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 85-21 – Regulations Governing Prescribing of Opioids and Buprenorphine
Department of Health Professions
Town Hall Action/Stage: 4768/7981
September 22, 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 Medicine (Board) proposes a permanent regulation for the prescription of opioids in the management of acute and chronic pain. This proposed regulation also sets rules for the use of buprenorphine in treating pain and, separately, as part of addiction treatment.

Prior to this, the Board promulgated an emergency regulation that became effective on March 15, 2017, followed by an amended emergency regulation that became effective on August 24, 2017. The emergency regulation is currently set to expire on September 14, 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 legislation enacted by the 2017 General Assembly which required the Boards of Medicine and Dentistry to adopt regulations governing opioid prescription, no

[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

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 Boards of Medicine and Dentistry to promulgate regulations for prescription of opioids.

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

- 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.*

Chapters 291 and 682 also require that the Board's regulations include rules for:

> *the use of buprenorphine in the treatment of addiction, including a requirement for referral to or consultation with a provider of substance abuse counseling in conjunction with treatment of opioid dependency with products containing buprenorphine.*

This proposed regulation will apply to all doctors and physician assistants. However, it will not apply to: (1) the treatment of acute and chronic pain related to cancer or to such pain treatment for patients in hospice care or palliative care, (2) the treatment of acute and chronic pain during a hospital admission, or in nursing homes or assisted living facilities that use a sole source pharmacy or (3) a patient enrolled in a clinical trial authorized by state or federal law.

Requirements in the Proposed Regulation

Requirements for Acute Pain Treatment. For the treatment of acute pain, the Board proposes to require that the doctor or physician assistant: (1) take a patient history, (2) perform a physical examination appropriate for the complaint, and (3) assess the patient's history and risk of substance misuse. The Board also proposes to limit opioid prescriptions for all non-surgical acute care to a seven-day supply unless extenuating circumstances are clearly documented. For opioids prescribed as a part of a surgical procedure, the Board proposes to limit such prescriptions to a 14 day supply within the perioperative period[3] unless extenuating circumstances are documented. The Board also 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 both Acute and Chronic Pain Treatment. In treating acute or chronic pain, the Board proposes four requirements. First, practitioners will be required to consider nonpharmacologic[4] and non-opioid treatments[5] "prior to treatment with opioids." Second, practitioners will be required to query the state's Prescription Monitoring Program (PMP), as set forth in § 54.1-2522.1, which 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." For acute pain treatment, this query will occur prior to initiating treatment; for chronic pain, this will occur prior to beginning treatment and at least every three months thereafter. Third, the Board proposes to require that, "practitioners shall carefully consider and document in the medical record the reasons to exceed 50 MME/day"[6] 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." Fourth, practitioners will be

[3] Perioperative is defined by the Oxford English Dictionary as "a process or treatment occurring or performed at or around the time of an operation."
[4] These treatments can include such things as physical therapy, chiropractic care and acupuncture.
[5] The Centers for Disease Control and Prevention's 2016 *Guideline for Prescribing Opioids for Chronic Pain* indicates that nonpharmacologic and non-opioid treatments include cognitive behavioral therapy, exercise therapy, interventional treatments, multimodal pain treatment, acetaminophen, nonsteroidal anti-inflammatory drugs, antidepressants, and anticonvulsants.
[6] MME is an abbreviation for morphine milligram equivalent, which provides a standard value for equating the potency of different opioids.

required to prescribe naloxone[7] "when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present." Practitioners also will be required to limit co-prescribing of drugs that may increase the risk of accidental overdose when taken with opioids.

Requirements Solely for the Treatment of Chronic Pain. For treatment of chronic pain, the Board proposes to specify medical record-keeping requirements. The Board also proposes to require signed patient agreements and urine or serum drug testing "at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter." Practitioners also will be required to regularly evaluate patients for opioid use disorder and to initiate treatment for opioid use disorder or to refer the patient for evaluation and treatment if opioid use disorder is diagnosed.

