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Emergency Regulation and 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 Dentists and Dental Hygienists	
Action title	Requirements for registration and practice of mobile dental clinics and portable dental operations	
Date this document prepared	6/12/09	

Preamble

The APA (Code of Virginia § 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

- 1) Please explain why this is an "emergency situation" as described above.
- 2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

The budget bills (HB1600 and SB950) of the 2009 Acts of the Assembly require the Board of Dentistry to revise its regulations to provide for registration of mobile dental clinics and portable dental operations. The legislation further requires that the Board promulgate regulations to implement the provisions of the act to be effective within 280 days of its enactment. Therefore, there is an "emergency situation" as defined in § 2.2-4011 of the Administrative Process Act.

The key provisions of the regulations are: 1) establishment of definitions of a "mobile dental clinic" and a portable dental operation;" 2) requirements for registration including information on locations, dates and practitioners providing services, certifications of agreements for follow-up care and access to emergency care, certification of availability of certain equipment and

resources, and conformity to operational and permitting standards; 3) requirements for operation of the clinic, including posting of licenses, written consent for treatment, information on treatment and needed follow-up for patients, and maintenance of patient records; and 4) exemptions from the requirements for registration for governmental agencies and periodic volunteer clinics providing free care.

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Legal basis

Other than the emergency authority described above, 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:

- 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 (§ <u>54.1-100</u> et seq.) and Chapter 25 (§ <u>54.1-2500</u> et seq.) of this title. ...

The specific mandate to promulgate regulations for the registration of mobile dental clinics is found in the budget bill:

"B. Notwithstanding the provisions of Chapter 27 of title 54.1 of the Code of Virginia, the Board of Dentistry shall revise its regulations pertaining to the licensure of dentists and dental hygienists to require that mobile dental clinics and other portable dental operations meet certain requirements to ensure that patient safety is protected, appropriate dental services are rendered, and needed follow-up care is provided. The revised regulations shall include, but not be limited to requirements for registration by the mobile clinics, locations where services are provided, reporting requirements by providers and other regulations to insure accountability of care rendered. These regulations shall apply to all mobile dental facilities or portable dental programs with the exception of those operated by federal, state or local governmental agencies, or by other entities deemed appropriate for exemption by the Board of Dentistry. The Board shall promulgate regulations to become effective within 280 days or less from the enactment of this act to implement these changes."

Purpose

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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 intent of the regulatory action is compliance with the statute that requires the Board to establish regulations for registration of mobile dental clinics and portable dental operations. Regulations include definitions of terminology used, requirements for registration, reporting requirements by providers, and other requirements to ensure accountability of care for services rendered.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

To protect the health and safety of persons served in mobile dental clinics, amendments to Chapter 20 require registration to include information about where and when the practices will be operating and which practitioners will be providing care. The clinics must also certify to agreements for follow-up care, emergency contact arrangements, access to all essential equipment and conformity to laws and regulations. There must be written consent to dental care in a mobile clinic, and patients must be provided with an information sheet that details who provided treatment, a description of the treatment and any additional dental needs, a recommendation or referral for follow-up care, and emergency contact information. Such requirements are necessary to ensure that patients (often school children) are not left with unresolved dental problems or with little or no information about what was done during a visit by a mobile clinic. Finally, regulations stipulate that the same rules and standards of care apply for practice in a mobile clinic as in a fixed facility.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10	n/a	Sets out definitions for words and terms used in the regulation	Definitions are added for a mobile dental clinic and a portable dental operation. The definitions are consistent with those used in the other states that also regulate such entities.
30	n/a	Establishes certain fees charged to entities the	An application fee of \$250 is established for registration of clinics or operations, and an annual

		Board regulates	renewal fee is set at \$150. Each application will be quite detailed and require a thorough review by staff and possibly one or more board members. A number of certifications are required, as well as information on ownership and operation of the facility. In addition, the regulation requires that the entity provide revisions to the information on locations and dates and on the dentists, dental hygienists or dental assistants II who will be providing dental services at least 10 days prior to the provision of such services. Therefore, there will be a need for constant review and updating of the registration application and renewal. The board has attempted to adopt a minimal fee consistent with its mandate to cover expenses with the fees it charges to regulated entities. In regulations in other states where mobile clinics are also registered, the fees range from \$500
n/a	332	Establishes the requirements for registration	application in Kansas to \$50 in Texas. Subsection A sets out the information to be included on an application for registration, including: 1. The name and address of the owner of the facility or operation and an official address of record for the facility or operation, which shall not be a post office address. Notice shall be given to the board within 30 days if there is a change in the ownership or the address of record for a mobile dental facility or portable dental operation; In order to ensure access to patient records in case of a complaint to the Board or if requested by the patient or another practitioner, there must be a permanent address from which the records can be obtained and the name of an owner who is responsible for the facility's or operation's compliance with laws and regulations 2. The name, address and license number of each dentist and dental hygienist or the name, address and registration number of each dental assistant II who will provide dental services in the facility or operation. The identity and license or registration number of any additional dentists, dental hygienists or dental assistants II providing dental services in a mobile dental facility or portable dental operation shall be provided to the board at least 10 days prior to the provision of such services; While the initial application will include

information about practitioners who will be providing services at a location, the clinic may employ different practitioners as it moves from location to location. It is necessary for the Board to maintain a listing of who will be working at a particular location prior to the operation of the clinic to ensure that they are appropriately authorizes to practice.

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3. The address or location of each place where the mobile dental facility or portable dental operation will provide dental services and the dates on which such services will be provided. Any additional locations or dates for the provision of dental services in a mobile dental facility or portable dental operation shall be provided to the board at least 10 days prior to the provision of such services.

