



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:	General supervision for dental hygienists
Date:	9/26/2002

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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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.

Chapter 170 of the 2002 Acts of the Assembly mandates that the board promulgate regulations to implement provisions of the act permitting certain practices of a dental hygienist to be performed under general supervision. The enactment clauses on the bill required the board to adopt emergency regulations, and the proposed regulations must replace those regulations prior to their expiration on July 18, 2003.

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.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

...
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 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

The legal authority to promulgate the amendments for general supervision of dental hygienists is found in Chapter 170 of the 2002 Acts of the Assembly.

<http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0170>

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.

Provisions in the amended regulation for an evaluation and order for services prior to having the patient treated under general supervision are intended to ensure that the quality of care and the health and safety of patients is being protected. To ensure that the patient is aware of the implications of general supervision, regulations require that the patient or a responsible adult is informed that a dentist will not be present and that no anesthesia can be used. Likewise, the Board determined that some procedures, especially those that involve the administration of drugs, are not appropriate to delegate under general supervision. While there is a limitation on the number of hygienists who can practice under the direction and supervision of a dentist, there is no limitation in the proposed regulation for the number of hygienists who can be supervised by a dentist in a free clinic or public health setting or working as a volunteer.

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.

Amendments to regulations are adopted to define “general supervision” of dental hygienists, to prescribe the number of hygienists that may work under general supervision at any one time with certain exceptions, to set out the criteria for such practice, and to determine the duties of a hygienist that may or may not be performed under general supervision. Dental hygiene services are limited to those ordered by a licensed dentist and rendered within a specific time period, not to exceed seven months.

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.

The primary advantages to the public of implementing the amended regulations are the possibility of expanding the accessibility of dental services to certain populations, such as residents of nursing homes and those receiving care at free clinics, and the ability of dental hygienists employed in dental offices to provide care when the dentist is not present. In addition, the proposed regulation may expand the availability of dental hygiene services in a free clinic, a public health program or other settings that utilize volunteers, because it eliminates the restriction of two hygienists per dentist if the hygienists are practicing under general supervision in those settings and allows hygienists who are not employed by a dentist or a governmental agency to volunteer their service.

While the hygienist will be allowed to see patients without the dentist being physically present, he may only provide those services that have been specifically ordered after a dentist has seen and evaluated the patient. Regulations require that the patient or a responsible adult must be told that no dentist is present and that no anesthesia can be administered, so the patient is adequately protected and informed. Likewise, the public is protected by the limitation on those duties or services that may be delegated under general supervision without the presence of a dentist. There are no disadvantages to the public as all amendments are intended to provide better access to qualified practitioners without any diminution in the quality of care.

There are no advantages or disadvantages to the agency; the amended regulation does not impose a new responsibility on the Board.

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 \$1,000) 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 dental hygienists and the dentists who supervise their practice.

Estimate of number of entities to be affected:

Currently, there are 3,655 dental hygienists and 5,347 dentists licensed in the Commonwealth.

Projected costs to the affected entities:

There is no projected costs for compliance. The amended regulations may provide greater access to dental hygiene care but will not increase or decrease the cost of that care.

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.

Chapter 170 of the 2002 Acts of the Assembly provides for practice by dental hygienists under general supervision by a dentist. Amendments to implement the provisions of Chapter 170 are outlined as follows:

18 VAC 60-20-10. Definitions.

To clarify the use of the term “general supervision,” the Board has added a definition that is consistent with the meaning attributed in § 54.1-2722 of the Code of Virginia. “General supervision” is defined as meaning that the dentist has evaluated the patient and issued a written order for specific, authorized services to be provided by a dental hygienist when the dentist is not present in the facility while the authorized services are being provided.

18 VAC 60-20-200. Employment of dental hygienists.

The amended regulation restricts to two the number of hygienists that a dentist can have practicing under direction or general supervision at one and the same time. To allow for expansion of dental services by hygienists working under general supervision, the amended regulation makes an exception for practice under general supervision occurring in a free clinic or public health setting or someone practicing as a volunteer.

