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: 6263 / 10045
February 1, 2024

The Department of Planning and Budget (DPB) 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 19. The analysis presented below represents DPB's best estimate of the potential economic impacts as of the date of this analysis.[1]

Summary of the Proposed Amendments to Regulation

The Board of Medicine (Board) proposes to update these regulations to incorporate the latest *Clinical Practice Guideline for Prescribing Opioids for Pain* issued by the Centers for Disease Control and Prevention (CDC); several other discretionary changes based on the feedback and information received by the Board; and editorial changes to improve clarity and remove obsolete references.

Background

These regulations govern prescribing of opioids and buprenorphine for pain by practitioners. Prescribing of these controlled substances were significantly amended in 2018 pursuant to a mandate by the General Assembly.[2] According to the Department of Health Professions (DHP), medical research and CDC guidelines surrounding opioid and buprenorphine prescribing have changed since that time, and the CDC issued new guidelines in late 2022.[3] The

[1] Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis 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.
[2] https://townhall.virginia.gov/l/ViewStage.cfm?stageid=8216
[3] https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm

proposed action would mainly incorporate the revised guidelines but also make other discretionary changes based on the feedback and information received by the Board, as well as editorial changes to improve clarity and remove obsolete references.

Estimated Benefits and Costs

The descriptions, rationales, and anticipated effects of the proposed changes are provided below. Changes that are prompted by the new CDC guidelines are indicated as "CDC," while other changes (those not prompted by the CDC guidelines) are indicated as "non-CDC."

Allow the use of other opioid reversal agents in addition to Naloxone if they are approved by the Federal Drug Administration (FDA) (non-CDC).

According to the Board, this change is in response to the expected approval by FDA of opioid reversal agents (also known as antagonists) other than Naloxone, which should soon be available to practitioners and the public. This change would still allow Naloxone to be used but would also allow use of new opioid reversal agents as they become available.

This change would benefit the makers of the new opioid reversal agents as they would have immediate access to the Virginia market under this change. Conversely, however, the incumbent maker of Naloxone, currently a de facto monopoly in Virginia, would no longer be sheltered from competition by this regulation. This would benefit consumers, because a monopoly can command higher prices at the expense of consumers by controlling supply. Additionally, the practitioners' ability to prescribe other opioid reversal agents if indicated would be possible and patients would have immediate access to any such new drugs. In essence, this change would remove a barrier to entry into the Virginia's market for opioid reversal agents.

Several changes would remove or revise the limits on opioid-related drugs and expand the use of buprenorphine.

One change in this category would increase the 7-day opioid prescription supply limit to 14 days for acute and subacute pain (CDC), and remove the limitation that practitioners must follow the manufacturer's directions for use (non-CDC). The Board reports that the 7-day limitation is too restrictive in practice, and that the use of opioids for off-label uses may not need to be, and sometimes should not be, in accordance with manufacturer directions. Practitioners and patients would likely benefit from this change in terms of a decrease in the need to write

prescriptions and the associated trips to the pharmacy, and perhaps fewer doctor visits as well. Practitioners and patients would likely also benefit from the ability to diverge from manufacturer directions when needed.

Another change would remove the daily limits on buprenorphine, which are currently eight milligrams when starting therapy and 24 milligrams after the initial stages of therapy (CDC). This change is intended to allow practitioners to make clinical decisions based on the patient that presents before them rather than be limited to a set dosage amount for initial and ongoing therapy. Like the previous change, this would provide more flexibility to the practitioners when needed, and patients who need a higher dosage of buprenorphine would also be accommodated.

A third set of changes would also allow buprenorphine treatment of a patient who has psychiatric comorbidities and is not stable (non-CDC). The Board determined that excluding these patients from buprenorphine treatment was unnecessarily limiting. Many patients who need treatment for opioid use disorder may present with psychiatric comorbidities, but those comorbidities are resolved with successful treatment for opioid use disorder. In addition, according to the Board, psychiatric comorbidities can be exacerbated by opioid use disorder, in which case it is proper to initiate treatment for both conditions simultaneously. With this change, practitioners would have buprenorphine treatment as an option for patients with psychiatric comorbidities. Thus, both practitioners and affected patients are likely to benefit from this change.

