Virginia Department of Planning and Budget

Economic Impact Analysis

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
Department of Health Professions
Town Hall Action/Stage: 5868/9608
August 26, 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 19. The analysis presented below represents DPB's best estimate of these economic impacts.[1]

Summary of the Proposed Amendments to Regulation

In response to a petition for rulemaking, the Board of Pharmacy (Board) proposes to incorporate certain allowances into the regulation that have been piloted and shown to be safe and effective. Specifically, the proposed amendments would allow (i) a pharmacist at a central distribution company to verify the Schedule VI drugs[2] that will be placed into an automated dispensing device (ADD) at a hospital, prior to delivery of the drugs to the receiving hospital, and (ii) pharmacy technicians at the receiving hospital to load the drugs directly into the ADD without further verification by a pharmacist at the hospital.

Background

In May 2021, the Board received a petition to amend sections 18 VAC 110-20-460 and 18 VAC 110-20-490 so as to allow a pharmacist at a central distribution company to verify 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] Schedule VI drugs are the least restricted category of scheduled drugs. They represent the lowest potential for abuse while still requiring a prescription. See https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3455/.

Schedule VI drugs to be placed in an ADD prior to delivery of the drugs to the receiving hospital, and pharmacy technicians at the receiving hospital to load the drugs directly into the ADD without further verification by a pharmacist at the hospital.[3] The petition received 40 comments, representing a number of Virginia hospitals, all in favor of the request. Commenters specifically cited the increased efficiency of using a centralized distribution model, and the resulting time savings for pharmacists and pharmacy technicians at the hospitals, as their primary rationale in supporting the petition. Subsequently, the Board voted unanimously to accept the petition and initiate rulemaking regarding the two sections.[4]

18 VAC 110-20-460 currently requires all Schedule II-VI drugs delivered to a hospital unit as floor-stock to be checked by a pharmacist before the drugs leave the hospital pharmacy. 18 VAC 110-20-490, which contains general provisions for the use of ADDs at hospital pharmacies, currently requires pharmacist verification for all drugs removed from the pharmacy to be placed in an ADD. The Board proposes to amend section 490 to add a subsection addressing the "Distribution of drugs from a central warehouser or wholesale distributor" specifically for use in ADDs and to amend section 460 by adding an exception for drugs covered by this new subsection.

The new subsection (490 D.) would require the central warehouser or wholesale distributor to have an on-site Virginia-licensed pharmacist (i) verify the accuracy of all Schedule VI drugs to be placed in an ADD prior to delivery of the drugs to the hospital pharmacy and (ii) perform barcode linking of any drug to the related drug files in the hospital information system and automated dispensing device. In addition, the warehouser/distributor would be required to maintain a record of all Schedule VI drugs distributed to a hospital for placement in each specific ADD and to provide an invoice to each hospital pharmacy indicating the drugs delivered to the hospital to be placed in a specific ADD. The recordkeeping requirements would include the date; drug name, dosage form, and strength; quantity; hospital name; hospital unit and a unique identifier for the specific ADD receiving the drug.

The new subsection would also specifically exempt the hospital pharmacist(s) from the current requirements in sections 460 and 490 regarding verification of and initialing for drugs

[3] See https://townhall.virginia.gov/L/viewpetition.cfm?petitionid=344.
[4] Minutes of the Board's September 24, 2021 meeting:
https://townhall.virginia.gov/L/GetFile.cfm?File=Meeting\30\33096\Minutes_DHP_33096_v2.pdf

leaving the pharmacy to be placed in an ADD. Pharmacists or pharmacy technicians loading the ADD would instead be required to scan the drugs as they are loaded into the ADD and initial the delivery record. Hospitals receiving drugs from the warehouser/distributor would be required to maintain a 90 percent barcode scanning rate for restocking ADDs.[5] If the scanning rate for restocking ADDs is less than 90 percent for any quarter, the receiving pharmacy would have to immediately reinstitute a 100 percent pharmacist verification process until a 90 percent scanning rate is achieved and documented in a subsequent quarter. To implement these security measures, receiving hospital pharmacies would be required to maintain quarterly reports of the restocking barcode scanning rate, bedside barcode scanning rate, and any errors in drug product received from the warehouser/distributor.

Virginia Code § 54.1-3434.02.(A)(5) authorizes use of ADDs only when the pharmacist-in-charge (PIC) of a pharmacy located within the hospital, or the PIC of any outside pharmacy providing pharmacy services to the hospital, is held accountable for the drugs dispensed from the ADD.[6] Virginia Code § 54.1-3434.02.(A)(6) requires the filling and stocking of all drugs in ADDs to be performed under the direction of the PIC who is an employee of the provider pharmacy, and for the PIC to be responsible for proper and accurate stocking and filling of the ADD. Thus, the proposed amendments aim to provide the flexibility requested in the petition by allowing verification to take place at the warehouse while ensuring that PICs meet statutory standards by requiring barcode linking and electronic inventory tracking of each drug.