Requirements for Treatment with Buprenorphine. The Board proposes four requirements for the prescribing of buprenorphine. First, the Board proposes to specify that buprenorphine is not to be used to treat acute pain in an outpatient setting except when a prescriber obtains a Substance Abuse and Mental Health Services Administration waiver and is treating pain in a patient whose primary diagnosis is the disease of addiction. Second, the Board proposes to ban the use of buprenorphine mono-product[8] in pill form for treating chronic pain. Third, the Board proposes to ban the use of the mono-product to treat addiction except: (1) for pregnant women, (2) when converting a patient from methadone or the mono-product to buprenorphine containing naloxone (limit of seven days), (3) in formulations other than tablet form for indications approved by the U.S. Food and Drug Administration, and (4) for up to three percent of any prescribers' addiction patients who have a demonstrated intolerance to naloxone. Fourth, the proposed regulation would also limit dosages of buprenorphine and the co-prescribing of certain other drugs with buprenorphine, as well as require PMP queries for addiction patients.

[7] Naloxone, sold under the brand name Narcan among others, is a medication used to block the effects of opioids, especially in overdose.

[8] Buprenorphine comes in two forms: the mono-product form of buprenorphine only contains buprenorphine and is sold under the name Subutex. The other form of buprenorphine also contains naloxone, and is sold under the brand name Suboxone. The mono-product is more subject to abuse, but a certain unknown portion of the population has an allergy/sensitivity to naloxone and therefore would not tolerate Suboxone.

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 the mandatory use of drug testing, restrictions on the use of buprenorphine, preferences for non-opioid treatments, and use of the PMP. Except for the estimated costs directly resulting from mandatory drug testing, and potential savings from decreased use of opioids in the state's Medicaid program, there are 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 misuse, including drug addiction, savings or cost avoidance could be achieved from reduction in expenditures on the treatment of, and consequences from, substance misuse.[9] 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[10] or a shift to illicit drugs.[11]

Direct Benefits and Costs of Drug Testing. Drug testing, typically through a urine drug screen (UDS) appears to confer direct benefits on all practitioners and a subset of patients, if confirmed test results are used to correctly refer them for substance misuse treatment or identify non-adherence to their treatment plan. As noted by the Centers for Disease Control and Prevention's (CDC) 2016 *Guideline for Prescribing Opioids for Chronic Pain* ("*Guideline*"), a UDS can: provide information about drug use that is not reported by the patient, including controlled substances and illicit drugs that increase risk for overdose when combined with opioids such as non-prescribed opioids, benzodiazepines, and heroin; assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects; and provide useful information about patients assumed not to be using unreported drugs.[12]

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[9] Florence, Curtis S, Chao Zhou, Feijun Luo, Likang Xu. *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*. Medical Care, 2016; 54 (10): 901

[10] 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

[11] Beletsky, Leo, and Corey Davis; *Today's fentanyl crisis: Prohibition's Iron Law, revisited*, International Journal of Drug Policy 46 (2017) 156–159.

[12] CDC *Guideline*, pages 30-31; https://www.cdc.gov/drugoverdose/prescribing/guideline.html

As noted in the literature,

> *Pain management is a critical element of patient care. Over the last 2 decades the emphasis on managing pain has led to a substantial increase in the prescription of opioids. While opioids can significantly improve the quality of life for the patients, there are many concerns.... Therefore, monitoring adherence for patients on (or considered candidates for) opioid treatment is a critical element of pain management…. Of the various tools, UDS is perhaps the most effective in detecting non-adherence, and is viewed as the de facto monitoring tool.*[13]

Monitoring urine toxicology also can help practitioners comply with federal Drug Enforcement Agency requirements, which require practitioners to minimize abuse and diversion.[14] However, quantitative data on the value of these benefits does not appear to be readily available. Moreover, because false positive and false negative test results are known to occur (discussed below), full realization of the benefits of UDS may utilization of both an initial immunoassay (dipstick) test in a practitioner's office followed by a confirmatory gas chromatography/mass spectrometry or high-performance liquid chromatography test (collectively referred to as GC/MS in this analysis) in a laboratory.

In order to quantify the costs of drug testing, the number of patients that will likely be affected by urine testing requirements must be estimated. The Board did not provide estimates of the number of patients affected, so estimates from relevant literature on the prevalence of chronic pain were considered. Estimates of the percentage of the population affected by acute pain do not appear to be readily available.

