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Proposed Regulation
Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC60-21-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Dentistry
Action title	Prescribing of opioids
Date this document prepared	9/15/17

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

Regulations for dentists prescribing of medications containing opioids and for continuing education for prescribers of controlled substances were promulgated as emergency regulations to address the opioid abuse crisis in Virginia; this proposed action will replace the emergency regulations with permanent regulations. Regulations for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and record-keeping. Management of chronic pain requires either referral to a pain management specialist or adherence to regulations of the Board of Medicine. All dentists who prescribe Schedule II through IV drugs will be required to take two hours of continuing education on pain management.

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.

PMP = Prescription Monitoring Program

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.).

In addition, the Board has been mandated to adopt regulations by passage of HB2167 and SB1180 in the 2017 General Assembly:

§ 54.1-2708.4. Board to adopt regulations related to prescribing of opioids.

The Board shall adopt regulations for the prescribing of opioids, which shall include guidelines for:

1. The treatment of acute pain, which shall include (i) requirements for an appropriate patient history and evaluation, (ii) limitations on dosages or day supply of drugs prescribed, (iii) requirements for appropriate documentation in the patient's health record, and (iv) a requirement that the prescriber request and review information contained in the Prescription Monitoring Program in accordance with § 54.1-2522.1;

2. The treatment of chronic pain, which shall include, in addition to the requirements for treatment of acute pain set forth in subdivision 1, requirements for (i) development of a treatment plan for the patient, (ii) an agreement for treatment signed by the provider and the patient that

includes permission to obtain urine drug screens, and (iii) periodic review of the treatment provided at specific intervals to determine the continued appropriateness of such treatment; and

3. Referral of patients to whom opioids are prescribed for substance abuse counseling or treatment, as appropriate.

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 regulatory action is the establishment of requirements for prescribing of controlled substances containing opioids to address the overdose and addiction crisis in the Commonwealth. The goal is to provide dentists with definitive rules to follow so they may feel more assured of their ability to treat pain in an appropriate manner to avoid under-prescribing or over-prescribing.

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.

Regulations for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and record-keeping. Management of chronic pain requires either referral to a pain management specialist or adherence to regulations of the Board of Medicine. All dentists who prescribe Schedule II through IV drugs will be required to take two hours of continuing education on pain management.

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 primary advantage to the public is a reduction in the amount of opioid medication that is available in our communities. A limitation on the quantity of opioids that may be prescribed should result in fewer people becoming addicted to pain medication, which sometimes leads them to turn to heroin and other illicit drugs. Persons who are receiving opioids for chronic pain should be more closely monitored to ensure that the prescribing is appropriate and

necessary. There are no disadvantages to the public; dentists prescribing for chronic pain must follow the regulations as those for Medicine.

2) The primary advantage to the Commonwealth is the potential reduction in the number of persons addicted to opioids and deaths from overdoses. There are no disadvantages.
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 "*To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 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*." There is no restraint on competition as a result of promulgating this regulation; all dentists must follow the same rules for prescribing of opioids. The proposed amendments are a foreseeable result of the statute requiring the Board to protect the safety and health of patients in the Commonwealth.

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 particularly affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Dentistry is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Elaine Yeatts at elaine.yeatts@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 527-4434.. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://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 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

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.

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**	a) 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; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going costs.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no costs to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Licensed dentists
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.	There are 7,127 dentists licensed in Virginia; all have authority to prescribe opioids. It is estimated that the vast majority are small businesses.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other	There should be no additional costs to the dentists for following these rules for prescribing.

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.	
Beneficial impact the regulation is designed to produce.	The primary benefit is a reduction in the amount of opioid medication that is available in our communities. It is not uncommon for an addicted person who is abusing heroin and/or prescription opioids to report that he/she became addicted following a medical or dental procedures for which there was a prescription for opioid medication.

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 Board has a specific statutory mandate to adopt regulations for the prescribing of opioids in the management of acute and chronic pain. There are no alternatives to the essential purpose of this action.

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 are no alternative regulatory methods consistent with health and safety of patients receiving prescriptions for opioids.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
2 commenters	Inquired about requirement for calculating MMEs. Most dentists are not familiar with MMEs.	The Board notified all dentists about the emergency regulations and posted a conversion chart on its website.
6 commenters	Expressed concern about the requirement to prescribe naloxone, especially if there is a concomitant use of benzodiazepines. Do not agree that a naloxone prescription is necessary for this entire group of patients.	The Board has amended section 103 to require the dentist to consider whether a prescription for naloxone is necessary for a patient also taking benzodiazepines. Prescribing naloxone for those patients is discretionary and dependent on the professional judgment of the dentist.
2 commenters	Had questions about interpretation of the regulation.	The Board reviewed the questions but did not find it necessary to amend regulations accordingly.

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.

The institution of the family and family stability is being severely impacted by the opioid addiction crisis in the Commonwealth. The impact of this action is intended to empower and instruct dentists in the appropriate prescribing of opioids to manage pain in such a manner as to prevent addiction and diversion.

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.

