Office of Regulatory Management

Economic Review Form

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-219-10 et seq.
VAC Chapter title(s)	Prescription Drug Price Transparency Regulation
Action title	Promulgation of New Regulation to Implement Chapter 304 of the 2021 Acts of Assembly, Special Session I
Date this document prepared	August 24, 2022

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	Chapter 304 (2021 Act of Assembly, Special Session I) mandates that health carriers, manufacturers, and pharmacy benefit managers (PBMs) report annually the cost of prescription drugs that meet the statutory reporting thresholds to the non-profit data services organization with whom the Virginia Department of Health (VDH) has a contract. Wholesale distributors may be required to report, but only if the data provided by health carriers, manufacturers, and PBMs is insufficient. • In the proposed stage, VDH is proposing to make permanent the majority of the previously promulgated emergency regulations, except for some minor changes to the definitions of 12VAC5-416, replacing a proprietary data element with a nonproprietary one, adding a data element so a reporter would indicate what reporting threshold a prescription drug was tied to, providing clarification to mandated reporters that all drug products (strengths, formulations, etc.) were reportable, and updating the version number of the submission manual. Direct Costs: Regulants with an annual reporting obligation are estimated to have an annual cost not to exceed $2,500 for reporting, recordkeeping and other administrative costs required for compliance. VDH will incur an annual cost of $275,000 under its contract with the non-profit data services organization for collection, compilation, and publication of data collected. Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.

(2) Quantitative Factors	Estimated Dollar Amount	Present Value

Direct Costs	(a) $11,925,000	(c) $10,477,435	
Direct Benefits	(b) $0	(d) $0	
(3) Benefits-Costs Ratio	0.00	(4) Net Benefit	-$10,477,435
(5) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect cost to regulants, due to the low cost of compliance per regulant, especially as many of these are already subject to prescription drug price transparency requirements in other states. Indirect costs related to price modifications, if any, would have already been incurred as part of compliance with prescription drug price transparency requirements in other states that predate Virginia's program. VDH will incur an indirect cost of $43,801 annually for a wage position to determine compliance, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act. VDH is not aware of any quantifiable indirect benefits.		
(6) Information Sources	National Academy for State Health Policy; Oregon Department of Consumer and Business Services; Maine Health Data Organization; Washington State Health Care Authority; Virginia Health Information; Ten2Eleven Business Solutions, LLC		
(7) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by policymakers to help make better informed decisions that affect healthcare costs in the Commonwealth, such as, potentially, the creation of a prescription drug affordability board or allowing the purchase of prescription drugs from Canada. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experienced price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.		

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct Costs & Benefits	Chapter 304 (2021 Act of Assembly, Special Session I) mandates that health carriers, manufacturers, and pharmacy benefit managers (PBMs) report annually the cost of prescription drugs that meet the statutory reporting thresholds to the non-profit data services organization with whom the Virginia Department of Health (VDH) has a contract. Wholesale distributors may be required to report, but only if the data provided by health carriers, manufacturers, and PBMs is insufficient. • The current emergency regulations incorporate those statutory requirements and address the mandate that the data collected by audited. Direct Costs: Regulants with an annual reporting obligation are estimated to have an annual cost not to exceed $2,500 for reporting, recordkeeping and other administrative costs required for compliance. VDH will incur an annual cost of $275,000 under its contract with the non-profit data services organization for collection, compilation, and publication of data collected. Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.

(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) $11,925,000	(c) $10,477,435	
Direct Benefits	(b) $0	(d) $0	
(3) Benefits-Costs Ratio	0.00	(4) Net Benefit	-$10,477,435

(5) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect cost to regulants, due to the low cost of compliance per regulant, especially as many of these are already subject to prescription drug price transparency requirements in other states. Indirect costs related to price modifications, if any, would have already been incurred as part of compliance with prescription drug price transparency requirements in other states that predate Virginia's program. VDH will incur an indirect cost of $43,801 annually for a wage position to determine compliance, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act.

	VDH is not aware of any quantifiable indirect benefits.
(6) Information Sources	National Academy for State Health Policy; Oregon Department of Consumer and Business Services; Maine Health Data Organization; Washington State Health Care Authority; Virginia Health Information; Ten2Eleven Business Solutions, LLC
(7) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by policymakers to help make better informed decisions that affect healthcare costs in the Commonwealth, such as, potentially, the creation of a prescription drug affordability board or allowing the purchase of prescription drugs from Canada. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs & Benefits	Chapter 304 (2021 Acts of Assembly, Special Session I) requires annual reporting by health carriers, manufacturers, and PBMs and requires the promulgation of regulations. Therefore, VDH does not have the authority to offer an alternative in lieu of regulation, nor does it have the authority to approve information disclosure requirements or performance standards in lieu of the mandatory reporting requirements. • The only alternative that VDH could potentially offer would be to remove specificity from the regulation about the minimum data elements to be provided. Direct Costs: Regulants with an annual reporting obligation are estimated to have an annual cost not to exceed $2,500 for reporting, recordkeeping and other administrative costs required for compliance. If there were less specificity about the minimum data elements to be provided, a portion of regulants would likely incur additional costs from having to supplement or correct incomplete

	reports, which VDH conservatively estimates to cost $250 and involve 15% of regulants. VDH will incur an annual cost of $275,000 under its contract with the non-profit data services organization for collection, compilation, and publication of data collected. Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.