Using information taken from the 2012 National Health Interview Survey (NHIS), National Institutes of Health staff estimated that 11.2 percent of the adult population experiences chronic pain—that is, they had pain every day for the preceding three months.[15] In Virginia, using 2016 Census Bureau data on population by age, this equates to 732,669 adults. On the high end, the Institutes of Medicine (IOM) report that common chronic pain conditions are prevalent among 37 percent of adults, "amounting to approximately 116 million adults in 2010—a

[13] Krishnamurthy et al., *Impact of Urine Drug Screening on No Shows and Dropouts among Chronic Pain Patients: A Propensity-Matched Cohort Study*. Pain Physician. 2016 Feb; 19(2):89-100.
[14] Vadivelu, et. al; *The Implications of Urine Drug Testing in Pain Management*, Current Drug Safety 2010, 5 (267-270).
[15] Nahin, Richard; *Estimates of Pain Prevalence and Severity in Adults: United States, 2012*." The Journal of Pain : official Journal of the American Pain Society 16.8 (2015): 769–780. Studies using National Health and Nutrition Examination Survey consistently estimated chronic pain (pain ≥3 months) prevalence at 13 to 15%. (Nahin 2012).

conservative estimate as neither acute pain nor children are included."[16] This equates to approximately 2.4 million adult Virginians.

Although these two estimates may indicate the extent of chronic pain among adults, they may not indicate the extent to which persons with chronic pain seek opioid therapy. A low-end estimate is supported by at least one study (Boudreau, et al, 2009),[17] that indicates that 3 to 4 percent of the adult population were prescribed longer-term opioid therapy.[18] (Note: to the extent that opioid prescription rates have increased since this study was conducted, this estimate would be too low.)

These three estimates will be used to estimate the potential number of adults in Virginia who could be affected by the proposed regulation (Table 1). Using these population estimates, and the Board's estimate that the average cost of an initial "dipstick" UDS is $50, direct costs of the new requirements for the initial UDS would likely be between $12 million and $141 million for the initial screen, assuming all persons with chronic pain seek opioid therapy. Subsequently, the annual cost for four quarters of drug tests would be between $57 million and $605 million, assuming all persons with chronic pain seek and continue to receive opioid therapy for a full year. To the extent these assumptions are not borne out, the cost would decrease. After the first year, these costs would decrease as patients shift from quarterly to biannual testing.

Table 1

Potential Ranges of Persons with Chronic Pain	Estimated Number of Adult Virginians with Chronic Pain	Cost of Initial Test *	Additional Cost of All First Year Quarterly Tests *
Boudreau et al (3.5%)	228,959	$12 million	$57 million
NHIS estimate (11.2%)	732,669	$37 million	$183 million
IOM estimate (37%)	2,420,423	$121 million	$605 million

* Assumes 100 percent of all persons with chronic pain within each of the three estimates are treated with opioids.

[16] Institutes of Medicine 2011 (p. 62).

[17] Boudreau, et al., *Trends in De-facto Long-term Opioid Therapy for Chronic Non-Cancer Pain*, Pharmacoepidemiol Drug Saf. 2009 December ; 18(12): 1166–1175. Note: the authors state that "Our results may not be generalizable to care delivered and /or financed in other types of health care systems and other regions of the US."

[18] Defined as episodes lasting longer than 90 days that had 120+ total days supply of dispensed medication or 10+ opioid prescriptions dispensed within a given year were classified as long-term opioid episodes. Boudreau et al., cited in Volkow and McLellan, *Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies*, N Engl J Med 2016;374:1253-63.

These estimated costs may potentially increase to the extent that testing is repeated because practitioners account for the possibility of unexpected drug screen results, such as false positive and false negative results in the immunoassay or "dipstick" test typically used in a practitioner's office.[19] A false positive result occurs when the test result is "positive" but the indicated substance is not actually present. A false negative occurs when the test fails to indicate the presence of substances that are actually present. These and other unexpected results that could prompt re-testing could occur for a variety of reasons, including failure to take the prescribed medication, testing error, metabolic differences, and drug interactions. Brahm et al. notes that false positive test results have been reported for certain antibiotics (quinolones and ofloxacin), certain antidepressants and antipsychotics, the hypertension medication Verapamil, as well as over-the-counter medications containing dextromethorphan, ibuprofen and naproxen.[20]