18 VAC 60-20-210. Requirements for direction and general supervision.

- Current regulations provide that dental hygienists and assistants may only engage in their respective duties under the direction and control of the dentist, and the dentist has to be present and evaluate the patient during the time the patient is in the facility. Since the amended law now permits practice under general supervision, the requirement for the dentist to always be present in the facility has been eliminated. There is also a proposed exception to the requirement that a hygienist be employed by a licensed dentist or governmental agency to permit voluntary practice under general supervision.
- Since the Board has determined that there are certain procedures that should not be delegated to a dental hygienist under general supervision, it has provided that the duties performed under direction must only be performed when the dentist is present in the facility and available to evaluate the patient during the time services are being provided.
- Those duties that may be delegated to a dental hygienist under general supervision can only be performed if 1) the treatment has been ordered by a licensed dentist licensed in writing with the services to be rendered within a specific time period, not to exceed seven months; 2) the dental hygienist has consented to providing services under general supervision.; 3) the patient or a responsible adult has been informed prior to the appointment that no dentist will be present, that no anesthesia can be administered, and that only those services prescribed by the dentist will be provided; and 4) written basic emergency procedures have been established and the hygienist is capable of implementing those procedures. General supervision cannot replace the use of direction when, in the professional judgment of the dentist, direction is necessary to meet the individual needs of the patient.

18 VAC 60-20-220. Dental hygienists.

- Amended regulations provide that the following duties can only be delegated to dental hygienists under direction with the dentist being present. Those include any scaling and root planing requiring the administration of anesthesia; the performance of an initial examination of teeth and surrounding tissues for assisting the dentist in the diagnosis; and subgingival irrigation or subgingival application of Schedule VI medicinal agents.
- In addition, there is a new listing of duties that can only be delegated to dental hygienists and may be delegated by written prescription to be performed under general supervision without the dentist being present. Those include scaling and root planing of natural and restored teeth without anesthesia; polishing of natural and restored teeth; and performing a clinical examination of teeth and surrounding tissues including the charting of carious lesions, periodontal pockets or other abnormal conditions for further evaluation and diagnosis by the dentist. The dentist may delegate under general supervision any other duties appropriate to the education and experience of the dental hygienist and the practice of the supervising dentist, with the exception of those specifically restricted to be performed under direction and those listed as nondelegable.
- Nothing in this section should be interpreted so as to prevent a licensed dental hygienist from providing services currently within his scope of practice including educational services, assessment, screening or data collection for the preparation of preliminary written records for evaluation by a licensed dentist.

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.

There were no alternatives to adoption of a regulation as it was mandated by Chapter 170 of the 2002 Acts of the Assembly. The Board did address several issues that arose during the development of regulations. To ensure that varying opinions were adequately considered, the Board heard public comment on the legislation and/or draft regulations at four public meetings and also solicited written comment prior to the adoption of emergency regulations. Additional comment was received following publication of the NOIRA and at the meeting at which proposed regulations were discussed and adopted.

Prior to the introduction of Senate Bill 503, a task force of the Virginia Dental Association (VDA) with involvement of several hygienists recommended that the group rescind its previous position in opposition to general supervision and that general supervision be permitted if certain requirements were met. In developing regulations, the Board utilized the recommendation of the VDA as well as those of the Virginia Dental Hygienist Association (VDHA) for implementation of the legislation. The major point of difference between the two professional groups involved the period of time within which the patient could be seen by a hygienist under general supervision following an evaluation and written prescription by the dentist. The VDA policy statement recommended that the patient be seen within 6 months of the prescription, and the VDHA recommended that the time period be 12 months for services rendered under general supervision. After much discussion, the Board agreed to a time requirement of 7 months that is

intended to permit a patient to be seen approximately once a year by the dentist and once a year by the hygienist. (The additional month is intended to accommodate potential scheduling problems.)

The other issue that arose during development of regulations centered around which duties could be delegated under general supervision. Under the theory that root planing typically involves the use of anesthesia, the Regulatory Committee recommended that it be restricted to performance only under direction with the dentist present. Several dental hygienists testified that they do root planing without anesthesia and that it should be delegable under general supervision. To accommodate that practice and continue to protect patients, the regulations specify that scaling and root planing not requiring anesthesia could be done under general supervision, but that the patient must be informed prior to the procedure that no dentist will be present and no anesthesia can be used.