Several changes would provide some administrative relief to practitioners.

The changes in this group would reduce the administrative burden on practitioners as the documentation requirements would be lessened and specific action would no longer be required in certain instances.

One of these changes would remove the requirement that providers document the rationale for prescribing doses between 16 and 24 milligrams of buprenorphine per day (CDC). Currently, a practitioner may prescribe up to 24 milligrams per day, but when the dosage is over 16 milligrams certain documentation of the rationale is required. This change is a direct result of removing the daily limits on buprenorphine, as discussed above.

Another change would no longer require a practitioner to document absence of any indicators for medication misuse or diversion and subsequently take appropriate action when misuse or diversion is indicated (non-CDC). Currently, practitioners are required to record and take appropriate action not only when indicators of misuse or diversion are present, but also when they are absent. Under this change, practitioners would be required to document and take appropriate action only when indicators are present and take appropriate action as part of the standard of care. The Board's rationale is that in other disciplines of medicine, practitioners are not required to document the absence of symptoms, and it is viewed as unnecessarily burdensome and stigmatizing to include the requirement in these regulations. The regulation would also be amended to remove the requirement that a prescriber "take appropriate action" upon documenting the presence of indicators of medication misuse or diversion. This requirement placed practitioners in a difficult position when working with vulnerable populations, and the Board states that it is additionally difficult to enforce.

The proposal would also change the requirement that a practitioner "assure that [relapse prevention strategies] are addressed by" a mental health service provider to "document referral to" a mental health services provider (CDC). The Board believes that practitioners have no way to "assure" strategies are addressed by another health professional. Documentation of a referral to a mental health service provider is a reasonable requirement that is attainable for prescribers. Additionally, the regulatory advisory panel and the Board felt that the limitation of a referral to only certain mental health providers was unnecessarily limiting. This is particularly true in the current environment, in which it is difficult to obtain appointments with any mental health practitioner.

Several proposed changes would add new requirements or limit existing options.

One such change would newly require the practitioner to taper an opioid if the treatment plan includes opioid tapering (non-CDC). This change requires that no opioid patient should have their treatment stopped without the use of a tapering plan and documentation of extenuating circumstances. The Board states that this is a direct result of complaints and communications it has received regarding practitioners who stop opioid treatment without tapering, which results in severe consequences for patients. The Board does, however, recognize that extenuating circumstances may exist, such as if the practitioner receives evidence in the form of drug tests

that indicate the patient is not taking the drugs as prescribed. In that example, the patient may be providing drugs to third parties or selling the medication, and continuing to provide prescription medication under such conditions would be inadvisable. Accordingly, tapering would not be required if extenuating circumstances exist and are documented. This change would help spare patients from severe withdrawal symptoms when appropriate, while balancing the need to address drug diversion.

Practitioners would also be required to take specific steps to address potential misuse (i.e., using the lowest effective dose, scheduling frequent office visits, performing pill counts, and checking the Prescription Monitoring Program) to reduce chances of buprenorphine misuse, in addition to diversion (non-CDC). Currently, practitioners are required to take certain steps to reduce the chances of diversion, and the proposal would also require that those steps be taken in order to reduce the chances of misuse. According to the Board, this change is intended to utilize the tools used to prevent diversion to also prevent misuse. This change is expected to help prevent misuse and benefit patients.

Another change in this group would require practitioners to include liver function tests if clinically indicated when performing and documenting their assessment of the patient (non-CDC). The Board proposes this change because it feels that liver function tests are an important component of assessing the risk of medication assisted treatment for any practitioner. Under this change, patients will be screened for liver function, thereby increasing the ability to diagnose liver problems and address patient safety and health when clinically indicated. However, any such additional tests would also add to the cost of treatment, which some patients may be responsible for, depending on the extent and nature of their insurance coverage.