Estimated Benefits and Costs

The proposed amendments would primarily benefit hospitals that use ADDs and the pharmacists and pharmacy technicians employed by those hospitals. As indicated by a number of commenters in favor of the petition, manually verifying every unit of every drug that is placed in an ADD is both time consuming and error-prone in a busy work environment where the hospital pharmacy staff may have competing demands on their time. In addition, Schedule VI drugs are the least restricted category and often the most prescribed, meaning they have to be restocked in ADDs more frequently compared to Schedule II-V drugs. Allowing a pharmacist at the

[5] This threshold and the measures to be followed if the threshold is not maintained were included in the pilot program and would be replicated as is in the regulation. See, for example, https://townhall.virginia.gov/L/GetFile.cfm?File=meeting%5C30%5C22759%5CMinutes_DHP_22759_v2.pdf for details about the pilot.

[6] See https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3434.02/.

warehouse to do the manual verification and barcode linking reduces the time hospital pharmacists and pharmacy technicians must spend in stocking ADDs without increasing the risk of drug loss or misuse. These changes would allow hospital pharmacists and pharmacy technicians to spend more of their time working directly with patients.

Hospitals that choose to use ADDs for Schedule VI drugs and the warehousers or wholesale distributors that supply these drugs to them would have to invest some time and effort to implement the requirements of the regulation. Specifically, warehousers/distributors would need to employ or arrange for licensed pharmacists to conduct the on-site verification and barcode linking. They would also need to implement systems for recordkeeping and invoicing as required in the proposed text. Hospitals using ADDs would have to share access to their drug inventory management system and perhaps train the pharmacist at the warehouse or distribution center to do the barcode linking accurately.

It should be noted that the regulation does not require warehousers or wholesale distributors of Schedule VI drugs to take any action unless they supply to a hospital that wants to take advantage of these allowances, in which case any compliance costs would likely be passed on to that hospital. Large hospital chains may run their own warehouse and thus pay for the compliance costs directly. Smaller hospitals that use ADDs may contract with warehouses that are either run by these larger hospital chains or by large pharmacies and would pay for the warehouser's compliance costs indirectly. In either case, the cost of implementing these requirements for the warehouse would either directly or indirectly be incurred by hospitals using ADDs, and those hospitals would choose to make this investment based on the expected time savings for their pharmacy staff.

Businesses and Other Entities Affected

The Department of Health Professions (DHP) reports that there are roughly 100 hospitals in Virginia, and that a large hospital may have as many as 75-100 ADDs.[7] Twenty-six hospitals have already participated in a pilot program to test these requirements and have reported 99 percent barcode scanning rates for restocking and at the bedside.[8] There are 121 licensed warehousers and 61 wholesale distributors. However, DHP reports that many warehousers may

[7] Agency Background Document (ABD) p. 5
[8] Email from DHP dated August 9, 2022. The pilot involved multiple hospitals under shared ownership that had their own central warehouse.

not possess drugs that lend themselves to this purpose and many only possess medical gases. It is unclear how many of the wholesale distributors would be affected by the proposed changes.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.[9] 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 central warehousers or wholesale distributors that could not be directly recouped from hospitals. Additionally, participation is voluntary. Thus, an adverse impact is not indicated.

Small Businesses[10] Affected:[11]

The proposed amendments could affect some hospitals, central warehousers, or wholesale distributors that may be small businesses if they use ADDs and elect to implement a centralized warehouse-based system for verification of Schedule VI drugs to stock ADDs.[12] However, since the proposed amendments do not create new costs for small businesses unless they choose to enter into an arrangement where Schedule VI drugs for ADDs are verified at a warehouse, an adverse economic impact is not indicated for small businesses.

[9] 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.

[10] 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."

[11] 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.

[12] Hospitals may operate as a non-profit rather than a traditional business, but would otherwise meet the criteria for small businesses as defined in footnote 8.

Localities[13] Affected[14]

The proposed amendments do not appear to disproportionately affect any particular localities or introduce costs for local governments. Accordingly, 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. Comments in favor of the petition state that these changes would free pharmacists from routine restocking tasks and thereby enable them to spend more time engaging with patients directly and providing clinical services. The magnitude of time savings for hospitals is unlikely to be large enough to result in layoffs for pharmacists or pharmacy technicians.

Effects on the Use and Value of Private Property

The proposed amendments could modestly increase the value of hospitals using ADDs by lowering pharmacy operation costs. The proposed amendments could also increase the value of some wholesalers or distributors based on their compensation for providing on-site verification and recordkeeping as value-adding services for supplying Schedule VI drugs to hospitals that use ADDs. The proposed amendments do not affect real estate development costs.

[13] "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.

[14] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.