Virginia Department of Planning and Budget

Economic Impact Analysis

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
18 VAC 110-21 Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Department of Health Professions
Town Hall Action/Stage: 5861/9562
May 10, 2022

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 14 (as amended, July 16, 2018). The analysis presented below represents DPB's best estimate of these economic impacts.[1]

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to make permanent certain changes that are currently implemented through an emergency regulation, which was promulgated in response to a 2021 legislative mandate.[2] The proposed amendments would primarily expand the scope of treatment that pharmacists would be allowed to initiate to include (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) or have a current emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA), (ii) tuberculin purified protein derivative for tuberculosis testing, and (iii) certain controlled substances for the prevention of human immunodeficiency virus (HIV).

[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] See https://townhall.virginia.gov/l/ViewStage.cfm?stageid=9452 for the Emergency/NOIRA; the emergency provisions are due to expire on June 21, 2023. See https://townhall.virginia.gov/l/viewmandate.cfm?mandateid=1202 for the legislative mandate.

Background

Chapter 731 of the 2020 Acts of Assembly allowed pharmacists to initiate treatment with opioid antagonists (such as naloxone), injectable or self-administered hormonal contraceptives, prenatal vitamins that require prescriptions, dietary fluoride supplements, and medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost of an over-the-counter equivalent of the same drug. The legislation included conditions that would have to be met for pharmacists to initiate treatment, including that the treatment setting comply with the Health Insurance Portability and Accountability Act (HIPAA), and directed the Board to promulgate regulations to implement the provisions of the Act within 280 days of its enactments.[3]

Chapter 731 also directed the Board to establish a working group to provide recommendations regarding the development of protocols for other types of treatments that pharmacists could initiate, and to then submit its findings and recommendations to the Governor and the Chairs of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.[4] The report filed with the General Assembly indicates that working group members voted unanimously (or nearly unanimously) to make the following recommendations:[5]

(i) Pharmacists should be authorized to order and administer vaccines included on the immunization schedule published by the CDC for persons 18 years of age and older, to require reporting to the Virginia Immunization Information System (VIIS), and to require that pharmacists inform the patient's primary care provider of the vaccine administration.

[3] See https://townhall.virginia.gov/l/ViewAction.cfm?actionid=5604 for that regulatory action and https://townhall.virginia.gov/l/viewmandate.cfm?mandateid=1061 for the corresponding legislative mandate. The emergency provisions will remain in effect until July 2, 2022, unless extended for six months, as requested, until January 1, 2023. The proposed stage that would make those emergency provisions permanent has been completed, and received no public comments.

[4] The working group consisted of members of the Board of Pharmacy, Board of Medicine, Virginia Department of Health (VDH), Department of Medical Assistance Services, administrators and faculty members from various pharmacy schools and medical schools in Virginia, and representatives from the following organizations: Virginia Association of Health Plans, Virginia Pharmacist Association, Medical Society of Virginia, Virginia Society of Health-Systems Pharmacists, Virginia Association of Chain Drug Stores, and National Association of Chain Drug Stores.

[5] See https://rga.lis.virginia.gov/Published/2020/RD480 for the full report. A number of other conditions that had been proposed for the working group's consideration in Chapter 731 did not receive unanimous support.

(ii) Pharmacists should be authorized to initiate treatment with and dispense and administer tuberculin purified protein derivative for tuberculosis testing,

(iii) Pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances for the prevention of HIV, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to CDC guidelines and recommendations.[6]

(iv) Pharmacists should be authorized to dispense and administer devices, controlled paraphernalia, and possibly other durable medical equipment to lower out-of-pocket expenses, for which the patient's health insurance provider requires a prescription.[7]

Subsequently, Chapter 231 of the 2021 Acts of Assembly incorporated the working group's recommendations in statute and directed the Board to promulgate regulations implementing the changes made by the Act within 280 days of its enactment. Accordingly, the proposed changes summarized below would mirror the statutory changes in the 2021 legislative mandate.[8]

- 18 VAC 110-20-150 *Physical Standards for all pharmacies* would be amended to require that the physical setting of a pharmacy in which a pharmacist treats with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment comply with HIPAA. (The underlined phrase would be added.)
- 18 VAC 110-21-46 *Initiation of treatment by a pharmacist* would be amended as follows:
    - Section A would authorize a pharmacist to initiate treatment with, dispense, or administer certain "controlled paraphernalia, and other supplies and equipment" in addition to certain drugs and devices.

[6] Working group members from VDH specifically referred to their experience working with pharmacists to perform HIV testing to indicate that a well-constructed statewide protocol could meet public need and that pre- and post-exposure prophylaxis could be built into the protocol.