An additional change would remove the allowance that pregnant women may be treated with the buprenorphine mono product (CDC). According to the Board, the latest CDC guidelines state that buprenorphine or methadone is the preferred treatment for pregnant women, not the buprenorphine mono product. Therefore, this limitation and reference would be deleted. The Board also notes that if a mother needs an exemption to take the mono-product, it can still be prescribed under the existing three-percent rule, and that this change would improve patient safety.

Significant clarifying changes (non-CDC).

The Board also proposes to make several clarifying changes. First, to be consistent with CDC guidelines the definition of "acute pain" would be revised and a definition for "subacute pain" would be added. Also, certain changes in descriptions of categories would be made for consistency with CDC guidelines and current terminology. The Board states that changes in descriptions of type of pain, such as acute or subacute, do not affect practitioners since they can already prescribe for these categories. So, for example, the changes do not newly "allow" opioid prescriptions for subacute pain, because practitioners can already prescribe for any pain by virtue of having a license. Additionally, patients can already receive opioids for any type of pain. Thus, there would be no change in practice.

Other clarifying changes would remove obsolete references to the SAMHSA (federal Substance Abuse and Mental Health Services Administration) waiver, known as "X-waivers," to prescribe buprenorphine, as that waiver is no longer issued by SAMHSA.

Lastly, the Board would add language stating that DMAS (Department of Medical Assistance Services) members should not pay for services involving prescription of an opioid for pain management related to opioid use disorder. This change incorporates the 2018 DMAS rule[4] addressing cases where some members have been asked by their providers for cash or other items of monetary value in exchange for Medicaid covered substance use disorder services.

Businesses and Other Entities Affected

The proposed amendments mainly affect individual practitioners that prescribe opioids and buprenorphine as part of pain management, opioid use disorder treatment, or surgery, as well as their patients. DHP has no data regarding the number of practitioners that prescribe opioids for these purposes. As of March 31, 2023, DHP reported a total of 53,127 prescribers under the Board (42,132 medical doctors, 4,941 doctors of osteopathy, and 6,054 physician assistants). The Board believes practitioners affected by the regulatory amendments would likely be a minority of those numbers. No practitioners or patients appear to be disproportionately affected.

The Code of Virginia requires the DPB to assess whether an adverse impact may result from the proposed regulation.[5] An adverse impact is indicated if there is any increase in net cost

[4] https://www.dmas.virginia.gov/media/1332/virginia-medicaid-providers-cannot-charge-cash-to-medicaid-enrolled-members-for-covered-substance-use-disorder-treatment.pdf

[5] Pursuant to Code § 2.2-4007.04(D): 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

or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As noted above, all but one of the changes (i.e., the cost of newly required liver function screening) are expected to benefit patients based on the rationales provided or explained by the Board. The cost of liver screening does not appear to outweigh the benefits to patients. Similarly, the new administrative requirements to prescribers do not appear to outweigh the benefits to them from many other changes. Thus, an adverse impact on patients/prescribers is not indicated.

However, the proposed changes would replace a reference to Naloxone by name and would instead use generic "FDA approved opioid reversal agents." This change would expose the maker of Naloxone to competition from new and upcoming substitute drugs. Thus, an adverse impact on the incumbent maker of Naloxone is indicated.

Small Businesses[6] Affected:[7]

The proposed changes do not appear to adversely affect small businesses.

Localities[8] Affected[9]

The proposed amendments do not introduce costs for localities, nor do they disproportionately affect them.

Projected Impact on Employment

The proposed amendments do not appear to directly affect total employment.

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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. Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

[6] 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."

[7] 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.

[8] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[9] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Effects on the Use and Value of Private Property

As mentioned above one of the proposed amendments would eliminate language protecting the maker of Naloxone from competition when and if other substitute drugs are approved by the FDA. Thus, the asset value of that incumbent company may be negatively affected when that occurs. No other significant effect on the use and value of private property nor on real estate development costs is expected.