent tissues, or any necessary related procedures, and are services the training for which is included in the curricula of dental schools or advanced postgraduate education programs accredited by the Commission of Dental Accreditation of the American Dental Association or continuing educational programs recognized by the Board of Dentistry, or (ii) are not provided incident to a head or facial trauma sustained by the patient. The regulations shall include, but need not be limited to, provisions for: (1) promotion of patient safety; (2) identification and categorization of procedures for the purpose of issuing certificates; (3) establishment of an application process for certification to perform such procedures; (4) establishment of minimum education, training, and experience requirements for certification to perform such procedures, including consideration of whether a licensee has been granted practice privileges to perform such procedures from an accredited

hospital located in the Commonwealth and consideration of the presentation of a letter attesting to the training of the applicant to perform such procedures from the chairman of an accredited postgraduate residency program; (5) development of protocols for proctoring and criteria for requiring such proctoring; and (6) implementation of a quality assurance review process for such procedures performed by certificate holders.

B. In promulgating the minimum education, training, and experience requirements for oral and maxillofacial surgeons to perform such procedures and the regulations related thereto, the Board of Dentistry shall consult with an advisory committee comprised of three members selected by the Medical Society of Virginia and three members selected by the Virginia Society of Oral and Maxillofacial Surgeons. All members of the advisory committee shall be licensed by the Board of Dentistry or the Board of Medicine and shall engage in active clinical practice. The committee shall have a duty to act collaboratively and in good faith to recommend the education, training, and experience necessary to promote patient safety in the performance of such procedures. The advisory committee shall prepare a written report of its recommendations and shall submit this report to the Board of Dentistry and shall also submit its recommendations to the Board of Medicine for such comments as may be deemed appropriate, prior to the promulgation of draft regulations. The advisory committee may meet periodically to advise the Board of Dentistry on the regulation of such procedures.

C. In promulgating the regulations required by this section, the Board shall take due consideration of the education, training, and experience requirements adopted by the American Dental Association Council on Dental Education or the Commission on Dental Accreditation. Further, the Board's regulations shall require that complaints arising out of performance of such procedures be enforced solely by the Board of Dentistry and reviewed jointly by a physician licensed by the Board of Medicine who actively practices in a related specialty and by an oral and maxillofacial surgeon licensed by the Board of Dentistry.

However, upon receipt of reports of such complaints the Board of Dentistry shall promptly notify the Board of Medicine which shall maintain the confidentiality of such complaint consistent with § 54.1-2400.2.

(2001, c. 662.)

§ 54.1-2709.2. Registration and certain data required.

The Board of Dentistry shall require all oral and maxillofacial surgeons to annually register with the Board and to report and make available the following information:

- 1. The names of medical schools or schools of dentistry attended and dates of graduation;*
- 2. Any graduate medical or graduate dental education at any institution approved by the Accreditation Council for Graduation Medical Education, the Commission on Dental Accreditation, American Dental Association;*
- 3. Any specialty board certification or eligibility for certification as approved by the Commission on Dental Accreditation, American Dental Association;*
- 4. The number of years in active, clinical practice as specified by regulations of the Board;*
- 5. Any insurance plans accepted, managed care plans in which the oral and maxillofacial surgeon participates, and hospital affiliations, including specification of any privileges granted by the hospital;*
- 6. Any appointments, within the most recent ten-year period, of the oral and maxillofacial surgeon to a dental school faculty and any publications in peer-reviewed literature within the most recent five-year period and as specified by regulations of the Board;*
- 7. The location of any primary and secondary practice settings and the approximate percentage of the oral and maxillofacial surgeon's time spent practicing in each setting;*
- 8. The access to any translating service provided to the primary practice setting of the oral and maxillofacial surgeon;*
- 9. The status of the oral and maxillofacial surgeon's participation in the Virginia Medicaid Program;*
- 10. Any final disciplinary or other action required to be reported to the Board by health care institutions, other practitioners, insurance companies, health maintenance organizations, and professional organizations pursuant to §§ 54.1-2906, 54.1-2709.3, and 54.1-2709.4 that results in a suspension or*

revocation of privileges or the termination of employment or a final order of the Board relating to disciplinary action; and

11. Other information related to the competency of oral and maxillofacial surgeons as specified in the regulations of the Board.

The Board shall promulgate regulations to implement the provisions of this section, including, but not limited to, the release, upon request by a consumer, of such information relating to an oral and maxillofacial surgeon. The regulations promulgated by the Board shall provide for reports to include all paid claims in categories indicating the level of significance of each award or settlement.