[7] The working group noted that the term "drugs" as defined in law does not include "devices" such as glucometers, controlled paraphernalia such as insulin pen needles and hypodermic syringes, and possibly other durable medical equipment.

[8] Note that the proposed text intentionally duplicates changes that have been made under action 5604 (see fn 3). Thus, if the emergency provisions in that action expire without extension before the final stage has been completed, the provisions of Chapter 731 of the 2020 Acts will remain in effect until June 21, 2023 under the emergency provisions of this action (5861), and would be made permanent by the proposed stage being reviewed here. However, the economic impacts of the initial changes have been analyzed at the proposed stage for action 5604 and will not be repeated here; see https://townhall.virginia.gov/l/GetFile.cfm?File=30\5604\9242\EIA_DHP_9242_v1.pdf.

- Item 6 would be amended to include "controlled paraphernalia and other supplies and equipment" covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-pf-pocket cost to purchase an over-the-counter equivalent of the same controlled paraphernalia or other supplies and equipment. This provision currently only applies to "drugs and devices."
- Items 7-9 would be added to section A to add vaccines listed on the CDC's immunization schedule, including those that have an EUA from the US FDA, tuberculin purified protein derivative for tuberculosis testing, and controlled substances for the prevention of HIV pursuant to the CDC's guidelines and recommendations.
- Section B would be amended to require that pharmacists follow the statewide protocol when dispensing or administering "controlled paraphernalia, and other supplies and equipment" in addition to following these requirements with the currently authorized treatment with drugs and devices.
- Additionally, section B would be amended to require that pharmacists report vaccinations to VIIS in accordance with the requirements of § 32.1-46.01 of the Code of Virginia.

Estimated Benefits and Costs

The proposed amendments would largely benefit individuals seeking vaccinations, tuberculosis testing, or HIV prophylaxis by allowing them to obtain the necessary treatment at pharmacies instead of going to a physician. Pharmacies often have extended hours of operation compared to physicians' offices, may not require advance appointments, and may be more conveniently located for some people.

The proposed amendments would also benefit individuals who need controlled paraphernalia (such as insulin pen needles, hypodermic syringes, or glucometers) that is covered by their insurance, so that their out-of-pocket expenditures would be lower than if they purchased over-the-counter equivalents. These individuals could now get these controlled paraphernalia at a lower price from their local pharmacy, without having to obtain a prescription from their healthcare provider *ex ante* or trying to obtain reimbursements from their insurance carrier *ex post*.

Providing controlled paraphernalia and other medical supplies at a lower price to some consumers would not necessarily result in revenue losses for the pharmacies, and could lead to higher revenues. Pharmacies would likely recover some portion of the remainder of the retail price from insurers, as they currently do for drugs, and may experience a modest increase in the overall quantity sold. Thus the extent to which pharmacies' revenue may increase would depend on the dollar-value of insurance reimbursements and the increase in quantity sold as a result of lower out-of-pocket costs to some consumers.

Pharmacies would benefit from the additional revenue that would be collected as a result of pharmacists being authorized to provide an expanded range of services. Pharmacies could face some additional costs arising from ensuring HIPAA compliance of the physical location and the requirement that vaccinations be reported to VIIS. However, the proposed regulation would only authorize, not require, pharmacists to initiate treatment and provide vaccines or other drugs, devices or controlled paraphernalia. Additional revenue to pharmacies where pharmacists elect to initiate treatment would likely cover the costs associated with providing these additional services.

Businesses and Other Entities Affected

The Department of Health Professions (DHP) reports that there are 15,326 licensed pharmacists, but not all pharmacists would be directly affected.[9] DHP also reports that pharmacists are not licensed by specialty (compounding, radiopharmaceutical, hospital, etc.), nor are they identified by work setting. Only pharmacists working in retail pharmacies, who dispense drugs directly to consumers, would be directly affected by the proposed amendments.

DHP also reports that there are 1,769 licensed pharmacies, but only pharmacies that dispense to a consumer would be directly affected by the proposed changes.[10] Data provided by DHP indicates that at least 1,063 pharmacy licenses are held by retail pharmacy chains or by retail grocery chains that have pharmacies, and another 10 pharmacy licenses are held by public health centers (run by city or community services board) or student health centers at colleges and universities. Thus, at least 61 percent of licensed pharmacies appear to be affected by the proposed changes. The remaining 696 pharmacy licenses include 187 hospitals, including

[9] See Agency Background Document (ABD) page 7: https://townhall.virginia.gov/l/GetFile.cfm?File=30\5861\9562\AgencyStatement_DHP_9562_v2.pdf.
[10] *Ibid.*

teaching hospitals, and 509 independent health centers, free clinics, and independent pharmacies. Many of these places likely dispense directly to customers, but the exact number could not be identified based on the list of licensed entities alone, and would require significantly more time to verify individually.