Proposed Regulations are identical to Emergency Regulations except in section 103 –see bolded language

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
101	Section 101 sets out definitions for words and terms used in this chapter. They include a definition for acute pain to mean pain that occurs within the normal course of a disease	18VAC60-21-10	The Board adopted definitions identical to those adopted by the Board of Medicine for consistency.

	or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months. The definition for chronic pain means non-malignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.		
102	Section 102 sets out the rules for evaluation of a patient. Subsection A requires that non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days. Subsection B requires that prior to initiating treatment with a controlled substance for a complaint of acute pain, the prescriber must perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in the Code of Virginia and conduct an assessment of the patient's history and risk of substance abuse.	§§ 54.1-3303 and 54.1-2522.1	The intent of this section is to ensure that dentists prescribe opioids only when absolutely necessary, rather than as a routine treatment and that the prescription be limited in quantity and dosage. Prior to prescribing a controlled substance for pain, the dentist has legal obligations in the establishment of a practitioner/patient relationship and in checking the PMP and also a professional obligation to assess the patient's risk.
103	Section 103 establishes the requirements for treatment of acute pain with opioids. Subsection A specifies that initiation of opioid treatment for patients with acute pain shall be with short-acting opioids. When prescribing a controlled substance containing an opioid, a practitioner is limited to a quantity that do not exceed a **seven-day** supply as determined by the manufacturer's directions for use**,** unless extenuating circumstances are clearly documented in the patient record. Subsection A also sets the following limits on dosages: 1. The dentist must carefully consider and document in the patient record the reasons to exceed 50 MME/day. 2. Prior to exceeding 120 MME/day, the dentist must document in the patient record the reasonable justification for such doses and shall refer to or consult with a pain management specialist. **3. Naloxone must be prescribed for any patient when there is any risk factor of prior overdose, substance**	§§ 54.1-2706 (13) and 54.1-3408	Legislation introduced in the General Assembly would have limited prescribing for acute pain to 7 days and for emergency room discharge to 3 days. The medical and dental communities requested that the boards make the decision about prescribing limitation through regulation, and the Boards of Dentistry and Medicine determined that a consistent 7-day limit was advisable. In each case, the prescriber can document circumstances that would warrant prescribing outside the limits. A specified limitation on days of prescribing will reduce the amount of unused or unnecessary opioids available for abuse or diversion. It will also encourage practitioners to prescribe non-opioid controlled substances that may be just as effective but not addictive. Regulations for Medicine allow prescribing for 14 days following a surgical procedure, but dentists

	abuse, or doses in excess of 120 MME/day, and shall be considered when concomitant benzodiazepine is present. Subsection B provided that when an opioid is prescribed for more than 7 days, the patient must be re-evaluated, the need for continued prescribing must be documented in the patient record, and the dentist must check the PMP. Subsection C limits co-prescribing of certain substances. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.		believe it is important to re-evaluate a dental patient if there is pain to the extent an opioid is necessary beyond seven days. Since there are many controlled substances containing opioids, the acceptable limitation on dosage is translated into morphine milligram equivalency (MME). Typically, a patient should not be prescribed a dosage in excess of 50 MME per day. If a prescriber exceeds 120 MME per day for a patient, there must be a clear justification or consultation with or referral to a pain specialist. **Change from emergency regulation:** **The emergency regulation requires a dentist to prescribe naloxone for a patient when any risk factor of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.** **Comment on the NOIRA largely focused on concern that prescribing for naloxone for every patient who may also have taken a small dose of benzodiazepine, such as a valium, was excessive. The Board concurred and amended the regulation to specify naloxone prescribing when there are factors of high risk but to leave it up to the professional judgment of the dentist when he/she has a patient who has taken a valium before a dental procedure or may have a prescription for another benzodiazepine that he takes occasionally.** Subsection C lists drugs, for which there is a high risk of overdose if co-prescribed with an opioid.

			Regulations require documentation of the circumstances necessitating co-prescribing and the tapering plan in place.
104	Section 104 requires that the patient record include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed.	§§ 54.1-3303 and 32.1-127.1:03 18VAC60-21-90	Requirements for the patient record in the treatment of a patient with are consistent with the establishment of a bona fide practitioner-patient relationship and Board regulations for complete records.
105	Section 105 sets out the requirements for prescribing opioids for treatment of the chronic pain patient. If a dentist treats a patient for whom an opioid prescription is necessary for chronic pain, he shall either: 1. Refer the patient to a medical doctor who is pain management specialist; or 2. Comply with regulations of the Board of Medicine, 18VAC85-21-60 through 18VAC85-21-120, if he chooses to manage the chronic pain with an opioid prescription	§§ 54.1-3303 and 54.1-2522.1	Prescribing for chronic pain with a substance containing an opioid (longer than 30 days) requires a more in-depth evaluation of the patient because of the high risk of addiction. While it is possible that a small number of chronic pain conditions could be managed by dentists, the RAP and the Board believe that long-term prescribing of opioids is not appropriate in dentistry. Therefore, regulations specify that a patient should be referred to a pain management specialist; or if the dentist does choose to manage chronic pain, he or she must comply with Board of Medicine regulations.
106	A dentist who prescribes Schedules II through IV controlled substances during one license renewal cycle shall obtain two hours of continuing education on pain management during the next renewal cycle following April 24, 2017 and every two years thereafter. Continuing education hours required for prescribing of controlled substances may be included in the 15 hours required for renewal of licensure.	§ 54.1-2709	The requirement for continuing education is consistent with other boards that regulate prescribers or dispensers. The Board of Medicine is requiring prescribers to complete two hours of continuing education (CE) in pain management, proper prescribing of controlled substances, and the diagnosis and management of addiction in the 24 months prior to the next biennial renewal. Continuing education hours required for prescribing of controlled substances may be included in the 15 hours required for renewal of licensure. *The proposed regulation is identical to the readopted*

			emergency regulations readopted and will allow dentists to use a VDA course offered in the fall of 2017 to fulfill the two-hour requirement of section 106.