(2001, c. 662.)

§ 54.1-2709.3. Reports of disciplinary action against oral and maxillofacial surgeons; immunity from liability.

A. The presidents of the Virginia Dental Association and the Virginia Society of Oral and Maxillofacial Surgeons shall report to the Board of Dentistry any disciplinary actions taken by his organization against any oral and maxillofacial surgeon licensed under this chapter if such disciplinary action is a result of conduct involving professional ethics, professional incompetence, moral turpitude, drug or alcohol abuse.

B. The president of any association, society, academy or organization shall report to the Board of Dentistry any disciplinary action taken against any oral and maxillofacial surgeon licensed under this chapter if such disciplinary action is a result of conduct involving professional ethics, professional incompetence, moral turpitude, drug addictions or alcohol abuse.

C. Any report required by this section shall be in writing directed to the Board of Dentistry, shall give the name and address of the person who is the subject of the report and shall describe fully the circumstances surrounding the conduct to be reported.

D. Any person making a report required by this section or testifying in a judicial or administrative proceeding as a result of such report shall be immune from any civil liability resulting therefrom unless such person acted in bad faith or with malicious intent.

E. In the event that any organization enumerated in subsection A or any component thereof receives a complaint against an oral and maxillofacial surgeon, such organization may, in lieu of considering disciplinary action against such oral and maxillofacial surgeon, request that the Board investigate the matter pursuant to this chapter, in which event any person participating in the decision to make such a request or testifying in a judicial or administrative proceeding as a result of such request shall be immune from any civil liability alleged to have resulted therefrom unless such person acted in bad faith or with malicious intent.

(2001, c. 662.)

§ 54.1-2709.4. Further reporting requirements.

A. The following matters shall be reported to the Board:

1. Any disciplinary action taken against an oral and maxillofacial surgeon licensed under this chapter by another state or by a federal health institution or voluntary surrender of a license in another state while under investigation;

2. Any malpractice judgment against an oral and maxillofacial surgeon licensed under this chapter;

3. Any incident of two settlements of malpractice claims against an individual oral and maxillofacial surgeon licensed under this chapter within a three-year period; and

4. Any evidence that indicates to a reasonable probability that an oral and maxillofacial surgeon licensed under this chapter is or may be professionally incompetent, guilty of unprofessional conduct or mentally or physically unable to engage safely in the practice of his profession.

B. The following persons and entities are subject to the reporting requirements set forth in this section:

1. Any oral and maxillofacial surgeon licensed under this chapter who is the subject of a disciplinary action, settlement judgment or evidence for which reporting is required pursuant to this section;

2. Any other person licensed under this chapter, except as provided in the Health Practitioners' Intervention Program;

3. *The presidents of all professional societies in the Commonwealth, and their component societies whose members are regulated by the Board, except as provided for in the protocol agreement entered into by the Health Practitioners' Intervention Program;*
 4. *All health care institutions licensed by the Commonwealth;*
 5. *The malpractice insurance carrier of any oral and maxillofacial surgeon who is the subject of a judgment or of two settlements within a three-year period. The carrier shall not be required to report any settlements except those in which it has participated that have resulted in a least two settlements on behalf of an individual oral and maxillofacial surgeon during a three-year period; and*
 6. *Any health maintenance organization licensed by the Commonwealth.*
- C. No person or entity shall be obligated to report any matter to the Board if the person or entity has actual notice that the matter has already been reported to the Board.*
- D. Any report required by this section shall be in writing directed to the Board, shall give the name and address of the person who is the subject of the report and shall describe the circumstances surrounding the conduct required to be reported.*
- E. Any person making a report required by this section shall be immune from any civil liability or criminal prosecution resulting therefrom unless such person acted in bad faith or with malicious intent.*
- F. The clerk of any circuit court or any district court in the Commonwealth shall report to the Board the conviction of any oral and maxillofacial surgeon known by such clerk to be licensed under this chapter of any (i) misdemeanor involving a controlled substance, marijuana or substance abuse or involving an act of moral turpitude or (ii) felony.*
- (2001, c. 662.)*

The Office of the Attorney General has certified by letter that the Board has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