Although re-testing is recommended by the CDC's Guideline, testing without confirmatory GC/MS testing may have unintended adverse consequences:

> *the use of medications with the potential for false-positive UDS results may present a significant liability for individuals required to undergo random or periodic UDSs as a component of a recovery or court-ordered monitoring program or as a condition of employment. In addition, false-positive UDS results may affect the clinician–patient relationship by raising issues of trust.*[21]

Of note, the CDC Guideline also only recommends initial drug testing before treatment, and states that clinicians should "consider" drug testing on an annual basis thereafter:

> *While experts agreed that clinicians should use urine drug testing before initiating opioid therapy for chronic pain, they disagreed on how frequently urine drug testing should be conducted during long-term opioid therapy. Most experts agreed that urine drug testing at least annually for all patients was reasonable.*

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

[19] A review of the diagnostic accuracy of urine drug testing found that, in a worst case scenario, 32.9% of patients' specimens to the lab because of abnormal results. (Christo, et al., *Urine Drug Testing In Chronic Pain*, Pain Physician 2011; 14:123-143). Pollack, et al, (2001) reported a false positive rate of 7% for simple urine tests. Vadivelu, et al. reports that 11-21% of initial immunoassay tests are disproven by a followup GC/MS.

[20] Brahm, et al.; *Commonly prescribed medications and potential false-positive urine drug screens*; Am J Health-Syst Pharm—Vol 67 Aug 15, 2010, 1344-1350.

[21] Brahm, et al.

must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations."[22]

As noted in the literature, "the interpretation of opioid testing results is far less straightforward than many health care providers who utilize this testing appreciate."[23] There are two main types of urine drug screening: immunoassay testing and chromatography (i.e., gas chromatography/mass spectrometry [GC/MS] or high-performance liquid chromatography). Immunoassay tests use antibodies to detect the presence of drugs. These tests can be processed rapidly, are inexpensive, and are the preferred initial test for screening.[24] When urine tests have unexpected results, the CDC *Guideline* recommends that a, "confirmatory test using a method selective enough to differentiate specific opioids and metabolites (e.g. gas or liquid chromatography/ mass spectrometry) might be warranted."[25] Although these tests can cost several hundred dollars or more, they are the forensic criterion standard means of confirming initial screening tests because they have a low incidence of false positive results and are very sensitive and specific.[26]

Board staff referred to the CDC Guideline, and also stated that the treatment agreement signed by the patient would indicate the actions to be taken if unexpected results (positive or negative) cannot be explained. Board staff report that these actions could include referral for substance abuse counseling or release from care (with the patient being given a reasonable amount of time to find a new health care practitioner).[27] Although board staff noted that the retesting could be accomplished by administering another dipstick test, repeated dipstick tests may not yield different results. For instance, unexpected positive test results can be caused by various classes of non-narcotic prescription and over the counter medications, and unexpected negative results can result from individual rapid metabolism rates. In instances where unexpected results are caused by confounding factors (rather than random test error), repeated dipstick test

[22] CDC *Guideline*, page 4.
[23] Milone, Michael; *Laboratory Testing for Prescription Opioids*, J Med Toxicol. 2012 Dec; 8(4): 408–416.
[24] Standridge et al., *Urine Drug Screening: A Valuable Office Procedure*, Am Fam Physician. 2010 Mar 1;81(5):635-640.
[25] Unexpected results would include tests that are positive for non-prescribed or illicit drugs, and tests that are negative for expected prescription drugs.
[26] Addiction Doctor Mary McMasters estimates that GC/MS testing costs between $200 and $300. See also Vadivelu, et al.
[27] Board staff reports that the "reasonable time" would vary according to the availability of other health care options but would be at least 30 days.

would be unlikely to yield different results. Additionally, the CDC Guideline calls for use of GC/MS testing to confirm dipstick test results..

