Virginia Department of Planning and Budget

Economic Impact Analysis

12 VAC 5-219 Prescription Drug Price Transparency Regulation
Virginia Department of Health
Town Hall Action/Stage: 5819 / 9814
January 5, 2023

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

As the result of a 2021 legislative mandate, the Virginia Department of Health (VDH) proposes to make permanent an emergency regulation that establishes new prescription drug pricing reporting requirements.

Background

Chapter 304 (2021 Acts of Assembly, Special Session I)[2] directed VDH to enter into a contract or an agreement with a nonprofit data services organization (NDSO) to annually collect, compile, and make available information about prescription drug pricing to appear on its

[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://leg1.state.va.us/cgi-bin/legp504.exe?212+ful+CHAP0304

website. The legislation also requires every carrier,[3] pharmacy benefits manager,[4] and drug manufacturer to report information about prescription drug prices to this organization. Additionally, it allows VDH to require wholesale distributors to report certain data about prescription drug costs when VDH determines that the data provided by the other entities is insufficient.

For carriers, the legislation directs annual reporting to the NDSO of the following information on spending on prescription drugs in total, before enrollee cost sharing, for each health benefit plan offered by the carrier in the Commonwealth:

> 1. For covered outpatient prescription drugs that were prescribed to enrollees during the calendar year, the names of (i) the 25 most frequently prescribed outpatient prescription drugs, (ii) the names of the 25 outpatient prescription drugs covered at the greatest cost, calculated using the total annual spending by such health benefit plan for each outpatient prescription drug covered by the health benefit plan; and (iii) the 25 outpatient prescription drugs that experienced the greatest year-over-year increase in cost, calculated using the total annual spending by such health benefit plan for each outpatient prescription drug covered by the health benefit plan;
>
> 2. The percent increase in annual net spending for prescription drugs after accounting for aggregated rebates, discounts, or other reductions in price;
>
> 3. The percent increase in premiums that were attributable to each health care service, including prescription drugs;
>
> 4. The percentage of specialty drugs with utilization management requirements; and
>
> 5. The premium reductions that were attributable to specialty drug utilization management.

[3] Per Code of Virginia § 38.2-3407.10, "Carrier" means: 1. Any insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense incurred basis; 2. Any corporation providing individual or group accident and sickness subscription contracts; 3. Any health maintenance organization providing health care plans for health care services; 4. Any corporation offering prepaid dental or optometric services plans; or 5. Any other person or organization that provides health benefit plans subject to state regulation, and includes an entity that arranges a provider panel for compensation. See https://law.lis.virginia.gov/vacode/38.2-3407.10/

[4] Per Code of Virginia § 38.2-3407.15:4, "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. The term includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a carrier. "Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a carrier for the benefit of enrollees. See https://law.lis.virginia.gov/vacode/title38.2/chapter34/section38.2-3407.15:4/

The legislation specifies that every carrier offering a health benefit plan shall require each pharmacy benefits manager with which it enters into a contract to report to the NDSO annually the following information for each drug reported by the carrier:

1. The aggregate amount of rebates received by the pharmacy benefits manager;

2. The aggregate amount of rebates distributed to the relevant health benefit plan; and

3. The aggregate amount of rebates passed on to enrollees of each health benefit plan at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount.

For manufacturers, specific annual reporting requirements (to the NDSO) in the legislation include the following for each (i) brand-name drug and biologic other than a biosimilar with a wholesale acquisition cost of $100 or more for a 30-day supply or a single course of treatment and any increase of 15 percent or more in the wholesale acquisition cost of such brand-name drug or biologic over the preceding calendar year; (ii) biosimilar with an initial wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched; and (iii) generic drug with a price increase that results in an increase in the wholesale acquisition cost of such generic drug that is equal to 200 percent or more during the preceding 12-month period, when the wholesale acquisition cost of such generic drug is equal to or greater than $100, annually adjusted by the Consumer Price Index for All Urban Consumers, for a 30-day supply, with such increase defined as the difference between the wholesale acquisition cost of the generic drug after such increase and the average wholesale acquisition cost of such generic drug during the previous 12 months:

1. The name of the prescription drug;

2. Whether the drug is a brand name or generic;

3. The effective date of the change in wholesale acquisition cost;

4. Aggregate, company-level research and development costs for the most recent year for which final audit data is available;

5. The name of each of the manufacturer's new prescription drugs approved by the U.S. Food and Drug Administration within the previous three calendar years;

6. The name of each of the manufacturer's prescription drugs that, within the previous three calendar years, became subject to generic competition and for which there is a therapeutically equivalent generic version; and

7. A concise statement regarding the factor or factors that caused the increase in wholesale acquisition cost.

The legislation also directed VDH to adopt regulations that are to include: (i) provisions related to the specification of prescription drugs for the purpose of data collection and procedures for auditing information provided by carriers, pharmacy benefits managers, wholesale distributors, and manufacturers and (ii) a schedule of civil penalties for failure to report information. It specifies that civil penalties are not to exceed $2,500 per day from the date on which such reporting is required.

