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Final 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	12/14/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. 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 final 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

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 December 14, 2018, the Board of Dentistry adopted amendments to 18VAC60-21-10 et seq., Regulations Governing the Practice of Dentistry.

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

The Board was 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.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity'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 was 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 regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's 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 for the protection of public health and safety.

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 regulatory change, 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, include a specific statement to that effect.

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 list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected

by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected – none

Localities Particularly Affected - none

Other Entities Particularly Affected - none

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

Commenter	Comment	Agency response
Dr. Edward Radcliffe	Used prednisone for several years to relieve pain; gave him an understanding of possible harmful effects of drugs.	The Board appreciates the comment.
Jonathan Wong	Disagrees with use of MMEs as a measure of risk; average dentist is not familiar Widespread use of naloxone is not the answer to opioid problem; blanket requirement to prescribe naloxone for high risks patients unnecessary overuse.	While the Board acknowledges that some dentists are not familiar with MMEs, it does believe that measure is consistent with national standards for prescribing opioid medications. The Board did not amend its requirement for prescribing of naloxone for patients with certain high risks factors, but did make naloxone discretionary in co-prescribing opioids with benzodiazepines.
Cynthia Williams	Suggests that the Dentistry regulations mirror the regulations for Medicine for co-prescribing naloxone.	The Board of Dentistry requirement for prescribing of naloxone for patients with certain high risks factors is identical to Medicine, but it did make naloxone discretionary in co-prescribing opioids with benzodiazepines.
Walter Saxon	Asked for further clarification of an assessment of the patient's history and risk of substance abuse. Objected to requirement for 2 hours of CE on pain management every 2 years.	The Board may consider guidance for such assessment but generally leaves that to the professional judgement of the practitioner. The Board considered the comment but declined to amend the requirement, as it believes dentists who prescribe Schedules II to IV drugs may benefit for further education on pain management.

Detail of Changes Made Since the Previous Stage

*Please list all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

There are no changes to the text since published as a proposed action.

Detail of All Changes Proposed in this Regulatory Action

*Please list all changes proposed in this action and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

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 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.	18VAC60-21-10	The Board adopted definitions identical to those adopted by the Board of Medicine for consistency.
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**	§§ 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

	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 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.		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 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. 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 proposed 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.*