Indirect Benefits and Costs of Drug Testing. The use of drug screens appears to have a mix of benefits and costs. As noted by the CDC Guideline, practitioners should use unexpected results to improve patient safety. This could include several strategies that, if properly designed and applied, would appear to confer this benefit. Examples of responses to an unexpected drug screen result include a change in pain management strategy, tapering or discontinuing opioids, more frequent re-evaluation, offering naloxone, or referring for treatment for substance use disorder. The CDC notes that practitioners:

> *should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.*

Board staff appear to agree with this guidance, adding that a patient could also be released from care if they do not comply with the treatment plan.[28] However, the Board has stated that patients should not be abandoned. As noted in a letter from the Board to practitioners:

> *As you consider these regulations, make sure that the needs of patients currently receiving opioids for chronic pain are taken into account. It is critically important that no patients in Virginia find themselves looking for narcotics outside of the medical system – ie, on the street.*[29]

However, as documented in some of the available literature, the use of drug screens may create a disincentive for certain patients to continue seeking treatment. Thus certain patients may stop pursuing opioid therapy, including those who test positive for unexpected substances and those who do not.[30] Moreover, Board staff also acknowledge that the drug testing and other requirements in the proposed regulation will create disincentives for primary care physicians to treat pain using opioid therapy. And given that the Board has stated that the regulation is, in part, designed to "provide the board with a tool to discipline physicians whose practices do not meet

[28] In order to not abandon patients, doctors would likely provide referrals to other pain doctors and would give patients a "reasonable" amount of time to find another doctor. The doctors to whom such patients would be referred are under no obligation to treat them however.

[29] https://www.dhp.virginia.gov/medicine/newsletters/OpioidPrescribingBuprenorphine03142017.pdf

[30] Krishnamurthy et al found that administration of urine drug screens at a first doctor visit was associated with an increased rate of no-shows (23.75%) when compared to patients who did not undergo urine drug screens at a first doctor visit (10.24%). Krishnamurthy et al., *Impact of Urine Drug Screening on No Shows and Dropouts among Chronic Pain Patients: A Propensity-Matched Cohort Study.* Pain Physician. 2016 Feb; 19(2):89-100.

the standard of care,"[31] the regulation may cause some primary care physicians to no longer treat chronic pain patients with opioids.

In addition, examples of some recent literature notes that, "individuals who lost access [to prescription opioids] have turned to cheaper, more accessible, and more potent black market opioid alternatives—including heroin—in unprecedented numbers."[32] Thus an additional unintended consequence of the regulations may be a shift in demand from legal prescriptions to illegal street drugs, including heroin and illicitly-produced fentanyl (in combination or separately). As noted in a recent issue of the International Journal of Drug Policy, "prescribing restrictions forced a minority of dependent users to more potent and available street heroin."[33] The federal Drug Enforcement Administration notes that "fentanyl can serve as substitute for heroin in opioid dependent individuals."[34]

As noted by the Board, "the purpose of the regulations" is in part "to assist physicians in treating opioid dependent patients."[35] However, to the extent that some patients, particularly those with substance use disorder, no longer obtain treatment, they may seek illicit substances. It is not clear if this is occurring in Virginia, but data released by the Office of the Chief Medical Examiner (OCME) indicate that "there has not been a significant increase or decrease in fatal prescription opioid overdoses" from 2007 to 2016, but "fatal fentanyl overdoses increased by 176.4% from 2015 to 2016."[36] (This trend is illustrated in the figure below.) Notwithstanding the increase in deaths from fentanyl, on average more than 400 fatalities still result in part from prescription opioids each year.[37]

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[31] http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\\meeting\26\25243\Minutes_DHP_25243_v2.pdf.

[32] Beletsky, Leo, and Corey Davis; *Today's fentanyl crisis: Prohibition's Iron Law, revisited*, International Journal of Drug Policy 46 (2017) 156–159.

[33] Rhodes, Tim; *Fentanyl in the US heroin supply: A rapidly changing risk environment*, International Journal of Drug Policy 46 (2017) 107–111.