Some physicians' offices may be indirectly affected by the proposed changes to the extent that current and prospective patients substitute office visits with pharmacist-initiated treatment, leading to revenue losses for these entities. The changes proposed here would specifically affect physicians that prescribe controlled paraphernalia and other medical supplies, and those that provide vaccinations, tuberculosis testing, and HIV prophylactics. This could include some of the roughly 187 hospitals with pharmacy licenses mentioned previously, provided they do not already dispense directly to consumers and only to the extent that current and future patients choose to substitute physician-initiated treatment for pharmacist-initiated treatment.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.[11] An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As noted above, the proposed amendments do not create any new costs for pharmacies that could not be directly recouped, and would likely increase pharmacies' net revenue. However, some physicians' offices may experience a reduction in net revenue to the extent that the proposed amendments cause a substitution towards pharmacist-initiated treatment by existing and prospective patients. Thus, an adverse impact is indicated for physicians' offices.

[11] 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. 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.

Small Businesses[12] Affected:[13]

The proposed amendments could benefit some small businesses, such as independent pharmacies and health centers with retail pharmacies, while hurting some others, such as physicians' offices.[14]

Types and Estimated Number of Small Businesses Affected

As mentioned previously, there are up to 509 small, independently-operated pharmacies and health centers that would benefit to the extent that they dispense directly to consumers. The number of physicians' offices that are small businesses (without a pharmacy license) that may be adversely impacted by revenue losses is not known.

Costs and Other Effects

Physicians' offices and small for-profit hospitals, including ones with pharmacy licenses that do not dispense directly to consumers, may lose revenue to the extent that their current and prospective patients substitute physician-initiated treatment for pharmacist-initiated treatment as a result of the proposed changes. Small hospitals with pharmacy licenses that do not currently dispense directly to consumers may choose to start doing so, and may take other measures to expand their availability, in an effort to reduce or prevent revenue losses. However, they would likely incur some costs to implement such changes. Thus, an adverse economic impact[15] is indicated for physicians' offices and small for-profit hospitals because there do not appear to be any offsetting direct benefits to these small businesses.

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[12] 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."

[13] 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.

[14] Some of these small businesses include local chains with roughly two to twelve locations. They are independent in the sense that they do not belong to a national chain. The proposed amendments would also benefit a number of free clinics and other health centers that may operate as a non-profit rather than a traditional business, but would otherwise meet the criteria for small businesses as defined in footnote 12.

[15] Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined.

Alternative Method that Minimizes Adverse Impact

There are no clear alternative methods that both reduce adverse impact to physicians and small hospitals and meet the intended policy goals of safely expanding access for consumers by allowing pharmacist-initiated treatment.

Localities[16] Affected[17]

At least five pharmacy licenses appear to be held by cities or community services boards, which receive funding from local governments, specifically the city of Alexandria (two licenses), Norfolk city community services board, Bedford county and Fairfax county.[18] The proposed amendments do not introduce costs for local governments. Accordingly, no additional funds would be required, and an adverse economic impact is not indicated.

Projected Impact on Employment

The proposed amendments do not appear to affect total employment in the short run. Any expansion in the scope of responsibilities for pharmacists could lead to an increase in the demand for pharmacists. Even if pharmacists are able to delegate some of their existing responsibilities to pharmacy technicians, this would lead to an increased demand for pharmacy technicians. This may induce more individuals to enter these professions and increase the pharmacist and pharmacy technician labor force in the long run. The proposed amendments are unlikely to affect physicians' offices and hospitals to a sufficient degree to adversely impact the employment of physicians, nurses, or other medical personnel.

Effects on the Use and Value of Private Property

The proposed amendments would increase the scope of services provided by privately owned pharmacies, including large retail pharmacy chains and grocery store chains that have pharmacies as well as small independent pharmacies, to the extent that they dispense directly to consumers. As mentioned previously, this is likely to increase the net revenue for these entities, and could lead to a modest increase in the value of these businesses. At the same time, the proposed amendments may modestly reduce the value of some private clinics and hospitals to the

[16] "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.
[17] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.
[18] There may be more locality funded pharmacies and health centers. These are difficult to identify since many health centers or pharmacies named after a county could be private entities, so only names with "health department" or "city of" were included in this estimate.

extent that their revenues are reduced by patients switching to pharmacist-initiated treatment. The proposed amendments do not affect real estate development costs.