In mandating certification of oral and maxillofacial surgeons to perform cosmetic procedures on the head and neck, § 54.1-2709.1 requires that regulations include six specific criteria – the first of which is the “promotion of patient safety.” Regulations establishing a profile of such surgeons (including disciplinary and malpractice history), standards for minimal competency in performing certain procedures, and a system for quality assurance review of their practice are all intended to protect the health, safety and welfare of citizens of Virginia who may elect to become cosmetic surgery patients. Similar requirements and oversight for a specialized practice by a regulatory board do not exist for other health care professionals, but were included to fulfill a statutory mandate in the interest of patient safety.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

Proposed regulations provide requirements for the registration and profiling of all oral and maxillofacial surgeons to include a fee of \$175 for initial registration and renewal. The profiling requirements include the provision of information that is available to the public as specified in the Code. Included on the profile is information about final disciplinary actions with the notices outlining the charges and reports on paid malpractice claims. The oral and maxillofacial surgeon is required to provide initial information and any updates within 30 days.

The regulations also set forth the requirements and qualifications for oral and maxillofacial surgeons who want to be certified to perform specified cosmetic procedures above the clavicle or within the head and neck region of the body. Certification is not required for procedures that are part of the normal care and treatment of the patient, such as treatment of facial fractures, repair of cleft lip and palate deformity, and facial augmentation procedures. The regulations establish qualifications for certification including completion of a residency program, board certification, current hospital privileges, and specialized training evidenced by documentation of proctored cases and course work. Finally, there are requirements for quality assurance review for procedures performed by a certificate holder and a process established for complaints against such practitioners.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

Primary advantages and disadvantages to the public:

Prior to a statutory mandate for registration and certification, oral and maxillofacial surgeons have been credentialed and have held hospital privileges to perform a variety of reconstructive surgeries in the area of the head and neck. In addition, a small number of oral and maxillofacial surgeons have performed similar elective procedures for cosmetic purposes, both in licensed hospitals and out-patient settings. There is no evidence that the public has been harmed by their practice, so the Board believes the proposed regulations are sufficient to ensure that those procedures performed for cosmetic purposes may be performed with competency and safety. In fact, public health and safety is better protected by a thorough review of credentials and training for cosmetic surgery by a committee of peers, as is now required by "emergency" regulations. Since the emergency regulations went into effect on December 1, 2001, there have been no reports of unsafe practice by certified oral and maxillofacial surgeons.

Primary advantages and disadvantages to the agency:

There are no advantages or disadvantages to the agency. The agency will continue to incur costs for registration, profiling and certification of oral and maxillofacial surgeons, but those costs are offset by additional revenue derived from fees. There has been a considerable amount of staff time involved in the development of regulations and a regulatory program, but the expenditure of personnel should level off after the initial registration and certification. Providing for a clear standard and certification may alleviate some of the concerns and questions about the ability of oral and maxillofacial surgeons to include cosmetic surgery in their scope of practice.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some one-time costs (less than \$2,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be licensed dentists who are registered with the Board as oral and maxillofacial surgeons and those who are also certified to perform cosmetic procedures.

Estimate of number of entities to be affected:

Currently, there are 170 dentists registered as oral and maxillofacial surgeons and 6 oral and maxillofacial surgeons certified to perform cosmetic procedures.

Projected costs to the affected entities:

The cost for compliance will be borne by dentists who have a specialty in oral and maxillofacial surgery. The statute mandates that oral and maxillofacial surgeons be registered by the Board and that a profile of information on each such practitioner be collected and made available to the public. The primary cost associated with the registration is related to profiling, which is similar to the physician profiling with the Board of Medicine. Since there are such a small number of oral and maxillofacial surgeons (170 compared with approximately 28,000 doctors on the physician profile), the on-line system for data entry and consumer access used by Medicine was not found to be cost-effective. The agency continues to explore ways to create a web-based system for profiling of oral and maxillofacial surgeons. Costs associated with registration and profiling are those of the staff of the Board of Dentistry, a project manager and data personnel and mailings for the project. Annualized costs are currently estimated at \$14,000, but do not include investigations and disciplinary proceedings associated with non-compliance with the registration and profiling requirements or with failure to provide current or accurate information. In addition, a web-based system may still be developed if it can be projected to be cost-effective. There are currently 170 oral and maxillofacial surgeons who have paid \$175 for registration (including profiling) for total annual income to the board of \$29,750. Once all oral and maxillofacial surgeons have completed their profile and the Board has dealt with the non-compliance cases, the registration fee may be lowered to amount sufficient to sustain the costs associated with this activity. Until all cost factors are known, the annual fee of \$175 per dentist is a reasonable estimation.