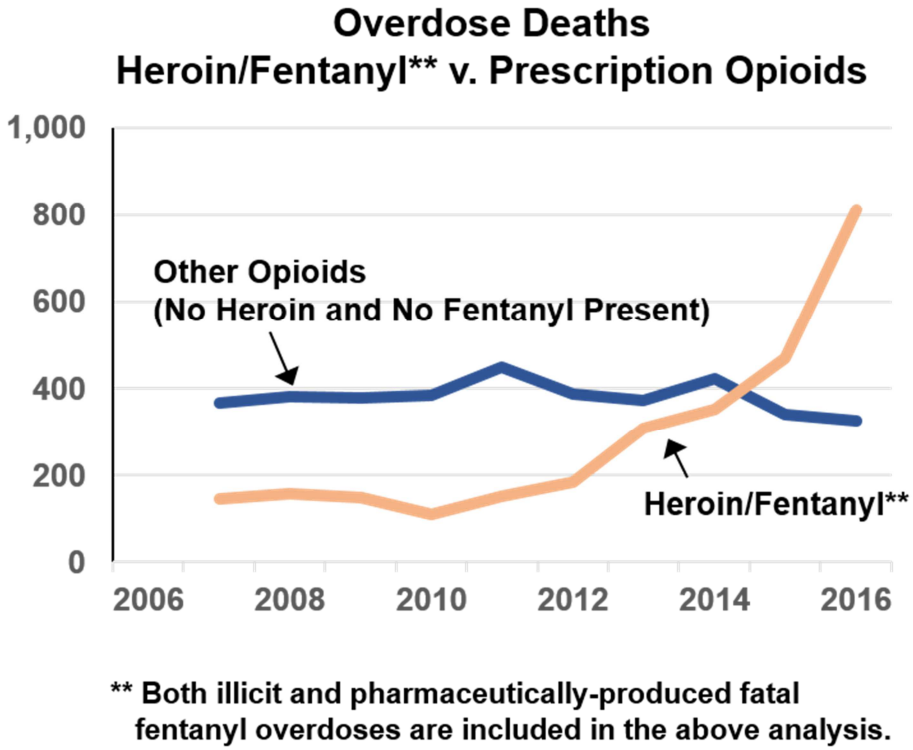
[34] https://departments.arlingtonva.us/wp-content/uploads/sites/6/2017/06/heroin_fentanyl_brochure.pdf

[35] http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\\meeting\26\25243\Minutes_DHP_25243_v2.pdf.

[36] http://www.vdh.virginia.gov/content/uploads/sites/18/2016/04/Fatal-Drug-Overdoses-Quarterly-Report-Q1-2017_Updated.pdf

[37] The OCME notes that drug-related deaths often have more than one drug causing or contributing to death. Therefore, some of the deaths attributed to prescription opioids and fentanyl may have multiple drugs on board.

Although it does not appear that the OCME can determine whether the fentanyl was illicit or pharmaceutically-produced, staff at the Department of Forensic Science (DFS) reports that over the last 12 years submissions of prescription fentanyl have averaged between 25 and 27 samples per year. In contrast, data reported by DFS indicate that the number of submissions of illicit fentanyl increased by 1,656 percent from 2013 to 2016.[38]



Indirect Benefits and Costs of Restrictions on Use of Buprenorphine. The Board's proposed restrictions on the use of buprenorphine are aimed at decreasing the abuse of the mono-product of this drug ("Subutex") because it has become a popular drug of abuse. To the extent the proposed regulation decreases abuse, then a benefit will be conferred. However, any decrease in the abuse of this drug attributable to these proposed restrictions would need to be weighed against the costs that may accrue for chronic pain patients and individuals in addiction treatment.

Board staff reports that the cost of Suboxone (which contains buprenorphine plus naloxone) is higher than the cost of Subutex. To the extent, therefore, that certain patients are no longer able to obtain prescriptions for Subutex, then they will likely incur increased costs. As noted by Board staff, demand for opiates is highest in the places where health insurance coverage

[38] http://www.dfs.virginia.gov/wp-content/uploads/2017/07/CY16DfsDataReport_Final.pdf Slide 27

is lowest. Therefore, these cost increases may disproportionally fall upon patients who pay for prescriptions (and drug screens) out of pocket. Additionally, it is reported that some portion of the general population has an allergy or sensitivity to naloxone and would not be able to take Suboxone.

