Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC60-20-10 et seq.
Regulation title	Regulations Governing the Practice of Dentistry and Dental Hygiene
Action title	Criteria for informed consent
Document preparation date	4/4/07

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Board intends to amend its regulations to specify requirements for informed consent in the performance of dental treatments. In its proposed regulatory action, the Board intends to set out general requirements rather than the specific content of an informed consent document. It will consider the regulations of the Board of Medicine for its practitioners, as well as guidance offered by boards regulating the practice of dentistry in other states. Its intent is to ensure that dentists, like physicians, are required to appropriately inform a patient of the risks and benefits involved in dental treatment.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Dentistry 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. …

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

Provisions of a proposed regulatory action may be similar to those found in the regulations of the Board of Medicine in which the practitioner is required to: 1) accurately inform a patient or his legally authorized representative of the diagnoses, prognosis and prescribed treatment or plan of care; and 2) present information relating to the patient's care to a patient or his legally authorized representative in understandable terms and encourage participation in the decisions regarding the patient's care. The practitioner is prohibited from deliberately making a false or misleading statement regarding his skill or the efficacy or value of a medication, treatment, or procedure prescribed or directed by the practitioner in the treatment of any disease or condition.

In medicine, before surgery or any invasive procedure is performed, informed consent must be obtained from the patient in accordance with the policies of the health care entity. Practitioners must inform patients of the risks, benefits, and alternatives of the recommended surgery or invasive procedure that a reasonably prudent practitioner in similar practice in Virginia would tell a patient. Regulations in dentistry would need to specify the meaning of an "invasive procedure," but in medicine, it means any diagnostic or therapeutic procedure performed on a patient that is not part of routine, general care and for which the usual practice within the health care entity is to document specific informed consent from the patient or surrogate decision-maker prior to proceeding.

There will also need to be provisions for informed consent in the instance of a minor or a patient who is incapable of making an informed decision on his own behalf or is incapable of communicating such a decision due to a physical or mental disorder. Additionally, the regulation should include an exception to the requirement for consent prior to performance of surgery or an invasive procedure in an emergency situation when a delay in obtaining consent would likely result in imminent harm to the patient.

The need for some requirement for informed consent arises from the significant changes that have occurred in dentistry in the last decade, in which more general dentists are now offering more involved care, often with the assistance of sedation or anesthesia. The Board believes it is necessary to ensure that the public is properly informed about the risks and benefits of certain treatments or procedures and also has information about the options and possible complications.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

At its meeting in December of 2006, the Board was asked by one of its members to consider adopting guidance on informed consent similar to the position adopted by the state of Maine. The Regulatory/Legislative Committee was requested to study the proposal for a guidance document to address documenting informed consent. After a review of guidance and regulations from other boards, the Committee recommended that a Notice of Intended Regulatory Action be adopted to incorporate general requirements for informed consent into regulations. Without provisions in regulations, the Board would have no ability to enforce its guidance, and the public would not be adequately protected from dentists who embark on a course of treatment for which the patient is not appropriately informed about options, risks and benefits.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact of the proposed regulatory action on the institution of the family and family stability.