Following publication of the emergency regulations, several issues were raised and addressed by the Board in the promulgation of proposed regulations. Testimony to the board indicated that the definition of "general supervision" had created some misunderstanding. To clarify the terminology, the Board changed "prescribed authorized services" to "issued an order for the specific, authorized services." Some dentists thought a written "prescription" was required rather than a written order in the patient's chart. Likewise, the phrase "without the requirement for the dentist to be present" was modified to read "when the dentist is not present" to clarify that general supervision was not appropriate when the dentist is present and available for direction.

The major objection to language in the emergency regulation that was raised by the free clinics and the dental hygienists was the restriction of the number of hygienists who could work under the general supervision of a dentist and the requirement that the hygienists be employed by a dentist or a governmental agency. Together, the requirements eliminated the possibility of utilizing larger numbers of hygienists who might be willing to work in a free clinic or public health program or who were currently not employed but might be willing to volunteer their services. In response, the Board modified sections 200 and 210 to grant exceptions to the ratio requirement of two hygienists per dentist and to the requirement that a hygienist must be employed, provided he is volunteering his services.

During promulgation of the proposed regulation, hygienists also raised the issue of whether they could apply or administer certain controlled substances under general supervision. Board counsel advised that the Drug Control Act (§ 54.1-3408) does not authorize dental hygienists to possess and administer controlled substances apart from the dentist, so any such activity would be prohibited under general supervision. It was agreed that if it became apparent that a patient required anesthesia for a certain procedure, such as scaling and root planing, that patient should be turned over to another dentist in the office or rescheduled when the treating dentist can be present.

With the passage of Senate Bill 503 (Chapter 170 of the 2002 Acts), the Board was mandated to promulgate regulations implementing provisions of the laws within 280 days. It adopted emergency regulations, which will be effective until July 18, 2003 and proposes these amendments as permanent regulations.

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 August 12, 2002 until September 11, 2002. During the 30-day comment period, there were several written comments from members of the public, and verbal testimony to the board indicated that there was some confusion and concern about the emergency regulations.

A free clinic in Virginia and the Virginia Association of Free Clinics commented that the requirement for "employment" was a barrier to the implementation of general supervision in those settings. The Board amended its regulation accordingly (see Alternatives).

The Virginia Dental Hygienists' Association commented that general supervision has improved the management of dental patients and patient access to oral healthcare. It has not been as effective in settings that serve indigent and underserved patients because of the requirement that the dentist perform the initial evaluation. The Board did not amend its regulations to permit treatment by the hygienist without an initial evaluation by a dentist, because the law prohibits the establishment of a final diagnosis or treatment plan by a hygienist. Therefore, it is necessary for a dentist to determine the diagnosis and plan of treatment. The Association also spoke about the restrictiveness of the employment requirement and supported the ability of a hygienist to volunteer care to indigent patients, and the Board responded by amending sections 200 and 210. Finally, the Association raised questions about the application of topical anesthesia by hygienists under general supervision. The Board was unable to amend the regulations, because such a change would necessitate an amendment to the Code.

Other comments from the Virginia Dental Association and individual hygienists were requests for interpretation of the regulation. Those included billing questions (which were not addressed by the board) and practice questions (such as whether hygienist were allowed to deliver bleaching trays in the absence of a dentist) that were addressed on an individual basis and responses provided by the Board.

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 the emergency regulations and the proposed regulations. The public, including representatives of the Free Clinic Association, the Virginia Dental Hygiene Association and the Virginia Dental Association, participated in and commented on draft regulations 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. These regulations 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.

The proposed regulatory action would not strengthen or erode the authority and rights of parents, encourage or discourage economic self-sufficiency, strengthen or erode the marital commitment or increase or decrease disposable family income. The ability of dental hygienists to provide prescribed services in settings where a dentist is not readily available may benefit some persons who have limited access to such services.