The fee for an application for certification to perform cosmetic procedures is \$225 and the annual renewal fee is \$100, which must include staff time and mailing costs for sending and processing applications, the cost of hiring three oral and maxillofacial experts to review the credentials provided, and any costs related to the investigation of a complaint and administrative proceedings of a case against a certified oral and maxillofacial surgeon. There is an expert review cost of \$150 for each application package, and the remainder of the fees must cover the cost related to staff, board member per diem and meetings, and mailings. Since this is a new certification, the costs related to discipline are unknown.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

The specific provisions of proposed regulations are as follows (*Changes from the emergency regulation are noted in italics*):

18 VAC 60-20-10. Definitions.

A definition for “proctored cases” is added to clarify the term as used in requirements for certification of oral and maxillofacial surgeons.

18 VAC 60-20-250. Registration of oral and maxillofacial surgeons.

Pursuant to a statutory mandate in § 54.1-2709.2 of the Code, the Board is required to annually register all oral and maxillofacial surgeons and to report certain information to the public. Regulations implementing this mandate require an annual fee of \$175, which is intended to cover the cost of a public profile system for the surgeons. Fees for late renewal or reinstatement of a lapsed registration are also set. *The reinstatement fee was modified to be consistent with proposed regulations on fees for dentists, so there is a set fee of \$175 plus the renewal fee. The emergency regulation required \$55 for each year the registration had been lapsed.*

18 VAC 60-20-260. Profile of information for oral and maxillofacial surgeons.

This section lists the specific information the practitioner is required to submit and be included on a public profile. It also requires the submission to occur within 30 days of an initial request or of a change in the information. *The body that recognizes specialty board certification for dentists was changed to reflect the accurate name.*

18 VAC 60-20-270. Reporting of malpractice paid claims.

Specifics about the reporting of malpractice claims are set forth in this section, including the period of time that is covered, the content of the report, and the definitions of relative amounts of the claims. *The methodology for reporting relative frequency of paid claims was modified to be consistent with current system in place for both oral and maxillofacial profiles and doctors. Likewise, the regulation on posting of disciplinary notices and orders was changed to specify that adjudicated notices and final orders or decision documents would be posted, along with information on the availability of unadjudicated notices and orders that are subject to being vacated.*

18 VAC 60-20-280. Non-compliance or falsification of profile.

Failure to provide required information may constitute unprofessional conduct by the licensee; intentional falsification of information is unprofessional conduct and will subject the licensee to disciplinary action.

18 VAC 60-20-290. Certification to perform cosmetic procedures; applicability.

Subsection A establishes the applicability for the need to be certified and the anatomical limitation for which surgeries may be performed under such certification.

Subsection B lists the specific procedures for which a surgeon may be certified depending on the qualifications and competencies he demonstrates.

18 VAC 60-20-300. Certification not required.

This section lists the specific procedures for which a surgeon need not be certified, but are considered within the current scope of practice for an oral and maxillofacial surgeon.

18 VAC 60-20-310. Credentials required for certification.

This section sets forth the credentials required for certification to perform cosmetic procedures. Those credentials include an active, unrestricted license from the board, a fee of \$225, an oral and maxillofacial residency from an accredited dental program, board certification or eligibility in oral and maxillofacial surgery, current privileges in a hospital and documentation of education and experience in performance of cosmetic procedures. *There was a clarification stating that if*

*either the oral and maxillofacial residency or the cosmetic clinical fellowship was completed after July 1, 1996, that would serve as evidence of education in cosmetic procedures. The cosmetic clinical fellowship was added because that may have occurred several years after the residency but would have provided the required training. The second change was to require **sufficient** training in specific procedures for certification; the regulation is supplemented by a checklist for reviewer's to guide them in making recommendations about the sufficiency of training.*

18 VAC 60-20-320. Renewal of certification.

Each oral and maxillofacial surgeon who wishes to renew his certification must pay a fee of \$100 by December 31st of each year. *Language setting forth requirements and fees for late renewal and reinstatement were not included in the emergency regulation but are added in the proposed amendments.*

18 VAC 60-20-330. Quality assurance review for procedures performed by certificate holders.

Provisions are adopted for a quality assurance review as mandated in subdivision 6 of § 54.1-2709.1 A. Certifying bodies, such as the Joint Commission on Accreditation of Healthcare Organizations, conduct quality assurance reviews on procedures performed in facilities they accredit. Therefore, the Board will require a random audit of charts and quality assurance review for cosmetic procedures not performed in an accredited facility. Costs for the review will be covered by the certification and renewal fees paid by certified oral and maxillofacial surgeons. The Board will use persons qualified to perform cosmetic procedures as reviewers and will require surgeons to maintain a separate system by which charts on those patients may be identified.

