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Emergency Regulation and Notice of Intended Regulatory Action
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	8/23/17

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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

Emergency regulations for optometrists prescribing of controlled substances containing opioids are being promulgated as emergency regulations to address the opioid abuse crisis in Virginia. 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

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

On November 16, 2016, State Health Commissioner Marissa Levine declared the opioid addiction crisis to be a public health emergency in Virginia. In his news conference about the opioid crisis, Governor McAuliffe noted that the Declaration would "provide a framework for further actions to fight it, and to save Virginians' lives." One of those "further actions" was adoption of emergency regulations by the Boards of Medicine and Nursing setting out rules for prescribing of opioids and buprenorphine, and by the Board of Dentistry adoption of regulations for prescribing of opioids for acute pain. Although optometrists are only authorized to prescribe Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedules III, IV and VI controlled substances, the Board of Optometry has determined that it should also adopt emergency regulations.

The authority in § 2.2-4011 authorizes an agency to adopt emergency regulations when they "are necessitated by an emergency situation." The Declaration by Commissioner Levine is indeed evidence that such an emergency situation exists in the Commonwealth.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

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 describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

As noted above, 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.

Regulations in this chapter were drafted and circulated prior to the Board meeting on Board meeting on July 21, 2017. Comments from the Virginia Optometric Association were considered in the adoption of emergency regulations. To the extent consistent with public health and safety, recommendations from interested parties were incorporated into the regulations.

Substance

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of Virginians.

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.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The Board of Optometry is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action 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.

The Board will not convene a regulatory advisory panel but will hear and consider comment at any meeting at which this subject matter will be discussed during an open comment period.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The Board has an obligation to participate in the efforts to combat opioid addiction. There are no alternatives to the essential purpose of this 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.

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.