In response to concerns raised about restrictions on prescription of the mono-product that did not account for individuals who had an allergy or sensitivity, as well as the ability to pay, the Board voted to allow treatment with the mono-product for up to three percent of any prescribers' addiction patients who have a demonstrated intolerance to naloxone. This allowance was made for individuals in addiction treatment but not for chronic pain patients (who presumably would have the same incidence of Naloxone allergies). The Board believes that this three percent allowance will be sufficient to cover the portion of addiction patients who have a true allergy/insensitivity. These individuals are not likely, however, to be evenly spread among all doctors. This means that some doctors may have more than three percent of their patients for whom the mono-product would be the preferred treatment and some may have less. Because of this, some patients and practitioners may see disruptions in treatment.

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 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 CDC Guideline, 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.

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. Board staff reports that some hospitals already require PMP queries for prescriptions issued in the emergency rooms (ER). Other hospitals that do not currently have this policy will likely accrue staff time costs. 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. Additionally, to the extent that use of the PMP lowers the number of doses of opioids, the new requirement will provide the benefit of reducing the risk from use of opioids. The Department of Health Professions (DHP), citing the CDC, indicates that individuals taking greater than 90 MME/day are at a higher risk of overdose and death. DHP adds that since the adoption of emergency regulation, PMP data indicate that "the total number of patients prescribed high dosages declined from 169,145 individuals in the fourth quarter of 2016 to 137,618 individuals in the third quarter of 2017, or an 18.6% decline in individuals receiving greater than 100 MME/day."[39]

Indirect Benefits and Costs of Record-Keeping Requirements. The Board's proposed record-keeping requirements for acute pain are likely already common medical practice; 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 practitioners in an acute care setting perform a risk assessment for substance misuse[40] on all patients who may be prescribed opioids may not presently be a part of standard patient care. To the extent that practitioners treating acute pain do not currently assess risk of substance misuse, costs would be incurred for their time to perform such assessments.

Businesses and Entities Affected

These proposed regulatory changes will affect all doctors of medicine, osteopathic medicine, and podiatry as well as physician assistants. These proposed regulations also will

[39] http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\26\4760\7981\EIARes_DHP_7981_v1.pdf
[40] The term "substance misuse" is not defined in the proposed regulation.

affect all patients (both acute care and chronic care) who have been treated with opioids since the emergency regulation went into effect, and all patients who may be treated with opioids in the future. Additionally, individuals in treatment for addiction who are prescribed buprenorphine will be affected. Health insurance providers also will be affected. Board staff reports that the Board currently licenses 38,646 doctors of medicine, 3,117 doctors of osteopathic medicine, 616 doctors of podiatry, and 3,647 physician assistants. The Board has no estimates of the number of chronic pain patients that might be affected by this proposed regulation. Based on estimates of the number of the American adults who suffer from common chronic pain conditions, the changes contained in this proposed regulation will likely affect at least hundreds of thousands of chronic care patients in Virginia and may affect as many as several million, depending upon the extent to which they seek opioid therapy.

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, which may allow former addicts to hold employment, productivity would increase.

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

Based on Virginia Employment Commission data, there are 4,757 offices of physicians with fewer than 500 employees in the Commonwealth, thus likely qualifying as small businesses. These firms likely will incur increased costs associated with book keeping, staff wages, increased documentation requirements, and new drug testing requirements for chronic pain patients in the proposed regulation. 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.

Alternative Method that Minimizes Adverse Impact

Allowing doctors, and the nurse practitioners who work with them, 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.

Adverse Impacts:

Businesses:

Doctors 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 in the proposed regulation.

Localities:

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

Other Entities:

Chronic pain patients, or their insurance providers, will likely incur annual costs on account of drug testing requirements and on account of restrictions on the prescription of buprenorphine mono-product that are in the proposed regulation.

The Department of Human Resource Management reports that the Commonwealth of Virginia will likely incur increased costs because of these proposed regulatory changes, including additional costs for drug testing. The Department of Medical Assistance Services (DMAS) may incur increased costs for Medicaid patients

who are in treatment for chronic pain or who are undergoing addiction treatment with Buprenorphine. These latter costs may be offset to some degree by reductions in expenditures on prescription opioids, according to DHP, which reports that DMAS has experienced "an annual reduction in drug spending on opioids of approximately $466,000."[41] The Department of Corrections may incur increased costs for drug testing and limitations on prescribing of Buprenorphine for prisoners housed in prisons statewide.

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Legal Mandates

[41] http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\26\4760\7981\EIARes_DHP_7981_v1.pdf

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.