18 VAC 60-20-331. Complaints against certificate holders for cosmetic procedures.

This section was added to set out a procedure for such complaints as required by law, including notification to the Board of Medicine when the board's receives a investigative report. The complaint must be reviewed and an opinion rendered by both a physician practicing in a related specialty and by an oral and maxillofacial surgeon. Confidentiality of the complaint is required.

Alternatives

Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The Board has a statutory mandate to promulgate regulations establishing a registration of oral and maxillofacial surgeons and a certification of board certified or eligible surgeons to perform certain procedures. Regulations for the registration of oral and maxillofacial surgeons for the purpose of producing a profile of those practitioners were based on a similar requirement for physicians. Regulations for certification to perform cosmetic surgery were more difficult since there are few models to consider. Therefore, the Board sought information from other states, credentialing bodies, schools of dentistry and medicine, and individual practitioners.

As mandated by the legislation, the Board was also required to consult with an advisory committee of persons named by the Medical Society of Virginia and by the Virginia Society of Oral and Maxillofacial Surgeons. Prior to the adoption of emergency regulations, that committee met on three occasions to review the mandate for certification and draft recommendations for certification, including the specific procedures that could be performed and the prerequisite qualifications. While the members were able to agree on several basic criteria for oral and maxillofacial surgeons, they remained in disagreement about the necessary education, the scope of certification, and the training and experience required for certification. Therefore, the report that was produced listed the areas of agreement and a side-by-side comparison of the differing recommendations from the two sides on what the requirements should be for oral and maxillofacial surgeons who want to perform cosmetic procedures.

Those areas of agreement included:

- Completion of an accredited oral and maxillofacial residency
- Board certification or board eligibility by the American Board of Oral and Maxillofacial Surgery
- Credentialing for surgical procedures involving certain anatomical areas within the head and neck region of the body
- Privileges as an oral and maxillofacial surgeon on a hospital staff

The areas of disagreement with the position of each profession represented were as follows:

Educational requirements

Medical	Dental
12 months of clinical rotations, including internal medicine and surgery	DDS or DMD degree with a residency in oral & maxillofacial surgery from a program accredited by the Commission on Dental Accreditation.

Scope of Certification

Medical	Dental
<p>Certification can only be granted for the full scope of procedures covered by this legislation and cannot support the certification of individual procedures</p>	<p>Credentialing by procedure. Every initial application for certification must contain a request for the specific clinical certification desired by the applicant. The evaluation of the request shall be based on the applicant's education, training, experience, demonstrated competence, and other relevant information.</p> <p>Anatomical areas and surgical procedures which will not need to be credentialed include:</p> <ul style="list-style-type: none"> • Treatment of facial diseases and injuries, including maxillofacial structures. • Facial Fractures • Cleft Lip and palate deformity • Facial deformity and wound treatment • Mentoplasty and facial augmentation procedures • Procedures requiring extra-oral incisions

Training and Experience

Medical	Dental																				
<p>A one-year clinical fellowship in esthetic surgery in accordance with the standards of the Commission on Dental Accreditation with a minimum of 125 proctored cases of esthetic surgery as follows:</p> <table border="1" data-bbox="186 1171 727 1791"> <thead> <tr> <th><u>Procedure</u></th> <th><u>Required Number of Cases</u> (Total of 125)</th> </tr> </thead> <tbody> <tr> <td>Rhinoplasty</td> <td>20</td> </tr> <tr> <td>Blepharoplasty</td> <td>20</td> </tr> <tr> <td>Rhydidectomy</td> <td>20</td> </tr> <tr> <td>Genioplasty</td> <td>10</td> </tr> <tr> <td>Submental liposuction</td> <td>10</td> </tr> <tr> <td>Laser resurfacing or dermabrasion</td> <td>10</td> </tr> <tr> <td>Browlift (either open or endoscopic technique)</td> <td>15</td> </tr> <tr> <td>Platysmal muscle plication</td> <td>10</td> </tr> <tr> <td>Otoplasty</td> <td>10</td> </tr> </tbody> </table>	<u>Procedure</u>	<u>Required Number of Cases</u> (Total of 125)	Rhinoplasty	20	Blepharoplasty	20	Rhydidectomy	20	Genioplasty	10	Submental liposuction	10	Laser resurfacing or dermabrasion	10	Browlift (either open or endoscopic technique)	15	Platysmal muscle plication	10	Otoplasty	10	<ol style="list-style-type: none"> 1. Letter from the individual's program director documenting the training received in the residency-training program and/or fellowship training to substantiate adequate training in the specific areas of requested certification. (minimum of 10 proctored cases in each area) 2. Documentation of the various surgical procedures performed during residency training and/or fellowship training that specify the number of procedures performed as a primary or assistant surgeon with appropriate supervision.
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Requirements for current oral/maxillofacial surgeons