Specifically, the proposed regulation has the following sections: 12VAC5-219-10 *Definitions*, 12VAC5-219-20 *Registration*, 12VAC5-219-30 *Notice*, 12VAC5-219-40 *Allowable variances*, 12VAC5-219-50 *Carrier reporting requirements*, 12VAC5-219-60 *Pharmacy benefits manager reporting requirements*, 12VAC5-219-70 *Manufacturer reporting requirements*, 12VAC5-219-80 *Wholesale distributor reporting requirements*, 12VAC5-219-90 *Method of report submission*, 12VAC5-219-100 *Data validation; notification; response*, 12VAC5-219-110 *Audit; corrective action plan*, 12VAC5-219-120 *Sanctions*, 12VAC5-219-130 *Civil penalty*, 12VAC5-219-140 *Informal fact-finding proceeding*, and 12VAC5-219-9999 *Documents Incorporated by Reference*. The proposed text is consistent with the legislation and does not produce cost beyond that which is already required by the legislation.

Estimated Benefits and Costs

Costs

Costs for pharmaceutical manufacturers, carriers, pharmacy benefit managers, and possibly pharmaceutical wholesalers would be limited to the costs of projected reporting, recordkeeping and other administrative costs required for compliance. VDH estimates that these costs are not likely to exceed $2,500 per firm per year.

Costs for VDH include $275,000 annually for its contract with the NDSO for collection, compilation, and publication of data collected, and $43,801 annually for a wage position to determine compliance with the prescription drug price transparency program requirements, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act.[5]

[5] Source: VDH

Benefits

The prescription drug price transparency program is beneficial in that it produces increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs. This can potentially enable policymakers to make better informed decisions that affect healthcare costs in the Commonwealth.

The required public reporting by manufacturers of price increases over a set threshold with a statement regarding the factor or factors that caused the increase may discourage some price increases above the threshold. There is some evidence that this has happened in other states that started prescription drug price transparency programs before Virginia. Vermont's Medicaid program explained in its 2020 report that compared to 2016, there was a 79 percent decline in the number of drugs reaching the state's per year price increase reporting threshold.[6] The program report concludes that fewer manufacturers are excessively increasing the price of drugs. Similarly, Oregon's transparency program reported that compared to its first year of implementation in 2019, the program received 70 percent fewer reports for price increases in 2020.[7] However, during that same time, Oregon saw a 15 percent increase in the number of drugs with high launch prices.[8]

Businesses and Other Entities Affected

The proposed regulation affects the 231 pharmaceutical manufacturers, 100 carriers, 36 pharmacy benefit managers, and potentially the 300 pharmaceutical wholesalers that do business in the Commonwealth.[9]

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.[10] An adverse impact is indicated if there is any increase in net cost or

[6] See https://gmcboard.vermont.gov/sites/gmcb/files/documents/Merged_DVHA_Act193_2021Submission.pdf and https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/

[7] See https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2020.pdf and https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/

[8] The Oregon report states that "New high-cost drugs are reported to the program when they are priced at $670 or more. This is the financial threshold set by the federal government to categorize a drug as a specialty drug under Medicare Part D."

[9] Data source: VDH

[10] 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

reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. The costs from the program stem from the legislation. Thus, no adverse impact for the proposed regulation is indicated.

Small Businesses[11] Affected:[12]

Types and Estimated Number of Small Businesses Affected

VDH does not have data on how many, if any of the pharmaceutical, manufacturers, carriers, pharmacy benefit managers, and pharmaceutical wholesalers would qualify as small businesses.

Costs and Other Effects

The reporting, recordkeeping and other administrative costs are due to the legislation rather than the proposed regulation.

Alternative Method that Minimizes Adverse Impact

The proposed regulation does not create adverse impact.

Localities[13] Affected[14]

The proposed regulation neither disproportionally affects particular localities, nor introduces costs for local governments.

Projected Impact on Employment

VDH plans to hire an individual to determine compliance with the prescription drug price transparency program requirements, assess and collect penalties for non-compliance, and provide

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.

[11] 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."

[12] 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.

[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.

administrative support for any resulting proceedings under the Administrative Process Act.[15] The contracted NDSO, Virginia Health Information, has hired a prescription drug data consultant for the program.[16]

Effects on the Use and Value of Private Property

As described above, the legislation requires affected firms to report information and incur some cost. The proposed regulation provides detail on how the reporting is to be done, but does not directly add to the cost. The proposed regulation does not affect real estate development costs.

[15] Source: VDH
[16] Source: Virginia Health Information