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Proposed 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	3/2/18

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

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 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 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 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 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. 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 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 Optometry 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 expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Licensed optometrists with TPA certification
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 1,669 TPA-certified optometrists licensed in Virginia. Almost all are employees of optometric practices which would be considered small businesses.
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.**	The Board does not believe there are any additional costs associated with these proposed amendments.

Beneficial impact the regulation is designed to produce.	The primary benefit is more oversight of the prescribing of opioid drugs and potentially fewer drugs available for abuse or diversion.

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 believe optometrists have a professional obligation to participate in the efforts to combat opioid addiction. 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 is no regulatory flexibility to achieve the purpose of public health and safety in the prescribing of opioids.

Public comment

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

There was a 30-day comment period on the Notice of Intended Regulatory Action to replace emergency regulations from 11/13/17 to 12/13/17; no comment was received.

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 optometrists in the appropriate prescribing of opioids to manage pain in such a manner as to prevent diversion or abuse.

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.

The proposed action will replace emergency regulations currently in effect; there are **no changes** from the emergency 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.