Virginia Department of Planning and Budget

Economic Impact Analysis

18 VAC 110-30 Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Department of Health Professions
Town Hall Action/Stage: 5605 / 9244
June 7, 2021

Summary of the Proposed Amendments to Regulation

Pursuant to Chapters 609 and 610 of the 2020 Acts of Assembly (legislation), an emergency regulation became effective on January 4, 2021 that: 1) amended the term "practitioner" to include nurse practitioners or physician assistants for the purpose of issuing a limited-use license, and 2) added a limited-use license for practitioners to sell Schedule VI controlled substances (excluding the combination of misoprostol and methotrexate), and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, and 3) specify that a limited-use facility permit may be issued to a nonprofit facility for the purpose of dispensing the same.

The emergency regulation will expire on July 3, 2022. Also pursuant to the legislation, the Board proposes to replace the emergency regulation with an identical permanent regulation.

Background

Practitioner of the Healing Arts

"Practitioner" or "practitioner of the healing arts" is currently defined as "a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine." The Board proposes to add the following sentence to the definition: "For the purpose of a limited-use permit for a nonprofit facility, a 'practitioner' or 'practitioner of the healing arts' may also mean a physician assistant with a current active license issued by the Board of Medicine or a nurse practitioner with a current active license issued by the Joint Boards of Nursing and Medicine."

Licenses

Both the current (pre-emergency) regulation and the proposed regulation require that prior to engaging in the sale of controlled substances, practitioners must be issued a license for this purpose by the Board. The Board proposes to add the following statement:

> Prior to engaging in the sale of Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, a doctor of medicine, osteopathic medicine or podiatry, a nurse practitioner, or a physician assistant shall make application on a form provided by the board and be issued a limited-use license.

The statement is essentially straight from the legislation.

Permits

The current (pre-emergency) regulation and the proposed regulation both require that any location at which practitioners of the healing arts are to sell controlled substances must first obtain a permit issued by the Board. Both the current and proposed regulations also state the following concerning limited-use permits:

> B. For good cause shown, the board may issue a limited-use facility permit when the scope, degree, or type of services provided to the patient is of a limited nature. The permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of this chapter may be waived.
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> 1. The limited-use facility permit application shall list the regulatory requirements for which a waiver is requested, if any, and a brief explanation as to why each requirement should not apply to that practice.
>
> 2. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion shall accompany the application.
>
> 3. The issuance and continuation of a limited-use facility permit shall be subject to continuing compliance with the conditions set forth by the board.

The Board proposes to add:

> 4. A limited-use facility permit may be issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances.

Thus, under the current (pre-emergency) regulation, facilities may already obtain a limited-use permit when the practitioner is a doctor of medicine, osteopathic medicine or podiatry.

Combining the proposed new sentence for the definition of "practitioner" or "practitioner of the healing arts" with the proposed added text on permits (B.4), limited-use permits could also be issued for the specific purpose described in B.4 when the practitioner is a physician assistant or a nurse practitioner.

Schedule VI Controlled Substances

The U.S. Drug Enforcement Administration (DEA) classifies drugs, substances, and certain chemicals used to make drugs into five categories based on their abuse potential.[1] States generally follow the DEA classifications with some exceptions.[2] Virginia adds a sixth category known as "Schedule VI" for controlled substances with the lowest abuse potential. Schedule VI includes:[3]

- Any compound, mixture, or preparation containing any stimulant or depressant drug that is exempt from the first five categories.
- Any potentially toxic drug not included in the first five categories that has not yet been determined safe except under supervision of a licensed practitioner.
- Any drug not included in the first five categories that is otherwise restricted by federal law.

Examples of Schedule VI controlled substances include blood pressure and cholesterol lowering agents, antibiotics, birth control, diabetes medications, etc.[4]

Estimated Benefits and Costs

The primary impacts of the legislation and the proposal are that: 1) physician assistants and nurse practitioners may be issued a limited-use license to sell Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, and 2) nonprofit facilities may be issued a limited-use facility permit where physician

[1] See https://www.dea.gov/drug-information/drug-scheduling
[2] For example, Gabapentin was classified as Schedule VI in Virginia until July 1, 2019, when the Virginia General Assembly reassigned it to Schedule V although it is not currently on the DEA Schedule. See
https://www.deadiversion.usdoj.gov/drug_chem_info/gabapentin.pdf
https://www.dhp.virginia.gov/pharmacy/docs/Gabapentin06172019.pdf
https://www.carlislemedical.com/2019/06/gabapentin-to-become-a-controlled-substance-in-virginia/
https://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+CHAP0214+hil
[3] See https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3455/
[4] Source: Department of Health Professions

assistants and nurse practitioners may make such sales. Under the current (pre-emergency) regulation, physician assistants and nurse practitioners cannot sell controlled substances.

Some nonprofit clinics are run by nurse practitioners or physician assistants. The proposal would newly allow Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to be sold at such clinics. Free clinics are among nonprofit clinics that could be affected; thus the proposal could potentially increase access to needed medication for their clients.

Through the first five months of the emergency regulation being in effect, the Department of Health Professions has not received any applications for either the limited-use license from nurse practitioners or physician assistants or the limited-use facility permit issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances. Based on this evidence, it does not appear that the legislation and the proposal will have a large impact.

Businesses and Other Entities Affected

The proposal would potentially affect nurse practitioners and physician assistants who provide care in nonprofit health clinics who wish to dispense Schedule VI controlled substances and hypodermic syringes and needles for the administration of prescribed controlled substances. The proposal would also potentially affect such nonprofit clinics. To the extent that nurse practitioners and physician assistants obtain the limited-use license and do dispense in nonprofit health clinics, some poor citizens of the Commonwealth may get increased access to needed medications. Since through the first five months of the emergency regulation being in effect no nurse practitioners or physician assistants have applied for the limited-use license, and no nonprofit facilities have applied for the associated limited-use permit, it does not appear that many entities will be affected in practice.

The proposal does not produce any costs.

Small Businesses[5] Affected:

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

[5] 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."

Localities[6] Affected[7]

The proposed amendments apply throughout the Commonwealth, but may particularly affect poorer localities since free clinics are expected to be among the entities most affected. The proposed amendments do not introduce costs for local governments.

Projected Impact on Employment

The proposed amendments do not appear to affect total employment.

Effects on the Use and Value of Private Property

The proposal is unlikely to substantively affect the use and value of private property. The proposed amendments do not affect real estate development costs.

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.

[6] "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.

[7] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.