Requirements for oral/maxillofacial surgeons who did not meet the training/experience requirements during residency

Medical	Dental
<p>Educational courses that provide for 12 months of clinical rotations including internal medicine and surgery, or the equivalent thereof must be completed. Practicing surgeons must complete the same number of proctored cases required of resident surgeons. Surgical procedures that may have been performed in the past in an unsupervised or unproctored manner should not be considered to have the same educational value as proctored cases. Such cases would not count toward standard OMFS training and should not count towards training under the new definition of dentistry.</p>	<ol style="list-style-type: none"> 1. Has completed both didactic and clinically approved courses in the specific area requested for certification. 2. Provide documentation of the number of hours of didactic and clinical training. <ul style="list-style-type: none"> • Dates attended • Location of training course • Copy of certificate of attendance (including the number of contact hours) 3. Documentation of any (if applicable) current privileges to perform cosmetic surgical procedures within a Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredited hospital 4. Documentation of the number of surgical procedures performed as a primary or assistant surgeon.

The report of the advisory committee with written recommendations was first submitted to the Board of Medicine for its comment. That board offered its opinions on issues related to the standards of education, the scope of certification, the surgical competence and patient safety, and the comparability of surgical training for maxillofacial and physician surgeons. In the opinion of the Board of Medicine, medical education, training and experience are necessary to ensure public safety for “non-physicians” who wish to perform cosmetic surgery.

Both the report of the advisory committee and the response of the Board of Medicine were reviewed and considered by the Board of Dentistry prior to its adoption of emergency regulations. The alternatives recommended by both sides of the issue were presented, and the Board sought to promulgate regulations that addressed the specific components of the regulation required by subsection A of § 54.1-2709.1 as well as the concerns expressed about public safety.

Again, the Advisory Committee was convened to offer advice and recommendations to the Board in the promulgation of permanent regulations to replace the emergency regulations. At its meeting on March 20, 2002, the committee recommended the draft regulations which were later considered and adopted by the Board. One of the physician members of the committee introduced a dissenting opinion that reiterated the positions and objections raised during the discussion of emergency regulations.

In addition, the Board held a public hearing on May 2, 2002 on the draft regulation to offer interested parties the opportunity to present comment prior to the Board’s adoption on May 3rd. The same physician presented testimony that the regulations are less stringent than the standards of the American Dental Association Council on Dental Education and that the public may be harmed by inadequately trained individuals if the regulations are not revised. Another dental

member of the advisory committee also presented testimony that contended the standard of 125 cases referenced by the physician was the standard for fellowship training in cosmetic surgery, not for clinical practice, and included cases in all procedures.

On May 17, 2002, the Legislative Committee of the Board of Medicine considered the proposed regulations adopted by the Board of Dentistry for cosmetic surgery certification and again expressed the opinion that the education and training of the oral and maxillofacial surgeon is insufficient to adequately perform such procedures.

While the Board recognized that there are different pathways of education, training and experience for plastic surgeons and oral and maxillofacial surgeons, it contends that both have demonstrated their ability to practice with safety and competency. Prior to SB 806, oral and maxillofacial surgeons have been credentialed and have held hospital privileges to perform a variety of reconstructive surgeries in the area of the head and neck. There is little evidence that the public has been harmed by their practice, so the Board believes the regulations it has adopted are sufficient to ensure that those procedures performed for cosmetic purposes may also be performed with competency and safety.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the board's intent to amend its regulations was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the board. Public comment was received until December 19, 2001. During the 30-day comment period, no comments were received from members of the public but comment from the medical members of the advisory committee and from the Board of Medicine is noted in the section on Alternatives.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Members of the Board met in open session to work on draft regulations, and the public has been invited to comment during the course of those meetings. No comments have been received regarding the need for clarity in the proposed amendments. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable

regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. Regulations governing the practice of optometry will be reviewed again during the 2004-05 fiscal year.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

In its preliminary analysis of the proposed regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability and no effect on family income.