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: 5355/8840
February 10, 2020

Summary of the Proposed Amendments to Regulation

The Board of Medicine (Board) proposes to amend 18 VAC 85-21 *Regulations Governing Prescribing of Opioids and Buprenorphine* in order to require that prescriptions of medications containing opioids be transmitted electronically from the prescribing authority to the pharmacist. The proposed amendment would make permanent the existing emergency text and is intended to prevent the abuse of prescription drugs containing opioids.

Background

Section 54.1-3408.02 of the Code of Virginia, as effective until July 1, 2020, states that prescriptions may be transmitted electronically or by facsimile machine and shall be treated as valid original prescriptions.[1] The 2017 Acts of Assembly (Chapters 115 and 429) amended and reenacted this section of the Code to require that "any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription." The reenacted section containing this requirement takes effect on July 1, 2020.[2] The same acts also updated the definition of "electronic prescriptions" to be "a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be transmitted in accordance with 21 C.F.R. Part 1300."[3]

[1] See https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3408.02/
[2] See http://lis.virginia.gov/cgi-bin/legp604.exe?171+ful+CHAP0429
[3] See Definitions effective July 1, 2020: https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3401/

Subsequently, pursuant to a statutory change requested by the Board,[4] Chapter 664 of the 2019 Acts of Assembly further amended this section to insert ten exemptions to this requirement and to authorize the licensing health regulatory board to grant a hardship waiver for one year.[5] Chapter 664 also required that the Board of Medicine, the Board of Nursing, the Board of Dentistry, and the Board of Optometry promulgate regulations to implement the waivers within 280 days of the act's enactment. Hence, the Board of Medicine promulgated an emergency regulation that became effective on September 18, 2019.[6]

The proposed amendment, which is identical to the emergency text currently in effect, adds a section to the regulation (specifically 18 VAC 85-21-21) containing two sub-sections as quoted below.

> 18VAC85-21-21. Electronic prescribing.
> A. Beginning July 1, 2020, a prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia.
> B. Upon written request, the board may grant a one-time waiver of the requirement of subsection A of this section, for a period not to exceed one year, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

Thus, the proposed amendment would inform readers as to the electronic transmission requirement and the waiver that may be obtained, but readers would need to refer to § 54.1-3408.02 of the Code to find the exemptions that were added by Chapter 664 of the 2019 Acts of Assembly.

The exemptions provided in the Code would directly affect the potential cost of transmitting electronic prescriptions in a variety of settings. Thus, although they are not explicitly mentioned in the text of the regulation, the exemptions are listed here for the reader's reference, with parenthetical notes inserted for clarity of context.

> §§ 54.1-3408.02.C. The requirements of subsection B (electronic transmission) shall not apply if:
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> 1. The prescriber dispenses the controlled substance that contains an opioid directly to the patient or the patient's agent;

[4] See https://townhall.virginia.gov/L/GetFile.cfm?File=Meeting\30\26790\Agenda_DHP_26790_v1.pdf (page 172)
[5] See http://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+CHAP0664
[6] See https://townhall.virginia.gov/l/ViewStage.cfm?stageid=8714

2. The prescription is for an individual who is residing in a hospital, assisted living facility, nursing home, or residential health care facility or is receiving services from a hospice provider or outpatient dialysis facility;

3. The prescriber experiences temporary technological or electrical failure or other temporary extenuating circumstance that prevents the prescription from being transmitted electronically, provided that the prescriber documents the reason for this exception in the patient's medical record;

4. The prescriber issues a prescription to be dispensed by a pharmacy located on federal property, provided that the prescriber documents the reason for this exception in the patient's medical record;

5. The prescription is issued by a licensed veterinarian for the treatment of an animal;

6. The FDA requires the prescription to contain elements that are not able to be included in an electronic prescription;

7. The prescription is for an opioid under a research protocol;

8. The prescription is issued in accordance with an executive order of the Governor of a declared emergency;

9. The prescription cannot be issued electronically in a timely manner and the patient's condition is at risk, provided that the prescriber documents the reason for this exception in the patient's medical record; or

10. The prescriber has been issued a waiver pursuant to subsection D (hardship waiver).

Further, Chapter 664 also amends § 54.1-3410 of the Code, effective July 1, 2020, which addresses when pharmacists may sell and dispense drugs. It adds a subsection to clarify that, "A dispenser who receives a non-electronic prescription for a controlled substance containing an opioid is not required to verify that one of the exceptions set forth in § 54.1-3408.02 applies and may dispense such controlled substance pursuant to such prescription and applicable law."

Estimated Benefits and Costs

The 2017 Acts of Assembly (Chapters 115 and 429) also directed the Secretary of Health and Human Resources to convene a work group of interested stakeholders to review actions necessary for the implementation of electronic prescriptions for controlled substances and evaluate the burden on prescribers, including the inability of prescribers to comply with the deadline. The E-Prescribing Workgroup's final report indicates that roughly 75 percent of

providers and nearly 99 percent of pharmacies in Virginia had already adopted electronic prescriptions by 2018 and face no additional costs.[7]

The remaining providers who need to implement e-prescription by July 1, 2020 would face additional costs, particularly those in remote areas without reliable internet connectivity. If this imposes a significant economic burden, these providers could mitigate these costs in the short run by obtaining a waiver from the Board by July 1, 2020 for a period of up to a year.[8] The remaining one percent of pharmacies would likely find it beneficial to adopt e-prescriptions if they dispense opiates and intend to continue to do so. Finally, the public would stand to benefit to the extent that increasing electronic prescriptions of controlled substances decreases instances of substance abuse.

Businesses and Other Entities Affected

The Board currently has 38,947 licensed doctors of medicine and surgery, 3,834 licensed doctors of osteopathic medicine, 553 licensed doctors of podiatry, and 4,224 licensed physician assistants. Licensees would only be affected by the new requirements if (i) they prescribe medications containing opioids, (ii) they do not work in a type of facility that is included in the exemptions listed above, and (iii) they do not already use e-prescription technology.

Small Businesses[9] Affected

The Department of Health Professions could not provide information on the number of licensees who may be proprietors or employees of a small business. However, there do not appear to be disproportionately higher costs for small businesses.

Localities[10] Affected[11]

The proposed amendments potentially affect prescribers and patients in all localities. The proposed amendments are unlikely to introduce new costs for local governments.

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[7] https://rga.lis.virginia.gov/Published/2018/RD416

[8] In communications with the Department of Health Professions, they stated that providers would need to have their waiver in place by July 1st or they would be in violation of the regulation and the law if they did not e-prescribe opioids after the deadline.

[9] 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."

[10] "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.

[11] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Projected Impact on Employment

The proposed amendments are unlikely to affect total employment in the industry.

Effects on the Use and Value of Private Property

The proposed amendments are unlikely to affect the use or value of private property. Real estate development costs are unlikely to be affected.

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 14 (as amended, July 16, 2018). 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(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 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.