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Final Regulation
Agency Background Document

Agency name	Board of Optometry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC105-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Optometry
Action title	Prescribing of opioids
Date this document prepared	6/28/19

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 optometrists prescribing of controlled substances containing opioids were promulgated as emergency regulations to address the opioid abuse crisis in Virginia. This action will replace the emergency regulations with permanent regulation. Regulations for the management of acute pain require prescribing a dosage not to exceed seven days and include requirements for the evaluation of the patient and limitations on quantity. Regulations provide requirements for prescribing an opioid beyond seven days to include a re-evaluation of the patient, check of the Prescription Monitoring Program, and specific information in the patient record. Finally, if a TPA-certified optometrist finds an opioid prescription for chronic pain is necessary, he or she is required to refer the patient to a physician or comply with Board of Medicine regulation for managing chronic pain.

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
TPA = therapeutic pharmaceutical agents

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 June 28, 2019, the Board of Optometry amended 18VAC105-20-10 et seq., Regulations Governing the Practice of Optometry.

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.

There was a legislative mandate for the Boards of Medicine and Dentistry to adopt emergency regulations for prescribing of opioids. While the Board of Optometry was not included in the mandate, members believe optometrists have a professional obligation to participate in the efforts to combat opioid addiction.

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 Optometry 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. ...

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 opioid addiction crisis was declared to be a public health emergency in Virginia on November 21, 2016. In the declaration announcement, it was noted that by the end of 2016, the numbers of fatal opioid overdose deaths were expected to increase by 77 percent, compared to five years ago. In 2014, for the first time in Virginia, more people died from opioid overdoses than fatal car accidents. Emergency department visits for heroin overdose for January-September 2016 increased 89 percent, compared to the same nine-month period in 2015. In the first half of 2016, the total number of fatal drug overdoses in Virginia increased 35 percent, when compared to the same time period in 2015, and in 2013, fatal drug overdoses became the number one cause of unnatural death. In addition to overdoses from opioids, overdoses from heroin and other illicit drugs continue to soar. Many of those who become addicted to heroin started with an addiction to prescription drugs. In order to stem the tide of addiction, practitioners need enforceable rules for proper prescribing of drugs containing an opioid in the treatment of pain to protect the public health and safety.

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 optometrists 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.

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. There are no disadvantages to the public; the only covered substance optometrists prescribe is hydrocodone with acetaminophen so these regulations will not have a negative impact on such prescribing .
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 TPA-certified optometrists 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.

There was a public comment period from February 4, 2019 to April 5, 2019; a public hearing was conducted on February 8, 2019. The only comment was an email read at the hearing from the Virginia Optometric Association stating that "our professional association supports these proposed regulations."

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 were no changes made since the previous stage.

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.*

The final action will replaces emergency regulations currently in effect; there are **no changes** from the emergency regulation or the proposed regulation.

Current section number	New section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
5	N/A	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. There are also definitions for "controlled substance"," MME", and "Prescription Monitoring Program." *Definitions used in this chapter are identical to those in emergency regulations for Medicine, Dentistry, Nursing and Veterinary Medicine.*
N/A	48	N/A	Subsection A specifies that the optometrist should consider treatment with non-opioid substances prior to initiation of opioid treatment for patients with acute pain.

			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. Subsection C provides that when prescribing a controlled substance containing an opioid, a practitioner should prescribe the lowest effective dose for the fewest number of days, not to exceed a **seven-day** supply as determined by the manufacturer's directions for use**,** unless extenuating circumstances are clearly documented in the patient record. The optometrist must carefully consider and document in the patient record the reasons to exceed 50 MME/day. Naloxone should be considered for any patient when risk factors of prior overdose, substance abuse, or concomitant benzodiazepine are present. Subsection D provides that when an opioid is prescribed for more than seven days, the patient must be re-evaluated, the need for continued prescribing must be documented in the patient record, and the optometrist must check the PMP. Subsection E specifies the content of the patient record to 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 (including date, type, dosage, strength, and quantity prescribed). Subsection F 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. *The intent of this section is to ensure that TPA-certified optometrists 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 optometrist 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.* *The Boards of Dentistry and Medicine determined that a consistent seven-day limit was advisable, and this Board agreed. 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. *Optometrists can prescribe a limited number of controlled substances containing opioids, so the acceptable limitation on dosage translated into morphine milligram equivalency (MME) should never exceed 50 MME per day.* *While these regulations do not require prescribing of naloxone, an overdose antidote, they do specify that it should be considered under the conditions listed in subsection C. A specified standard in regulation should assist practitioners in determining dosages that are consistent with the standard of care in prescribing for pain.*
N/A	49	N/A	Section 49 sets out the requirements for prescribing opioids for treatment of the chronic pain patient. If an optometrist 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. *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 optometrists, the Board believes that long-term prescribing of opioids is generally not appropriate in optometry. Therefore, regulations specify that a patient should be referred to a pain management specialist; or if the optometrist does choose to manage chronic pain, he or she must comply with Board of Medicine regulations.*
70	N/A	Sets out requirements for continuing education	TPA-certified optometrists are required to devote at least 10 of the required 20 hours of continuing education in the areas of ocular and general pharmacology, diagnosis and treatment of the human eye and its adnexa, including treatment with new pharmaceutical agents, or new or advanced clinical devices, techniques, modalities, or procedures. The emergency regulations added “pain management” to the list of topics to encourage practitioners to become better educated about addiction and the prescribing of opioids.