The address or location where services are being provided will vary as the clinic operation moves about the state, so the Board must be informed about its location as schedules are made.

Subsection B requires that an application for registration of a mobile dental facility or portable dental operation include certain certifications:

1. That there is a written agreement for emergency follow-up care for patients to include identification of and arrangements for treatment in a dental office which is permanently established within a reasonable geographic area;

Once a child (or adult) has been seen at a mobile clinic, that facility will move on to another location. To ensure that a patient is not left with an unresolved need for emergency care, there must be a written agreement with dentists in the area who are willing to take patients seen at a mobile clinic.

2. Certification that the facility or operation has access to communication facilities that enable the dental personnel to contact assistance in the event of a medical or dental emergency;

The requirement for communication facilities to contact assistance is essential to deal with a medical or dental emergency.

3. Certification that the facility has a water supply and all equipment necessary to provide the dental services to be rendered therein;

The Board did not choose to specify what

			equipment must be a part of or contained within a mobile clinic (as other states have done in their regulations), but this rule does specify that there must be a water supply and all equipment necessary to provide whatever dental care is being rendered. 4. Certification that the facility or operation conforms to all applicable federal, state and local laws, regulations and ordinances dealing with radiographic equipment, sanitation, zoning, flammability and construction standards; and 5. Certification that the applicant possesses all applicable city or county licenses or permits to operate the facility or operation. Finally, the Board is not requiring submission of
			copies of all such permits, licenses, etc. (as other states have done in their regulations), but does require that the facility certify that is compliant with all applicable ordinances, laws and regulations.
			Subsection C makes it clear that registration may be denied or revoked for a violation of provisions of § 54.1-2706 of the Code of Virginia.
n/a	342	Establishes the requirements for operation of a clinic or operation	Subsection A requires that a copy of the registration of the facility or operation and copies of the licenses of the dentists and dental hygienists or registrations of the dental assistants II shall be displayed in plain view of patients.
			To ensure accountability for the services being provided, it is necessary for patients to know whether the mobile facility is appropriately registered and the identity of the licensees providing care in that facility.
			Subsection B requires that prior to treatment, the facility or operation shall obtain written consent from the patient or if the patient is a minor or incapable of consent, his parent, guardian or authorized representative.
			Mobile dental clinics are used most often at local schools; it is essential that a parent or guardian be aware of and give consent to treatment. In some cases, a portable dental operation is taken to nursing homes, so the patient may be incapable of consent, which must then come from an authorized
			representative of the patient.

with an information sheet or if the patient, his parent, guardian or authorized agent has given written consent to an institution or school to have access to the patient's dental health record, the institution may be provided a copy of the information. At a minimum, the information sheet shall include:

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- 1. Patient name, date of service and location where treatment was provided;
- 2. Name of dentist and dental hygienist who provided services;
- 3. Description of the treatment rendered and tooth numbers, when appropriate;
- 4. Billed service codes and fees associated with treatment:
- 5. Description of any additional dental needs observed or diagnosed;
- 6. Referral or recommendation to another dentist if the facility or operation is unable to provide follow-up treatment; and
 - 7. Emergency contact information.

In every state where mobile clinics are regulated, there is a requirement for an information sheet to be given to patients at the conclusion of the appointment (in the case of a child, the parent may consent for the sheet to be given to the school for the school to then give to the parent). A patient must have that information because a patient record is not readily available as it would be from a local dentist in case additional problems occur or follow-up treatment is needed.

Subsection D requires patient records to be maintained, as required by 18VAC60-20-15, in a secure manner within the facility or at the address of record listed on the registration application. Records shall be made available upon request by the patient, his parent guardian or authorized representative and shall be available to the board for inspection and copying.

Subsection E specifies that the practice of dentistry and dental hygiene in a mobile dental clinic or portable dental operation shall be in accordance with the laws and regulations governing the practice.

The same standard of care applies to the practice

			of dentistry or dental hygiene regardless of the setting in which dental care is provided.
n/a	352	Sets out the entities that are exempt from the requirements for registration	Those entities that are exempt include: 1) federal, state and local governmental agencies; and 2) Dental treatment which is provided without charge to patients or to any third party payer and which is not provided on a regular basis (recurring at fixed or uniform intervals). The law provides an exception for "those operated by federal, state or local governmental agencies, or by other entities deemed appropriate for exemption by the Board of Dentistry." The Board has exempted through regulation those clinics or operations that are set up periodically to provide free dental care to underserved populations, which would include the volunteer projects operated by the Virginia Dental Association.

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. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

There are no alternatives to the promulgation of regulations, which are required by the budget bills of the 2009 Acts of the Assembly.

On April 22, 2009, the Regulatory/Legislative Committee reviewed a draft of regulations that was based on provisions of the law in Virginia and on requirements found in other states. The budget bill specified the subject areas regulations must include – requirements for registration, locations where services are provided, reporting requirements, and other regulations to ensure accountability of care. In addition, regulations, laws and application forms in Texas, Kansas, Tennessee, South Carolina, Indiana and Mississippi were used as a basis for draft regulations. The Committee recommended those requirements it believed were necessary to ensure accountability, access to records, continuity of care and safe dental practice.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action to replace the emergency regulations with permanent regulations, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency/board is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

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Anyone wishing to submit written comments may send them to Elaine Yeatts at the Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or Elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434 or by posting on the Regulatory Townhall at www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period on the Notice of Intended Regulatory Action.

At the conclusion of the NOIRA comment, the Board will adopt proposed regulations to replace the emergency regulation. A public hearing and 60 days of comment will be held at that time.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent 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.

There is no potential impact on the institution of the family.