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Fast-Track Regulation Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC60-21
Regulation title(s)	Regulations Governing the Practice of Dentistry
Action title	Posting of DEA number
Date this document prepared	9/27/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The posting requirements in section 30 are amended to allow a dentist who administers, prescribes, or dispenses Schedules II through V controlled substances to maintain a copy of his current registration with the federal Drug Enforcement Administration in a readily retrievable manner at each practice location rather than displaying it to the public along with his current license.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

DEA = Drug Enforcement Administration

Statement of final agency action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On September 16, 2016, the Board of Dentistry adopted amendments to 18VAC60-21-10 et seq., Regulations Governing the Practice of Dentistry.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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 (§ 2.2-4000 et seq.) that 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.).

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amendment is to reduce the possibility of fraud in the acquisition of prescription drugs by illegal use of a dentist's DEA number. The Board's amendment maintains access to the DEA registration for purposes of inspection or investigation, but eliminates the

posting requirement which made the DEA information readily accessible for any potential illegal prescriptions. The goal of protection of the health and safety of the public is enhanced by the security of a dentist's DEA registration.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

This proposal is in response to a petition for rulemaking, which was supported by comments from 56 dentists. It will not be controversial because it is fully supported by the dental community and the Board.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

The posting requirements in section 30 are amended to allow a dentist who administers, prescribes, or dispenses Schedules II through V controlled substances to maintain a copy of his current registration with the federal Drug Enforcement Administration in a readily retrievable manner at each practice location rather than displaying it to the public along with his current license.

Issues

Please identify the issues associated with the proposed regulatory action, including: 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 indicate.

- 1) The advantage to the public is less risk of the illegal use of a dentist's DEA number to obtain controlled substances. There are no disadvantages.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act (§2.2-4000.) which are reasonable and necessary to administer effectively the regulatory system.*" There is no restraint on competition as a result of promulgating this regulation.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities affected.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There is no regulatory flexibility in order to amend a current requirement that dentists believe may put them and the public at risk.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>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 or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>None</p>

<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Dentists licensed in Virginia</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 7147 dentists with current licenses in Virginia. Almost all would be small businesses.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>There are no costs – the current regulation requires posting of the DEA registration; the amended regulation allows maintenance of a copy of the registration at each practice location.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Less exposure of DEA information that could be used by someone for writing an illegal, fake prescription to obtain drugs.</p>

Alternatives

Please describe any viable 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The proposed amendment is a less burdensome and intrusive alternative to the current regulation.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this 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 impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
30	For a dentist to display his current DEA registration with his current license in a place conspicuous and readable by patients in each practice setting.	<p>Subsection C is amended to require a dentist who administers, prescribes, or dispenses Schedules II through V controlled substances to <u>maintain a copy of his current registration with the federal Drug Enforcement Administration in a readily retrievable manner at each practice location.</u></p> <p><i>The intent is to reduce the risk of an unauthorized person copying the DEA number of a dentist from his registration that is currently required to be posted for the public. By requiring the dentist to maintain a copy in a readily retrievable manner, the Board is assured of access to the information in an inspection or an investigation without risking the availability of a DEA registration number for an illegal prescription.</i></p>