Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes ☒ Not Needed ☐

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).

Virginia Department of Planning and Budget

Economic Impact Analysis

18 VAC 60-21 – Regulations Governing the Practice of Dentistry
Department of Health Professions
Town Hall Action/Stage: 4778/8060
November 1, 2017

Summary of the Proposed Amendments to Regulation

Pursuant to Chapters 291[1] and 682[2] of the 2017 *Acts of Assembly*, the Board of Dentistry (Board) proposes a new regulation for the prescription of opioids in the management of acute and chronic pain. This regulation will replace an emergency regulation that became effective on April 24, 2017 and that is currently set to expire on October 23, 2018.

Result of Analysis

There are insufficient data to accurately compare the magnitude of the benefits versus the costs.

Estimated Economic Impact

The Board reports that this regulation is being proposed to "address the opioid abuse crisis in Virginia." Prior to the legislation enacted by the 2017 General Assembly, no regulations existed for opioid treatment of acute or chronic pain. In March 2017, Chapters 291 and 682 of the *Acts of the Assembly* became law. Each Chapter requires the Board of Dentistry to promulgate regulations for prescription of opioids.

Acute and chronic pain are defined in the proposed regulation as follows:

[1] http://leg1.state.va.us/cgi-bin/legp504.exe?171+ful+CHAP0291
[2] http://leg1.state.va.us/cgi-bin/legp504.exe?171+ful+CHAP0682

- Acute pain, is "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."
- Chronic pain, is "nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period of greater than three months."

For the treatment of acute pain, these Chapters require that the Board's regulation 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.*

For the treatment of chronic pain, the Chapters require the regulations to include the requirements listed above for acute pain treatment, as well as 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 [UDS], and (iii) periodic review of the treatment provided at specific intervals to determine the continued appropriateness of such treatment.*
>
> This proposed regulation will apply to all dentists.

Requirements in the Proposed Regulation

Requirements for Evaluation of the Patient in Prescribing for Acute Pain. For the evaluation of the patient, the regulation (section 102) requires that the dentist: (1) consider nonpharmacologic and non-opioid treatment for pain prior to treatment with opioids, (2) take a health history, (3) perform a physical examination appropriate for the complaint, and (4) assess the patient's history and risk of substance abuse, and (5) query the state's Prescription Monitoring Program (PMP), as set forth in § 54.1-2522.1. Section 54.2522.1 requires queries when initiating a new course of treatment in which an opioid prescription is anticipated to last more than seven consecutive days. That section also provides that a prescriber may make additional queries "as may be required by routine prescribing practices."

Requirements for Treatment of Acute Pain with Opioids. The Board proposes to limit opioid prescriptions for all acute care to the lowest effective dose, and for no more than seven days unless extenuating circumstances are clearly documented. The Board also proposes to require that, "practitioners shall carefully consider and document in the medical record the

reasons to exceed 50 MME/day"[3] if they prescribe opioids in excess of that daily dosage, and to require that, "prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist." Dentists will be required to prescribe naloxone[4] "when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present." Finally, dentists will also be required to limit co-prescribing of drugs that may increase the risk of accidental overdose when taken with opioids.

If another prescription for an opioid is to be written beyond seven days, the Board also proposes (in section 103) to require that the patient be re-evaluated and that a check of the PMP be run for the patient's prescription history. The Board proposes to set record-keeping requirements for acute pain to include a description of the pain, a presumptive diagnosis, a treatment plan, and information on medication prescribed or administered

Requirements for the Treatment of Chronic Pain. For treatment of chronic pain, the Board proposes to require that dentists either refer a patient to a medical doctor who is a pain management specialist or comply with the Board of Medicine's regulation, sections 18 VAC 85-21-60 through 18 VAC 85-21-120. Board staff reports that although very few dentists treat chronic pain, oral and maxillofacial surgeons may occasionally treat chronic pain.

Benefits and Costs of the Proposed Regulation

The requirements in the proposed regulation appear to confer a mix of benefits and costs, including those resulting from restrictions on medicine dosages, preferences for non-opioid treatments, and use of the PMP. Except for the estimated costs directly resulting from mandatory drug testing (listed in Board of Medicine rules for treatment of chronic pain), there is insufficient quantitative data to accurately determine, and thus compare, the magnitude of direct benefits versus direct costs. In part this is because the scope and range of potential impacts (cost and benefit) cannot be readily identified. To the extent that the proposed regulation reduces the rate of prescription substance abuse, including drug addiction, savings or cost avoidance could be achieved from reduction in expenditures on the treatment of, and consequences from, substance

[3] MME is an abbreviation for morphine milligram equivalent, which provides a standard value for equating the potency of different opioids.
[4] Naloxone, sold under the brand name Narcan among others, is a medication used to block the effects of opioids, especially in overdose.

abuse. However, to the extent that the regulations create a disincentive to obtaining, or limit access to, opioid therapy, any savings or cost avoidance may be offset by direct and indirect costs resulting from untreated pain[5] or a shift to illicit drugs.[6]

Indirect Benefits and Costs of Prescription Monitoring Program (PMP) Queries. Virginia statute presently requires PMP checks for any prescriptions anticipated to be used for more than seven consecutive days. This regulation proposes to require PMP queries as set forth in §54.1-2522.1 of the Code of Virginia prior to initiating treatment with opioids and PMP queries "if another prescription for an opioid is to be written beyond seven days." To the extent that the regulation is also interpreted to require PMP checks for all prescriptions, as a "routine prescribing practice" (rather than just prescriptions anticipated to last more than seven continuous days), practitioners may incur additional time costs for running those queries. To the extent that use of the PMP lowers the volume of drugs diverted from licit to illicit uses, the new requirement will provide the benefit of reductions in the costs of illicit drug use in the state.