(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) $12,065,000	(c) $10,600,440	
Direct Benefits	(b) $0	(d) $0	
(3) Benefits-Costs Ratio	0.00	(4) Net Benefit	-$10,600,440

(5) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect cost to regulants, due to the low cost of compliance per regulant, especially as many of these are already subject to prescription drug price transparency requirements in other states. Indirect costs related to price modifications, if any, would have already been incurred as part of compliance with prescription drug price transparency requirements in other states that predate Virginia's program. VDH will incur an indirect cost of $43,801 annually for a wage position to determine compliance, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act. VDH is not aware of any quantifiable indirect benefits.
(6) Information Sources	National Academy for State Health Policy; Oregon Department of Consumer and Business Services; Maine Health Data Organization; Washington State Health Care Authority; Virginia Health Information; Ten2Eleven Business Solutions, LLC
(7) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by policymakers to help make better informed decisions that affect healthcare costs in the Commonwealth, such as, potentially, the creation of a prescription drug

	affordability board or allowing the purchase of prescription drugs from Canada. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	Local partners will not be affected by direct costs or benefits of the regulatory change as they are not subject to the mandates contained in Chapter 304 (2021 Acts of Assembly, Special Session I) and thus will incur no direct cost or benefit.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) $0
Direct Benefits	(b) $0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or benefits for local partners. To the extent that prescription drug price increases may be moderated, VDH cannot quantify that indirect benefit at this time.
(4) Information Sources	See response to (1) of this Table.
(5) Assistance	N/A
(6) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by local partners to make better informed decisions that affect healthcare costs in the

	Commonwealth. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs & Benefits	Families will not be affected by direct costs or benefits of the regulatory change as they are not subject to the mandates contained in Chapter 304 (2021 Acts of Assembly, Special Session I) and thus will incur no direct cost or benefit.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) $0
Direct Benefits	(b) $0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or benefits for families. To the extent that prescription drug price increases may be moderated, VDH cannot quantify that indirect benefit at this time.
(4) Information Sources	See response to (1) of this Table.
(5) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by local partners to make better informed decisions that affect healthcare costs in the Commonwealth. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements;

	however, launch prices and overall spending on prescription drugs have continued to increase.

Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	Direct Costs: Regulants with an annual reporting obligation are estimated to have an annual cost not to exceed $2,500 for reporting, recordkeeping and other administrative costs required for compliance. VDH speculate that they may be at most 50 small businesses affected (and possibly none), though health carriers, manufacturers, and PBMs are not required to disclose nor have any volunteered whether they qualify as "small businesses" within the meaning of Code of Virginia § 2.2-4007.1. VDH will incur an annual cost of $275,000 under its contract with the non-profit data services organization for collection, compilation, and publication of data collected; assuming there are 50 small business impacted, 14% of the $275,000 is attributable to small businesses or $37,466. Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) 1,624,660
Direct Benefits	(b) $0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect cost to small businesses, due to the low cost of compliance per regulant, especially as many of these are already subject to prescription drug price transparency requirements in other states. Indirect costs related to price modifications, if any, would have already been incurred as part of compliance with prescription drug price transparency requirements in other states that predate Virginia's program. VDH will incur an indirect cost of $43,801 annually for a wage position to determine compliance, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act; assuming there are 50 small business impacted, 14% of the $43,801 is attributable to small businesses or $5,967. VDH is not aware of any quantifiable indirect benefits.

(4) Alternatives	Chapter 304 (2021 Acts of Assembly, Special Session I) requires annual reporting by health carriers, manufacturers, and PBMs and does not grant VDH the authority to exempt or excuse small businesses from these statutory mandates. However, VDH did build some flexibility into the regulation for all regulants in that individual regulants may ask for a variance that would allow for an individualized alternative to enable compliance with the purpose of a specific regulatory standard, if compliance would otherwise be economically burdensome and be an impractical hardship unique to the regulant.
(5) Information Sources	National Academy for State Health Policy; Virginia Health Information; Ten2Eleven Business Solutions, LLC
(6) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by local partners to make better informed decisions that affect healthcare costs in the Commonwealth. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	**Initial Count**	**Additions**	**Subtractions**	**Net Change**
416	151	10	0	10