Indirect Benefits and Costs of Record-Keeping Requirements. The Board's proposed record-keeping requirements for acute pain are likely already common for dental practices; thus licensees are unlikely to incur any costs from that portion of the proposed regulation that covers the treatment of acute pain. Likewise, most of the proposed requirements for taking a patient history and assessing a patient's complaint are likely common practice now and should not cause any additional costs. The proposed requirement that dentists in an acute care setting perform a risk assessment for substance misuse on all patients who may be prescribed opioids may not presently be a part of standard patient care. To the extent that doctors treating acute pain do not currently assess risk of substance abuse, costs would be incurred for their time to perform such assessments.

Indirect Benefits and Costs of Preferences for Alternative Treatments. The proposed regulation's requirements that alternative treatments (both nonpharmacologic and non-opioid) be given consideration prior to prescription of opioids for both acute pain and chronic pain is being

[5] Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC): National Academies Press (US); 2011. https://www.ncbi.nlm.nih.gov/books/NBK91497/pdf/Bookshelf_NBK91497.pdf

[6] *Today's fentanyl crisis: Prohibition's Iron Law, revisited*, International Journal of Drug Policy 46 (2017) 156–159.

proposed to reduce the number of such prescriptions. Board staff state that nonpharmacologic treatments may include physical therapy, chiropractic, and acupuncture.

In addition, non-opioid treatments can include treatment with acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) as well as selected antidepressants and anticonvulsants. Although these drugs do not have the addiction risks of opioids, they may pose other health risks for certain patients. As noted by the 2016 Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain*,[7] although NSAIDs are recommended as first-line treatment for osteoarthritis or low back pain they do have risks, including gastrointestinal bleeding or perforation as well as renal and cardiovascular risks. Increasing use of non-opioid treatments like NSAIDs will therefore need to balance the benefits of non-opioid therapy with these and other risks.

Direct Benefits and Costs of Rules for Treating Chronic Pain. Very few dentists will likely treat chronic pain. To the extent that they do, they will be required to follow Board of Medicine rules for such treatment. An analysis of the benefits and costs for the Board of Medicine's rules for chronic pain treatment can be found on the Virginia Regulatory Town Hall.[8]

Businesses and Entities Affected

These proposed regulatory changes will affect all 7,127 dentists currently licensed in the Commonwealth as well as any individuals who will be licensed as dentists in the future. Board staff report that the vast majority of these dentists are small businesses. These proposed regulations will also affect all dental patients who require acute or chronic pain management. Health insurance providers also may also be affected.

Localities Particularly Affected

No locality likely will be affected by these proposed regulatory changes.

Projected Impact on Employment

To the extent that these proposed regulatory changes lead to fewer individuals being effectively treated for chronic pain, employee absenteeism may increase, which would tend to depress total productivity. To the extent that this regulation reduces rates of addiction, thereby allowing former addicts to hold employment, productivity may increase.

[7] https://www.cdc.gov/drugoverdose/prescribing/guideline.html
[8] http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\26\4760\7981\EIA_DHP_7981_v2.pdf.

Effects on the Use and Value of Private Property

There is no apparent impact on the use and value of private property.

Real Estate Development Costs

These proposed regulatory changes are unlikely to affect real estate development costs in the Commonwealth.

Small Businesses:

Definition

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Costs and Other Effects

Small business dentists will likely incur increased costs associated with book keeping, staff wages, increased documentation requirements, and new drug testing requirements for chronic pain patients that will be enforced. Alternatively, adherence to the practices required by the regulation may have an unknown impact on liability insurance and associated costs that may result in savings. It is unclear to what extent these costs or savings may be passed on to insurance companies, patients, or other third parties.

Alternative Method that Minimizes Adverse Impact

Allowing dentists the discretion as to whether and how often to use drug testing would likely decrease the costs listed above. As noted above, the CDC only recommends that practitioners "consider" drug testing on an annual basis after the initial screen. For both the initial UDS and subsequent testing, however, it appears that the CDC concludes that practitioners should retain the discretion to determine whether to administer a test. The CDC notes that the recommendation to use drug testing is a Category B recommendation, which is one where "different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations."[9]

[9] CDC *Guideline*, page 4.

Adverse Impacts:

Businesses:

Dentists who practice independently may incur changes to current business practices related to increased bookkeeping, staff impacts associated with increased documentation requirements, and implementation of new drug testing requirements for chronic pain patients. It is unclear to what extent these costs may be passed on to insurance companies, patients, or other third parties.

Localities:

Localities in the Commonwealth are unlikely to see any adverse impacts from these proposed regulatory changes.

Other Entities:

To the extent that dentists treat chronic pain patients, this proposed regulation may lead to those patients, or their insurance companies, incurring increased annual costs on account of drug testing requirements. To the extent that treatment by oral and maxillofacial surgeons is covered by health insurance or dental insurance, the Commonwealth of Virginia may incur increased costs on account of these proposed regulatory changes, including employee health benefits, and the Department of Medical Assistance Services may incur increased costs for Medicaid patients who are in treatment for chronic pain.

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Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further, the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.